

NOVEMBER 25, 2016

**RULES COMMITTEE PRINT 114-67**  
**TEXT OF HOUSE AMENDMENT TO THE SENATE**  
**AMENDMENT TO H.R. 34, TSUNAMI WARNING,**  
**EDUCATION, AND RESEARCH ACT OF 2015**  
**[Showing the text of the 21st Century Cures Act.]**

In lieu of the matter proposed to be added after the enacting clause, insert the following:

**1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the  
3 “21st Century Cures Act”.

4 (b) TABLE OF CONTENTS.—The table of contents for  
5 this Act is as follows:

Sec. 1. Short title; table of contents.

DIVISION A—21ST CENTURY CURES

Sec. 1000. Short title.

TITLE I—INNOVATION PROJECTS AND STATE RESPONSES TO  
OPIOID ABUSE

Sec. 1001. NIH innovation projects.

Sec. 1002. FDA innovation projects.

Sec. 1003. Account for the state response to the opioid abuse crisis.

Sec. 1004. Budgetary treatment.

TITLE II—DISCOVERY

Subtitle A—National Institutes of Health Reauthorization

Sec. 2001. National Institutes of Health Reauthorization.

Sec. 2002. EUREKA prize competitions.

Subtitle B—Advancing Precision Medicine

- Sec. 2011. Precision Medicine Initiative.
- Sec. 2012. Privacy protection for human research subjects.
- Sec. 2013. Protection of identifiable and sensitive information.
- Sec. 2014. Data sharing.

Subtitle C—Supporting Young Emerging Scientists

- Sec. 2021. Investing in the next generation of researchers.
- Sec. 2022. Improvement of loan repayment program.

Subtitle D—National Institutes of Health Planning and Administration

- Sec. 2031. National Institutes of Health strategic plan.
- Sec. 2032. Triennial reports.
- Sec. 2033. Increasing accountability at the National Institutes of Health.
- Sec. 2034. Reducing administrative burden for researchers.
- Sec. 2035. Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements.
- Sec. 2036. High-risk, high-reward research.
- Sec. 2037. National Center for Advancing Translational Sciences.
- Sec. 2038. Collaboration and coordination to enhance research.
- Sec. 2039. Enhancing the rigor and reproducibility of scientific research.
- Sec. 2040. Improving medical rehabilitation research at the National Institutes of Health.
- Sec. 2041. Task force on research specific to pregnant women and lactating women.
- Sec. 2042. Streamlining National Institutes of Health reporting requirements.
- Sec. 2043. Reimbursement for research substances and living organisms.
- Sec. 2044. Sense of Congress on increased inclusion of underrepresented populations in clinical trials.

Subtitle E—Advancement of the National Institutes of Health Research and Data Access

- Sec. 2051. Technical updates to clinical trials database.
- Sec. 2052. Compliance activities reports.
- Sec. 2053. Updates to policies to improve data.
- Sec. 2054. Consultation.

Subtitle F—Facilitating Collaborative Research

- Sec. 2061. National neurological conditions surveillance system.
- Sec. 2062. Tick-borne diseases.
- Sec. 2063. Accessing, sharing, and using health data for research purposes.

Subtitle G—Promoting Pediatric Research

- Sec. 2071. National pediatric research network.
- Sec. 2072. Global pediatric clinical study network.

TITLE III—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

- Sec. 3001. Patient experience data.
- Sec. 3002. Patient-focused drug development guidance.
- Sec. 3003. Streamlining patient input.
- Sec. 3004. Report on patient experience drug development.

Subtitle B—Advancing New Drug Therapies

- Sec. 3011. Qualification of drug development tools.
- Sec. 3012. Targeted drugs for rare diseases.
- Sec. 3013. Reauthorization of program to encourage treatments for rare pediatric diseases.
- Sec. 3014. GAO study of priority review voucher programs.
- Sec. 3015. Amendments to the Orphan Drug grants.
- Sec. 3016. Grants for studying continuous drug manufacturing.

Subtitle C—Modern Trial Design and Evidence Development

- Sec. 3021. Novel clinical trial designs.
- Sec. 3022. Real world evidence.
- Sec. 3023. Protection of human research subjects.
- Sec. 3024. Informed consent waiver or alteration for clinical investigations.

Subtitle D—Patient Access to Therapies and Information

- Sec. 3031. Summary level review.
- Sec. 3032. Expanded access policy.
- Sec. 3033. Accelerated approval for regenerative advanced therapies.
- Sec. 3034. Guidance regarding devices used in the recovery, isolation, or delivery of regenerative advanced therapies.
- Sec. 3035. Report on regenerative advanced therapies.
- Sec. 3036. Standards for regenerative medicine and regenerative advanced therapies.
- Sec. 3037. Health care economic information.
- Sec. 3038. Combination product innovation.

Subtitle E—Antimicrobial Innovation and Stewardship

- Sec. 3041. Antimicrobial resistance monitoring.
- Sec. 3042. Limited population pathway.
- Sec. 3043. Prescribing authority.
- Sec. 3044. Susceptibility test interpretive criteria for microorganisms; antimicrobial susceptibility testing devices.

Subtitle F—Medical Device Innovations

- Sec. 3051. Breakthrough devices.
- Sec. 3052. Humanitarian device exemption.
- Sec. 3053. Recognition of standards.
- Sec. 3054. Certain class I and class II devices.
- Sec. 3055. Classification panels.
- Sec. 3056. Institutional review board flexibility.
- Sec. 3057. CLIA waiver improvements.
- Sec. 3058. Least burdensome device review.
- Sec. 3059. Cleaning instructions and validation data requirement.
- Sec. 3060. Clarifying medical software regulation.

Subtitle G—Improving Scientific Expertise and Outreach at FDA

- Sec. 3071. Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service.
- Sec. 3072. Hiring authority for scientific, technical, and professional personnel.
- Sec. 3073. Establishment of Food and Drug Administration Intercenter Institutes.

- Sec. 3074. Scientific engagement.
- Sec. 3075. Drug surveillance.
- Sec. 3076. Reagan-Udall Foundation for the Food and Drug Administration.

#### Subtitle H—Medical Countermeasures Innovation

- Sec. 3081. Medical countermeasure guidelines.
- Sec. 3082. Clarifying BARDA contracting authority.
- Sec. 3083. Countermeasure budget plan.
- Sec. 3084. Medical countermeasures innovation.
- Sec. 3085. Streamlining Project BioShield procurement.
- Sec. 3086. Encouraging treatments for agents that present a national security threat.
- Sec. 3087. Paperwork Reduction Act waiver during a public health emergency.
- Sec. 3088. Clarifying Food and Drug Administration emergency use authorization.

#### Subtitle I—Vaccine Access, Certainty, and Innovation

- Sec. 3091. Predictable review timelines of vaccines by the Advisory Committee on Immunization Practices.
- Sec. 3092. Review of processes and consistency of Advisory Committee on Immunization Practices recommendations.
- Sec. 3093. Encouraging vaccine innovation.

#### Subtitle J—Technical Corrections

- Sec. 3101. Technical corrections.
- Sec. 3102. Completed studies.

### TITLE IV—DELIVERY

- Sec. 4001. Assisting doctors and hospitals in improving quality of care for patients.
- Sec. 4002. Transparent reporting on usability, security, and functionality.
- Sec. 4003. Interoperability.
- Sec. 4004. Information blocking.
- Sec. 4005. Leveraging electronic health records to improve patient care.
- Sec. 4006. Empowering patients and improving patient access to their electronic health information.
- Sec. 4007. GAO study on patient matching.
- Sec. 4008. GAO study on patient access to health information.
- Sec. 4009. Streamlining transfers used for educational purposes.
- Sec. 4010. Improving Medicare local coverage determinations.
- Sec. 4011. Medicare pharmaceutical and technology ombudsman.
- Sec. 4012. Medicare site-of-service price transparency.
- Sec. 4013. Telehealth services in Medicare.

### TITLE V—SAVINGS

- Sec. 5001. Savings in the Medicare Improvement Fund.
- Sec. 5002. Medicaid reimbursement to States for durable medical equipment.
- Sec. 5003. Penalties for violations of grants, contracts, and other agreements.
- Sec. 5004. Reducing overpayments of infusion drugs.
- Sec. 5005. Increasing oversight of termination of Medicaid providers.
- Sec. 5006. Requiring publication of fee-for-service provider directory.
- Sec. 5007. Fairness in Medicaid supplemental needs trusts.

- Sec. 5008. Eliminating Federal financial participation with respect to expenditures under Medicaid for agents used for cosmetic purposes or hair growth.
- Sec. 5009. Amendment to the Prevention and Public Health Fund.
- Sec. 5010. Strategic Petroleum Reserve drawdown.
- Sec. 5011. Rescission of portion of ACA territory funding.
- Sec. 5012. Medicare coverage of home infusion therapy.

DIVISION B—HELPING FAMILIES IN MENTAL HEALTH CRISIS

- Sec. 6000. Short title.

TITLE VI—STRENGTHENING LEADERSHIP AND ACCOUNTABILITY

Subtitle A—Leadership

- Sec. 6001. Assistant Secretary for Mental Health and Substance Use.
- Sec. 6002. Strengthening the leadership of the Substance Abuse and Mental Health Services Administration.
- Sec. 6003. Chief Medical Officer.
- Sec. 6004. Improving the quality of behavioral health programs.
- Sec. 6005. Strategic plan.
- Sec. 6006. Biennial report concerning activities and progress.
- Sec. 6007. Authorities of centers for mental health services, substance abuse prevention, and substance abuse treatment.
- Sec. 6008. Advisory councils.
- Sec. 6009. Peer review.

Subtitle B—Oversight and Accountability

- Sec. 6021. Improving oversight of mental and substance use disorders programs through the Assistant Secretary for Planning and Evaluation.
- Sec. 6022. Reporting for protection and advocacy organizations.
- Sec. 6023. GAO study.

Subtitle C—Interdepartmental Serious Mental Illness Coordinating Committee

- Sec. 6031. Interdepartmental Serious Mental Illness Coordinating Committee.

TITLE VII—ENSURING MENTAL AND SUBSTANCE USE DISORDERS PREVENTION, TREATMENT, AND RECOVERY PROGRAMS KEEP PACE WITH SCIENCE AND TECHNOLOGY

- Sec. 7001. Encouraging innovation and evidence-based programs.
- Sec. 7002. Promoting access to information on evidence-based programs and practices.
- Sec. 7003. Priority mental health needs of regional and national significance.
- Sec. 7004. Priority substance use disorder treatment needs of regional and national significance.
- Sec. 7005. Priority substance use disorder prevention needs of regional and national significance.

TITLE VIII—SUPPORTING STATE PREVENTION ACTIVITIES AND RESPONSES TO MENTAL HEALTH AND SUBSTANCE USE DISORDER NEEDS

- Sec. 8001. Community mental health services block grant.

- Sec. 8002. Substance abuse prevention and treatment block grant.
- Sec. 8003. Additional provisions related to the block grants.
- Sec. 8004. Study of distribution of funds under the substance abuse prevention and treatment block grant and the community mental health services block grant.

TITLE IX—PROMOTING ACCESS TO MENTAL HEALTH AND  
SUBSTANCE USE DISORDER CARE

Subtitle A—Helping Individuals and Families

- Sec. 9001. Grants for treatment and recovery for homeless individuals.
- Sec. 9002. Grants for jail diversion programs.
- Sec. 9003. Promoting integration of primary and behavioral health care.
- Sec. 9004. Projects for assistance in transition from homelessness.
- Sec. 9005. National Suicide Prevention Lifeline Program.
- Sec. 9006. Connecting individuals and families with care.
- Sec. 9007. Strengthening community crisis response systems.
- Sec. 9008. Garrett Lee Smith Memorial Act reauthorization.
- Sec. 9009. Adult suicide prevention.
- Sec. 9010. Mental health awareness training grants.
- Sec. 9011. Sense of Congress on prioritizing American Indians and Alaska Native youth within suicide prevention programs.
- Sec. 9012. Evidence-based practices for older adults.
- Sec. 9013. National violent death reporting system.
- Sec. 9014. Assisted outpatient treatment.
- Sec. 9015. Assertive community treatment grant program.
- Sec. 9016. Sober truth on preventing underage drinking reauthorization.
- Sec. 9017. Center and program repeals.

Subtitle B—Strengthening the Health Care Workforce

- Sec. 9021. Mental and behavioral health education and training grants.
- Sec. 9022. Strengthening the mental and substance use disorders workforce.
- Sec. 9023. Clarification on current eligibility for loan repayment programs.
- Sec. 9024. Minority fellowship program.
- Sec. 9025. Liability protections for health professional volunteers at community health centers.
- Sec. 9026. Reports.

Subtitle C—Mental Health on Campus Improvement

- Sec. 9031. Mental health and substance use disorder services on campus.
- Sec. 9032. Interagency Working Group on College Mental Health.
- Sec. 9033. Improving mental health on college campuses.

TITLE X—STRENGTHENING MENTAL AND SUBSTANCE USE  
DISORDER CARE FOR CHILDREN AND ADOLESCENTS

- Sec. 10001. Programs for children with a serious emotional disturbance.
- Sec. 10002. Increasing access to pediatric mental health care.
- Sec. 10003. Substance use disorder treatment and early intervention services for children and adolescents.
- Sec. 10004. Children's recovery from trauma.
- Sec. 10005. Screening and treatment for maternal depression.
- Sec. 10006. Infant and early childhood mental health promotion, intervention, and treatment.

## TITLE XI—COMPASSIONATE COMMUNICATION ON HIPAA

- Sec. 11001. Sense of Congress.
- Sec. 11002. Confidentiality of records.
- Sec. 11003. Clarification on permitted uses and disclosures of protected health information.
- Sec. 11004. Development and dissemination of model training programs.

## TITLE XII—MEDICAID MENTAL HEALTH COVERAGE

- Sec. 12001. Rule of construction related to Medicaid coverage of mental health services and primary care services furnished on the same day.
- Sec. 12002. Study and report related to Medicaid managed care regulation.
- Sec. 12003. Guidance on opportunities for innovation.
- Sec. 12004. Study and report on Medicaid emergency psychiatric demonstration project.
- Sec. 12005. Providing EPSDT services to children in IMDs.
- Sec. 12006. Electronic visit verification system required for personal care services and home health care services under Medicaid.

## TITLE XIII—MENTAL HEALTH PARITY

- Sec. 13001. Enhanced compliance with mental health and substance use disorder coverage requirements.
- Sec. 13002. Action plan for enhanced enforcement of mental health and substance use disorder coverage.
- Sec. 13003. Report on investigations regarding parity in mental health and substance use disorder benefits.
- Sec. 13004. GAO study on parity in mental health and substance use disorder benefits.
- Sec. 13005. Information and awareness on eating disorders.
- Sec. 13006. Education and training on eating disorders.
- Sec. 13007. Clarification of existing parity rules.

## TITLE XIV—MENTAL HEALTH AND SAFE COMMUNITIES

## Subtitle A—Mental Health and Safe Communities

- Sec. 14001. Law enforcement grants for crisis intervention teams, mental health purposes.
- Sec. 14002. Assisted outpatient treatment programs.
- Sec. 14003. Federal drug and mental health courts.
- Sec. 14004. Mental health in the judicial system.
- Sec. 14005. Forensic assertive community treatment initiatives.
- Sec. 14006. Assistance for individuals transitioning out of systems.
- Sec. 14007. Co-occurring substance abuse and mental health challenges in drug courts.
- Sec. 14008. Mental health training for Federal uniformed services.
- Sec. 14009. Advancing mental health as part of offender reentry.
- Sec. 14010. School mental health crisis intervention teams.
- Sec. 14011. Active-shooter training for law enforcement.
- Sec. 14012. Co-occurring substance abuse and mental health challenges in residential substance abuse treatment programs.
- Sec. 14013. Mental health and drug treatment alternatives to incarceration programs.
- Sec. 14014. National criminal justice and mental health training and technical assistance.

- Sec. 14015. Improving Department of Justice data collection on mental illness involved in crime.
- Sec. 14016. Reports on the number of mentally ill offenders in prison.
- Sec. 14017. Department of Veterans Affairs patients' rights.
- Sec. 14018. Reauthorization of appropriations.

#### Subtitle B—Comprehensive Justice and Mental Health

- Sec. 14021. Sequential intercept model.
- Sec. 14022. Prison and jails.
- Sec. 14023. Allowable uses.
- Sec. 14024. Law enforcement training.
- Sec. 14025. Federal law enforcement training.
- Sec. 14026. GAO report.
- Sec. 14027. Evidence based practices.
- Sec. 14028. Transparency, program accountability, and enhancement of local authority.
- Sec. 14029. Grant accountability.

#### DIVISION C—INCREASING CHOICE, ACCESS, AND QUALITY IN HEALTH CARE FOR AMERICANS

- Sec. 15000. Short title.

#### TITLE XV—PROVISIONS RELATING TO MEDICARE PART A

- Sec. 15001. Development of Medicare HCPCS version of MS-DRG codes for similar hospital services.
- Sec. 15002. Establishing beneficiary equity in the Medicare hospital readmission program.
- Sec. 15003. Five-year extension of the rural community hospital demonstration program.
- Sec. 15004. Regulatory relief for LTCHs.
- Sec. 15005. Savings from IPPS MACRA pay-for through not applying documentation and coding adjustments.
- Sec. 15006. Extension of certain LTCH Medicare payment rules.
- Sec. 15007. Application of rules on the calculation of hospital length of stay to all LTCHs.
- Sec. 15008. Change in Medicare classification for certain hospitals.
- Sec. 15009. Temporary exception to the application of the Medicare LTCH site neutral provisions for certain spinal cord specialty hospitals.
- Sec. 15010. Temporary extension to the application of the Medicare LTCH site neutral provisions for certain discharges with severe wounds.

#### TITLE XVI—PROVISIONS RELATING TO MEDICARE PART B

- Sec. 16001. Continuing Medicare payment under HOPD prospective payment system for services furnished by mid-build off-campus outpatient departments of providers.
- Sec. 16002. Treatment of cancer hospitals in off-campus outpatient department of a provider policy.
- Sec. 16003. Treatment of eligible professionals in ambulatory surgical centers for meaningful use and MIPS.
- Sec. 16004. Continuing Access to Hospitals Act of 2016.



- Sec. 16005. Delay of implementation of Medicare fee schedule adjustments for wheelchair accessories and seating systems when used in conjunction with complex rehabilitation technology (CRT) wheelchairs.
- Sec. 16006. Allowing physical therapists to utilize locum tenens arrangements under Medicare.
- Sec. 16007. Extension of the transition to new payment rates for durable medical equipment under the Medicare program.
- Sec. 16008. Requirements in determining adjustments using information from competitive bidding programs.

#### TITLE XVII—OTHER MEDICARE PROVISIONS

- Sec. 17001. Delay in authority to terminate contracts for Medicare Advantage plans failing to achieve minimum quality ratings.
- Sec. 17002. Requirement for enrollment data reporting for Medicare.
- Sec. 17003. Updating the Welcome to Medicare package.
- Sec. 17004. No payment for items and services furnished by newly enrolled providers or suppliers within a temporary moratorium area.
- Sec. 17005. Preservation of Medicare beneficiary choice under Medicare Advantage.
- Sec. 17006. Allowing end-stage renal disease beneficiaries to choose a Medicare Advantage plan.
- Sec. 17007. Improvements to the assignment of beneficiaries under the Medicare Shared Savings Program.

#### TITLE XVIII—OTHER PROVISIONS

- Sec. 18001. Exception from group health plan requirements for qualified small employer health reimbursement arrangements.

#### DIVISION D—CHILD AND FAMILY SERVICES AND SUPPORT

- Sec. 19000. Short title.

#### TITLE XIX—INVESTING IN PREVENTION AND FAMILY SERVICES

- Sec. 19001. Purpose.

##### Subtitle A—Prevention Activities Under Title IV–E

- Sec. 19011. Foster care prevention services and programs.
- Sec. 19012. Foster care maintenance payments for children with parents in a licensed residential family-based treatment facility for substance abuse.
- Sec. 19013. Title IV–E payments for evidence-based kinship navigator programs.

##### Subtitle B—Enhanced Support Under Title IV–B

- Sec. 19021. Elimination of time limit for family reunification services while in foster care and permitting time-limited family reunification services when a child returns home from foster care.
- Sec. 19022. Reducing bureaucracy and unnecessary delays when placing children in homes across State lines.
- Sec. 19023. Enhancements to grants to improve well-being of families affected by substance abuse.

Subtitle C—Miscellaneous

- Sec. 19031. Reviewing and improving licensing standards for placement in a relative foster family home.
- Sec. 19032. Development of a statewide plan to prevent child abuse and neglect fatalities.
- Sec. 19033. Modernizing the title and purpose of title IV–E.
- Sec. 19034. Effective dates.

TITLE XX—ENSURING THE NECESSITY OF A PLACEMENT THAT IS NOT IN A FOSTER FAMILY HOME

- Sec. 20001. Limitation on Federal financial participation for placements that are not in foster family homes.
- Sec. 20002. Assessment and documentation of the need for placement in a qualified residential treatment program.
- Sec. 20003. Protocols to prevent inappropriate diagnoses.
- Sec. 20004. Additional data and reports regarding children placed in a setting that is not a foster family home.
- Sec. 20005. Effective dates; application to waivers.

TITLE XXI—CONTINUING SUPPORT FOR CHILD AND FAMILY SERVICES

- Sec. 21001. Supporting and retaining foster families for children.
- Sec. 21002. Extension of child and family services programs.
- Sec. 21003. Improvements to the John H. Chafee foster care independence program and related provisions.

TITLE XXII—CONTINUING INCENTIVES TO STATES TO PROMOTE ADOPTION AND LEGAL GUARDIANSHIP

- Sec. 22001. Reauthorizing adoption and legal guardianship incentive programs.

TITLE XXIII—TECHNICAL CORRECTIONS

- Sec. 23001. Technical corrections to data exchange standards to improve program coordination.
- Sec. 23002. Technical corrections to State requirement to address the developmental needs of young children.

TITLE XXIV—ENSURING STATES REINVEST SAVINGS RESULTING FROM INCREASE IN ADOPTION ASSISTANCE

- Sec. 24001. Delay of adoption assistance phase-in.
- Sec. 24002. GAO study and report on State reinvestment of savings resulting from increase in adoption assistance.

TITLE XXV—SOCIAL IMPACT PARTNERSHIPS TO PAY FOR RESULTS

- Sec. 25001. Short title.
- Sec. 25002. Social Impact Partnerships to Pay for Results.
- Sec. 25003. Extension of TANF program.
- Sec. 25004. Strengthening welfare research and evaluation and development of a What Works Clearinghouse.
- Sec. 25005. Technical corrections to data exchange standards to improve program coordination.

1           **DIVISION A—21ST CENTURY**  
2                           **CURES**

3   **SECTION 1000. SHORT TITLE.**

4           This Division may be cited as the “21st Century  
5 Cures Act”.

6   **TITLE   I—INNOVATION**  
7           **PROJECTS AND STATE RE-**  
8           **SPONSES TO OPIOID ABUSE**

9   **SEC. 1001. NIH INNOVATION PROJECTS.**

10           (a) IN GENERAL.—The Director of the National In-  
11 stitutes of Health (referred to in this section as the “Di-  
12 rector of NIH”) shall use any funds appropriated pursu-  
13 ant to the authorization of appropriations in subsection  
14 (b)(3) to carry out the National Institutes of Health inno-  
15 vation projects described in subsection (b)(4) (referred to  
16 in this section as the “NIH Innovation Projects”).

17           (b) NATIONAL INSTITUTES OF HEALTH INNOVATION  
18 ACCOUNT.—

19                   (1) ESTABLISHMENT OF NIH INNOVATION AC-  
20           COUNT.—There is established in the Treasury an ac-  
21           count, to be known as the “NIH Innovation Ac-  
22           count” (referred to in this subsection as the “Ac-  
23           count”), for purposes of carrying out the NIH Inno-  
24           vation Projects described in paragraph (4).

1           (2) TRANSFER OF DIRECT SPENDING SAV-  
2 INGS.—

3           (A) IN GENERAL.—The following amounts  
4 shall be transferred to the Account from the  
5 general fund of the Treasury:

6                   (i) For fiscal year 2017,  
7                   \$372,000,000.

8                   (ii) For fiscal year 2018,  
9                   \$526,000,000.

10                   (iii) For fiscal year 2019,  
11                   \$721,000,000.

12                   (iv) For fiscal year 2020,  
13                   \$507,000,000.

14                   (v) For fiscal year 2021,  
15                   \$424,000,000.

16                   (vi) For fiscal year 2022,  
17                   \$496,000,000.

18                   (vii) For fiscal year 2023,  
19                   \$1,085,000,000.

20                   (viii) For fiscal year 2024,  
21                   \$407,000,000.

22                   (ix) For fiscal year 2025,  
23                   \$107,000,000.

24                   (x) For fiscal year 2026,  
25                   \$151,000,000.

1 (B) AMOUNTS DEPOSITED.—Any amounts  
2 transferred under subparagraph (A) shall re-  
3 main unavailable in the Account until such  
4 amounts are appropriated pursuant to para-  
5 graph (3).

6 (3) APPROPRIATIONS.—

7 (A) AUTHORIZATION OF APPROPRIA-  
8 TIONS.—For each of the fiscal years 2017  
9 through 2026, there is authorized to be appro-  
10 priated from the Account to the Director of  
11 NIH, for the purpose of carrying out the NIH  
12 Innovation Projects, an amount not to exceed  
13 the total amount transferred to the Account  
14 under paragraph (2)(A), to remain available  
15 until expended.

16 (B) OFFSETTING FUTURE APPROPRIA-  
17 TIONS.—For any of fiscal years 2017 through  
18 2026, for any discretionary appropriation under  
19 the heading “NIH Innovation Account” pro-  
20 vided to the Director of NIH pursuant to the  
21 authorization of appropriations under subpara-  
22 graph (A) for the purpose of carrying out the  
23 NIH Innovation Projects, the total amount of  
24 such appropriations for the applicable fiscal  
25 year (not to exceed the total amount remaining

1 in the Account) shall be subtracted from the es-  
2 timate of discretionary budget authority and  
3 the resulting outlays for any estimate under the  
4 Congressional Budget and Impoundment Con-  
5 trol Act of 1974 or the Balanced Budget and  
6 Emergency Deficit Control Act of 1985, and  
7 the amount transferred to the Account shall be  
8 reduced by the same amount.

9 (4) NIH INNOVATION PROJECTS.—NIH Inno-  
10 vation Projects authorized to be funded under this  
11 section shall consist of the following and, of the total  
12 amounts authorized to be appropriated under para-  
13 graph (3), there are authorized to be appropriated to  
14 each such project a total amount not to exceed the  
15 following, over the period of fiscal years 2017  
16 through 2026:

17 (A) For the Precision Medicine Initiative,  
18 including for the advancement of a cohort of in-  
19 dividuals to support the goals of the Precision  
20 Medicine Initiative, not to exceed a total of  
21 \$1,400,000,000, as follows:

22 (i) For fiscal year 2017, \$0.

23 (ii) For fiscal year 2018,  
24 \$114,000,000.

1 (iii) For fiscal year 2019,  
2 \$23,000,000.

3 (iv) For fiscal year 2020,  
4 \$136,000,000.

5 (v) For fiscal year 2021, \$78,000,000.

6 (vi) For fiscal year 2022,  
7 \$245,000,000.

8 (vii) For fiscal year 2023,  
9 \$580,000,000.

10 (viii) For fiscal year 2024,  
11 \$180,000,000.

12 (ix) For fiscal year 2025,  
13 \$30,000,000.

14 (x) For fiscal year 2026,  
15 \$14,000,000.

16 (B) For the Brain Research through Ad-  
17 vancing Innovative Neurotechnologies Initiative  
18 (known as the “BRAIN Initiative”), not to ex-  
19 ceed a total of \$1,564,000,000, as follows:

20 (i) For fiscal year 2017, \$0.

21 (ii) For fiscal year 2018,  
22 \$124,000,000.

23 (iii) For fiscal year 2019,  
24 \$25,000,000.

1 (iv) For fiscal year 2020,  
2 \$135,000,000.

3 (v) For fiscal year 2021, \$83,000,000.

4 (vi) For fiscal year 2022,  
5 \$251,000,000.

6 (vii) For fiscal year 2023,  
7 \$505,000,000.

8 (viii) For fiscal year 2024,  
9 \$227,000,000.

10 (ix) For fiscal year 2025,  
11 \$77,000,000.

12 (x) For fiscal year 2026,  
13 \$137,000,000.

14 (C) To support cancer research, such as  
15 the development of cancer vaccines, the develop-  
16 ment of more sensitive diagnostic tests for can-  
17 cer, immunotherapy and the development of  
18 combination therapies, and research that has  
19 the potential to transform the scientific field,  
20 that has inherently higher risk, and that seeks  
21 to address major challenges related to cancer,  
22 not to exceed a total of \$1,802,000,000, as fol-  
23 lows:

24 (i) For fiscal year 2017,  
25 \$372,000,000.



1 (ii) For fiscal year 2018,  
2 \$278,000,000.

3 (iii) For fiscal year 2019,  
4 \$663,000,000.

5 (iv) For fiscal year 2020,  
6 \$226,000,000.

7 (v) For fiscal year 2021,  
8 \$263,000,000.

9 (D) For the National Institutes of Health,  
10 in coordination with the Food and Drug Admin-  
11 istration, to award grants and contracts for  
12 clinical research to further the field of regenera-  
13 tive medicine using adult stem cells, including  
14 autologous stem cells, for which grants and con-  
15 tracts shall be contingent upon the recipient  
16 making available non-Federal contributions to-  
17 ward the costs of such research in an amount  
18 not less than \$1 for each \$1 of Federal funds  
19 provided in the award, not to exceed a total of  
20 \$30,000,000, as follows:

21 (i) For fiscal year 2017, \$0.

22 (ii) For each of fiscal years 2018  
23 through 2020, \$10,000,000.

24 (iii) For each of fiscal years 2021  
25 through 2026, \$0.

1 (c) ACCOUNTABILITY AND OVERSIGHT.—

2 (1) WORK PLAN.—

3 (A) IN GENERAL.—Not later than 180  
4 days after the date of enactment of this Act,  
5 the Director of NIH shall submit to the Com-  
6 mittee on Health, Education, Labor, and Pen-  
7 sions and the Committee on Appropriations of  
8 the Senate and the Committee on Energy and  
9 Commerce and the Committee on Appropria-  
10 tions of the House of Representatives, a work  
11 plan including the proposed allocation of funds  
12 authorized to be appropriated pursuant to sub-  
13 section (b)(3) for each of fiscal years 2017  
14 through 2026 for the NIH Innovation Projects  
15 and the contents described in subparagraph  
16 (B).

17 (B) CONTENTS.—The work plan submitted  
18 under subparagraph (A) shall include—

19 (i) recommendations from the Advi-  
20 sory Committee described in subparagraph  
21 (C);

22 (ii) the amount of money to be obli-  
23 gated or expended in each fiscal year for  
24 each NIH Innovation Project;

1 (iii) a description and justification of  
2 each such project; and

3 (iv) a description of how each such  
4 project supports the strategic research pri-  
5 orities identified in the NIH Strategic Plan  
6 under subsection (m) of section 402 of the  
7 Public Health Service Act (42 U.S.C.  
8 282), as added by section 2031.

9 (C) RECOMMENDATIONS.—Prior to sub-  
10 mitting the work plan under this paragraph,  
11 the Director of NIH shall seek recommenda-  
12 tions from the Advisory Committee to the Di-  
13 rector of NIH appointed under section 222 of  
14 the Public Health Service Act (42 U.S.C. 217a)  
15 on—

16 (i) the allocations of funds appro-  
17 priated pursuant to the authorization of  
18 appropriations under subsection (b)(3) for  
19 each of fiscal years 2017 through 2026;  
20 and

21 (ii) on the contents of the proposed  
22 work plan.

23 (2) REPORTS.—

24 (A) ANNUAL REPORTS.—Not later than  
25 October 1 of each of fiscal years 2018 through

1           2027, the Director of NIH shall submit to the  
2           Committee on Health, Education, Labor, and  
3           Pensions and the Committee on Appropriations  
4           of the Senate and the Committee on Energy  
5           and Commerce and the Committee on Appro-  
6           priations of the House of Representatives, a re-  
7           port including—

8                   (i) the amount of money obligated or  
9                   expended in the prior fiscal year for each  
10                  NIH Innovation Project;

11                  (ii) a description of any such project  
12                  using funds provided pursuant to the au-  
13                  thorization of appropriations under sub-  
14                  section (b)(3); and

15                  (iii) whether such projects are advanc-  
16                  ing the strategic research priorities identi-  
17                  fied in the NIH Strategic Plan under sub-  
18                  section (m) of section 402 of the Public  
19                  Health Service Act (42 U.S.C. 282), as  
20                  added by section 2031.

21           (B) **ADDITIONAL REPORTS.**—At the re-  
22           quest of the Committee on Health, Education,  
23           Labor, and Pensions or the Committee on Ap-  
24           propriations of the Senate, or the Committee on  
25           Energy and Commerce or the Committee on

1 Appropriations of the House of Representatives,  
2 the Director of NIH shall provide an update in  
3 the form of testimony and any additional re-  
4 ports to the respective congressional committee  
5 regarding the allocation of funding under this  
6 section or the description of the NIH Innova-  
7 tion Projects.

8 (d) LIMITATIONS.—Notwithstanding any transfer au-  
9 thority authorized by this Act or any appropriations Act,  
10 any funds made available pursuant to the authorization  
11 of appropriations under subsection (b)(3) may not be used  
12 for any purpose other than a NIH Innovation Project.

13 (e) SUNSET.—This section shall expire on September  
14 30, 2026.

15 **SEC. 1002. FDA INNOVATION PROJECTS.**

16 (a) IN GENERAL.—The Commissioner of Food and  
17 Drugs (referred to in this section as the “Commissioner”)  
18 shall use any funds appropriated pursuant to the author-  
19 ization of appropriations under subsection (b)(3) to carry  
20 out the activities described in subsection (b)(4).

21 (b) FDA INNOVATION ACCOUNT.—

22 (1) ESTABLISHMENT OF FDA INNOVATION AC-  
23 COUNT.—There is established in the Treasury an ac-  
24 count, to be known as the “FDA Innovation Ac-  
25 count” (referred to in this subsection as the “Ac-

1 count”), for purposes of carrying out the activities  
2 described in paragraph (4).

3 (2) TRANSFER OF DIRECT SPENDING SAV-  
4 INGS.—

5 (A) IN GENERAL.—For each of fiscal years  
6 2018 through 2026, the following amounts shall  
7 be transferred to the Account from the general  
8 fund of the Treasury:

9 (i) For fiscal year 2018, \$30,000,000.

10 (ii) For fiscal year 2019,  
11 \$60,000,000.

12 (iii) For fiscal year 2020,  
13 \$60,000,000.

14 (iv) For fiscal year 2021,  
15 \$50,000,000.

16 (v) For fiscal year 2022, \$50,000,000.

17 (vi) For fiscal year 2023,  
18 \$50,000,000.

19 (vii) For fiscal year 2024,  
20 \$50,000,000.

21 (viii) For fiscal year 2025,  
22 \$75,000,000.

23 (ix) For fiscal year 2026,  
24 \$75,000,000.

1 (B) AMOUNTS DEPOSITED.—Any amounts  
2 transferred under subparagraph (A) shall re-  
3 main unavailable in the Account until such  
4 amounts are appropriated pursuant to para-  
5 graph (3).

6 (3) APPROPRIATIONS.—

7 (A) AUTHORIZATION OF APPROPRIA-  
8 TIONS.—For each of the fiscal years 2018  
9 through 2026, there is authorized to be appro-  
10 priated from the Account to the Commissioner,  
11 for the purpose of carrying out the activities de-  
12 scribed in paragraph (5), an amount not to ex-  
13 ceed the total amount transferred to the Ac-  
14 count under paragraph (2)(A), to remain avail-  
15 able until expended.

16 (B) OFFSETTING FUTURE APPROPRIA-  
17 TIONS.—For any of fiscal years 2018 through  
18 2026, for any discretionary appropriation under  
19 the heading “FDA Innovation Account” pro-  
20 vided to the Commissioner pursuant to the au-  
21 thorization of appropriations under subpara-  
22 graph (A) for the purpose of carrying out the  
23 projects activities described in paragraph (4),  
24 the total amount of such appropriations in the  
25 applicable fiscal year (not to exceed the total

1 amount remaining in the Account) shall be sub-  
2 tracted from the estimate of discretionary budg-  
3 et authority and the resulting outlays for any  
4 estimate under the Congressional Budget and  
5 Impoundment Control Act of 1974 or the Bal-  
6 anced Budget and Emergency Deficit Control  
7 Act of 1985, and the amount transferred to the  
8 Account shall be reduced by the same amount.

9 (4) FDA ACTIVITIES.—The activities authorized  
10 to be funded under this section are the activities  
11 under subtitles A through F (including the amend-  
12 ments made by such subtitles) of title III, section  
13 565A of the Federal Food, Drug, and Cosmetic Act,  
14 as added by section 3086 of this Act, and section  
15 1014 of such Act, as added by section 3073 of this  
16 Act.

17 (c) ACCOUNTABILITY AND OVERSIGHT.—

18 (1) WORK PLAN.—

19 (A) IN GENERAL.—Not later than 180  
20 days after the date of enactment of this Act,  
21 the Commissioner shall submit to the Com-  
22 mittee on Health, Education, Labor, and Pen-  
23 sions and the Committee on Appropriations of  
24 the Senate and the Committee on Energy and  
25 Commerce and the Committee on Appropria-



1           tions of the House of Representatives, a work  
2           plan including the proposed allocation of funds  
3           appropriated pursuant to the authorization of  
4           appropriations under subsection (b)(3) for each  
5           of fiscal years 2018 through 2026 and the con-  
6           tents described in subparagraph (B).

7           (B) CONTENTS.—The work plan submitted  
8           under subparagraph (A) shall include—

9                   (i) recommendations from the Advi-  
10                   sory Committee described in subparagraph  
11                   (C);

12                   (ii) the amount of money to be obli-  
13                   gated or expended in each fiscal year for  
14                   each activity described in subsection (b)(4);  
15                   and

16                   (iii) a description and justification of  
17                   each such project activity.

18           (C) RECOMMENDATIONS.—Prior to sub-  
19           mitting the work plan under this paragraph,  
20           the Commissioner shall seek recommendations  
21           from the Science Board to the Food and Drug  
22           Administration, on the proposed allocation of  
23           funds appropriated pursuant to the authoriza-  
24           tion of appropriations under subsection (b)(3)

1 for each of fiscal years 2018 through 2026 and  
2 on the contents of the proposed work plan.

3 (2) REPORTS.—

4 (A) ANNUAL REPORTS.—Not later than  
5 October 1 of each of fiscal years 2019 through  
6 2027, the Commissioner shall submit to the  
7 Committee on Health, Education, Labor, and  
8 Pensions and the Committee on Appropriations  
9 of the Senate and the Committee on Energy  
10 and Commerce and the Committee on Appro-  
11 priations of the House of Representatives, a re-  
12 port including—

13 (i) the amount of money obligated or  
14 expended in the prior fiscal year for each  
15 activity described in subsection (b)(4);

16 (ii) a description of all such activities  
17 using funds provided pursuant to the au-  
18 thorization of appropriations under sub-  
19 section (b)(3); and

20 (iii) how the activities are advancing  
21 public health.

22 (B) ADDITIONAL REPORTS.—At the re-  
23 quest of the Committee on Health, Education,  
24 Labor, and Pensions or the Committee on Ap-  
25 propriations of the Senate, or the Committee on

1 Energy and Commerce or the Committee on  
2 Appropriations of the House of Representatives,  
3 the Commissioner shall provide an update in  
4 the form of testimony and any additional re-  
5 ports to the respective congressional committee  
6 regarding the allocation of funding under this  
7 section or the description of the activities un-  
8 dertaken with such funding.

9 (d) LIMITATIONS.—Notwithstanding any transfer au-  
10 thority authorized by this Act or any appropriations Act,  
11 any funds made available pursuant to the authorization  
12 of appropriations in subsection (b)(3) shall not be used  
13 for any purpose other than an activity described in sub-  
14 section (b)(4).

15 (e) SUNSET.—This section shall expire on September  
16 30, 2026.

17 **SEC. 1003. ACCOUNT FOR THE STATE RESPONSE TO THE**  
18 **OPIOID ABUSE CRISIS.**

19 (a) IN GENERAL.—The Secretary of Health and  
20 Human Services (referred to in this section as the “Sec-  
21 retary”) shall use any funds appropriated pursuant to the  
22 authorization of appropriations under subsection (b) to  
23 carry out the grant program described in subsection (c)  
24 for purposes of addressing the opioid abuse crisis within  
25 the States.

1 (b) ACCOUNT FOR THE STATE RESPONSE TO THE  
2 OPIOID ABUSE CRISIS.—

3 (1) ESTABLISHMENT.—There is established in  
4 the Treasury an account, to be known as the “Ac-  
5 count For the State Response to the Opioid Abuse  
6 Crisis” (referred to in this subsection as the “Ac-  
7 count”), to carry out the opioid grant program de-  
8 scribed in subsection (c).

9 (2) TRANSFER OF DIRECT SPENDING SAV-  
10 INGS.—

11 (A) IN GENERAL.—The following amounts  
12 shall be transferred to the Account from the  
13 general fund of the Treasury:

14 (i) For fiscal year 2017,  
15 \$500,000,000.

16 (ii) For fiscal year 2018,  
17 \$500,000,000.

18 (B) AMOUNTS DEPOSITED.—Any amounts  
19 transferred under subparagraph (A) shall re-  
20 main unavailable in the Account until such  
21 amounts are appropriated pursuant to para-  
22 graph (3).

23 (3) APPROPRIATIONS.—

24 (A) AUTHORIZATION OF APPROPRIA-  
25 TIONS.—In each of the fiscal years 2017 and

1           2018, there is authorized to be appropriated  
2           from the Account to the Secretary, for the  
3           grant program described in subsection (c), an  
4           amount not to exceed the total amount trans-  
5           ferred to the Account under paragraph (2)(A),  
6           to remain available until expended.

7           (B) OFFSETTING FUTURE APPROPRIA-  
8           TIONS.—In each of fiscal years 2017 and 2018,  
9           for any discretionary appropriation under the  
10          heading “Account For the State Response to  
11          the Opioid Abuse Crisis” for the grant program  
12          described in subsection (c), the total amount of  
13          such appropriations in the applicable fiscal year  
14          (not to exceed the total amount remaining in  
15          the Account) shall be subtracted from the esti-  
16          mate of discretionary budget authority and the  
17          resulting outlays for any estimate under the  
18          Congressional Budget and Impoundment Con-  
19          trol Act of 1974 or the Balanced Budget and  
20          Emergency Deficit Control Act of 1985, and  
21          the amount transferred to the Account shall be  
22          reduced by the same amount.

23          (c) OPIOID GRANT PROGRAM.—

24               (1) STATE RESPONSE TO THE OPIOID ABUSE  
25          CRISIS.—Subject to the availability of appropria-

1        tions, the Secretary shall award grants to States for  
2        the purpose of addressing the opioid abuse crisis  
3        within such States, in accordance with subparagraph  
4        (B). In awarding such grants, the Secretary may  
5        give preference to States with an incidence or preva-  
6        lence of opioid use disorders that is substantially  
7        higher relative to other States.

8            (2) OPIOID GRANTS.—Grants awarded to a  
9        State under this subsection shall be used for car-  
10       rying out activities that supplement activities per-  
11       taining to opioids undertaken by the State agency  
12       responsible for administering the substance abuse  
13       prevention and treatment block grant under subpart  
14       II of part B of title XIX of the Public Health Serv-  
15       ice Act (42 U.S.C. 300x–21 et seq.), which may in-  
16       clude public health-related activities such as the fol-  
17       lowing:

18            (A) Improving State prescription drug  
19        monitoring programs.

20            (B) Implementing prevention activities,  
21        and evaluating such activities to identify effec-  
22        tive strategies to prevent opioid abuse.

23            (C) Training for health care practitioners,  
24        such as best practices for prescribing opioids,  
25        pain management, recognizing potential cases

1 of substance abuse, referral of patients to treat-  
2 ment programs, and overdose prevention.

3 (D) Supporting access to health care serv-  
4 ices, including those services provided by Feder-  
5 ally certified opioid treatment programs or  
6 other appropriate health care providers to treat  
7 substance use disorders.

8 (E) Other public health-related activities,  
9 as the State determines appropriate, related to  
10 addressing the opioid abuse crisis within the  
11 State.

12 (d) ACCOUNTABILITY AND OVERSIGHT.—A State re-  
13 ceiving a grant under subsection (c) shall include in a re-  
14 port related to substance abuse submitted to the Secretary  
15 pursuant to section 1942 of the Public Health Service Act  
16 (42 U.S.C. 300x–52), a description of—

17 (1) the purposes for which the grant funds re-  
18 ceived by the State under such subsection for the  
19 preceding fiscal year were expended and a descrip-  
20 tion of the activities of the State under the program;  
21 and

22 (2) the ultimate recipients of amounts provided  
23 to the State in the grant.

1 (e) LIMITATIONS.—Any funds made available pursu-  
2 ant to the authorization of appropriations under sub-  
3 section (b)—

4 (1) notwithstanding any transfer authority in  
5 any appropriations Act, shall not be used for any  
6 purpose other than the grant program in subsection  
7 (c); and

8 (2) shall be subject to the same requirements as  
9 substance abuse prevention and treatment programs  
10 under titles V and XIX of the Public Health Service  
11 Act (42 U.S.C. 290aa et seq., 300w et seq.).

12 (f) SUNSET.—This section shall expire on September  
13 30, 2026.

14 **SEC. 1004. BUDGETARY TREATMENT.**

15 (a) STATUTORY PAYGO SCORECARDS.—The budg-  
16 etary effects of division A of this Act shall not be entered  
17 on either PAYGO scorecard maintained pursuant to sec-  
18 tion 4(d) of the Statutory Pay-As-You-Go Act of 2010.

19 (b) SENATE PAYGO SCORECARDS.—The budgetary  
20 effects of division A of this Act shall not be entered on  
21 any PAYGO scorecard maintained for purposes of section  
22 201 of S. Con. Res. 21 (110th Congress).

23 (c) RESERVATION OF SAVINGS.—None of the funds  
24 in the NIH Innovation Account, the FDA Innovation Ac-  
25 count, or the Account For the State Response to the



1 Opioid Abuse Crisis established by this title shall be made  
2 available except to the extent provided in advance in ap-  
3 propriations Acts, and legislation or an Act that rescinds  
4 or reduces amounts in such accounts shall not be esti-  
5 mated as a reduction in direct spending under the Con-  
6 gressional Budget and Impoundment Control Act of 1974  
7 or the Balanced Budget and Emergency Deficit Control  
8 Act of 1985.

9 **TITLE II—DISCOVERY**  
10 **Subtitle A—National Institutes of**  
11 **Health Reauthorization**

12 **SEC. 2001. NATIONAL INSTITUTES OF HEALTH REAUTHOR-**  
13 **IZATION.**

14 Section 402A(a)(1) of the Public Health Service Act  
15 (42 U.S.C. 282a(a)(1)) is amended—

16 (1) in subparagraph (B), by striking “and” at  
17 the end;

18 (2) in subparagraph (C), by striking the period  
19 at the end and inserting a semicolon; and

20 (3) by adding at the end the following new sub-  
21 paragraphs:

22 “(D) \$34,851,000,000 for fiscal year  
23 2018;

24 “(E) \$35,585,871,000 for fiscal year 2019;

25 and

1                   “(F) \$36,472,442,775 for fiscal year  
2                   2020.”.

3 **SEC. 2002. EUREKA PRIZE COMPETITIONS.**

4           (a) IN GENERAL.—Pursuant to the authorities and  
5 processes established under section 24 of the Stevenson-  
6 Wydler Technology Innovation Act of 1980 (15 U.S.C.  
7 3719), the Director of the National Institutes of Health  
8 shall support prize competitions for one or both of the fol-  
9 lowing goals:

10           (1) Identifying and funding areas of biomedical  
11 science that could realize significant advancements  
12 through a prize competition.

13           (2) Improving health outcomes, particularly  
14 with respect to human diseases and conditions—

15                   (A) for which public and private invest-  
16 ment in research is disproportionately small rel-  
17 ative to Federal Government expenditures on  
18 prevention and treatment activities with respect  
19 to such diseases and conditions, such that Fed-  
20 eral expenditures on health programs would be  
21 reduced;

22                   (B) that are serious and represent a sig-  
23 nificant disease burden in the United States; or

24                   (C) for which there is potential for signifi-  
25 cant return on investment to the United States.

1 (b) TRACKING; REPORTING.—The Director of the  
2 National Institutes of Health shall—

3 (1) collect information on—

4 (A) the effect of innovations funded  
5 through the prize competitions under this sec-  
6 tion in advancing biomedical science or improv-  
7 ing health outcomes pursuant to subsection (a);  
8 and

9 (B) the effect of the innovations on Fed-  
10 eral expenditures; and

11 (2) include the information collected under  
12 paragraph (1) in the triennial report under section  
13 403 of the Public Health Service Act (42 U.S.C.  
14 283) (as amended by section 2032).

## 15 **Subtitle B—Advancing Precision** 16 **Medicine**

### 17 **SEC. 2011. PRECISION MEDICINE INITIATIVE.**

18 Part H of title IV of the Public Health Service Act  
19 (42 U.S.C. 289 et seq.) is amended by adding at the end  
20 the following:

#### 21 **“SEC. 498E. PRECISION MEDICINE INITIATIVE.**

22 “(a) IN GENERAL.—The Secretary is encouraged to  
23 establish and carry out an initiative, to be known as the  
24 ‘Precision Medicine Initiative’ (in this section referred to

1 as the ‘Initiative’), to augment efforts to address disease  
2 prevention, diagnosis, and treatment.

3 “(b) COMPONENTS.—The Initiative described under  
4 subsection (a) may include—

5 “(1) developing a network of scientists to assist  
6 in carrying out the purposes of the Initiative;

7 “(2) developing new approaches for addressing  
8 scientific, medical, public health, and regulatory  
9 science issues;

10 “(3) applying genomic technologies, such as  
11 whole genomic sequencing, to provide data on the  
12 molecular basis of disease;

13 “(4) collecting information voluntarily provided  
14 by a diverse cohort of individuals that can be used  
15 to better understand health and disease; and

16 “(5) other activities to advance the goals of the  
17 Initiative, as the Secretary determines appropriate.

18 “(c) AUTHORITY OF THE SECRETARY.—In carrying  
19 out this section, the Secretary may—

20 “(1) coordinate with the Secretary of Energy,  
21 private industry, and others, as the Secretary deter-  
22 mines appropriate, to identify and address the ad-  
23 vanced supercomputing and other advanced tech-  
24 nology needs for the Initiative;

1           “(2) develop and utilize public-private partner-  
2           ships; and

3           “(3) leverage existing data sources.

4           “(d) REQUIREMENTS.—In the implementation of the  
5 Initiative under subsection (a), the Secretary shall—

6           “(1) ensure the collaboration of the National  
7 Institutes of Health, the Food and Drug Adminis-  
8 tration, the Office of the National Coordinator for  
9 Health Information Technology, and the Office for  
10 Civil Rights of the Department of Health and  
11 Human Services;

12           “(2) comply with existing laws and regulations  
13 for the protection of human subjects involved in re-  
14 search, including the protection of participant pri-  
15 vacy;

16           “(3) implement policies and mechanisms for ap-  
17 propriate secure data sharing across systems that  
18 include protections for privacy and security of data;

19           “(4) consider the diversity of the cohort to en-  
20 sure inclusion of a broad range of participants, in-  
21 cluding consideration of biological, social, and other  
22 determinants of health that contribute to health dis-  
23 parities;

24           “(5) ensure that only authorized individuals  
25 may access controlled or sensitive, identifiable bio-

1 logical material and associated information collected  
2 or stored in connection with the Initiative; and

3 “(6) on the appropriate Internet website of the  
4 Department of Health and Human Services, identify  
5 any entities with access to such information and pro-  
6 vide information with respect to the purpose of such  
7 access, a summary of the research project for which  
8 such access is granted, as applicable, and a descrip-  
9 tion of the biological material and associated infor-  
10 mation to which the entity has access.

11 “(e) REPORT.—Not later than 1 year after the date  
12 of enactment of the 21st Century Cures Act, the Secretary  
13 shall submit a report on the relevant data access policies  
14 and procedures to the Committee on Health, Education,  
15 Labor, and Pensions of the Senate and the Committee on  
16 Energy and Commerce of the House of Representatives.  
17 Such report shall include steps the Secretary has taken  
18 to consult with experts or other heads of departments or  
19 agencies of the Federal Government in the development  
20 of such policies.”.

21 **SEC. 2012. PRIVACY PROTECTION FOR HUMAN RESEARCH**  
22 **SUBJECTS.**

23 (a) IN GENERAL.—Subsection (d) of section 301 of  
24 the Public Health Service Act (42 U.S.C. 241) is amended  
25 to read as follows:

1           “(d)(1)(A) If a person is engaged in biomedical, be-  
2           havioral, clinical, or other research, in which identifiable,  
3           sensitive information is collected (including research on  
4           mental health and research on the use and effect of alcohol  
5           and other psychoactive drugs), the Secretary, in coordina-  
6           tion with other agencies, as applicable—

7                   “(i) shall issue to such person a certificate of  
8           confidentiality to protect the privacy of individuals  
9           who are the subjects of such research if the research  
10          is funded wholly or in part by the Federal Govern-  
11          ment; and

12                   “(ii) may, upon application by a person engaged  
13          in research, issue to such person a certificate of con-  
14          fidentiality to protect the privacy of such individuals  
15          if the research is not so funded.

16          “(B) Except as provided in subparagraph (C), any  
17          person to whom a certificate is issued under subparagraph  
18          (A) to protect the privacy of individuals described in such  
19          subparagraph shall not disclose or provide to any other  
20          person not connected with the research the name of such  
21          an individual or any information, document, or biospeci-  
22          men that contains identifiable, sensitive information about  
23          such an individual and that was created or compiled for  
24          purposes of the research.

1           “(C) The disclosure prohibition in subparagraph (B)  
2 shall not apply to disclosure or use that is—

3           “(i) required by Federal, State, or local laws,  
4 excluding instances described in subparagraph (D);

5           “(ii) necessary for the medical treatment of the  
6 individual to whom the information, document, or  
7 biospecimen pertains and made with the consent of  
8 such individual;

9           “(iii) made with the consent of the individual to  
10 whom the information, document, or biospecimen  
11 pertains; or

12           “(iv) made for the purposes of other scientific  
13 research that is in compliance with applicable Fed-  
14 eral regulations governing the protection of human  
15 subjects in research.

16           “(D) Any person to whom a certificate is issued  
17 under subparagraph (A) to protect the privacy of an indi-  
18 vidual described in such subparagraph shall not, in any  
19 Federal, State, or local civil, criminal, administrative, leg-  
20 islative, or other proceeding, disclose or provide the name  
21 of such individual or any such information, document, or  
22 biospecimen that contains identifiable, sensitive informa-  
23 tion about the individual and that was created or compiled  
24 for purposes of the research, except in the circumstance  
25 described in subparagraph (C)(iii).



1       “(E) Identifiable, sensitive information protected  
2 under subparagraph (A), and all copies thereof, shall be  
3 immune from the legal process, and shall not, without the  
4 consent of the individual to whom the information per-  
5 tains, be admissible as evidence or used for any purpose  
6 in any action, suit, or other judicial, legislative, or admin-  
7 istrative proceeding.

8       “(F) Identifiable, sensitive information collected by a  
9 person to whom a certificate has been issued under sub-  
10 paragraph (A), and all copies thereof, shall be subject to  
11 the protections afforded by this section for perpetuity.

12       “(G) The Secretary shall take steps to minimize the  
13 burden to researchers, streamline the process, and reduce  
14 the time it takes to comply with the requirements of this  
15 subsection.

16       “(2) The Secretary shall coordinate with the heads  
17 of other applicable Federal agencies to ensure that such  
18 departments have policies in place with respect to the  
19 issuance of a certificate of confidentiality pursuant to  
20 paragraph (1) and other requirements of this subsection.

21       “(3) Nothing in this subsection shall be construed to  
22 limit the access of an individual who is a subject of re-  
23 search to information about himself or herself collected  
24 during such individual’s participation in the research.

1           “(4) For purposes of this subsection, the term ‘identi-  
2       fiable, sensitive information’ means information that is  
3       about an individual and that is gathered or used during  
4       the course of research described in paragraph (1)(A)  
5       and—

6           “(A) through which an individual is identified;  
7       or

8           “(B) for which there is at least a very small  
9       risk, as determined by current scientific practices or  
10      statistical methods, that some combination of the in-  
11      formation, a request for the information, and other  
12      available data sources could be used to deduce the  
13      identity of an individual.”.

14      (b) **APPLICABILITY.**—Beginning 180 days after the  
15      date of enactment of this Act, all persons engaged in re-  
16      search and authorized by the Secretary of Health and  
17      Human Services to protect information under section  
18      301(d) of the Public Health Service Act (42 U.S.C.  
19      241(d)) prior to the date of enactment of this Act shall  
20      be subject to the requirements of such section (as amend-  
21      ed by this Act).

1 **SEC. 2013. PROTECTION OF IDENTIFIABLE AND SENSITIVE**  
2 **INFORMATION.**

3 Section 301 of the Public Health Service Act (42  
4 U.S.C. 241) is amended by adding at the end the fol-  
5 lowing:

6 “(f)(1) The Secretary may exempt from disclosure  
7 under section 552(b)(3) of title 5, United States Code,  
8 biomedical information that is about an individual and  
9 that is gathered or used during the course of biomedical  
10 research if—

11 “(A) an individual is identified; or

12 “(B) there is at least a very small risk, as de-  
13 termined by current scientific practices or statistical  
14 methods, that some combination of the information,  
15 the request, and other available data sources could  
16 be used to deduce the identity of an individual.

17 “(2)(A) Each determination of the Secretary under  
18 paragraph (1) to exempt information from disclosure shall  
19 be made in writing and accompanied by a statement of  
20 the basis for the determination.

21 “(B) Each such determination and statement of basis  
22 shall be available to the public, upon request, through the  
23 Office of the Chief FOIA Officer of the Department of  
24 Health and Human Services.

25 “(3) Nothing in this subsection shall be construed to  
26 limit a research participant’s access to information about

1 such participant collected during the participant’s partici-  
2 pation in the research.”.

3 **SEC. 2014. DATA SHARING.**

4 (a) IN GENERAL.—Section 402(b) of the Public  
5 Health Service Act (42 U.S.C. 282(b)) is amended—

6 (1) in paragraph (23), by striking “and” at the  
7 end;

8 (2) in paragraph (24), by striking the period  
9 and inserting “; and”; and

10 (3) by inserting after paragraph (24) the fol-  
11 lowing:

12 “(25) may require recipients of National Insti-  
13 tutes of Health awards to share scientific data, to  
14 the extent feasible, generated from such National In-  
15 stitutes of Health awards in a manner that is con-  
16 sistent with all applicable Federal laws and regula-  
17 tions, including such laws and regulations for the  
18 protection of—

19 “(A) human research participants, includ-  
20 ing with respect to privacy, security, informed  
21 consent, and protected health information; and

22 “(B) proprietary interests, confidential  
23 commercial information, and the intellectual  
24 property rights of the funding recipient.”.

1 (b) CONFIDENTIALITY.—Nothing in the amendments  
2 made by subsection (a) authorizes the Secretary of Health  
3 and Human Services to disclose any information that is  
4 a trade secret, or other privileged or confidential informa-  
5 tion, described in section 552(b)(4) of title 5, United  
6 States Code, or section 1905 of title 18, United States  
7 Code, or be construed to require recipients of grants or  
8 cooperative agreements through the National Institutes of  
9 Health to share such information.

10 **Subtitle C—Supporting Young**  
11 **Emerging Scientists**

12 **SEC. 2021. INVESTING IN THE NEXT GENERATION OF RE-**  
13 **SEARCHERS.**

14 (a) IN GENERAL.—Part A of title IV of the Public  
15 Health Service Act (42 U.S.C. 281 et seq.) is amended  
16 by adding at the end the following:

17 **“SEC. 404M. NEXT GENERATION OF RESEARCHERS.**

18 **“(a) NEXT GENERATION OF RESEARCHERS INITIA-**  
19 **TIVE.—**There shall be established within the Office of the  
20 Director of the National Institutes of Health, the Next  
21 Generation of Researchers Initiative (referred to in this  
22 section as the ‘Initiative’), through which the Director  
23 shall coordinate all policies and programs within the Na-  
24 tional Institutes of Health that are focused on promoting

1 and providing opportunities for new researchers and ear-  
2 lier research independence.

3 “(b) ACTIVITIES.—The Director of the National In-  
4 stitutes of Health, through the Initiative shall—

5 “(1) promote policies and programs within the  
6 National Institutes of Health that are focused on  
7 improving opportunities for new researchers and  
8 promoting earlier research independence, including  
9 existing policies and programs, as appropriate;

10 “(2) develop, modify, or prioritize policies, as  
11 needed, within the National Institutes of Health to  
12 promote opportunities for new researchers and ear-  
13 lier research independence, such as policies to in-  
14 crease opportunities for new researchers to receive  
15 funding, enhance training and mentorship programs  
16 for researchers, and enhance workforce diversity;

17 “(3) coordinate, as appropriate, with relevant  
18 agencies, professional and academic associations,  
19 academic institutions, and others, to improve and  
20 update existing information on the biomedical re-  
21 search workforce in order to inform programs re-  
22 lated to the training, recruitment, and retention of  
23 biomedical researchers; and

24 “(4) carry out other activities, including evalua-  
25 tion and oversight of existing programs, as appro-

1        appropriate, to promote the development of the next gen-  
2        eration of researchers and earlier research independ-  
3        ence.”.

4        (b) CONSIDERATION OF RECOMMENDATIONS.—In  
5        carrying out activities under section 404M(b) of the Public  
6        Health Service Act, the Director of the National Institutes  
7        of Health shall take into consideration the recommenda-  
8        tions made by the National Academies of Sciences, Engi-  
9        neering, and Medicine as part of the comprehensive study  
10       on policies affecting the next generation of researchers  
11       under the Department of Health and Human Services Ap-  
12       propriations Act, 2016 (Public Law 114–113), and submit  
13       a report to the Committee on Health, Education, Labor,  
14       and Pensions and the Committee on Appropriations of the  
15       Senate, and the Committee on Energy and Commerce and  
16       the Committee on Appropriations of the House of Rep-  
17       resentatives, with respect to any actions taken by the Na-  
18       tional Institutes of Health based on the recommendations  
19       not later than 2 years after the completion of the study  
20       required pursuant to the Department of Health and  
21       Human Services Appropriations Act, 2016.

22       **SEC. 2022. IMPROVEMENT OF LOAN REPAYMENT PROGRAM.**

23        (a) INTRAMURAL LOAN REPAYMENT PROGRAM.—  
24        Section 487A of the Public Health Service Act (42 U.S.C.  
25        288–1) is amended—

1           (1) by amending the section heading to read as  
2 follows: “**INTRAMURAL LOAN REPAYMENT PRO-**  
3 **GRAM**”;

4           (2) in subsection (a)—

5           (A) by striking “The Secretary shall carry  
6 out a program” and inserting “The Director of  
7 the National Institutes of Health shall, as ap-  
8 propriate and based on workforce and scientific  
9 priorities, carry out a program through the sub-  
10 categories listed in subsection (b)(1) (or modi-  
11 fied subcategories as provided for in subsection  
12 (b)(2))”;

13           (B) by striking “conduct” and inserting  
14 “conduct research”;

15           (C) by striking “research with respect to  
16 acquired immune deficiency syndrome”; and

17           (D) by striking “\$35,000” and inserting  
18 “\$50,000”;

19           (3) by redesignating subsection (b) as sub-  
20 section (d);

21           (4) by inserting after subsection (a), the fol-  
22 lowing:

23           “(b) SUBCATEGORIES OF RESEARCH.—



1           “(1) IN GENERAL.—In carrying out the pro-  
2           gram under subsection (a), the Director of the Na-  
3           tional Institutes of Health—

4                   “(A) shall continue to focus on—

5                           “(i) general research;

6                           “(ii) research on acquired immune de-  
7                           ficiency syndrome; and

8                           “(iii) clinical research conducted by  
9                           appropriately qualified health professional  
10                          who are from disadvantaged backgrounds;  
11                          and

12                          “(B) may focus on an area of emerging  
13                          scientific or workforce need.

14           “(2) ELIMINATION OR ESTABLISHMENT OF  
15           SUBCATEGORIES.—The Director of the National In-  
16           stitutes of Health may eliminate one or more subcat-  
17           egories provided for in paragraph (1) due to changes  
18           in workforce or scientific needs related to biomedical  
19           research. The Director may establish other sub-  
20           category areas based on workforce and scientific pri-  
21           orities if the total number of subcategories does not  
22           exceed the number of subcategories listed in para-  
23           graph (1).

24           “(c) LIMITATION.—The Director of the National In-  
25           stitutes of Health may not enter into a contract with a

1 health professional pursuant to subsection (a) unless such  
2 professional has a substantial amount of education loans  
3 relative to income (as determined pursuant to guidelines  
4 issued by the Director).”; and

5 (5) by adding at the end the following:

6 “(e) AVAILABILITY OF APPROPRIATIONS.—Amounts  
7 available for carrying out this section shall remain avail-  
8 able until the expiration of the second fiscal year begin-  
9 ning after the fiscal year for which such amounts are made  
10 available.”.

11 (b) EXTRAMURAL LOAN REPAYMENT PROGRAM.—  
12 Section 487B of the Public Health Service Act (42 U.S.C.  
13 288–2) is amended—

14 (1) by amending the section heading to read as  
15 follows: “**EXTRAMURAL LOAN REPAYMENT PRO-**  
16 **GRAM**”;

17 (2) in subsection (a)—

18 (A) by striking “The Secretary, in con-  
19 sultation with the Director of the Eunice Ken-  
20 nedy Shriver National Institute of Child Health  
21 and Human Development, shall establish a pro-  
22 gram” and inserting “IN GENERAL.—The Di-  
23 rector of the National Institutes of Health  
24 shall, as appropriate and based on workforce  
25 and scientific priorities, carry out a program

1 through the subcategories listed in subsection  
2 (b)(1) (or modified subcategories as provided  
3 for in subsection (b)(2)),”;

4 (B) by striking “(including graduate stu-  
5 dents)”;

6 (C) by striking “with respect to contracep-  
7 tion, or with respect to infertility,”; and

8 (D) by striking “service, not more than  
9 \$35,000” and inserting “research, not more  
10 than \$50,000”;

11 (3) by redesignating subsections (b) and (c) as  
12 subsections (d) and (e), respectively;

13 (4) by inserting after subsection (a), the fol-  
14 lowing:

15 “(b) SUBCATEGORIES OF RESEARCH.—

16 “(1) IN GENERAL.—In carrying out the pro-  
17 gram under subsection (a), the Director of the Na-  
18 tional Institutes of Health—

19 “(A) shall continue to focus on—

20 “(i) contraception or infertility re-  
21 search;

22 “(ii) pediatric research, including pe-  
23 diatric pharmacological research;

24 “(iii) minority health disparities re-  
25 search;

1 “(iv) clinical research; and

2 “(v) clinical research conducted by ap-  
3 propriately qualified health professional  
4 who are from disadvantaged backgrounds;  
5 and

6 “(B) may focus on an area of emerging  
7 scientific or workforce need.

8 “(2) ELIMINATION OR ESTABLISHMENT OF  
9 SUBCATEGORIES.—The Director of the National In-  
10 stitutes of Health may eliminate one or more subcat-  
11 egories provided for in paragraph (1) due to changes  
12 in workforce or scientific needs related to biomedical  
13 research. The Director may establish other sub-  
14 category areas based on workforce and scientific pri-  
15 orities if the total number of subcategories does not  
16 exceed the number of subcategories listed in para-  
17 graph (1).

18 “(c) LIMITATION.—The Director of the National In-  
19 stitutes of Health may not enter into a contract with a  
20 health professional pursuant to subsection (a) unless such  
21 professional has a substantial amount of education loans  
22 relative to income (as determined pursuant to guidelines  
23 issued by the Director).”;

24 (5) in subsection (d) (as so redesignated), by  
25 striking “The provisions” and inserting “APPLICA-

1 BILITY OF CERTAIN PROVISIONS REGARDING OBLI-  
2 GATED SERVICE.—The provisions’; and

3 (6) in subsection (e) (as so redesignated), by  
4 striking “Amounts” and inserting “AVAILABILITY  
5 OF APPROPRIATIONS.—Amounts”.

6 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

7 Title IV of the Public Health Service Act is amended—

8 (1) by striking section 464z-5 (42 U.S.C.  
9 285t-2);

10 (2) by striking section 487C (42 U.S.C. 288-  
11 3);

12 (3) by striking section 487E (42 U.S.C. 288-  
13 5);

14 (4) by striking section 487F (42 U.S.C. 288-  
15 5a), as added by section 205 of Public Law 106-  
16 505, relating to loan repayment for clinical research-  
17 ers; and

18 (5) by striking section 487F (42 U.S.C. 288-  
19 6), as added by section 1002(b) of Public Law 106-  
20 310 relating to pediatric research loan repayment.

21 (d) GAO REPORT.—Not later than 18 months after  
22 the date of enactment of this Act, the Comptroller General  
23 of the United States shall submit to Congress a report  
24 on the efforts of the National Institutes of Health to at-  
25 tract, retain, and develop emerging scientists, including

1 underrepresented individuals in the sciences, such as  
2 women, racial and ethnic minorities, and other groups.  
3 Such report shall include an analysis of the impact of the  
4 additional authority provided to the Secretary of Health  
5 and Human Services under this Act to address workforce  
6 shortages and gaps in priority research areas, including  
7 which centers and research areas offered loan repayment  
8 program participants the increased award amount.

9 **Subtitle D—National Institutes of**  
10 **Health Planning and Adminis-**  
11 **tration**

12 **SEC. 2031. NATIONAL INSTITUTES OF HEALTH STRATEGIC**  
13 **PLAN.**

14 (a) STRATEGIC PLAN.—Section 402 of the Public  
15 Health Service Act (42 U.S.C. 282) is amended—

16 (1) in subsection (b)(5), by inserting before the  
17 semicolon the following: “, and through the develop-  
18 ment, implementation, and updating of the strategic  
19 plan developed under subsection (m)”;

20 (2) by adding at the end the following:

21 “(m) NATIONAL INSTITUTES OF HEALTH STRATEGIC  
22 PLAN.—

23 “(1) IN GENERAL.—Not later than 2 years  
24 after the date of enactment of the 21st Century  
25 Cures Act, and at least every 6 years thereafter, the

1 Director of the National Institutes of Health shall  
2 develop and submit to the appropriate committees of  
3 Congress and post on the Internet website of the  
4 National Institutes of Health, a coordinated strategy  
5 (to be known as the ‘National Institutes of Health  
6 Strategic Plan’) to provide direction to the bio-  
7 medical research investments made by the National  
8 Institutes of Health, to facilitate collaboration across  
9 the institutes and centers, to leverage scientific op-  
10 portunity, and to advance biomedicine.

11 “(2) REQUIREMENTS.—The strategy under  
12 paragraph (1) shall—

13 “(A) identify strategic research priorities  
14 and objectives across biomedical research, in-  
15 cluding—

16 “(i) an assessment of the state of bio-  
17 medical and behavioral research, including  
18 areas of opportunity with respect to basic,  
19 clinical, and translational research;

20 “(ii) priorities and objectives to ad-  
21 vance the treatment, cure, and prevention  
22 of health conditions;

23 “(iii) emerging scientific opportuni-  
24 ties, rising public health challenges, and  
25 scientific knowledge gaps; and

1                   “(iv) the identification of near-, mid-  
2                   , and long-term scientific needs;

3                   “(B) consider, in carrying out subpara-  
4 graph (A)—

5                   “(i) disease burden in the United  
6 States and the potential for return on in-  
7 vestment to the United States;

8                   “(ii) rare diseases and conditions;

9                   “(iii) biological, social, and other de-  
10 terminants of health that contribute to  
11 health disparities; and

12                   “(iv) other factors the Director of Na-  
13 tional Institutes of Health determines ap-  
14 propriate;

15                   “(C) include multi-institute priorities, in-  
16 cluding coordination of research among insti-  
17 tutes and centers;

18                   “(D) include strategic priorities for fund-  
19 ing research through the Common Fund, in ac-  
20 cordance with section 402A(c)(1)(C);

21                   “(E) address the National Institutes of  
22 Health’s proposed and ongoing activities related  
23 to training and the biomedical workforce; and



1           “(F) describe opportunities for collabora-  
2           tion with other agencies and departments, as  
3           appropriate.

4           “(3) USE OF PLANS.—Strategic plans developed  
5           and updated by the national research institutes and  
6           national centers of the National Institutes of Health  
7           shall be prepared regularly and in such a manner  
8           that such plans will be informed by the strategic  
9           plans developed and updated under this subsection.  
10          Such plans developed by and updated by the na-  
11          tional research institutes and national centers shall  
12          have a common template.

13          “(4) CONSULTATION.—The Director of Na-  
14          tional Institutes of Health shall develop the strategic  
15          plan under paragraph (1) in consultation with the  
16          directors of the national research institutes and na-  
17          tional centers, researchers, patient advocacy groups,  
18          and industry leaders.”.

19          (b)           CONFORMING            AMENDMENT.—Section  
20          402A(c)(1)(C) of the Public Health Service Act (42  
21          U.S.C. 282a(c)(1)(C)) is amended by striking “Not later  
22          than June 1, 2007, and every 2 years thereafter,” and  
23          inserting “As part of the National Institutes of Health  
24          Strategic Plan required under section 402(m),”.

1 (c) STRATEGIC PLAN.—Section 492B(a) of the Pub-  
2 lic Health Service Act (42 U.S.C. 289a–2(a)) is amended  
3 by adding at the end the following:

4 “(3) STRATEGIC PLANNING.—

5 “(A) IN GENERAL.—The directors of the  
6 national institutes and national centers shall  
7 consult at least once annually with the Director  
8 of the National Institute on Minority Health  
9 and Health Disparities and the Director of the  
10 Office of Research on Women’s Health regard-  
11 ing objectives of the national institutes and na-  
12 tional centers to ensure that future activities by  
13 such institutes and centers take into account  
14 women and minorities and are focused on re-  
15 ducing health disparities.

16 “(B) STRATEGIC PLANS.—Any strategic  
17 plan issued by a national institute or national  
18 center shall include details on the objectives de-  
19 scribed in subparagraph (A).”.

20 **SEC. 2032. TRIENNIAL REPORTS.**

21 Section 403 of the Public Health Service Act (42  
22 U.S.C. 283) is amended—

23 (1) in the section heading, by striking “**BIEN-**  
24 **NIAL**” and inserting “**TRIENNIAL**” ; and

25 (2) in subsection (a)—

1 (A) in the matter preceding paragraph (1),  
2 by striking “biennial” and inserting “triennial”;

3 (B) by amending paragraph (3) to read as  
4 follows:

5 “(3) A description of intra-National Institutes  
6 of Health activities, including—

7 “(A) identification of the percentage of  
8 funds made available by each national research  
9 institute and national center with respect to  
10 each applicable fiscal year for conducting or  
11 supporting research that involves collaboration  
12 between the institute or center and 1 or more  
13 other national research institutes or national  
14 centers; and

15 “(B) recommendations for promoting co-  
16 ordination of information among the centers of  
17 excellence.”;

18 (C) in paragraph (4)—

19 (i) in subparagraph (B), by striking  
20 “demographic variables and other vari-  
21 ables” and inserting “demographic vari-  
22 ables, including biological and social vari-  
23 ables and relevant age categories (such as  
24 pediatric subgroups), and determinants of  
25 health,”; and

1 (ii) in subparagraph (C)(v)—

2 (I) by striking “demographic  
3 variables and such” and inserting  
4 “demographic variables, including rel-  
5 evant age categories (such as pediatric  
6 subgroups), information submitted by  
7 each national research institute and  
8 national center to the Director of Na-  
9 tional Institutes of Health under sec-  
10 tion 492B(f), and such”; and

11 (II) by striking “(regarding in-  
12 clusion of women and minorities in  
13 clinical research)” and inserting “and  
14 other applicable requirements regard-  
15 ing inclusion of demographic groups”;  
16 and

17 (D) in paragraph (6)—

18 (i) in the matter preceding subpara-  
19 graph (A), by striking “the following:” and  
20 inserting “the following—”;

21 (ii) in subparagraph (A)—

22 (I) by striking “An evaluation”  
23 and inserting “an evaluation”; and

24 (II) by striking the period and  
25 inserting “; and”;

1 (iii) by striking subparagraphs (B)  
2 and (D);  
3 (iv) by redesignating subparagraph  
4 (C) as subparagraph (B); and  
5 (v) in subparagraph (B), as redesign-  
6 nated by clause (iv), by striking “Rec-  
7 ommendations” and inserting “rec-  
8 ommendations”.

9 **SEC. 2033. INCREASING ACCOUNTABILITY AT THE NA-**  
10 **TIONAL INSTITUTES OF HEALTH.**

11 (a) APPOINTMENT AND TERMS OF DIRECTORS OF  
12 NATIONAL RESEARCH INSTITUTES AND NATIONAL CEN-  
13 TERS.—Subsection (a) of section 405 of the Public Health  
14 Service Act (42 U.S.C. 284) is amended to read as follows:

15 “(a) APPOINTMENT.—

16 “(1) IN GENERAL.—The Director of the Na-  
17 tional Cancer Institute shall be appointed by the  
18 President, and the Directors of the other national  
19 research institutes and national centers shall be ap-  
20 pointed by the Secretary, acting through the Direc-  
21 tor of National Institutes of Health. Each Director  
22 of a national research institute or national center  
23 shall report directly to the Director of National In-  
24 stitutes of Health.

25 “(2) APPOINTMENT.—

1           “(A) TERM.—A Director of a national re-  
2 search institute or national center who is ap-  
3 pointed by the Secretary, acting through the  
4 Director of National Institutes of Health, shall  
5 be appointed for 5 years.

6           “(B) REAPPOINTMENT.—At the end of the  
7 term of a Director of a national research insti-  
8 tute or national center, the Director may be re-  
9 appointed in accordance with standards applica-  
10 ble to the relevant appointment mechanism.  
11 There shall be no limit on the number of terms  
12 that a Director may serve.

13           “(C) VACANCIES.—If the office of a Direc-  
14 tor of a national research institute or national  
15 center becomes vacant before the end of such  
16 Director’s term, the Director appointed to fill  
17 the vacancy shall be appointed for a 5-year  
18 term starting on the date of such appointment.

19           “(D) CURRENT DIRECTORS.—Each Direc-  
20 tor of a national research institute or national  
21 center who is serving on the date of enactment  
22 of the 21st Century Cures Act shall be deemed  
23 to be appointed for a 5-year term under this  
24 subsection beginning on such date of enact-  
25 ment.

1           “(E) RULE OF CONSTRUCTION.—Nothing  
2           in this subsection shall be construed to limit the  
3           authority of the Secretary or the Director of  
4           National Institutes of Health to terminate the  
5           appointment of a director referred to in sub-  
6           paragraph (A) before the expiration of such di-  
7           rector’s 5-year term.

8           “(F) NATURE OF APPOINTMENT.—Ap-  
9           pointments and reappointments under this sub-  
10          section shall be made on the basis of ability and  
11          experience as it relates to the mission of the  
12          National Institutes of Health and its compo-  
13          nents, including compliance with any legal re-  
14          quirement that the Secretary or Director of Na-  
15          tional Institutes of Health determines relevant.

16          “(3) NONAPPLICATION OF CERTAIN PROVI-  
17          SION.—The restrictions contained in section 202 of  
18          the Departments of Labor, Health and Human  
19          Services, and Education, and Related Agencies Ap-  
20          propriations Act, 1993 (Public Law 102–394; 42  
21          U.S.C. 238f note) related to consultants and indi-  
22          vidual scientists appointed for limited periods of  
23          time shall not apply to Directors appointed under  
24          this subsection.”.

1 (b) REVIEW OF CERTAIN AWARDS BY DIRECTORS.—  
2 Section 405(b) of the Public Health Service Act (42  
3 U.S.C. 284(b)) is amended by adding at the end the fol-  
4 lowing:

5 “(3) Before an award is made by a national research  
6 institute or by a national center for a grant for a research  
7 program or project (commonly referred to as an ‘R-series  
8 grant’), other than an award constituting a noncompeti-  
9 tive renewal of such a grant, or a noncompetitive adminis-  
10 trative supplement to such a grant, the Director of such  
11 national research institute or national center shall, con-  
12 sistent with the peer review process—

13 “(A) review and make the final decision with  
14 respect to making the award; and

15 “(B) take into consideration, as appropriate—

16 “(i) the mission of the national research  
17 institute or national center and the scientific  
18 priorities identified in the strategic plan under  
19 section 402(m);

20 “(ii) programs or projects funded by other  
21 agencies on similar research topics; and

22 “(iii) advice by staff and the advisory  
23 council or board of such national research insti-  
24 tute or national center.”.



1           (c) REPORT ON DUPLICATION IN FEDERAL BIO-  
2 MEDICAL RESEARCH.—The Secretary of Health and  
3 Human Services (referred to in this subsection as the  
4 “Secretary”), shall, not later than 2 years after the date  
5 of enactment of this Act, submit a report to Congress on  
6 efforts to prevent and eliminate duplicative biomedical re-  
7 search that is not necessary for scientific purposes. Such  
8 report shall—

9           (1) describe the procedures in place to identify  
10          such duplicative research, including procedures for  
11          monitoring research applications and funded re-  
12          search awards to prevent unnecessary duplication;

13          (2) describe the steps taken to improve the pro-  
14          cedures described in paragraph (1), in response to  
15          relevant recommendations made by the Comptroller  
16          General of the United States;

17          (3) describe how the Secretary operationally  
18          distinguishes necessary and appropriate scientific  
19          replication from unnecessary duplication; and

20          (4) provide examples of instances where the  
21          Secretary has identified unnecessarily duplicative re-  
22          search and the steps taken to eliminate the unneces-  
23          sary duplication.

1 **SEC. 2034. REDUCING ADMINISTRATIVE BURDEN FOR RE-**  
2 **SEARCHERS.**

3 (a) PLAN PREPARATION AND IMPLEMENTATION OF  
4 MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—

5 (1) IN GENERAL.—Not later than 2 years after  
6 the date of enactment of this Act, the Secretary of  
7 Health and Human Services (referred to in this sec-  
8 tion as the “Secretary”) shall—

9 (A) lead a review by research funding  
10 agencies of all regulations and policies related  
11 to the disclosure of financial conflicts of inter-  
12 est, including the minimum threshold for re-  
13 porting financial conflicts of interest;

14 (B) make revisions, as appropriate, to har-  
15 monize existing policies and reduce administra-  
16 tive burden on researchers while maintaining  
17 the integrity and credibility of research findings  
18 and protections of human participants; and

19 (C) confer with the Office of the Inspector  
20 General about the activities of such office re-  
21 lated to financial conflicts of interest involving  
22 research funding agencies.

23 (2) CONSIDERATIONS.—In updating policies  
24 under paragraph (1)(B), the Secretary shall con-  
25 sider—

1 (A) modifying the timelines for the report-  
2 ing of financial conflicts of interest to just-in-  
3 time information by institutions receiving grant  
4 or cooperative agreement funding from the Na-  
5 tional Institutes of Health;

6 (B) ensuring that financial interest dislo-  
7 sure reporting requirements are appropriate for,  
8 and relevant to, awards that will directly fund  
9 research, which may include modification of the  
10 definition of the term “investigator” for pur-  
11 poses of the regulations and policies described  
12 in subparagraphs (A) and (B) of paragraph (1);  
13 and

14 (C) updating any applicable training mod-  
15 ules of the National Institutes of Health related  
16 to Federal financial interest disclosure.

17 (b) MONITORING OF SUBRECIPIENTS OF FUNDING  
18 FROM THE NATIONAL INSTITUTES OF HEALTH.—The Di-  
19 rector of the National Institutes of Health (referred to in  
20 this section as the “Director of National Institutes of  
21 Health”) shall implement measures to reduce the adminis-  
22 trative burdens related to monitoring of subrecipients of  
23 grants by primary awardees of funding from the National  
24 Institutes of Health, which may incorporate findings and

1 recommendations from existing and ongoing activities.

2 Such measures may include, as appropriate—

3 (1) an exemption from subrecipient monitoring  
4 requirements, upon request from the primary award-  
5 ees, provided that—

6 (A) the subrecipient is subject to Federal  
7 audit requirements pursuant to the Uniform  
8 Guidance of the Office of Management and  
9 Budget;

10 (B) the primary awardee conducts, pursu-  
11 ant to guidance of the National Institutes of  
12 Health, a pre-award evaluation of each sub-  
13 recipient's risk of noncompliance with Federal  
14 statutes and regulations, the conditions of the  
15 subaward, and any recurring audit findings;  
16 and

17 (C) such exemption does not absolve the  
18 primary awardee of liability for misconduct by  
19 subrecipients; and

20 (2) the implementation of alternative grant  
21 structures that obviate the need for subrecipient  
22 monitoring, which may include collaborative grant  
23 models allowing for multiple primary awardees.

24 (c) REPORTING OF FINANCIAL EXPENDITURES.—

25 The Secretary, in consultation with the Director of Na-

1 tional Institutes of Health, shall evaluate financial expend-  
2 iture reporting procedures and requirements for recipients  
3 of funding from the National Institutes of Health and take  
4 action, as appropriate, to avoid duplication between de-  
5 partment and agency procedures and requirements and  
6 minimize burden to funding recipients.

7 (d) ANIMAL CARE AND USE IN RESEARCH.—Not  
8 later than 2 years after the date of enactment of this Act,  
9 the Director of National Institutes of Health, in collabora-  
10 tion with the Secretary of Agriculture and the Commis-  
11 sioner of Food and Drugs, shall complete a review of ap-  
12 plicable regulations and policies for the care and use of  
13 laboratory animals and make revisions, as appropriate, to  
14 reduce administrative burden on investigators while main-  
15 taining the integrity and credibility of research findings  
16 and protection of research animals. In carrying out this  
17 effort, the Director of the National Institutes of Health  
18 shall seek the input of experts, as appropriate. The Direc-  
19 tor of the National Institutes of Health shall—

20 (1) identify ways to ensure such regulations  
21 and policies are not inconsistent, overlapping, or un-  
22 necessarily duplicative, including with respect to in-  
23 spection and review requirements by Federal agen-  
24 cies and accrediting associations;

1           (2) take steps to eliminate or reduce identified  
2           inconsistencies, overlap, or duplication among such  
3           regulations and policies; and

4           (3) take other actions, as appropriate, to im-  
5           prove the coordination of regulations and policies  
6           with respect to research with laboratory animals.

7           (e) DOCUMENTATION OF PERSONNEL EXPENSES.—

8           The Secretary shall clarify the applicability of the require-  
9           ments under the Office of Management and Budget Uni-  
10          form Guidance for management and certification systems  
11          adopted by entities receiving Federal research grants  
12          through the Department of Health and Human Services  
13          regarding documentation of personnel expenses, including  
14          clarification of the extent to which any flexibility to such  
15          requirements specified in such Uniform Guidance applies  
16          to entities receiving grants through the Department of  
17          Health and Human Services.

18          (f) RESEARCH POLICY BOARD.—

19                 (1) ESTABLISHMENT.—Not later than 1 year  
20                 after the date of enactment of this Act, the Director  
21                 of the Office of Management and Budget shall es-  
22                 tablish an advisory committee, to be known as the  
23                 “Research Policy Board” (referred to in this sub-  
24                 section as the “Board”), to provide Federal Govern-

1           ment officials with information on the effects of reg-  
2           ulations related to Federal research requirements.

3           (2) MEMBERSHIP.—

4           (A) IN GENERAL.—The Board shall in-  
5           clude not more than 10 Federal members, in-  
6           cluding each of the following Federal members  
7           or their designees:

8                   (i) The Administrator of the Office of  
9                   Information and Regulatory Affairs of the  
10                  Office of Management and Budget.

11                  (ii) The Director of the Office of  
12                  Science and Technology Policy.

13                  (iii) The Secretary of Health and  
14                  Human Services.

15                  (iv) The Director of the National  
16                  Science Foundation.

17                  (v) The secretaries and directors of  
18                  other departments and agencies that sup-  
19                  port or regulate scientific research, as de-  
20                  termined by the Director of the Office of  
21                  Management and Budget.

22           (B) NON-FEDERAL MEMBERS.—The Board  
23           shall be comprised of not less than 9 and not  
24           more than 12 representatives of academic re-  
25           search institutions, other private, nonprofit re-

1 search institutions, or other nonprofit organiza-  
2 tions with relevant expertise. Such members  
3 shall be appointed by a formal process, to be es-  
4 tablished by the Director of the Office of Man-  
5 agement and Budget, in consultation with the  
6 Federal membership, and that incorporates—

7 (i) nomination by members of the  
8 nonprofit scientific research community,  
9 including academic research institutions;  
10 and

11 (ii) procedures to fill membership po-  
12 sitions vacated before the end of a mem-  
13 ber's term.

14 (3) PURPOSE AND RESPONSIBILITIES.—The  
15 Board shall make recommendations regarding the  
16 modification and harmonization of regulations and  
17 policies having similar purposes across research  
18 funding agencies to ensure that the administrative  
19 burden of such research policy and regulation is  
20 minimized to the greatest extent possible and con-  
21 sistent with maintaining responsible oversight of fed-  
22 erally funded research. Activities of the Board may  
23 include—

24 (A) providing thorough and informed anal-  
25 ysis of regulations and policies;



1 (B) identifying negative or adverse con-  
2 sequences of existing policies and making ac-  
3 tionable recommendations regarding possible  
4 improvement of such policies;

5 (C) making recommendations with respect  
6 to efforts within the Federal Government to im-  
7 prove coordination of regulation and policy re-  
8 lated to research;

9 (D) creating a forum for the discussion of  
10 research policy or regulatory gaps, challenges,  
11 clarification, or harmonization of such policies  
12 or regulation, and best practices; and

13 (E) conducting ongoing assessment and  
14 evaluation of regulatory burden, including de-  
15 velopment of metrics, periodic measurement,  
16 and identification of process improvements and  
17 policy changes.

18 (4) EXPERT SUBCOMMITTEES.—The Board  
19 may form temporary expert subcommittees, as ap-  
20 propriate, to develop timely analysis on pressing  
21 issues and assist the Board in anticipating future  
22 regulatory challenges, including challenges emerging  
23 from new scientific advances.

24 (5) REPORTING REQUIREMENTS.—Not later  
25 than 2 years after the date of enactment of this Act,

1 and once thereafter, the Board shall submit a report  
2 to the Director of the Office of Management and  
3 Budget, the Administrator of the Office of Informa-  
4 tion and Regulatory Affairs of the Office of Manage-  
5 ment and Budget, the Director of the Office of  
6 Science and Technology Policy, the heads of relevant  
7 Federal departments and agencies, the Committee  
8 on Health, Education, Labor, and Pensions of the  
9 Senate, and the Committee on Energy and Com-  
10 merce of the House of Representatives containing  
11 formal recommendations on the conceptualization,  
12 development, harmonization, and reconsideration of  
13 scientific research policy, including the regulatory  
14 benefits and burdens.

15 (6) SUNSET.—The Board shall terminate on  
16 September 30, 2021.

17 (7) GAO REPORT.—Not later than 4 years  
18 after the date of enactment of this Act, the Comp-  
19 troller General of the United States shall conduct an  
20 independent evaluation of the activities carried out  
21 by the Board pursuant to this subsection and submit  
22 to the appropriate committees of Congress a report  
23 regarding the results of the independent evaluation.  
24 Such report shall review and assess the Board's ac-

1           activities with respect to the responsibilities described  
2           in paragraph (3).

3   **SEC. 2035. EXEMPTION FOR THE NATIONAL INSTITUTES OF**  
4                           **HEALTH FROM THE PAPERWORK REDUCTION**  
5                           **ACT REQUIREMENTS.**

6           Section 301 of the Public Health Service Act (42  
7 U.S.C. 241), as amended by section 2013, is further  
8 amended by adding at the end the following:

9           “(g) Subchapter I of chapter 35 of title 44, United  
10 States Code, shall not apply to the voluntary collection of  
11 information during the conduct of research by the Na-  
12 tional Institutes of Health.”.

13   **SEC. 2036. HIGH-RISK, HIGH-REWARD RESEARCH.**

14           (a) IN GENERAL.—Section 402 of the Public Health  
15 Service Act (42 U.S.C. 282), as amended by section 2031,  
16 is further amended by adding at the end the following:

17           “(n) UNIQUE RESEARCH INITIATIVES.—

18                   “(1) IN GENERAL.—The Director of NIH may  
19           approve, after consideration of a proposal under  
20           paragraph (2)(A), requests by the national research  
21           institutes and centers, or program officers within the  
22           Office of the Director to engage in transactions  
23           other than a contract, grant, or cooperative agree-  
24           ment with respect to projects that carry out—

1           “(A) the Precision Medicine Initiative  
2           under section 498E; or

3           “(B) section 402(b)(7), except that not  
4           more than 50 percent of the funds available for  
5           a fiscal year through the Common Fund under  
6           section 402A(c)(1) for purposes of carrying out  
7           such section 402(b)(7) may be used to engage  
8           in such other transactions.

9           “(2) REQUIREMENTS.—The authority provided  
10          under this subsection may be used to conduct or  
11          support high impact cutting-edge research described  
12          in paragraph (1) using the other transactions au-  
13          thority described in such paragraph if the institute,  
14          center, or office—

15                 “(A) submits a proposal to the Director of  
16                 NIH for the use of such authority before con-  
17                 ducting or supporting the research, including  
18                 why the use of such authority is essential to  
19                 promoting the success of the project;

20                 “(B) receives approval for the use of such  
21                 authority from the Director of NIH; and

22                 “(C) for each year in which the institute,  
23                 center, or office has used such authority in ac-  
24                 cordance with this subsection, submits a report  
25                 to the Director of NIH on the activities of the

1 institute, center, or office relating to such re-  
2 search.”.

3 (b) REPORT TO CONGRESS.—Not later than Sep-  
4 tember 30, 2020, the Secretary of Health and Human  
5 Services, acting through the Director of the National In-  
6 stitutes of Health, shall conduct an evaluation of the ac-  
7 tivities under subsection (n) of section 402 of the Public  
8 Health Service Act (42 U.S.C. 282), as added by sub-  
9 section (a), and submit a report to the Committee on  
10 Health, Education, Labor, and Pensions of the Senate and  
11 the Committee on Energy and Commerce of the House  
12 of Representatives on the results of such evaluation.

13 (c) DUTIES OF DIRECTORS OF INSTITUTES.—Section  
14 405(b)(1) of the Public Health Service Act (42 U.S.C.  
15 284(b)(1)) is amended—

16 (1) by redesignating subparagraphs (C) through  
17 (L) as subparagraphs (D) through (M), respectively;  
18 and

19 (2) by inserting after subparagraph (B), the  
20 following:

21 “(C) shall, as appropriate, conduct and support  
22 research that has the potential to transform the sci-  
23 entific field, has inherently higher risk, and that  
24 seeks to address major current challenges;”.

1 **SEC. 2037. NATIONAL CENTER FOR ADVANCING**  
2 **TRANSLATIONAL SCIENCES.**

3 (a) IN GENERAL.—Section 479(b) of the Public  
4 Health Service Act (42 U.S.C. 287(b)) is amended—

5 (1) in paragraph (1), by striking “phase IIA”  
6 and inserting “phase IIB”; and

7 (2) in paragraph (2)—

8 (A) in the matter preceding subparagraph  
9 (A), by striking “phase IIB” and inserting  
10 “phase III”;

11 (B) in subparagraph (A), by striking  
12 “phase IIB” and inserting “phase III”;

13 (C) in subparagraph (B), by striking  
14 “phase IIA” and inserting “phase IIB”; and

15 (D) in subparagraph (C), by striking  
16 “phase IIB” and inserting “phase III”.

17 (b) INCREASED TRANSPARENCY.—Section 479 of the  
18 Public Health Service Act (42 U.S.C. 287) is amended—

19 (1) in subsection (c)—

20 (A) in paragraph (4)(D), by striking  
21 “and” at the end;

22 (B) in paragraph (5), by striking the pe-  
23 riod and inserting a semicolon; and

24 (C) by adding at the end the following:

1           “(6) the methods and tools, if any, that have  
2           been developed since the last biennial report was  
3           prepared; and

4           “(7) the methods and tools, if any, that have  
5           been developed and are being utilized by the Food  
6           and Drug Administration to support medical product  
7           reviews.”; and

8           (2) by adding at the end the following:

9           “(d) INCLUSION OF LIST.—The first biennial report  
10          submitted under this section after the date of enactment  
11          of the 21st Century Cures Act shall include a complete  
12          list of all of the methods and tools, if any, which have  
13          been developed by research supported by the Center.

14          “(e) RULE OF CONSTRUCTION.—Nothing in this sec-  
15          tion shall be construed as authorizing the Secretary to dis-  
16          close any information that is a trade secret, or other privi-  
17          leged or confidential information subject to section  
18          552(b)(4) of title 5, United States Code, or section 1905  
19          of title 18, United States Code.”.

20       **SEC. 2038. COLLABORATION AND COORDINATION TO EN-**  
21                               **HANCE RESEARCH.**

22          (a) RESEARCH PRIORITIES; COLLABORATIVE RE-  
23          SEARCH PROJECTS.—Section 402(b) of the Public Health  
24          Service Act (42 U.S.C. 282(b)) is amended—

1           (1) by amending paragraph (4) to read as fol-  
2           lows:

3           “(4) shall assemble accurate data to be used to  
4           assess research priorities, including—

5                   “(A) information to better evaluate sci-  
6                   entific opportunity, public health burdens, and  
7                   progress in reducing health disparities; and

8                   “(B) data on study populations of clinical  
9                   research, funded by or conducted at each na-  
10                  tional research institute and national center,  
11                  which—

12                           “(i) specifies the inclusion of—

13                                   “(I) women;

14                                   “(II) members of minority  
15                                   groups;

16                                   “(III) relevant age categories, in-  
17                                   cluding pediatric subgroups; and

18                                   “(IV) other demographic vari-  
19                                   ables as the Director of the National  
20                                   Institutes of Health determines appro-  
21                                   priate;

22                                   “(ii) is disaggregated by research  
23                                   area, condition, and disease categories; and



1 “(iii) is to be made publicly available  
2 on the Internet website of the National In-  
3 stitutes of Health;” and

4 (2) in paragraph (8)—

5 (A) in subparagraph (A), by striking  
6 “and” at the end; and

7 (B) by adding at the end the following:

8 “(C) foster collaboration between clinical  
9 research projects funded by the respective na-  
10 tional research institutes and national centers  
11 that—

12 “(i) conduct research involving human  
13 subjects; and

14 “(ii) collect similar data; and

15 “(D) encourage the collaboration described  
16 in subparagraph (C) to—

17 “(i) allow for an increase in the num-  
18 ber of subjects studied; and

19 “(ii) utilize diverse study populations,  
20 with special consideration to biological, so-  
21 cial, and other determinants of health that  
22 contribute to health disparities;”.

23 (b) REPORTING.—Section 492B(f) of the Public  
24 Health Service Act (42 U.S.C. 289a–2(f)) is amended—

1           (1) by striking “biennial” each place such term  
2 appears and inserting “triennial”;

3           (2) by striking “The advisory council” and in-  
4 serting the following:

5           “(1) IN GENERAL.—The advisory council”; and

6           (3) by adding at the end the following:

7           “(2) CONTENTS.—Each triennial report pre-  
8 pared by an advisory council of each national re-  
9 search institute as described in paragraph (1) shall  
10 include each of the following:

11           “(A) The number of women included as  
12 subjects, and the proportion of subjects that are  
13 women, in any project of clinical research con-  
14 ducted during the applicable reporting period,  
15 disaggregated by categories of research area,  
16 condition, or disease, and accounting for single-  
17 sex studies.

18           “(B) The number of members of minority  
19 groups included as subjects, and the proportion  
20 of subjects that are members of minority  
21 groups, in any project of clinical research con-  
22 ducted during the applicable reporting period,  
23 disaggregated by categories of research area,  
24 condition, or disease and accounting for single-  
25 race and single-ethnicity studies.

1           “(C) For the applicable reporting period,  
2           the number of projects of clinical research that  
3           include women and members of minority groups  
4           and that—

5                   “(i) have been completed during such  
6                   reporting period; and

7                   “(ii) are being carried out during such  
8                   reporting period and have not been com-  
9                   pleted.

10           “(D) The number of studies completed  
11           during the applicable reporting period for which  
12           reporting has been submitted in accordance  
13           with subsection (c)(2)(A).”.

14           (c) COORDINATION.—Section 486(c)(2) of the Public  
15           Health Service Act (42 U.S.C. 287d(c)(2)) is amended by  
16           striking “designees” and inserting “senior-level staff des-  
17           ignees”.

18           (d) IN GENERAL.—Part A of title IV of the Public  
19           Health Service Act (42 U.S.C. 281 et seq.), as amended  
20           by section 2021, is further amended by adding at the end  
21           the following:

22           **“SEC. 404N. POPULATION FOCUSED RESEARCH.**

23           “The Director of the National Institutes of Health  
24           shall, as appropriate, encourage efforts to improve re-

1 search related to the health of sexual and gender minority  
2 populations, including by—

3 “(1) facilitating increased participation of sex-  
4 ual and gender minority populations in clinical re-  
5 search supported by the National Institutes of  
6 Health, and reporting on such participation, as ap-  
7 plicable;

8 “(2) facilitating the development of valid and  
9 reliable methods for research relevant to sexual and  
10 gender minority populations; and

11 “(3) addressing methodological challenges.”.

12 (e) REPORTING.—

13 (1) IN GENERAL.—The Secretary, in collabora-  
14 tion with the Director of the National Institutes of  
15 Health, shall as appropriate—

16 (A) continue to support research for the  
17 development of appropriate measures related to  
18 reporting health information about sexual and  
19 gender minority populations; and

20 (B) not later than 2 years after the date  
21 of enactment of this Act, disseminate and make  
22 public such measures.

23 (2) NATIONAL ACADEMY OF MEDICINE REC-  
24 OMMENDATIONS.—In developing the measures de-  
25 scribed in paragraph (1)(A), the Secretary shall take

1 into account recommendations made by the National  
2 Academy of Medicine.

3 (f) IMPROVING COORDINATION RELATED TO MINOR-  
4 ITY HEALTH AND HEALTH DISPARITIES.—Section 464z-  
5 3 of the Public Health Service Act (42 U.S.C. 285t) is  
6 amended—

7 (1) by redesignating subsection (h), relating to  
8 interagency coordination, that follows subsection (j)  
9 as subsection (k); and

10 (2) in subsection (k) (as so redesignated)—

11 (A) in the subsection heading, by striking  
12 “INTERAGENCY” and inserting “INTRA-NA-  
13 TIONAL INSTITUTES OF HEALTH”;

14 (B) by striking “as the primary Federal  
15 officials” and inserting “as the primary Federal  
16 official”;

17 (C) by inserting a comma after “review”;

18 (D) by striking “Institutes and Centers of  
19 the National Institutes of Health” and inserting  
20 “national research institutes and national cen-  
21 ters”; and

22 (E) by adding at the end the following:  
23 “The Director of the Institute may foster part-  
24 nerships between the national research insti-  
25 tutes and national centers and may encourage

1           the funding of collaborative research projects to  
2           achieve the goals of the National Institutes of  
3           Health that are related to minority health and  
4           health disparities.”.

5           (g) BASIC RESEARCH.—

6           (1) DEVELOPING POLICIES.—Not later than 2  
7           years after the date of enactment of this Act, the  
8           Director of the National Institutes of Health (re-  
9           ferred to in this section as the “Director of the Na-  
10          tional Institutes of Health”), taking into consider-  
11          ation the recommendations developed under section  
12          2039, shall develop policies for projects of basic re-  
13          search funded by National Institutes of Health to  
14          assess—

15                 (A) relevant biological variables including  
16                 sex, as appropriate; and

17                 (B) how differences between male and fe-  
18                 male cells, tissues, or animals may be examined  
19                 and analyzed.

20          (2) REVISING POLICIES.—The Director of the  
21          National Institutes of Health may update or revise  
22          the policies developed under paragraph (1) as appro-  
23          priate.

24          (3) CONSULTATION AND OUTREACH.—In devel-  
25          oping, updating, or revising the policies under this

1 section, the Director of the National Institutes of  
2 Health shall—

3 (A) consult with—

4 (i) the Office of Research on Women’s  
5 Health;

6 (ii) the Office of Laboratory Animal  
7 Welfare; and

8 (iii) appropriate members of the sci-  
9 entific and academic communities; and

10 (B) conduct outreach to solicit feedback  
11 from members of the scientific and academic  
12 communities on the influence of sex as a vari-  
13 able in basic research, including feedback on  
14 when it is appropriate for projects of basic re-  
15 search involving cells, tissues, or animals to in-  
16 clude both male and female cells, tissues, or  
17 animals.

18 (4) ADDITIONAL REQUIREMENTS.—The Direc-  
19 tor of the National Institutes of Health shall—

20 (A) ensure that projects of basic research  
21 funded by the National Institutes of Health are  
22 conducted in accordance with the policies devel-  
23 oped, updated, or revised under this section, as  
24 applicable; and

1 (B) encourage that the results of such re-  
2 search, when published or reported, be  
3 disaggregated as appropriate with respect to  
4 the analysis of any sex differences.

5 (h) CLINICAL RESEARCH.—

6 (1) IN GENERAL.—Not later than 1 year after  
7 the date of enactment of this Act, the Director of  
8 the National Institutes of Health, in consultation  
9 with the Director of the Office of Research on Wom-  
10 en’s Health and the Director of the National Insti-  
11 tute on Minority Health and Health Disparities,  
12 shall update the guidelines established under section  
13 492B(d) of Public Health Service Act (42 U.S.C.  
14 289a–2(d)) in accordance with paragraph (2).

15 (2) REQUIREMENTS.—The updated guidelines  
16 described in paragraph (1) shall—

17 (A) reflect the science regarding sex dif-  
18 ferences;

19 (B) improve adherence to the requirements  
20 under section 492B of the Public Health Serv-  
21 ice Act (42 U.S.C. 289a–2), including the re-  
22 porting requirements under subsection (f) of  
23 such section; and

24 (C) clarify the circumstances under which  
25 studies should be designed to support the con-



1 duct of analyses to detect significant differences  
2 in the intervention effect due to demographic  
3 factors related to section 492B of the Public  
4 Health Service Act, including in the absence of  
5 prior studies that demonstrate a difference in  
6 study outcomes on the basis of such factors and  
7 considering the effects of the absence of such  
8 analyses on the availability of data related to  
9 demographic differences.

10 (i) APPROPRIATE AGE GROUPINGS IN CLINICAL RE-  
11 SEARCH.—

12 (1) INPUT FROM EXPERTS.—Not later than  
13 180 days after the date of enactment of this Act, the  
14 Director of the National Institutes of Health shall  
15 convene a workshop of experts on pediatric and older  
16 populations to provide input on—

17 (A) appropriate age groups to be included  
18 in research studies involving human subjects;  
19 and

20 (B) acceptable justifications for excluding  
21 participants from a range of age groups from  
22 human subjects research studies.

23 (2) POLICY UPDATES.—Not later than 180  
24 days after the conclusion of the workshop under  
25 paragraph (1), the Director of the National Insti-

1       tutes of Health shall make a determination with re-  
2       spect to whether the policies of the National Insti-  
3       tutes of Health on the inclusion of relevant age  
4       groups in clinical studies need to be updated, and  
5       shall update such policies as appropriate. In making  
6       the determination, the Director of the National In-  
7       stitutes of Health shall take into consideration  
8       whether such policies—

9               (A) address the consideration of age as an  
10              inclusion variable in research involving human  
11              subjects; and

12             (B) identify the criteria for justification for  
13              any age-related exclusions in such research.

14             (3) PUBLIC AVAILABILITY OF FINDINGS AND  
15              CONCLUSIONS.—The Director of the National Insti-  
16              tutes of Health shall—

17             (A) make the findings and conclusions re-  
18              sulting from the workshop under paragraph (1)  
19              and updates to policies in accordance with para-  
20              graph (2), as applicable, available to the public  
21              on the Internet website of the National Insti-  
22              tutes of Health; and

23             (B) ensure that age-related data reported  
24              in the triennial report under section 403 of the  
25              Public Health Service Act (42 U.S.C. 283) (as

1           amended by section 2032) are made available to  
2           the public on the Internet website of the Na-  
3           tional Institutes of Health.

4   **SEC. 2039. ENHANCING THE RIGOR AND REPRODUCIBILITY**  
5                           **OF SCIENTIFIC RESEARCH.**

6           (a) ESTABLISHMENT.—Not later than 1 year after  
7   the date of enactment of this Act, the Secretary of Health  
8   and Human Services, acting through the Director of the  
9   National Institutes of Health, shall convene a working  
10  group under the Advisory Committee to the Director of  
11  the National Institutes of Health (referred to in this sec-  
12  tion as the “Advisory Committee”), appointed under sec-  
13  tion 222 of the Public Health Service Act (42 U.S.C.  
14  217a), to develop and issue recommendations through the  
15  Advisory Committee for a formal policy, which may incor-  
16  porate or be informed by relevant existing and ongoing  
17  activities, to enhance rigor and reproducibility of scientific  
18  research funded by the National Institutes of Health.

19          (b) CONSIDERATIONS.—In developing and issuing  
20  recommendations through the Advisory Committee under  
21  subsection (a), the working group established under such  
22  subsection shall consider, as appropriate—

23               (1) preclinical experiment design, including  
24               analysis of sex as a biological variable;

25               (2) clinical experiment design, including—

1 (A) the diversity of populations studied for  
2 clinical research, with respect to biological, so-  
3 cial, and other determinants of health that con-  
4 tribute to health disparities;

5 (B) the circumstances under which sum-  
6 mary information regarding biological, social,  
7 and other factors that contribute to health dis-  
8 parities should be reported; and

9 (C) the circumstances under which clinical  
10 studies, including clinical trials, should conduct  
11 an analysis of the data collected during the  
12 study on the basis of biological, social, and  
13 other factors that contribute to health dispari-  
14 ties;

15 (3) applicable levels of rigor in statistical meth-  
16 ods, methodology, and analysis;

17 (4) data and information sharing in accordance  
18 with applicable privacy laws and regulations; and

19 (5) any other matter the working group deter-  
20 mines relevant.

21 (c) POLICIES.—Not later than 18 months after the  
22 date of enactment of this Act, the Director of the National  
23 Institutes of Health shall consider the recommendations  
24 developed by the working group and issued by the Advi-

1 sory Committee under subsection (a) and develop or up-  
2 date policies as appropriate.

3 (d) REPORT.—Not later than 2 years after the date  
4 of enactment of this Act, the Director of the National In-  
5 stitutes of Health shall issue a report to the Secretary of  
6 Health and Human Services, the Committee on Health,  
7 Education, Labor, and Pensions of the Senate, and the  
8 Committee on Energy and Commerce of the House of  
9 Representatives regarding recommendations developed  
10 under subsection (a) and any subsequent policy changes  
11 implemented, to enhance rigor and reproducibility in sci-  
12 entific research funded by the National Institutes of  
13 Health.

14 (e) CONFIDENTIALITY.—Nothing in this section au-  
15 thORIZES the Secretary of Health and Human Services to  
16 disclose any information that is a trade secret, or other  
17 privileged or confidential information, described in section  
18 552(b)(4) of title 5, United States Code, or section 1905  
19 of title 18, United States Code.

20 **SEC. 2040. IMPROVING MEDICAL REHABILITATION RE-**  
21 **SEARCH AT THE NATIONAL INSTITUTES OF**  
22 **HEALTH.**

23 (a) IN GENERAL.—Section 452 of the Public Health  
24 Service Act (42 U.S.C. 285g–4) is amended—

1           (1) in subsection (b), by striking “conduct and  
2           support” and inserting “conduct, support, and co-  
3           ordination”;

4           (2) in subsection (c)(1)(C), by striking “of the  
5           Center” and inserting “within the Center”;

6           (3) in subsection (d)—

7                   (A) by striking “(d)(1) In consultation”  
8                   and all that follows through the end of para-  
9                   graph (1) and inserting the following:

10           “(d)(1) The Director of the Center, in consultation  
11 with the Director of the Institute, the coordinating com-  
12 mittee established under subsection (e), and the advisory  
13 board established under subsection (f), shall develop a  
14 comprehensive plan (referred to in this section as the ‘Re-  
15 search Plan’) for the conduct, support, and coordination  
16 of medical rehabilitation research.”;

17                   (B) in paragraph (2)—

18                           (i) in subparagraph (A), by striking “;  
19                           and” and inserting a semicolon;

20                           (ii) in subparagraph (B), by striking  
21                           the period and inserting “; and”; and

22                           (iii) by adding at the end the fol-  
23                           lowing:

24                   “(C) include goals and objectives for con-  
25                   ducting, supporting, and coordinating medical reha-

1           bilitation research, consistent with the purpose de-  
2           scribed in subsection (b).”;

3                   (C) by striking paragraph (4) and insert-  
4           ing the following:

5           “(4) The Director of the Center, in consultation with  
6 the Director of the Institute, the coordinating committee  
7 established under subsection (e), and the advisory board  
8 established under subsection (f), shall revise and update  
9 the Research Plan periodically, as appropriate, or not less  
10 than every 5 years. Not later than 30 days after the Re-  
11 search Plan is so revised and updated, the Director of the  
12 Center shall transmit the revised and updated Research  
13 Plan to the President, the Committee on Health, Edu-  
14 cation, Labor, and Pensions of the Senate, and the Com-  
15 mittee on Energy and Commerce of the House of Rep-  
16 resentatives.”; and

17                   (D) by adding at the end the following:

18           “(5) The Director of the Center, in consultation with  
19 the Director of the Institute, shall, prior to revising and  
20 updating the Research Plan, prepare a report for the co-  
21 ordinating committee established under subsection (e) and  
22 the advisory board established under subsection (f) that  
23 describes and analyzes the progress during the preceding  
24 fiscal year in achieving the goals and objectives described  
25 in paragraph (2)(C) and includes expenditures for reha-

1 bilitation research at the National Institutes of Health.  
2 The report shall include recommendations for revising and  
3 updating the Research Plan, and such initiatives as the  
4 Director of the Center and the Director of the Institute  
5 determine appropriate. In preparing the report, the Direc-  
6 tor of the Center and the Director of the Institute shall  
7 consult with the Director of the National Institutes of  
8 Health.”;

9 (4) in subsection (e)—

10 (A) in paragraph (2), by inserting “peri-  
11 odically host a scientific conference or workshop  
12 on medical rehabilitation research and” after  
13 “The Coordinating Committee shall”; and

14 (B) in paragraph (3), by inserting “the Di-  
15 rector of the Division of Program Coordination,  
16 Planning, and Strategic Initiatives within the  
17 Office of the Director of the National Institutes  
18 of Health,” after “shall be composed of”;

19 (5) in subsection (f)(3)(B)—

20 (A) by redesignating clauses (ix) through  
21 (xi) as clauses (x) through (xii), respectively;  
22 and

23 (B) by inserting after clause (viii) the fol-  
24 lowing:



1           “(ix) The Director of the Division of Program  
2           Coordination, Planning, and Strategic Initiatives.”;  
3           and

4           (6) by adding at the end the following:

5           “(g)(1) The Secretary and the heads of other Federal  
6           agencies shall jointly review the programs carried out (or  
7           proposed to be carried out) by each such official with re-  
8           spect to medical rehabilitation research and, as appro-  
9           priate, enter into agreements preventing duplication  
10          among such programs.

11          “(2) The Secretary shall, as appropriate, enter into  
12          interagency agreements relating to the coordination of  
13          medical rehabilitation research conducted by agencies of  
14          the National Institutes of Health and other agencies of  
15          the Federal Government.

16          “(h) For purposes of this section, the term ‘medical  
17          rehabilitation research’ means the science of mechanisms  
18          and interventions that prevent, improve, restore, or re-  
19          place lost, underdeveloped, or deteriorating function.”.

20          (b) CONFORMING AMENDMENT.—Section 3 of the  
21          National Institutes of Health Amendments of 1990 (42  
22          U.S.C. 285g–4 note) is amended—

23                  (1) in subsection (a), by striking “IN GEN-  
24          ERAL.—”; and

25                  (2) by striking subsection (b).

1 **SEC. 2041. TASK FORCE ON RESEARCH SPECIFIC TO PREG-**  
2 **NANT WOMEN AND LACTATING WOMEN.**

3 (a) **TASK FORCE ON RESEARCH SPECIFIC TO PREG-**  
4 **NANT WOMEN AND LACTATING WOMEN.—**

5 (1) **ESTABLISHMENT.—**Not later than 90 days  
6 after the date of enactment of this Act, the Sec-  
7 retary of Health and Human Services (referred to in  
8 this section as the “Secretary”) shall establish a  
9 task force, in accordance with the Federal Advisory  
10 Committee Act (5 U.S.C. App.), to be known as the  
11 “Task Force on Research Specific to Pregnant  
12 Women and Lactating Women” (in this section re-  
13 ferred to as the “Task Force”).

14 (2) **DUTIES.—**The Task Force shall provide ad-  
15 vice and guidance to the Secretary regarding Fed-  
16 eral activities related to identifying and addressing  
17 gaps in knowledge and research regarding safe and  
18 effective therapies for pregnant women and lactating  
19 women, including the development of such therapies  
20 and the collaboration on and coordination of such  
21 activities.

22 (3) **MEMBERSHIP.—**

23 (A) **FEDERAL MEMBERS.—**The Task Force  
24 shall be composed of each of the following Fed-  
25 eral members, or the designees of such mem-  
26 bers:

1 (i) The Director of the Centers for  
2 Disease Control and Prevention.

3 (ii) The Director of the National In-  
4 stitutes of Health, the Director of the Eu-  
5 nice Kennedy Shriver National Institute of  
6 Child Health and Human Development,  
7 and the directors of such other appropriate  
8 national research institutes.

9 (iii) The Commissioner of Food and  
10 Drugs.

11 (iv) The Director of the Office on  
12 Women's Health.

13 (v) The Director of the National Vac-  
14 cine Program Office.

15 (vi) The head of any other research-  
16 related agency or department not described  
17 in clauses (i) through (v) that the Sec-  
18 retary determines appropriate, which may  
19 include the Department of Veterans Af-  
20 fairs and the Department of Defense.

21 (B) NON-FEDERAL MEMBERS.—The Task  
22 Force shall be composed of each of the fol-  
23 lowing non-Federal members, including—

24 (i) representatives from relevant med-  
25 ical societies with subject matter expertise

1 on pregnant women, lactating women, or  
2 children;

3 (ii) nonprofit organizations with ex-  
4 pertise related to the health of women and  
5 children;

6 (iii) relevant industry representatives;  
7 and

8 (iv) other representatives, as appro-  
9 priate.

10 (C) LIMITATIONS.—The non-Federal mem-  
11 bers described in subparagraph (B) shall—

12 (i) compose not more than one-half,  
13 and not less than one-third, of the total  
14 membership of the Task Force; and

15 (ii) be appointed by the Secretary.

16 (4) TERMINATION.—

17 (A) IN GENERAL.—Subject to subpara-  
18 graph (B), the Task Force shall terminate on  
19 the date that is 2 years after the date on which  
20 the Task Force is established under paragraph  
21 (1).

22 (B) EXTENSION.—The Secretary may ex-  
23 tend the operation of the Task Force for one  
24 additional 2-year period following the 2-year pe-  
25 riod described in subparagraph (A), if the Sec-

1           retary determines that the extension is appro-  
2           priate for carrying out the purpose of this sec-  
3           tion.

4           (5) MEETINGS.—The Task Force shall meet  
5           not less than 2 times each year and shall convene  
6           public meetings, as appropriate, to fulfill its duties  
7           under paragraph (2).

8           (6) TASK FORCE REPORT TO CONGRESS.—Not  
9           later than 18 months after the date on which the  
10          Task Force is established under paragraph (1), the  
11          Task Force shall prepare and submit to the Sec-  
12          retary, the Committee on Health, Education, Labor,  
13          and Pensions of the Senate, and the Committee on  
14          Energy and Commerce of the House of Representa-  
15          tives a report that includes each of the following:

16                 (A) A plan to identify and address gaps in  
17                 knowledge and research regarding safe and ef-  
18                 fective therapies for pregnant women and lac-  
19                 tating women, including the development of  
20                 such therapies.

21                 (B) Ethical issues surrounding the inclu-  
22                 sion of pregnant women and lactating women in  
23                 clinical research.

24                 (C) Effective communication strategies  
25                 with health care providers and the public on in-

1           formation relevant to pregnant women and lac-  
2           tating women.

3           (D) Identification of Federal activities, in-  
4           cluding—

5                 (i) the state of research on pregnancy  
6                 and lactation;

7                 (ii) recommendations for the coordina-  
8                 tion of, and collaboration on research re-  
9                 lated to pregnant women and lactating  
10                women;

11                (iii) dissemination of research findings  
12                and information relevant to pregnant  
13                women and lactating women to providers  
14                and the public; and

15                (iv) existing Federal efforts and pro-  
16                grams to improve the scientific under-  
17                standing of the health impacts on pregnant  
18                women, lactating women, and related birth  
19                and pediatric outcomes, including with re-  
20                spect to pharmacokinetics,  
21                pharmacodynamics, and toxicities.

22           (E) Recommendations to improve the de-  
23           velopment of safe and effective therapies for  
24           pregnant women and lactating women.

1 (b) CONFIDENTIALITY.—Nothing in this section shall  
2 authorize the Secretary of Health and Human Services to  
3 disclose any information that is a trade secret, or other  
4 privileged or confidential information, described in section  
5 552(b)(4) of title 5, United States Code, or section 1905  
6 of title 18, United States Code.

7 (c) UPDATING PROTECTIONS FOR PREGNANT  
8 WOMEN AND LACTATING WOMEN IN RESEARCH.—

9 (1) IN GENERAL.—Not later than 2 years after  
10 the date of enactment of this Act, the Secretary,  
11 considering any recommendations of the Task Force  
12 available at such time and in consultation with the  
13 heads of relevant agencies of the Department of  
14 Health and Human Services, shall, as appropriate,  
15 update regulations and guidance, as applicable, re-  
16 garding the inclusion of pregnant women and lac-  
17 tating women in clinical research.

18 (2) CRITERIA FOR EXCLUDING PREGNANT OR  
19 LACTATING WOMEN.—In updating any regulations or  
20 guidance described in paragraph (1), the Secretary  
21 shall consider any appropriate criteria to be used by  
22 institutional review boards and individuals reviewing  
23 grant proposals for excluding pregnant women or  
24 lactating women as a study population requiring ad-

1           ditional protections from participating in human  
2           subject research.

3 **SEC. 2042. STREAMLINING NATIONAL INSTITUTES OF**  
4                                   **HEALTH REPORTING REQUIREMENTS.**

5           (a) TRANS-NATIONAL INSTITUTES OF HEALTH RE-  
6 SEARCH REPORTING.—Section 402A(c)(2) of the Public  
7 Health Service Act (42 U.S.C. 282a(c)(2)) is amended—

8                           (1) by amending subparagraph (B) to read as  
9 follows:

10                                   “(B) REPORTING.—Not later than 2 years  
11 after the date of enactment of 21st Century  
12 Cures Act, the head of each national research  
13 institute or national center shall submit to the  
14 Director of the National Institutes of Health a  
15 report, to be included in the triennial report  
16 under section 403, on the amount made avail-  
17 able by the institute or center for conducting or  
18 supporting research that involves collaboration  
19 between the institute or center and 1 or more  
20 other national research institutes or national  
21 centers.”; and

22                           (2) in subparagraphs (D) and (E) by striking  
23 “(B)(i)” each place it appears and inserting “(B)”.



1 (b) FRAUD AND ABUSE REPORTING.—Section 403B  
2 of the Public Health Service Act (42 U.S.C. 283a–1) is  
3 amended—

4 (1) by striking subsection (b);

5 (2) by redesignating subsection (c) as sub-  
6 section (b); and

7 (3) in subsection (b) (as so redesignated), by  
8 striking “subsections (a) and (b)” and inserting  
9 “subsection (a)”.

10 (c) DOCTORAL DEGREES REPORTING.—Section  
11 403C(a)(2) of the Public Health Service Act (42 U.S.C.  
12 283a–2(a)(2)) is amended by striking “(not including any  
13 leaves of absence)”.

14 (d) VACCINE REPORTING.—Section 404B of the Pub-  
15 lic Health Service Act (42 U.S.C. 283d) is amended—

16 (1) by striking subsection (b); and

17 (2) by striking “(a) DEVELOPMENT OF NEW  
18 VACCINES.—The Secretary” and inserting “The  
19 Secretary”.

20 (e) NATIONAL CENTER FOR ADVANCING  
21 TRANSLATIONAL SCIENCES.—Section 479(c) of the Public  
22 Health Service Act (42 U.S.C. 287(c)) is amended—

23 (1) in the subsection heading, by striking “AN-  
24 NUAL” and inserting “BIENNIAL”; and

1           (2) in the matter preceding paragraph (1), by  
2 striking “an annual report” and inserting “a report  
3 on a biennial basis”.

4           (f) REVIEW OF CENTERS OF EXCELLENCE.—

5           (1) REPEAL.—Section 404H of the Public  
6 Health Service Act (42 U.S.C. 283j) is repealed.

7           (2) CONFORMING AMENDMENT.—Section  
8 399EE(e) of the Public Health Service Act (42  
9 U.S.C. 280–4(c)) is amended by striking “399CC,  
10 404H,” and inserting “399CC”.

11          (g) RAPID HIV TEST REPORT.—Section 502(a) of  
12 the Ryan White CARE Act Amendments of 2000 (42  
13 U.S.C. 300cc note) is amended—

14           (1) by striking paragraph (2); and

15           (2) by redesignating paragraph (3) as para-  
16 graph (2).

17          (h) NATIONAL INSTITUTE OF NURSING RE-  
18 SEARCH.—

19           (1) REPEAL.—Section 464Y of the Public  
20 Health Service Act (42 U.S.C. 285q–3) is repealed.

21           (2) CONFORMING AMENDMENT.—Section  
22 464X(g) of the Public Health Service Act (42  
23 U.S.C. 285q–2(g)) is amended by striking “biennial  
24 report made under section 464Y,” and inserting  
25 “triennial report made under section 403”.

1 **SEC. 2043. REIMBURSEMENT FOR RESEARCH SUBSTANCES**  
2 **AND LIVING ORGANISMS.**

3 Section 301 of the Public Health Service Act (42  
4 U.S.C. 241), as amended by section 2035, is further  
5 amended—

6 (1) in the flush matter at the end of subsection

7 (a)—

8 (A) by redesignating such matter as sub-  
9 section (h)(1); and

10 (B) by moving such matter so as to appear  
11 at the end of such section; and

12 (2) in subsection (h) (as so redesignated), by  
13 adding at the end the following:

14 “(2) Where research substances and living organisms  
15 are made available under paragraph (1) through contrac-  
16 tors, the Secretary may direct such contractors to collect  
17 payments on behalf of the Secretary for the costs incurred  
18 to make available such substances and organisms and to  
19 forward amounts so collected to the Secretary, in the time  
20 and manner specified by the Secretary.

21 “(3) Amounts collected under paragraph (2) shall be  
22 credited to the appropriations accounts that incurred the  
23 costs to make available the research substances and living  
24 organisms involved, and shall remain available until ex-  
25 pended for carrying out activities under such accounts.”.

1 **SEC. 2044. SENSE OF CONGRESS ON INCREASED INCLUSION**  
2 **OF UNDERREPRESENTED POPULATIONS IN**  
3 **CLINICAL TRIALS.**

4 It is the sense of Congress that the National Institute  
5 on Minority Health and Health Disparities should include  
6 within its strategic plan under section 402(m) of the Pub-  
7 lic Health Service Act (42 U.S.C. 282(m)) ways to in-  
8 crease representation of underrepresented populations in  
9 clinical trials.

10 **Subtitle E—Advancement of the**  
11 **National Institutes of Health Re-**  
12 **search and Data Access**

13 **SEC. 2051. TECHNICAL UPDATES TO CLINICAL TRIALS**  
14 **DATABASE.**

15 Section 402(j)(2)(D) of the Public Health Service Act  
16 (42 U.S.C. 282(j)(2)(D)) is amended—

17 (1) in clause (ii)(I), by inserting before the  
18 semicolon “, unless the responsible party affirma-  
19 tively requests that the Director of the National In-  
20 stitutes of Health publicly post such clinical trial in-  
21 formation for an applicable device clinical trial prior  
22 to such date of clearance or approval”; and

23 (2) by adding at the end the following:

24 “(iii) **OPTION TO MAKE CERTAIN**  
25 **CLINICAL TRIAL INFORMATION AVAILABLE**  
26 **EARLIER.**—The Director of the National

1 Institutes of Health shall inform respon-  
2 sible parties of the option to request that  
3 clinical trial information for an applicable  
4 device clinical trial be publicly posted prior  
5 to the date of clearance or approval, in ac-  
6 cordance with clause (ii)(I).

7 “(iv) COMBINATION PRODUCTS.—An  
8 applicable clinical trial for a product that  
9 is a combination of drug, device, or biologi-  
10 cal product shall be considered—

11 “(I) an applicable drug clinical  
12 trial, if the Secretary determines  
13 under section 503(g) of the Federal  
14 Food, Drug, and Cosmetic Act that  
15 the primary mode of action of such  
16 product is that of a drug or biological  
17 product; or

18 “(II) an applicable device clinical  
19 trial, if the Secretary determines  
20 under such section that the primary  
21 mode of action of such product is that  
22 of a device.”.

23 **SEC. 2052. COMPLIANCE ACTIVITIES REPORTS.**

24 (a) DEFINITIONS.—In this section:

1           (1) APPLICABLE CLINICAL TRIAL.—The term  
2           “applicable clinical trial” has the meaning given the  
3           term in section 402(j) of the Public Health Service  
4           Act (42 U.S.C. 282(j)).

5           (2) SECRETARY.—The term “Secretary” means  
6           the Secretary of Health and Human Services.

7           (b) REPORT ON ACTIVITIES TO ENCOURAGE COMPLI-  
8           ANCE.—Not later than 2 years after the date of enactment  
9           of this Act, the Secretary, acting through the Director of  
10          the National Institutes of Health and in collaboration with  
11          the Commissioner of Food and Drugs, shall submit to the  
12          Committee on Health, Education, Labor, and Pensions of  
13          the Senate and the Committee on Energy and Commerce  
14          of the House of Representatives, a report that describes  
15          education and outreach, guidance, enforcement, and other  
16          activities undertaken to encourage compliance with section  
17          402(j) of the Public Health Service Act (42 U.S.C.  
18          282(j)).

19          (c) REPORTS ON CLINICAL TRIALS.—

20                 (1) IN GENERAL.—Not later than 2 years after  
21                 the final compliance date under the final rule imple-  
22                 menting section 402(j) of the Public Health Service  
23                 Act, and every 2 years thereafter for the next 4  
24                 years, the Secretary, acting through the Director of  
25                 the National Institutes of Health and in collabora-

1           tion with the Commissioner of Food and Drugs,  
2           shall submit to the Committee on Health, Edu-  
3           cation, Labor, and Pensions of the Senate and the  
4           Committee on Energy and Commerce of the House  
5           of Representatives, a report describing—

6                   (A) the total number of applicable clinical  
7                   trials with complete data bank registration in-  
8                   formation registered during the period for  
9                   which the report is being prepared (broken  
10                  down by each year of such reporting period);

11                  (B) the total number of applicable clinical  
12                  trials registered during the period for which the  
13                  report is being prepared for which results have  
14                  been submitted to the data bank (broken down  
15                  by each year of such reporting period);

16                  (C) the activities undertaken by the Sec-  
17                  retary to educate responsible persons about  
18                  data bank registration and results submission  
19                  requirements, including through issuance of  
20                  guidance documents, informational meetings,  
21                  and training sessions; and

22                  (D) the activities described in the report  
23                  submitted under subsection (b).

24           (2) ACTIONS TO ENFORCE COMPLIANCE.—After  
25           the Secretary has undertaken the educational activi-

1 ties described in paragraph (1)(C), the Secretary  
2 shall include in subsequent reports submitted under  
3 paragraph (1) the number of actions taken by the  
4 Secretary during the period for which the report is  
5 being prepared to enforce compliance with data bank  
6 registration and results submission requirements.

7 **SEC. 2053. UPDATES TO POLICIES TO IMPROVE DATA.**

8 Section 492B(c) of the Public Health Service Act (42  
9 U.S.C. 289a-2(c)) is amended—

10 (1) by striking “In the case” and inserting the  
11 following:

12 “(1) IN GENERAL.—In the case”; and

13 (2) by adding at the end the following:

14 “(2) REPORTING REQUIREMENTS.—For any  
15 new and competing project of clinical research sub-  
16 ject to the requirements under this section that re-  
17 ceives a grant award 1 year after the date of enact-  
18 ment of the 21st Century Cures Act, or any date  
19 thereafter, for which a valid analysis is provided  
20 under paragraph (1)—

21 “(A) and which is an applicable clinical  
22 trial as defined in section 402(j), the entity con-  
23 ducting such clinical research shall submit the  
24 results of such valid analysis to the clinical trial  
25 registry data bank expanded under section



1           402(j)(3), and the Director of the National In-  
2           stitutes of Health shall, as appropriate, con-  
3           sider whether such entity has complied with the  
4           reporting requirement described in this sub-  
5           paragraph in awarding any future grant to such  
6           entity, including pursuant to section  
7           402(j)(5)(A)(ii) when applicable; and

8           “(B) the Director of the National Insti-  
9           tutes of Health shall encourage the reporting of  
10          the results of such valid analysis described in  
11          paragraph (1) through any additional means  
12          determined appropriate by the Director.”.

13 **SEC. 2054. CONSULTATION.**

14          Not later than 90 days after the date of enactment  
15          of this Act, the Secretary of Health and Human Services  
16          shall consult with relevant Federal agencies, including the  
17          Food and Drug Administration, the Office of the National  
18          Coordinator for Health Information Technology, and the  
19          National Institutes of Health, as well as other stake-  
20          holders (including patients, researchers, physicians, indus-  
21          try representatives, and developers of health information  
22          technology) to receive recommendations with respect to  
23          enhancements to the clinical trial registry data bank under  
24          section 402(j) of the Public Health Service Act (42 U.S.C.

1 282(j)), including with respect to usability, functionality,  
2 and search capability.

3 **Subtitle F—Facilitating**  
4 **Collaborative Research**

5 **SEC. 2061. NATIONAL NEUROLOGICAL CONDITIONS SUR-**  
6 **VEILLANCE SYSTEM.**

7 Part P of title III of the Public Health Service Act  
8 (42 U.S.C. 280g et seq.) is amended by inserting after  
9 section 399S the following:

10 **“SEC. 399S-1. SURVEILLANCE OF NEUROLOGICAL DIS-**  
11 **EASES.**

12 “(a) IN GENERAL.—The Secretary, acting through  
13 the Director of the Centers for Disease Control and Pre-  
14 vention and in coordination with other agencies as the Sec-  
15 retary determines, shall, as appropriate—

16 “(1) enhance and expand infrastructure and ac-  
17 tivities to track the epidemiology of neurological dis-  
18 eases; and

19 “(2) incorporate information obtained through  
20 such activities into an integrated surveillance sys-  
21 tem, which may consist of or include a registry, to  
22 be known as the National Neurological Conditions  
23 Surveillance System.

24 “(b) RESEARCH.—The Secretary shall ensure that  
25 the National Neurological Conditions Surveillance System

1 is designed in a manner that facilitates further research  
2 on neurological diseases.

3 “(c) CONTENT.—In carrying out subsection (a), the  
4 Secretary—

5 “(1) shall provide for the collection and storage  
6 of information on the incidence and prevalence of  
7 neurological diseases in the United States;

8 “(2) to the extent practicable, shall provide for  
9 the collection and storage of other available informa-  
10 tion on neurological diseases, including information  
11 related to persons living with neurological diseases  
12 who choose to participate, such as—

13 “(A) demographics, such as age, race, eth-  
14 nicity, sex, geographic location, family history,  
15 and other information, as appropriate;

16 “(B) risk factors that may be associated  
17 with neurological diseases, such as genetic and  
18 environmental risk factors and other informa-  
19 tion, as appropriate; and

20 “(C) diagnosis and progression markers;

21 “(3) may provide for the collection and storage  
22 of information relevant to analysis on neurological  
23 diseases, such as information concerning—

24 “(A) the natural history of the diseases;

25 “(B) the prevention of the diseases;

1           “(C) the detection, management, and  
2           treatment approaches for the diseases; and

3           “(D) the development of outcomes meas-  
4           ures;

5           “(4) may address issues identified during the  
6           consultation process under subsection (d); and

7           “(5) initially may address a limited number of  
8           neurological diseases.

9           “(d) CONSULTATION.—In carrying out this section,  
10          the Secretary shall consult with individuals with appro-  
11          priate expertise, which may include—

12           “(1) epidemiologists with experience in disease  
13           surveillance or registries;

14           “(2) representatives of national voluntary  
15           health associations that—

16           “(A) focus on neurological diseases; and

17           “(B) have demonstrated experience in re-  
18           search, care, or patient services;

19           “(3) health information technology experts or  
20           other information management specialists;

21           “(4) clinicians with expertise in neurological  
22           diseases; and

23           “(5) research scientists with experience con-  
24           ducting translational research or utilizing surveil-  
25           lance systems for scientific research purposes.

1       “(e) GRANTS.—The Secretary may award grants to,  
2 or enter into contracts or cooperative agreements with,  
3 public or private nonprofit entities to carry out activities  
4 under this section.

5       “(f) COORDINATION WITH OTHER FEDERAL, STATE,  
6 AND LOCAL AGENCIES.—Subject to subsection (h), the  
7 Secretary shall—

8               “(1) make information and analysis in the Na-  
9 tional Neurological Conditions Surveillance System  
10 available, as appropriate—

11                       “(A) to Federal departments and agencies,  
12 such as the National Institutes of Health and  
13 the Department of Veterans Affairs; and

14                       “(B) to State and local agencies; and

15               “(2) identify, build upon, leverage, and coordi-  
16 nate among existing data and surveillance systems,  
17 surveys, registries, and other Federal public health  
18 infrastructure, wherever practicable.

19       “(g) PUBLIC ACCESS.—Subject to subsection (h), the  
20 Secretary shall ensure that information and analysis in the  
21 National Neurological Conditions Surveillance System are  
22 available, as appropriate, to the public, including research-  
23 ers.

24       “(h) PRIVACY.—The Secretary shall ensure that in-  
25 formation and analysis in the National Neurological Con-

1 ditions Surveillance System are made available only to the  
2 extent permitted by applicable Federal and State law, and  
3 in a manner that protects personal privacy, to the extent  
4 required by applicable Federal and State privacy law, at  
5 a minimum.

6 “(i) REPORTS.—

7 “(1) REPORT ON INFORMATION AND ANAL-  
8 YSES.—Not later than 1 year after the date on  
9 which any system is established under this section,  
10 the Secretary shall submit an interim report to the  
11 Committee on Health, Education, Labor, and Pen-  
12 sions of the Senate and the Committee on Energy  
13 and Commerce of the House of Representatives re-  
14 garding aggregate information collected pursuant to  
15 this section and epidemiological analyses, as appro-  
16 priate. Such report shall be posted on the Internet  
17 website of the Department of Health and Human  
18 Services and shall be updated biennially.

19 “(2) IMPLEMENTATION REPORT.—Not later  
20 than 4 years after the date of the enactment of this  
21 section, the Secretary shall submit a report to the  
22 Congress concerning the implementation of this sec-  
23 tion. Such report shall include information on—

1           “(A) the development and maintenance of  
2           the National Neurological Conditions Surveil-  
3           lance System;

4           “(B) the type of information collected and  
5           stored in the surveillance system;

6           “(C) the use and availability of such infor-  
7           mation, including guidelines for such use; and

8           “(D) the use and coordination of databases  
9           that collect or maintain information on neuro-  
10          logical diseases.

11          “(j) DEFINITION.—In this section, the term ‘national  
12          voluntary health association’ means a national nonprofit  
13          organization with chapters, other affiliated organizations,  
14          or networks in States throughout the United States with  
15          experience serving the population of individuals with neu-  
16          rological disease and have demonstrated experience in neu-  
17          rological disease research, care, and patient services.

18          “(k) AUTHORIZATION OF APPROPRIATIONS.—To  
19          carry out this section, there is authorized to be appro-  
20          priated \$5,000,000 for each of fiscal years 2018 through  
21          2022.”.

22          **SEC. 2062. TICK-BORNE DISEASES.**

23          (a) IN GENERAL.—The Secretary of Health and  
24          Human Services (referred to in this section as “the Sec-  
25          retary”) may continue to conduct or support epidemiolog-

1 ical, basic, translational, and clinical research related to  
2 vector-borne diseases, including tick-borne diseases.

3 (b) REPORTS.—The Secretary shall ensure that each  
4 triennial report under section 403 of the Public Health  
5 Service Act (42 U.S.C. 283) (as amended by section 2032)  
6 includes information on actions undertaken by the Na-  
7 tional Institutes of Health to carry out subsection (a) with  
8 respect to tick-borne diseases.

9 (c) TICK-BORNE DISEASES WORKING GROUP.—

10 (1) ESTABLISHMENT.—The Secretary may es-  
11 tablish a working group, to be known as the Tick-  
12 Borne Disease Working Group (referred to in this  
13 section as the “Working Group”), comprised of rep-  
14 resentatives of appropriate Federal agencies and  
15 other non-Federal entities, as appropriate, to provide  
16 expertise and to review all efforts within the Depart-  
17 ment of Health and Human Services related to tick-  
18 borne diseases, to help ensure interagency coordina-  
19 tion and minimize overlap, and to examine research  
20 priorities.

21 (2) RESPONSIBILITIES.—The working group  
22 shall—

23 (A) not later than 2 years after the date  
24 of enactment of this Act, develop or update a  
25 summary of—



1 (i) ongoing tick-borne disease re-  
2 search, including research related to  
3 causes, prevention, treatment, surveillance,  
4 diagnosis, diagnostics, duration of illness,  
5 and intervention for individuals with tick-  
6 borne diseases;

7 (ii) advances made pursuant to such  
8 research;

9 (iii) Federal activities related to tick-  
10 borne diseases, including—

11 (I) epidemiological activities re-  
12 lated to tick-borne diseases; and

13 (II) basic, clinical, and  
14 translational tick-borne disease re-  
15 search related to the pathogenesis,  
16 prevention, diagnosis, and treatment  
17 of tick-borne diseases;

18 (iv) gaps in tick-borne disease re-  
19 search described in clause (iii)(II);

20 (v) the Working Group's meetings re-  
21 quired under paragraph (4); and

22 (vi) the comments received by the  
23 Working Group;

24 (B) make recommendations to the Sec-  
25 retary regarding any appropriate changes or

1 improvements to such activities and research;  
2 and

3 (C) solicit input from States, localities, and  
4 nongovernmental entities, including organiza-  
5 tions representing patients, health care pro-  
6 viders, researchers, and industry regarding sci-  
7 entific advances, research questions, surveil-  
8 lance activities, and emerging strains in species  
9 of pathogenic organisms.

10 (3) MEMBERSHIP.—The members of the work-  
11 ing group shall represent a diversity of scientific dis-  
12 ciplines.

13 (4) MEETINGS.—The Working Group shall  
14 meet not less than twice each year.

15 (5) REPORTING.—Not later than 2 years after  
16 the date of enactment of this Act, and every 2 years  
17 thereafter until termination of the Working Group  
18 pursuant to paragraph (6), the Working Group  
19 shall—

20 (A) submit a report on its activities under  
21 paragraph (2)(A) and any recommendations  
22 under paragraph (2)(B) to the Secretary, the  
23 Committee on Energy and Commerce of the  
24 House of Representatives, and the Committee

1 on Health, Education, Labor, and Pensions of  
2 the Senate; and

3 (B) make such report publicly available on  
4 the Internet website of the Department of  
5 Health and Human Services.

6 (6) SUNSET.—The Working Group under this  
7 section shall terminate 6 years after the date of en-  
8 actment of this Act.

9 **SEC. 2063. ACCESSING, SHARING, AND USING HEALTH DATA**  
10 **FOR RESEARCH PURPOSES.**

11 (a) GUIDANCE RELATED TO REMOTE ACCESS.—Not  
12 later than 1 year after the date of enactment of this Act,  
13 the Secretary of Health and Human Services (referred to  
14 in this section as the “Secretary”) shall issue guidance  
15 clarifying that subparagraph (B) of section  
16 164.512(i)(1)(ii) of part 164 of the Rule (prohibiting the  
17 removal of protected health information by a researcher)  
18 does not prohibit remote access to health information by  
19 a researcher for such purposes as described in section  
20 164.512(i)(1)(ii) of part 164 of the Rule so long as—

21 (1) at a minimum, security and privacy safe-  
22 guards, consistent with the requirements of the  
23 Rule, are maintained by the covered entity and the  
24 researcher; and

1           (2) the protected health information is not cop-  
2           ied or otherwise retained by the researcher.

3           (b) GUIDANCE RELATED TO STREAMLINING AU-  
4 THORIZATION.—Not later than 1 year after the date of  
5 enactment of this Act, the Secretary shall issue guidance  
6 on the following:

7           (1) AUTHORIZATION FOR USE AND DISCLOSURE  
8           OF HEALTH INFORMATION.—Clarification of the cir-  
9           cumstances under which the authorization for the  
10          use or disclosure of protected health information,  
11          with respect to an individual, for future research  
12          purposes contains a sufficient description of the pur-  
13          pose of the use or disclosure, such as if the author-  
14          ization—

15                 (A) sufficiently describes the purposes such  
16                 that it would be reasonable for the individual to  
17                 expect that the protected health information  
18                 could be used or disclosed for such future re-  
19                 search;

20                 (B) either—

21                         (i) states that the authorization will  
22                         expire on a particular date or on the occur-  
23                         rence of a particular event; or

1 (ii) states that the authorization will  
2 remain valid unless and until it is revoked  
3 by the individual; and

4 (C) provides instruction to the individual  
5 on how to revoke such authorization at any  
6 time.

7 (2) REMINDER OF THE RIGHT TO REVOKE.—  
8 Clarification of the circumstances under which it is  
9 appropriate to provide an individual with an annual  
10 notice or reminder that the individual has the right  
11 to revoke such authorization.

12 (3) REVOCATION OF AUTHORIZATION.—Clari-  
13 fication of appropriate mechanisms by which an in-  
14 dividual may revoke an authorization for future re-  
15 search purposes, such as described in paragraph  
16 (1)(C).

17 (c) WORKING GROUP ON PROTECTED HEALTH IN-  
18 FORMATION FOR RESEARCH.—

19 (1) ESTABLISHMENT.—Not later than 1 year  
20 after the date of enactment of this Act, the Sec-  
21 retary shall convene a working group to study and  
22 report on the uses and disclosures of protected  
23 health information for research purposes, under the  
24 Health Insurance Portability and Accountability Act  
25 of 1996 (Public Law 104–191).

1           (2) MEMBERS.—The working group shall in-  
2           clude representatives of—

3                   (A) relevant Federal agencies, including  
4                   the National Institutes of Health, the Centers  
5                   for Disease Control and Prevention, the Food  
6                   and Drug Administration, and the Office for  
7                   Civil Rights;

8                   (B) the research community;

9                   (C) patients;

10                   (D) experts in civil rights, such as privacy  
11                   rights;

12                   (E) developers of health information tech-  
13                   nology;

14                   (F) experts in data privacy and security;

15                   (G) health care providers;

16                   (H) bioethicists; and

17                   (I) other experts and entities, as the Sec-  
18                   retary determines appropriate.

19           (3) REPORT.—Not later than 1 year after the  
20           date on which the working group is convened under  
21           paragraph (1), the working group shall conduct a re-  
22           view and submit a report to the Secretary containing  
23           recommendations on whether the uses and disclo-  
24           sures of protected health information for research  
25           purposes should be modified to allow protected

1 health information to be available, as appropriate,  
2 for research purposes, including studies to obtain  
3 generalizable knowledge, while protecting individuals'  
4 privacy rights. In conducting the review and making  
5 recommendations, the working group shall—

6 (A) address, at a minimum—

7 (i) the appropriate manner and timing  
8 of authorization, including whether addi-  
9 tional notification to the individual should  
10 be required when the individual's protected  
11 health information will be used or disclosed  
12 for such research;

13 (ii) opportunities for individuals to set  
14 preferences on the manner in which their  
15 protected health information is used in re-  
16 search;

17 (iii) opportunities for patients to re-  
18 voke authorization;

19 (iv) notification to individuals of a  
20 breach in privacy;

21 (v) existing gaps in statute, regula-  
22 tion, or policy related to protecting the pri-  
23 vacy of individuals, and

24 (vi) existing barriers to research re-  
25 lated to the current restrictions on the

1 uses and disclosures of protected health in-  
2 formation; and

3 (B) consider, at a minimum—

4 (i) expectations and preferences on  
5 how an individual's protected health infor-  
6 mation is shared and used;

7 (ii) issues related to specific sub-  
8 groups of people, such as children, incar-  
9 cerated individuals, and individuals with a  
10 cognitive or intellectual disability impact-  
11 ing capacity to consent;

12 (iii) relevant Federal and State laws;

13 (iv) models of facilitating data access  
14 and levels of data access, including data  
15 segmentation, where applicable;

16 (v) potential impacts of disclosure and  
17 non-disclosure of protected health informa-  
18 tion on access to health care services; and

19 (vi) the potential uses of such data.

20 (4) REPORT SUBMISSION.—The Secretary shall  
21 submit the report under paragraph (3) to the Com-  
22 mittee on Health, Education, Labor, and Pensions  
23 of the Senate and the Committee on Energy and  
24 Commerce of the House of Representatives, and  
25 shall post such report on the appropriate Internet



1 website of the Department of Health and Human  
2 Services.

3 (5) TERMINATION.—The working group con-  
4 vened under paragraph (1) shall terminate the day  
5 after the report under paragraph (3) is submitted to  
6 Congress and made public in accordance with para-  
7 graph (4).

8 (d) DEFINITIONS.—In this section:

9 (1) THE RULE.—References to “the Rule” refer  
10 to part 160 or part 164, as appropriate, of title 45,  
11 Code of Federal Regulations (or any successor regu-  
12 lation).

13 (2) PART 164.—References to a specified section  
14 of “part 164”, refer to such specified section of part  
15 164 of title 45, Code of Federal Regulations (or any  
16 successor section).

## 17 **Subtitle G—Promoting Pediatric** 18 **Research**

### 19 **SEC. 2071. NATIONAL PEDIATRIC RESEARCH NETWORK.**

20 Section 409D(d) of the Public Health Service Act (42  
21 U.S.C. 284h(d)) is amended—

22 (1) in paragraph (1), by striking “in consulta-  
23 tion with the Director of the Eunice Kennedy Shriv-  
24 er National Institute of Child Health and Human  
25 Development and in collaboration with other appro-

1        appropriate national research institutes and national cen-  
2        ters that carry out activities involving pediatric re-  
3        search, may provide for the establishment of” and  
4        inserting “in collaboration with the national research  
5        institutes and national centers that carry out activi-  
6        ties involving pediatric research, shall support”; and

7                (2) in paragraph (2)(A) and the first sentence  
8        of paragraph (2)(E), by striking “may” each place  
9        such term appears and inserting “shall”.

10 **SEC. 2072. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK.**

11        It is the sense of Congress that—

12                (1) the National Institutes of Health should en-  
13        courage a global pediatric clinical study network by  
14        providing grants, contracts, or cooperative agree-  
15        ments to support new and early stage investigators  
16        who participate in the global pediatric clinical study  
17        network;

18                (2) the Secretary of Health and Human Serv-  
19        ices (referred to in this section as the “Secretary”)  
20        should engage with clinical investigators and appro-  
21        priate authorities outside of the United States, in-  
22        cluding the European Union, during the formation  
23        of the global pediatric clinical study network to en-  
24        courage the participation of such investigator and  
25        authorities; and

1           (3) once a global pediatric clinical study net-  
2           work is established and becomes operational, the  
3           Secretary should continue to encourage and facili-  
4           tate the participation of clinical investigators and  
5           appropriate authorities outside of the United States,  
6           including in the European Union, to participate in  
7           the network with the goal of enhancing the global  
8           reach of the network.

9           **TITLE III—DEVELOPMENT**  
10          **Subtitle A—Patient-Focused Drug**  
11           **Development**

12          **SEC. 3001. PATIENT EXPERIENCE DATA.**

13           Section 569C of the Federal Food, Drug, and Cos-  
14          metic Act (21 U.S.C. 360bbb–8c) is amended—

15           (1) in subsection (a)—

16           (A) in the subsection heading, by striking  
17           “IN GENERAL” and inserting “PATIENT EN-  
18           GAGEMENT IN DRUGS AND DEVICES”;

19           (B) by redesignating paragraphs (1) and  
20           (2) as subparagraphs (A) and (B), respectively,  
21           and moving such subparagraphs 2 ems to the  
22           right; and

23           (C) by striking “The Secretary” and in-  
24           serting the following:

25           “(1) IN GENERAL.—The Secretary”;

1           (2) by redesignating subsections (b) through (e)  
2           as paragraphs (2) through (5), respectively, and  
3           moving such paragraphs 2 ems to the right; and

4           (3) by adding at the end the following:

5           “(b) STATEMENT OF PATIENT EXPERIENCE.—

6           “(1) IN GENERAL.—Following the approval of  
7           an application that was submitted under section  
8           505(b) of this Act or section 351(a) of the Public  
9           Health Service Act at least 180 days after the date  
10          of enactment of the 21st Century Cures Act, the  
11          Secretary shall make public a brief statement re-  
12          garding the patient experience data and related in-  
13          formation, if any, submitted and reviewed as part of  
14          such application.

15          “(2) DATA AND INFORMATION.—The data and  
16          information referred to in paragraph (1) are—

17                  “(A) patient experience data;

18                  “(B) information on patient-focused drug  
19                  development tools; and

20                  “(C) other relevant information, as deter-  
21                  mined by the Secretary.

22          “(c) PATIENT EXPERIENCE DATA.—For purposes of  
23          this section, the term ‘patient experience data’ includes  
24          data that—

1           “(1) are collected by any persons (including pa-  
2           tients, family members and caregivers of patients,  
3           patient advocacy organizations, disease research  
4           foundations, researchers, and drug manufacturers);  
5           and

6           “(2) are intended to provide information about  
7           patients’ experiences with a disease or condition, in-  
8           cluding—

9                   “(A) the impact of such disease or condi-  
10                  tion, or a related therapy, on patients’ lives;  
11                  and

12                   “(B) patient preferences with respect to  
13                  treatment of such disease or condition.”.

14 **SEC. 3002. PATIENT-FOCUSED DRUG DEVELOPMENT GUID-**  
15 **ANCE.**

16           (a) PUBLICATION OF GUIDANCE DOCUMENTS.—Not  
17 later than 180 days after the date of enactment of this  
18 Act, the Secretary of Health and Human Services (re-  
19 ferred to in this section as the “Secretary”), acting  
20 through the Commissioner of Food and Drugs, shall de-  
21 velop a plan to issue draft and final versions of one or  
22 more guidance documents, over a period of 5 years, re-  
23 garding the collection of patient experience data, and the  
24 use of such data and related information in drug develop-  
25 ment. Not later than 18 months after the date of enact-

1 ment of this Act, the Secretary shall issue a draft version  
2 of at least one such guidance document. Not later than  
3 18 months after the public comment period on the draft  
4 guidance ends, the Secretary shall issue a revised draft  
5 guidance or final guidance.

6 (b) PATIENT EXPERIENCE DATA.—For purposes of  
7 this section, the term “patient experience data” has the  
8 meaning given such term in section 569C of the Federal  
9 Food, Drug, and Cosmetic Act (as added by section 3001).

10 (c) CONTENTS.—The guidance documents described  
11 in subsection (a) shall address—

12 (1) methodological approaches that a person  
13 seeking to collect patient experience data for submis-  
14 sion to, and proposed use by, the Secretary in regu-  
15 latory decisionmaking may use, that are relevant  
16 and objective and ensure that such data are accurate  
17 and representative of the intended population, in-  
18 cluding methods to collect meaningful patient input  
19 throughout the drug development process and meth-  
20 odological considerations for data collection, report-  
21 ing, management, and analysis;

22 (2) methodological approaches that may be used  
23 to develop and identify what is most important to  
24 patients with respect to burden of disease, burden of

1 treatment, and the benefits and risks in the manage-  
2 ment of the patient's disease;

3 (3) approaches to identifying and developing  
4 methods to measure impacts to patients that will  
5 help facilitate collection of patient experience data in  
6 clinical trials;

7 (4) methodologies, standards, and technologies  
8 to collect and analyze clinical outcome assessments  
9 for purposes of regulatory decisionmaking;

10 (5) how a person seeking to develop and submit  
11 proposed draft guidance relating to patient experi-  
12 ence data for consideration by the Secretary may  
13 submit such proposed draft guidance to the Sec-  
14 retary;

15 (6) the format and content required for submis-  
16 sions under this section to the Secretary, including  
17 with respect to the information described in para-  
18 graph (1);

19 (7) how the Secretary intends to respond to  
20 submissions of information described in paragraph  
21 (1), if applicable, including any timeframe for re-  
22 sponse when such submission is not part of a regu-  
23 latory application or other submission that has an  
24 associated timeframe for response; and

1           (8) how the Secretary, if appropriate, antici-  
2           pates using relevant patient experience data and re-  
3           lated information, including with respect to the  
4           structured risk-benefit assessment framework de-  
5           scribed in section 505(d) of the Federal Food, Drug,  
6           and Cosmetic Act (21 U.S.C. 355(d)), to inform reg-  
7           ulatory decisionmaking.

8   **SEC. 3003. STREAMLINING PATIENT INPUT.**

9           Chapter 35 of title 44, United States Code, shall not  
10          apply to the collection of information to which a response  
11          is voluntary, that is initiated by the Secretary under sec-  
12          tion 569C of the Federal Food, Drug, and Cosmetic Act  
13          (21 U.S.C. 360bbb–8c) (as amended by section 3001) or  
14          section 3002.

15   **SEC. 3004. REPORT ON PATIENT EXPERIENCE DRUG DEVELOP-**  
16                                   **OPMENT.**

17          Not later than June 1 of 2021, 2026, and 2031, the  
18          Secretary of Health and Human Services, acting through  
19          the Commissioner of Food and Drugs, shall prepare and  
20          publish on the Internet website of the Food and Drug Ad-  
21          ministration a report assessing the use of patient experi-  
22          ence data in regulatory decisionmaking, in particular with  
23          respect to the review of patient experience data and infor-  
24          mation on patient-focused drug development tools as part  
25          of applications approved under section 505(c) of the Fed-



1 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(e))  
2 or section 351(a) of the Public Health Service Act (42  
3 U.S.C. 262(a)).

4 **Subtitle B—Advancing New Drug**  
5 **Therapies**

6 **SEC. 3011. QUALIFICATION OF DRUG DEVELOPMENT**  
7 **TOOLS.**

8 (a) IN GENERAL.—Chapter V of the Federal Food,  
9 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
10 ed by inserting after section 506F the following new sec-  
11 tion:

12 **“SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT**  
13 **TOOLS.**

14 “(a) PROCESS FOR QUALIFICATION.—

15 “(1) IN GENERAL.—The Secretary shall estab-  
16 lish a process for the qualification of drug develop-  
17 ment tools for a proposed context of use under  
18 which—

19 “(A)(i) a requestor initiates such process  
20 by submitting a letter of intent to the Sec-  
21 retary; and

22 “(ii) the Secretary accepts or declines to  
23 accept such letter of intent;

1           “(B)(i) if the Secretary accepts the letter  
2 of intent, a requestor submits a qualification  
3 plan to the Secretary; and

4           “(ii) the Secretary accepts or declines to  
5 accept the qualification plan; and

6           “(C)(i) if the Secretary accepts the quali-  
7 fication plan, the requestor submits to the Sec-  
8 retary a full qualification package;

9           “(ii) the Secretary determines whether to  
10 accept such qualification package for review;  
11 and

12           “(iii) if the Secretary accepts such quali-  
13 fication package for review, the Secretary con-  
14 ducts such review in accordance with this sec-  
15 tion.

16           “(2) ACCEPTANCE AND REVIEW OF SUBMIS-  
17 SIONS.—

18           “(A) IN GENERAL.—Subparagraphs (B),  
19 (C), and (D) shall apply with respect to the  
20 treatment of a letter of intent, a qualification  
21 plan, or a full qualification package submitted  
22 under paragraph (1) (referred to in this para-  
23 graph as ‘qualification submissions’).

24           “(B) ACCEPTANCE FACTORS; NONACCEPT-  
25 ANCE.—The Secretary shall determine whether

1 to accept a qualification submission based on  
2 factors which may include the scientific merit of  
3 the qualification submission. A determination  
4 not to accept a submission under paragraph (1)  
5 shall not be construed as a final determination  
6 by the Secretary under this section regarding  
7 the qualification of a drug development tool for  
8 its proposed context of use.

9 “(C) PRIORITIZATION OF QUALIFICATION  
10 REVIEW.—The Secretary may prioritize the re-  
11 view of a full qualification package submitted  
12 under paragraph (1) with respect to a drug de-  
13 velopment tool, based on factors determined ap-  
14 propriate by the Secretary, including—

15 “(i) as applicable, the severity, rarity,  
16 or prevalence of the disease or condition  
17 targeted by the drug development tool and  
18 the availability or lack of alternative treat-  
19 ments for such disease or condition; and

20 “(ii) the identification, by the Sec-  
21 retary or by biomedical research consortia  
22 and other expert stakeholders, of such a  
23 drug development tool and its proposed  
24 context of use as a public health priority.

1           “(D) ENGAGEMENT OF EXTERNAL EX-  
2           PERTS.—The Secretary may, for purposes of  
3           the review of qualification submissions, through  
4           the use of cooperative agreements, grants, or  
5           other appropriate mechanisms, consult with bio-  
6           medical research consortia and may consider  
7           the recommendations of such consortia with re-  
8           spect to the review of any qualification plan  
9           submitted under paragraph (1) or the review of  
10          any full qualification package under paragraph  
11          (3).

12          “(3) REVIEW OF FULL QUALIFICATION PACK-  
13          AGE.—The Secretary shall—

14                 “(A) conduct a comprehensive review of a  
15                 full qualification package accepted under para-  
16                 graph (1)(C); and

17                 “(B) determine whether the drug develop-  
18                 ment tool at issue is qualified for its proposed  
19                 context of use.

20          “(4) QUALIFICATION.—The Secretary shall de-  
21          termine whether a drug development tool is qualified  
22          for a proposed context of use based on the scientific  
23          merit of a full qualification package reviewed under  
24          paragraph (3).

25          “(b) EFFECT OF QUALIFICATION.—

1           “(1) IN GENERAL.—A drug development tool  
2 determined to be qualified under subsection (a)(4)  
3 for a proposed context of use specified by the re-  
4 questor may be used by any person in such context  
5 of use for the purposes described in paragraph (2).

6           “(2) USE OF A DRUG DEVELOPMENT TOOL.—  
7 Subject to paragraph (3), a drug development tool  
8 qualified under this section may be used for—

9           “(A) supporting or obtaining approval or  
10 licensure (as applicable) of a drug or biological  
11 product (including in accordance with section  
12 506(c)) under section 505 of this Act or section  
13 351 of the Public Health Service Act; or

14           “(B) supporting the investigational use of  
15 a drug or biological product under section  
16 505(i) of this Act or section 351(a)(3) of the  
17 Public Health Service Act.

18           “(3) RESCISSION OR MODIFICATION.—

19           “(A) IN GENERAL.—The Secretary may re-  
20 scind or modify a determination under this sec-  
21 tion to qualify a drug development tool if the  
22 Secretary determines that the drug development  
23 tool is not appropriate for the proposed context  
24 of use specified by the requestor. Such a deter-  
25 mination may be based on new information that

1 calls into question the basis for such qualifica-  
2 tion.

3 “(B) MEETING FOR REVIEW.—If the Sec-  
4 retary rescinds or modifies under subparagraph  
5 (A) a determination to qualify a drug develop-  
6 ment tool, the requestor involved shall, on re-  
7 quest, be granted a meeting with the Secretary  
8 to discuss the basis of the Secretary’s decision  
9 to rescind or modify the determination before  
10 the effective date of the rescission or modifica-  
11 tion.

12 “(c) TRANSPARENCY.—

13 “(1) IN GENERAL.—Subject to paragraph (3),  
14 the Secretary shall make publicly available, and up-  
15 date on at least a biannual basis, on the Internet  
16 website of the Food and Drug Administration the  
17 following:

18 “(A) Information with respect to each  
19 qualification submission under the qualification  
20 process under subsection (a), including—

21 “(i) the stage of the review process  
22 applicable to the submission;

23 “(ii) the date of the most recent  
24 change in stage status;

1           “(iii) whether external scientific ex-  
2           perts were utilized in the development of a  
3           qualification plan or the review of a full  
4           qualification package; and

5           “(iv) submissions from requestors  
6           under the qualification process under sub-  
7           section (a), including any data and evi-  
8           dence contained in such submissions, and  
9           any updates to such submissions.

10          “(B) The Secretary’s formal written deter-  
11          minations in response to such qualification sub-  
12          missions.

13          “(C) Any rescissions or modifications  
14          under subsection (b)(3) of a determination to  
15          qualify a drug development tool.

16          “(D) Summary reviews that document con-  
17          clusions and recommendations for determina-  
18          tions to qualify drug development tools under  
19          subsection (a).

20          “(E) A comprehensive list of—

21                 “(i) all drug development tools quali-  
22                 fied under subsection (a); and

23                 “(ii) all surrogate endpoints which  
24                 were the basis of approval or licensure (as  
25                 applicable) of a drug or biological product

1 (including in accordance with section  
2 506(e)) under section 505 of this Act or  
3 section 351 of the Public Health Service  
4 Act.

5 “(2) RELATION TO TRADE SECRETS ACT.—In-  
6 formation made publicly available by the Secretary  
7 under paragraph (1) shall be considered a disclosure  
8 authorized by law for purposes of section 1905 of  
9 title 18, United States Code.

10 “(3) APPLICABILITY.—Nothing in this section  
11 shall be construed as authorizing the Secretary to  
12 disclose any information contained in an application  
13 submitted under section 505 of this Act or section  
14 351 of the Public Health Service Act that is con-  
15 fidential commercial or trade secret information sub-  
16 ject to section 552(b)(4) of title 5, United States  
17 Code, or section 1905 of title 18, United States  
18 Code.

19 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
20 tion shall be construed—

21 “(1) to alter the standards of evidence under  
22 subsection (c) or (d) of section 505, including the  
23 substantial evidence standard in such subsection (d),  
24 or under section 351 of the Public Health Service  
25 Act (as applicable); or



1           “(2) to limit the authority of the Secretary to  
2           approve or license products under this Act or the  
3           Public Health Service Act, as applicable (as in effect  
4           before the date of the enactment of the 21st Century  
5           Cures Act).

6           “(e) DEFINITIONS.—In this section:

7           “(1) BIOMARKER.—The term ‘biomarker’—

8                   “(A) means a characteristic (such as a  
9                   physiologic, pathologic, or anatomic char-  
10                   acteristic or measurement) that is objectively  
11                   measured and evaluated as an indicator of nor-  
12                   mal biologic processes, pathologic processes, or  
13                   biological responses to a therapeutic interven-  
14                   tion; and

15                   “(B) includes a surrogate endpoint.

16           “(2) BIOMEDICAL RESEARCH CONSORTIA.—The  
17           term ‘biomedical research consortia’ means collabo-  
18           rative groups that may take the form of public-pri-  
19           vate partnerships and may include government agen-  
20           cies, institutions of higher education (as defined in  
21           section 101(a) of the Higher Education Act of  
22           1965), patient advocacy groups, industry representa-  
23           tives, clinical and scientific experts, and other rel-  
24           evant entities and individuals.

1           “(3) CLINICAL OUTCOME ASSESSMENT.—The  
2 term ‘clinical outcome assessment’ means—

3           “(A) a measurement of a patient’s symp-  
4 toms, overall mental state, or the effects of a  
5 disease or condition on how the patient func-  
6 tions; and

7           “(B) includes a patient-reported outcome.

8           “(4) CONTEXT OF USE.—The term ‘context of  
9 use’ means, with respect to a drug development tool,  
10 the circumstances under which the drug development  
11 tool is to be used in drug development and regu-  
12 latory review.

13           “(5) DRUG DEVELOPMENT TOOL.—The term  
14 ‘drug development tool’ includes—

15           “(A) a biomarker;

16           “(B) a clinical outcome assessment; and

17           “(C) any other method, material, or meas-  
18 ure that the Secretary determines aids drug de-  
19 velopment and regulatory review for purposes of  
20 this section.

21           “(6) PATIENT-REPORTED OUTCOME.—The term  
22 ‘patient-reported outcome’ means a measurement  
23 based on a report from a patient regarding the sta-  
24 tus of the patient’s health condition without amend-

1       ment or interpretation of the patient’s report by a  
2       clinician or any other person.

3           “(7) QUALIFICATION.—The terms ‘qualifica-  
4       tion’ and ‘qualified’ mean a determination by the  
5       Secretary that a drug development tool and its pro-  
6       posed context of use can be relied upon to have a  
7       specific interpretation and application in drug devel-  
8       opment and regulatory review under this Act.

9           “(8) REQUESTOR.—The term ‘requestor’ means  
10       an entity or entities, including a drug sponsor or a  
11       biomedical research consortia, seeking to qualify a  
12       drug development tool for a proposed context of use  
13       under this section.

14           “(9) SURROGATE ENDPOINT.—The term ‘surro-  
15       gate endpoint’ means a marker, such as a laboratory  
16       measurement, radiographic image, physical sign, or  
17       other measure, that is not itself a direct measure-  
18       ment of clinical benefit, and—

19           “(A) is known to predict clinical benefit  
20       and could be used to support traditional ap-  
21       proval of a drug or biological product; or

22           “(B) is reasonably likely to predict clinical  
23       benefit and could be used to support the accel-  
24       erated approval of a drug or biological product  
25       in accordance with section 506(c).”.

1 (b) GUIDANCE.—

2 (1) IN GENERAL.—The Secretary of Health and  
3 Human Services (referred to in this section as the  
4 “Secretary”) shall, in consultation with biomedical  
5 research consortia (as defined in subsection (e) of  
6 section 507 of the Federal Food, Drug, and Cos-  
7 metic Act (as added by subsection (a)) and other in-  
8 terested parties through a collaborative public proc-  
9 ess, issue guidance to implement such section 507  
10 that—

11 (A) provides a conceptual framework de-  
12 scribing appropriate standards and scientific  
13 approaches to support the development of bio-  
14 markers delineated under the taxonomy estab-  
15 lished under paragraph (3);

16 (B) with respect to the qualification proc-  
17 ess under such section 507—

18 (i) describes the requirements that en-  
19 tities seeking to qualify a drug develop-  
20 ment tool under such section shall observe  
21 when engaging in such process;

22 (ii) outlines reasonable timeframes for  
23 the Secretary’s review of letters, qualifica-  
24 tion plans, or full qualification packages  
25 submitted under such process; and

1 (iii) establishes a process by which  
2 such entities or the Secretary may consult  
3 with biomedical research consortia and  
4 other individuals and entities with expert  
5 knowledge and insights that may assist the  
6 Secretary in the review of qualification  
7 plans and full qualification submissions  
8 under such section; and

9 (C) includes such other information as the  
10 Secretary determines appropriate.

11 (2) TIMING.—Not later than 3 years after the  
12 date of the enactment of this Act, the Secretary  
13 shall issue draft guidance under paragraph (1) on  
14 the implementation of section 507 of the Federal  
15 Food, Drug, and Cosmetic Act (as added by sub-  
16 section (a)). The Secretary shall issue final guidance  
17 on the implementation of such section not later than  
18 6 months after the date on which the comment pe-  
19 riod for the draft guidance closes.

20 (3) TAXONOMY.—

21 (A) IN GENERAL.—For purposes of in-  
22 forming guidance under this subsection, the  
23 Secretary shall, in consultation with biomedical  
24 research consortia and other interested parties  
25 through a collaborative public process, establish

1 a taxonomy for the classification of biomarkers  
2 (and related scientific concepts) for use in drug  
3 development.

4 (B) PUBLIC AVAILABILITY.—Not later  
5 than 2 years after the date of the enactment of  
6 this Act, the Secretary shall make such tax-  
7 onomy publicly available in draft form for pub-  
8 lic comment. The Secretary shall finalize the  
9 taxonomy not later than 1 year after the close  
10 of the public comment period.

11 (c) MEETING AND REPORT.—

12 (1) MEETING.—Not later than 2 years after the  
13 date of the enactment of this Act, the Secretary  
14 shall convene a public meeting to describe and solicit  
15 public input regarding the qualification process  
16 under section 507 of the Federal Food, Drug, and  
17 Cosmetic Act, as added by subsection (a).

18 (2) REPORT.—Not later than 5 years after the  
19 date of the enactment of this Act, the Secretary  
20 shall make publicly available on the Internet website  
21 of the Food and Drug Administration a report. Such  
22 report shall include, with respect to the qualification  
23 process under section 507 of the Federal Food,  
24 Drug, and Cosmetic Act, as added by subsection (a),  
25 information on—

1 (A) the number of requests submitted, as  
2 a letter of intent, for qualification of a drug de-  
3 velopment tool (as defined in subsection (e) of  
4 such section 507);

5 (B) the number of such requests accepted  
6 and determined to be eligible for submission of  
7 a qualification plan or full qualification package  
8 (as such terms are defined in subsection (e) of  
9 such section 507), respectively;

10 (C) the number of such requests for which  
11 external scientific experts were utilized in the  
12 development of a qualification plan or review of  
13 a full qualification package;

14 (D) the number of qualification plans and  
15 full qualification packages, respectively, sub-  
16 mitted to the Secretary; and

17 (E) the drug development tools qualified  
18 through such qualification process, specified by  
19 type of tool, such as a biomarker or clinical out-  
20 come assessment (as such terms are defined in  
21 subsection (e) of such section 507).

22 **SEC. 3012. TARGETED DRUGS FOR RARE DISEASES.**

23 Subchapter B of chapter V of the Federal Food,  
24 Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.) is  
25 amended by inserting after section 529 the following:

1 **“SEC. 529A. TARGETED DRUGS FOR RARE DISEASES.**

2 “(a) PURPOSE.—The purpose of this section, through  
3 the approach provided for in subsection (b), is to—

4 “(1) facilitate the development, review, and ap-  
5 proval of genetically targeted drugs and variant pro-  
6 tein targeted drugs to address an unmet medical  
7 need in one or more patient subgroups, including  
8 subgroups of patients with different mutations of a  
9 gene, with respect to rare diseases or conditions that  
10 are serious or life-threatening; and

11 “(2) maximize the use of scientific tools or  
12 methods, including surrogate endpoints and other  
13 biomarkers, for such purposes.

14 “(b) LEVERAGING OF DATA FROM PREVIOUSLY AP-  
15 PROVED DRUG APPLICATION OR APPLICATIONS.—The  
16 Secretary may, consistent with applicable standards for  
17 approval under this Act or section 351(a) of the Public  
18 Health Service Act, allow the sponsor of an application  
19 under section 505(b)(1) of this Act or section 351(a) of  
20 the Public Health Service Act for a genetically targeted  
21 drug or a variant protein targeted drug to rely upon data  
22 and information—

23 “(1) previously developed by the same sponsor  
24 (or another sponsor that has provided the sponsor  
25 with a contractual right of reference to such data  
26 and information); and



1           “(2) submitted by a sponsor described in para-  
2           graph (1) in support of one or more previously ap-  
3           proved applications that were submitted under sec-  
4           tion 505(b)(1) of this Act or section 351(a) of the  
5           Public Health Service Act,  
6           for a drug that incorporates or utilizes the same or similar  
7           genetically targeted technology as the drug or drugs that  
8           are the subject of an application or applications described  
9           in paragraph (2) or for a variant protein targeted drug  
10          that is the same or incorporates or utilizes the same vari-  
11          ant protein targeted drug, as the drug or drugs that are  
12          the subject of an application or applications described in  
13          paragraph (2).

14          “(c) DEFINITIONS.—For purposes of this section—

15                 “(1) the term ‘genetically targeted drug’ means  
16                 a drug that—

17                         “(A) is the subject of an application under  
18                         section 505(b)(1) of this Act or section 351(a)  
19                         of the Public Health Service Act for the treat-  
20                         ment of a rare disease or condition (as such  
21                         term is defined in section 526) that is serious  
22                         or life-threatening;

23                         “(B) may result in the modulation (includ-  
24                         ing suppression, up-regulation, or activation) of

1 the function of a gene or its associated gene  
2 product; and

3 “(C) incorporates or utilizes a genetically  
4 targeted technology;

5 “(2) the term ‘genetically targeted technology’  
6 means a technology comprising non-replicating nu-  
7 cleic acid or analogous compounds with a common or  
8 similar chemistry that is intended to treat one or  
9 more patient subgroups, including subgroups of pa-  
10 tients with different mutations of a gene, with the  
11 same disease or condition, including a disease or  
12 condition due to other variants in the same gene;  
13 and

14 “(3) the term ‘variant protein targeted drug’  
15 means a drug that—

16 “(A) is the subject of an application under  
17 section 505(b)(1) of this Act or section 351(a)  
18 of the Public Health Service Act for the treat-  
19 ment of a rare disease or condition (as such  
20 term is defined in section 526) that is serious  
21 or life-threatening;

22 “(B) modulates the function of a product  
23 of a mutated gene where such mutation is re-  
24 sponsible in whole or in part for a given disease  
25 or condition; and

1           “(C) is intended to treat one or more pa-  
2           tient subgroups, including subgroups of patients  
3           with different mutations of a gene, with the  
4           same disease or condition.

5           “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
6           tion shall be construed to—

7           “(1) alter the authority of the Secretary to ap-  
8           prove drugs pursuant to this Act or section 351 of  
9           the Public Health Service Act (as authorized prior  
10          to the date of enactment of the 21st Century Cures  
11          Act), including the standards of evidence, and appli-  
12          cable conditions, for approval under such applicable  
13          Act; or

14          “(2) confer any new rights, beyond those au-  
15          thorized under this Act or the Public Health Service  
16          Act prior to enactment of this section, with respect  
17          to the permissibility of a sponsor referencing infor-  
18          mation contained in another application submitted  
19          under section 505(b)(1) of this Act or section 351(a)  
20          of the Public Health Service Act.”.

21   **SEC. 3013. REAUTHORIZATION OF PROGRAM TO ENCOUR-**  
22                   **AGE TREATMENTS FOR RARE PEDIATRIC DIS-**  
23                   **EASES.**

24          (a) IN GENERAL.—Section 529(b) of the Federal  
25          Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(b)) is

1 amended by striking paragraph (5) and inserting the fol-  
2 lowing:

3 “(5) **TERMINATION OF AUTHORITY.**—The Sec-  
4 retary may not award any priority review vouchers  
5 under paragraph (1) after September 30, 2020, un-  
6 less the rare pediatric disease product application—

7 “(A) is for a drug that, not later than Sep-  
8 tember 30, 2020, is designated under sub-  
9 section (d) as a drug for a rare pediatric dis-  
10 ease; and

11 “(B) is, not later than September 30,  
12 2022, approved under section 505(b)(1) of this  
13 Act or section 351(a) of the Public Health  
14 Service Act.”.

15 (b) **REPORT.**—The Advancing Hope Act of 2016  
16 (Public Law 114–229) is amended by striking section 3.

17 **SEC. 3014. GAO STUDY OF PRIORITY REVIEW VOUCHER**  
18 **PROGRAMS.**

19 (a) **STUDY.**—The Comptroller General of the United  
20 States (referred to in this section as the “Comptroller  
21 General”) shall conduct a study addressing the effective-  
22 ness and overall impact of the following priority review  
23 voucher programs, including any such programs amended  
24 or established by this Act:

1           (1) The neglected tropical disease priority re-  
2 view voucher program under section 524 of the Fed-  
3 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
4 360n).

5           (2) The rare pediatric disease priority review  
6 voucher program under section 529 of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C. 360ff).

8           (3) The medical countermeasure priority review  
9 voucher program under section 565A of the Federal  
10 Food, Drug, and Cosmetic Act, as added by section  
11 3086.

12       (b) ISSUANCE OF REPORT.—Not later than January  
13 31, 2020, the Comptroller General shall submit to the  
14 Committee on Health, Education, Labor, and Pensions of  
15 the Senate and the Committee on Energy and Commerce  
16 of the House of Representatives a report containing the  
17 results of the study under subsection (a).

18       (c) CONTENTS OF REPORTS.—The report submitted  
19 under subsection (b) shall address—

20           (1) for each drug for which a priority review  
21 voucher has been awarded as of initiation of the  
22 study—

23           (A) the indications for which the drug is  
24 approved under section 505(c) of the Federal  
25 Food, Drug, and Cosmetic Act (21 U.S.C.

1           355(c)), pursuant to an application under sec-  
2           tion 505(b)(1) of such Act, or licensed under  
3           section 351(a) of the Public Health Service Act  
4           (42 U.S.C. 262(a));

5           (B) whether, and to what extent, the  
6           voucher impacted the sponsor's decision to de-  
7           velop the drug; and

8           (C) whether, and to what extent, the ap-  
9           proval or licensure of the drug, as applicable  
10          and appropriate—

11           (i) addressed a global unmet need re-  
12          lated to the treatment or prevention of a  
13          neglected tropical disease, including wheth-  
14          er the sponsor of a drug coordinated with  
15          international development organizations;

16           (ii) addressed an unmet need related  
17          to the treatment of a rare pediatric dis-  
18          ease; or

19           (iii) affected the Nation's prepared-  
20          ness against a chemical, biological, radio-  
21          logical, or nuclear threat, including natu-  
22          rally occurring threats;

23          (2) for each drug for which a priority review  
24          voucher has been used—

1 (A) the indications for which such drug is  
2 approved under section 505(c) of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C.  
4 355(c)), pursuant to an application under sec-  
5 tion 505(b)(1) of such Act, or licensed under  
6 section 351(a) of the Public Health Service Act  
7 (42 U.S.C. 262);

8 (B) the value of the voucher, if trans-  
9 ferred; and

10 (C) the length of time between the date on  
11 which the voucher was awarded and the date on  
12 which the voucher was used; and

13 (3) an analysis of the priority review voucher  
14 programs described in subsection (a), including—

15 (A) the resources used by the Food and  
16 Drug Administration in reviewing drugs for  
17 which vouchers were used, including the effect  
18 of the programs on the Food and Drug Admin-  
19 istration's review of drugs for which priority re-  
20 view vouchers were not awarded or used;

21 (B) whether any improvements to such  
22 programs are necessary to appropriately target  
23 incentives for the development of drugs that  
24 would likely not otherwise be developed, or de-

1           veloped in as timely a manner, and, as applica-  
2           ble and appropriate—

3                   (i) address global unmet needs related  
4                   to the treatment or prevention of neglected  
5                   tropical diseases, including in countries in  
6                   which neglected tropical diseases are en-  
7                   demic; or

8                   (ii) address unmet needs related to  
9                   the treatment of rare pediatric diseases;  
10                  and

11                 (C) whether the sunset of the rare pedi-  
12                 atric disease program and medical counter-  
13                 measure program has had an impact on the  
14                 program, including any potential unintended  
15                 consequences.

16                 (d) PROTECTION OF NATIONAL SECURITY.—The  
17                 Comptroller General shall conduct the study and issue re-  
18                 ports under this section in a manner that does not com-  
19                 promise national security.

20         **SEC. 3015. AMENDMENTS TO THE ORPHAN DRUG GRANTS.**

21                 Section 5 of the Orphan Drug Act (21 U.S.C. 360ee)  
22                 is amended—

23                   (1) in subsection (a), by striking paragraph (1)  
24                   and inserting the following: “(1) defraying the costs



1 of developing drugs for rare diseases or conditions,  
2 including qualified testing expenses,”; and

3 (2) in subsection (b)(1)—

4 (A) in subparagraph (A)(ii), by striking  
5 “and” after the semicolon;

6 (B) in subparagraph (B), by striking the  
7 period and inserting “; and”; and

8 (C) by adding at the end the following:

9 “(C) prospectively planned and designed  
10 observational studies and other analyses con-  
11 ducted to assist in the understanding of the  
12 natural history of a rare disease or condition  
13 and in the development of a therapy, including  
14 studies and analyses to—

15 “(i) develop or validate a drug devel-  
16 opment tool related to a rare disease or  
17 condition; or

18 “(ii) understand the full spectrum of  
19 the disease manifestations, including de-  
20 scribing genotypic and phenotypic varia-  
21 bility and identifying and defining distinct  
22 subpopulations affected by a rare disease  
23 or condition.”.

1 **SEC. 3016. GRANTS FOR STUDYING CONTINUOUS DRUG**  
2 **MANUFACTURING.**

3 (a) IN GENERAL.—The Secretary of Health and  
4 Human Services may award grants to institutions of high-  
5 er education and nonprofit organizations for the purpose  
6 of studying and recommending improvements to the proc-  
7 ess of continuous manufacturing of drugs and biological  
8 products and similar innovative monitoring and control  
9 techniques.

10 (b) DEFINITIONS.—In this section—

11 (1) the term “drug” has the meaning given  
12 such term in section 201 of the Federal Food, Drug,  
13 and Cosmetic Act (21 U.S.C. 321);

14 (2) the term “biological product” has the mean-  
15 ing given such term in section 351(i) of the Public  
16 Health Service Act (42 U.S.C. 262(i)); and

17 (3) the term “institution of higher education”  
18 has the meaning given such term in section 101(a)  
19 of the Higher Education Act of 1965 (20 U.S.C.  
20 1001(a)).

21 **Subtitle C—Modern Trial Design**  
22 **and Evidence Development**

23 **SEC. 3021. NOVEL CLINICAL TRIAL DESIGNS.**

24 (a) PROPOSALS FOR USE OF NOVEL CLINICAL TRIAL  
25 DESIGNS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For  
26 purposes of assisting sponsors in incorporating complex

1 adaptive and other novel trial designs into proposed clin-  
2 ical protocols and applications for new drugs under section  
3 505 of the Federal Food, Drug, and Cosmetic Act (21  
4 U.S.C. 355) and biological products under section 351 of  
5 the Public Health Service Act (42 U.S.C. 262), the Sec-  
6 retary of Health and Human Services (referred to in this  
7 section as the “Secretary”) shall conduct a public meeting  
8 and issue guidance in accordance with subsection (b).

9 (b) GUIDANCE ADDRESSING USE OF NOVEL CLIN-  
10 ICAL TRIAL DESIGNS.—

11 (1) IN GENERAL.—The Secretary, acting  
12 through the Commissioner of Food and Drugs, shall  
13 update or issue guidance addressing the use of com-  
14 plex adaptive and other novel trial design in the de-  
15 velopment and regulatory review and approval or li-  
16 censure for drugs and biological products.

17 (2) CONTENTS.—The guidance under para-  
18 graph (1) shall address—

19 (A) the use of complex adaptive and other  
20 novel trial designs, including how such clinical  
21 trials proposed or submitted help to satisfy the  
22 substantial evidence standard under section  
23 505(d) of the Federal Food, Drug, and Cos-  
24 metic Act (21 U.S.C. 355(d));

1 (B) how sponsors may obtain feedback  
2 from the Secretary on technical issues related  
3 to modeling and simulations prior to—

4 (i) completion of such modeling or  
5 simulations; or

6 (ii) the submission of resulting infor-  
7 mation to the Secretary;

8 (C) the types of quantitative and quali-  
9 tative information that should be submitted for  
10 review; and

11 (D) recommended analysis methodologies.

12 (3) PUBLIC MEETING.—Prior to updating or  
13 issuing the guidance required by paragraph (1), the  
14 Secretary shall consult with stakeholders, including  
15 representatives of regulated industry, academia, pa-  
16 tient advocacy organizations, consumer groups, and  
17 disease research foundations, through a public meet-  
18 ing to be held not later than 18 months after the  
19 date of enactment of this Act.

20 (4) TIMING.—The Secretary shall update or  
21 issue a draft version of the guidance required by  
22 paragraph (1) not later than 18 months after the  
23 date of the public meeting required by paragraph (3)  
24 and finalize such guidance not later than 1 year

1 after the date on which the public comment period  
2 for the draft guidance closes.

3 **SEC. 3022. REAL WORLD EVIDENCE.**

4 Chapter V of the Federal Food, Drug, and Cosmetic  
5 Act is amended by inserting after section 505E (21 U.S.C.  
6 355f) the following:

7 **“SEC. 505F. UTILIZING REAL WORLD EVIDENCE.**

8 “(a) IN GENERAL.—The Secretary shall establish a  
9 program to evaluate the potential use of real world evi-  
10 dence—

11 “(1) to help to support the approval of a new  
12 indication for a drug approved under section 505(c);  
13 and

14 “(2) to help to support or satisfy postapproval  
15 study requirements.

16 “(b) REAL WORLD EVIDENCE DEFINED.—In this  
17 section, the term ‘real world evidence’ means data regard-  
18 ing the usage, or the potential benefits or risks, of a drug  
19 derived from sources other than randomized clinical trials.

20 “(c) PROGRAM FRAMEWORK.—

21 “(1) IN GENERAL.—Not later than 2 years  
22 after the date of enactment of the 21st Century  
23 Cures Act, the Secretary shall establish a draft  
24 framework for implementation of the program under  
25 this section.

1           “(2) CONTENTS OF FRAMEWORK.—The frame-  
2           work shall include information describing—

3                   “(A) the sources of real world evidence, in-  
4                   cluding ongoing safety surveillance, observa-  
5                   tional studies, registries, claims, and patient-  
6                   centered outcomes research activities;

7                   “(B) the gaps in data collection activities;

8                   “(C) the standards and methodologies for  
9                   collection and analysis of real world evidence;  
10                  and

11                  “(D) the priority areas, remaining chal-  
12                  lenges, and potential pilot opportunities that  
13                  the program established under this section will  
14                  address.

15           “(3) CONSULTATION.—

16                   “(A) IN GENERAL.—In developing the pro-  
17                   gram framework under this subsection, the Sec-  
18                   retary shall consult with regulated industry,  
19                   academia, medical professional organizations,  
20                   representatives of patient advocacy organiza-  
21                   tions, consumer organizations, disease research  
22                   foundations, and other interested parties.

23                   “(B) PROCESS.—The consultation under  
24                   subparagraph (A) may be carried out through  
25                   approaches such as—

1                   “(i) a public-private partnership with  
2                   the entities described in such subparagraph  
3                   in which the Secretary may participate;

4                   “(ii) a contract, grant, or other ar-  
5                   rangement, as the Secretary determines  
6                   appropriate, with such a partnership or an  
7                   independent research organization; or

8                   “(iii) public workshops with the enti-  
9                   ties described in such subparagraph.

10           “(d) PROGRAM IMPLEMENTATION.—The Secretary  
11 shall, not later than 2 years after the date of enactment  
12 of the 21st Century Cures Act and in accordance with the  
13 framework established under subsection (c), implement  
14 the program to evaluate the potential use of real world  
15 evidence.

16           “(e) GUIDANCE FOR INDUSTRY.—The Secretary  
17 shall—

18                   “(1) utilize the program established under sub-  
19                   section (a), its activities, and any subsequent pilots  
20                   or written reports, to inform a guidance for industry  
21                   on—

22                           “(A) the circumstances under which spon-  
23                           sors of drugs and the Secretary may rely on  
24                           real world evidence for the purposes described

1 in paragraphs (1) and (2) of subsection (a);  
2 and

3 “(B) the appropriate standards and meth-  
4 odologies for collection and analysis of real  
5 world evidence submitted for such purposes;

6 “(2) not later than 5 years after the date of en-  
7 actment of the 21st Century Cures Act, issue draft  
8 guidance for industry as described in paragraph (1);  
9 and

10 “(3) not later than 18 months after the close  
11 of the public comment period for the draft guidance  
12 described in paragraph (2), issue revised draft guid-  
13 ance or final guidance.

14 “(f) RULE OF CONSTRUCTION.—

15 “(1) IN GENERAL.—Subject to paragraph (2),  
16 nothing in this section prohibits the Secretary from  
17 using real world evidence for purposes not specified  
18 in this section, provided the Secretary determines  
19 that sufficient basis exists for any such nonspecified  
20 use.

21 “(2) STANDARDS OF EVIDENCE AND SEC-  
22 RETARY’S AUTHORITY.—This section shall not be  
23 construed to alter—

24 “(A) the standards of evidence under—



1 “(i) subsection (c) or (d) of section  
2 505, including the substantial evidence  
3 standard in such subsection (d); or

4 “(ii) section 351(a) of the Public  
5 Health Service Act; or

6 “(B) the Secretary’s authority to require  
7 postapproval studies or clinical trials, or the  
8 standards of evidence under which studies or  
9 trials are evaluated.”.

10 **SEC. 3023. PROTECTION OF HUMAN RESEARCH SUBJECTS.**

11 (a) **IN GENERAL.**—In order to simplify and facilitate  
12 compliance by researchers with applicable regulations for  
13 the protection of human subjects in research, the Sec-  
14 retary of Health and Human Services (referred to in this  
15 section as the “Secretary”) shall, to the extent practicable  
16 and consistent with other statutory provisions, harmonize  
17 differences between the HHS Human Subject Regulations  
18 and the FDA Human Subject Regulations in accordance  
19 with subsection (b).

20 (b) **AVOIDING REGULATORY DUPLICATION AND UN-**  
21 **NECESSARY DELAYS.**—The Secretary shall, as appro-  
22 priate—

23 (1) make such modifications to the provisions of  
24 the HHS Human Subject Regulations, the FDA

1 Human Subject Regulations, and the vulnerable pop-  
2 ulations rules as may be necessary—

3 (A) to reduce regulatory duplication and  
4 unnecessary delays;

5 (B) to modernize such provisions in the  
6 context of multisite and cooperative research  
7 projects; and

8 (C) to protect vulnerable populations, in-  
9 corporate local considerations, and support  
10 community engagement through mechanisms  
11 such as consultation with local researchers and  
12 human research protection programs, in a man-  
13 ner consistent with subparagraph (B); and

14 (2) ensure that human subject research that is  
15 subject to the HHS Human Subject Regulations and  
16 to the FDA Human Subject Regulations may—

17 (A) use joint or shared review;

18 (B) rely upon the review of—

19 (i) an independent institutional review  
20 board; or

21 (ii) an institutional review board of an  
22 entity other than the sponsor of the re-  
23 search; or

24 (C) use similar arrangements to avoid du-  
25 plication of effort.

1 (c) CONSULTATION.—In harmonizing or modifying  
2 regulations or guidance under this section, the Secretary  
3 shall consult with stakeholders (including researchers, aca-  
4 demic organizations, hospitals, institutional research  
5 boards, pharmaceutical, biotechnology, and medical device  
6 developers, clinical research organizations, patient groups,  
7 and others).

8 (d) TIMING.—The Secretary shall complete the har-  
9 monization described in subsection (a) not later than 3  
10 years after the date of enactment of this Act.

11 (e) PROGRESS REPORT.—Not later than 2 years after  
12 the date of enactment of this Act, the Secretary shall sub-  
13 mit to Congress a report on the progress made toward  
14 completing such harmonization.

15 (f) DEFINITIONS.—

16 (1) HUMAN SUBJECT REGULATIONS.—In this  
17 section:

18 (A) FDA HUMAN SUBJECT REGULA-  
19 TIONS.—The term “FDA Human Subject Reg-  
20 ulations” means the provisions of parts 50, 56,  
21 312, and 812 of title 21, Code of Federal Regu-  
22 lations (or any successor regulations).

23 (B) HHS HUMAN SUBJECT REGULA-  
24 TIONS.—The term “HHS Human Subject Reg-  
25 ulations” means the provisions of subpart A of

1 part 46 of title 45, Code of Federal Regulations  
2 (or any successor regulations).

3 (C) VULNERABLE POPULATION RULES.—

4 The term “vulnerable population rules”  
5 means—

6 (i) except in the case of research de-  
7 scribed in clause (ii), the provisions of sub-  
8 parts B through D of part 46, Code of  
9 Federal Regulations (or any successor reg-  
10 ulations); and

11 (ii) in the case of research that is sub-  
12 ject to FDA Human Subject Regulations,  
13 the provisions applicable to vulnerable pop-  
14 ulations under part 56 of title 21, Code of  
15 Federal Regulations (or any successor reg-  
16 ulations) and subpart D of part 50 of such  
17 title 21 (or any successor regulations).

18 (2) OTHER DEFINITIONS.—In this section:

19 (A) INSTITUTIONAL REVIEW BOARD.—The  
20 term “institutional review board” has the mean-  
21 ing that applies to the term “institutional re-  
22 view board” under the HHS Human Subject  
23 Regulations.

24 (B) LEAD INSTITUTIONAL REVIEW  
25 BOARD.—The term “lead institutional review

1 board” means an institutional review board that  
2 otherwise meets the requirements of the HHS  
3 Human Subject Regulations and enters into a  
4 written agreement with an institution, another  
5 institutional review board, a sponsor, or a prin-  
6 cipal investigator to approve and oversee human  
7 subject research that is conducted at multiple  
8 locations. References to an institutional review  
9 board include an institutional review board that  
10 serves a single institution and a lead institu-  
11 tional review board.

12 **SEC. 3024. INFORMED CONSENT WAIVER OR ALTERATION**  
13 **FOR CLINICAL INVESTIGATIONS.**

14 (a) DEVICES.—Section 520(g)(3) of the Federal  
15 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is  
16 amended—

17 (1) in subparagraph (D), by striking “except  
18 where subject to such conditions as the Secretary  
19 may prescribe, the investigator” and inserting the  
20 following: “except where, subject to such conditions  
21 as the Secretary may prescribe—

22 “(i) the proposed clinical testing poses no  
23 more than minimal risk to the human subject  
24 and includes appropriate safeguards to protect

1 the rights, safety, and welfare of the human  
2 subject; or

3 “(ii) the investigator”; and

4 (2) in the matter following subparagraph (D),  
5 by striking “subparagraph (D)” and inserting “sub-  
6 paragraph (D)(ii)”.

7 (b) DRUGS.—Section 505(i)(4) of the Federal Food,  
8 Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended  
9 by striking “except where it is not feasible or it is contrary  
10 to the best interests of such human beings” and inserting  
11 “except where it is not feasible, it is contrary to the best  
12 interests of such human beings, or the proposed clinical  
13 testing poses no more than minimal risk to such human  
14 beings and includes appropriate safeguards as prescribed  
15 to protect the rights, safety, and welfare of such human  
16 beings”.

17 **Subtitle D—Patient Access to**  
18 **Therapies and Information**

19 **SEC. 3031. SUMMARY LEVEL REVIEW.**

20 (a) FFDCA.—Section 505(c) of the Federal Food,  
21 Drug, and Cosmetic Act (21 U.S.C. 355(c)) is amended  
22 by adding at the end the following:

23 “(5)(A) The Secretary may rely upon qualified data  
24 summaries to support the approval of a supplemental ap-  
25 plication, with respect to a qualified indication for a drug,

1 submitted under subsection (b), if such supplemental ap-  
2 plication complies with subparagraph (B).

3 “(B) A supplemental application is eligible for review  
4 as described in subparagraph (A) only if—

5 “(i) there is existing data available and accept-  
6 able to the Secretary demonstrating the safety of the  
7 drug; and

8 “(ii) all data used to develop the qualified data  
9 summaries are submitted to the Secretary as part of  
10 the supplemental application.

11 “(C) The Secretary shall post on the Internet website  
12 of the Food and Drug Administration and update annu-  
13 ally—

14 “(i) the number of applications reviewed solely  
15 under subparagraph (A) or section 351(a)(2)(E) of  
16 the Public Health Service Act;

17 “(ii) the average time for completion of review  
18 under subparagraph (A) or section 351(a)(2)(E) of  
19 the Public Health Service Act;

20 “(iii) the average time for review of supple-  
21 mental applications where the Secretary did not use  
22 review flexibility under subparagraph (A) or section  
23 351(a)(2)(E) of the Public Health Service Act; and

24 “(iv) the number of applications reviewed under  
25 subparagraph (A) or section 351(a)(2)(E) of the

1 Public Health Service Act for which the Secretary  
2 made use of full data sets in addition to the quali-  
3 fied data summary.

4 “(D) In this paragraph—

5 “(i) the term ‘qualified indication’ means an in-  
6 dication for a drug that the Secretary determines to  
7 be appropriate for summary level review under this  
8 paragraph; and

9 “(ii) the term ‘qualified data summary’ means  
10 a summary of clinical data that demonstrates the  
11 safety and effectiveness of a drug with respect to a  
12 qualified indication.”.

13 (b) PHSA.—Section 351(a)(2) of the Public Health  
14 Service Act (42 U.S.C. 262(a)(2)) is amended by adding  
15 at the end the following:

16 “(E)(i) The Secretary may rely upon qualified data  
17 summaries to support the approval of a supplemental ap-  
18 plication, with respect to a qualified indication for a drug,  
19 submitted under this subsection, if such supplemental ap-  
20 plication complies with the requirements of subparagraph  
21 (B) of section 505(c)(5) of the Federal Food, Drug, and  
22 Cosmetic Act.

23 “(ii) In this subparagraph, the terms ‘qualified indi-  
24 cation’ and ‘qualified data summary’ have the meanings



1 given such terms in section 505(c)(5) of the Federal Food,  
2 Drug, and Cosmetic Act.”.

3 **SEC. 3032. EXPANDED ACCESS POLICY.**

4 Chapter V of the Federal Food, Drug, and Cosmetic  
5 Act is amended by inserting after section 561 (21 U.S.C.  
6 360bbb) the following:

7 **“SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR IN-**  
8 **VESTIGATIONAL DRUGS.**

9 “(a) IN GENERAL.—The manufacturer or distributor  
10 of one or more investigational drugs for the diagnosis,  
11 monitoring, or treatment of one or more serious diseases  
12 or conditions shall make available the policy of the manu-  
13 facturer or distributor on evaluating and responding to re-  
14 quests submitted under section 561(b) for provision of  
15 such a drug.

16 “(b) PUBLIC AVAILABILITY OF EXPANDED ACCESS  
17 POLICY.—The policies under subsection (a) shall be made  
18 public and readily available, such as by posting such poli-  
19 cies on a publicly available Internet website. Such policies  
20 may be generally applicable to all investigational drugs of  
21 such manufacturer or distributor.

22 “(c) CONTENT OF POLICY.—A policy described in  
23 subsection (a) shall include—

1           “(1) contact information for the manufacturer  
2           or distributor to facilitate communication about re-  
3           quests described in subsection (a);

4           “(2) procedures for making such requests;

5           “(3) the general criteria the manufacturer or  
6           distributor will use to evaluate such requests for in-  
7           dividual patients, and for responses to such requests;

8           “(4) the length of time the manufacturer or dis-  
9           tributor anticipates will be necessary to acknowledge  
10          receipt of such requests; and

11          “(5) a hyperlink or other reference to the clin-  
12          ical trial record containing information about the ex-  
13          panded access for such drug that is required under  
14          section 402(j)(2)(A)(ii)(II)(gg) of the Public Health  
15          Service Act.

16          “(d) NO GUARANTEE OF ACCESS.—The posting of  
17          policies by manufacturers and distributors under sub-  
18          section (a) shall not serve as a guarantee of access to any  
19          specific investigational drug by any individual patient.

20          “(e) REVISED POLICY.—Nothing in this section shall  
21          prevent a manufacturer or distributor from revising a pol-  
22          icy required under this section at any time.

23          “(f) APPLICATION.—This section shall apply to a  
24          manufacturer or distributor with respect to an investiga-  
25          tional drug beginning on the later of—

1           “(1) the date that is 60 calendar days after the  
2           date of enactment of the 21st Century Cures Act; or

3           “(2) the first initiation of a phase 2 or phase  
4           3 study (as such terms are defined in section  
5           312.21(b) and (c) of title 21, Code of Federal Regu-  
6           lations (or any successor regulations)) with respect  
7           to such investigational drug.”.

8   **SEC. 3033. ACCELERATED APPROVAL FOR REGENERATIVE**  
9                                   **ADVANCED THERAPIES.**

10          (a) IN GENERAL.—Section 506 of the Federal Food,  
11          Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

12                  (1) by transferring subsection (e) (relating to  
13                  construction) so that it appears before subsection (f)  
14                  (relating to awareness efforts); and

15                  (2) by adding at the end the following:

16          “(g) REGENERATIVE ADVANCED THERAPY.—

17                  “(1) IN GENERAL.—The Secretary, at the re-  
18                  quest of the sponsor of a drug, shall facilitate an ef-  
19                  ficient development program for, and expedite review  
20                  of, such drug if the drug qualifies as a regenerative  
21                  advanced therapy under the criteria described in  
22                  paragraph (2).

23                  “(2) CRITERIA.—A drug is eligible for designa-  
24                  tion as a regenerative advanced therapy under this  
25                  subsection if—

1           “(A) the drug is a regenerative medicine  
2           therapy (as defined in paragraph (8));

3           “(B) the drug is intended to treat, modify,  
4           reverse, or cure a serious or life-threatening dis-  
5           ease or condition; and

6           “(C) preliminary clinical evidence indicates  
7           that the drug has the potential to address  
8           unmet medical needs for such a disease or con-  
9           dition.

10          “(3) REQUEST FOR DESIGNATION.—The spon-  
11          sor of a drug may request the Secretary to designate  
12          the drug as a regenerative advanced therapy concu-  
13          rently with, or at any time after, submission of an  
14          application for the investigation of the drug under  
15          section 505(i) of this Act or section 351(a)(3) of the  
16          Public Health Service Act.

17          “(4) DESIGNATION.—Not later than 60 cal-  
18          endar days after the receipt of a request under para-  
19          graph (3), the Secretary shall determine whether the  
20          drug that is the subject of the request meets the cri-  
21          teria described in paragraph (2). If the Secretary de-  
22          termines that the drug meets the criteria, the Sec-  
23          retary shall designate the drug as a regenerative ad-  
24          vanced therapy and shall take such actions as are  
25          appropriate under paragraph (1). If the Secretary

1 determines that a drug does not meet the criteria for  
2 such designation, the Secretary shall include with  
3 the determination a written description of the ra-  
4 tionale for such determination.

5 “(5) ACTIONS.—The sponsor of a regenerative  
6 advanced therapy shall be eligible for the actions to  
7 expedite development and review of such therapy  
8 under subsection (a)(3)(B), including early inter-  
9 actions to discuss any potential surrogate or inter-  
10 mediate endpoint to be used to support the acceler-  
11 ated approval of an application for the product  
12 under subsection (c).

13 “(6) ACCESS TO EXPEDITED APPROVAL PATH-  
14 WAYS.—An application for a regenerative advanced  
15 therapy under section 505(b)(1) of this Act or sec-  
16 tion 351(a) of the Public Health Service Act may  
17 be—

18 “(A) eligible for priority review, as de-  
19 scribed in the Manual of Policies and Proce-  
20 dures of the Food and Drug Administration  
21 and goals identified in the letters described in  
22 section 101(b) of the Prescription Drug User  
23 Fee Amendments of 2012; and

24 “(B) eligible for accelerated approval  
25 under subsection (c), as agreed upon pursuant

1 to subsection (a)(3)(B), through, as appro-  
2 priate—

3 “(i) surrogate or intermediate  
4 endpoints reasonably likely to predict long-  
5 term clinical benefit; or

6 “(ii) reliance upon data obtained from  
7 a meaningful number of sites, including  
8 through expansion to additional sites, as  
9 appropriate.

10 “(7) POSTAPPROVAL REQUIREMENTS.—The  
11 sponsor of a regenerative advanced therapy that is  
12 granted accelerated approval and is subject to the  
13 postapproval requirements under subsection (c) may,  
14 as appropriate, fulfill such requirements, as the Sec-  
15 retary may require, through—

16 “(A) the submission of clinical evidence,  
17 clinical studies, patient registries, or other  
18 sources of real world evidence, such as elec-  
19 tronic health records;

20 “(B) the collection of larger confirmatory  
21 data sets, as agreed upon pursuant to sub-  
22 section (a)(3)(B); or

23 “(C) postapproval monitoring of all pa-  
24 tients treated with such therapy prior to ap-  
25 proval of the therapy.

1           “(8) DEFINITION.—For purposes of this sec-  
2           tion, the term ‘regenerative medicine therapy’ in-  
3           cludes cell therapy, therapeutic tissue engineering  
4           products, human cell and tissue products, and com-  
5           bination products using any such therapies or prod-  
6           ucts, except for those regulated solely under section  
7           361 of the Public Health Service Act and part 1271  
8           of title 21, Code of Federal Regulations.”.

9           (b) RULE OF CONSTRUCTION.—Nothing in this sec-  
10          tion and the amendments made by this section shall be  
11          construed to alter the authority of the Secretary of Health  
12          and Human Services—

13                 (1) to approve drugs pursuant to the Federal  
14          Food, Drug, and Cosmetic Act (21 U.S.C. 301 et  
15          seq.) and section 351 of the Public Health Service  
16          Act (42 U.S.C. 262) as authorized prior to the date  
17          of enactment of the 21st Century Cures Act, includ-  
18          ing the standards of evidence, and applicable condi-  
19          tions, for approval under such Acts; or

20                 (2) to alter the authority of the Secretary to re-  
21          quire postapproval studies pursuant to such Acts, as  
22          authorized prior to the date of enactment of the 21st  
23          Century Cures Act.

24           (c) CONFORMING AMENDMENT.—Section 506(e)(1)  
25          of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 356(e)(1)) is amended by inserting “and the 21st Century  
2 Cures Act” after “Food and Drug Administration Safety  
3 and Innovation Act”.

4 **SEC. 3034. GUIDANCE REGARDING DEVICES USED IN THE**  
5 **RECOVERY, ISOLATION, OR DELIVERY OF RE-**  
6 **GENERATIVE ADVANCED THERAPIES.**

7 (a) DRAFT GUIDANCE.—Not later than 1 year after  
8 the date of enactment of the 21st Century Cures Act, the  
9 Secretary of Health and Human Services, acting through  
10 the Commissioner of Food and Drugs, shall issue draft  
11 guidance clarifying how, in the context of regenerative ad-  
12 vanced therapies, the Secretary will evaluate devices used  
13 in the recovery, isolation, or delivery of regenerative ad-  
14 vanced therapies. In doing so, the Secretary shall specifi-  
15 cally address—

16 (1) how the Food and Drug Administration in-  
17 tends to simplify and streamline regulatory require-  
18 ments for combination device and cell or tissue prod-  
19 ucts;

20 (2) what, if any, intended uses or specific at-  
21 tributes would result in a device used with a regen-  
22 erative therapy product to be classified as a class III  
23 device;

24 (3) when the Food and Drug Administration  
25 considers it is necessary, if ever, for the intended use



1 of a device to be limited to a specific intended use  
2 with only one particular type of cell; and

3 (4) application of the least burdensome ap-  
4 proach to demonstrate how a device may be used  
5 with more than one cell type.

6 (b) FINAL GUIDANCE.—Not later than 12 months  
7 after the close of the period for public comment on the  
8 draft guidance under subsection (a), the Secretary of  
9 Health and Human Services shall finalize such guidance.

10 **SEC. 3035. REPORT ON REGENERATIVE ADVANCED THERA-**  
11 **PIES.**

12 (a) REPORT TO CONGRESS.—Before March 1 of each  
13 calendar year, the Secretary of Health and Human Serv-  
14 ices shall, with respect to the previous calendar year, sub-  
15 mit a report to the Committee on Health, Education,  
16 Labor, and Pensions of the Senate and the Committee on  
17 Energy and Commerce of the House of Representatives  
18 on—

19 (1) the number and type of applications for ap-  
20 proval of regenerative advanced therapies filed, ap-  
21 proved or licensed as applicable, withdrawn, or de-  
22 nied; and

23 (2) how many of such applications or therapies,  
24 as applicable, were granted accelerated approval or  
25 priority review.

1 (b) REGENERATIVE ADVANCED THERAPY.—In this  
2 section, the term “regenerative advanced therapy” has the  
3 meaning given such term in section 506(g) of the Federal  
4 Food, Drug, and Cosmetic Act, as added by section 3033  
5 of this Act.

6 **SEC. 3036. STANDARDS FOR REGENERATIVE MEDICINE AND**  
7 **REGENERATIVE ADVANCED THERAPIES.**

8 Subchapter A of chapter V of the Federal Food,  
9 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
10 ed by inserting after section 506F the following:

11 **“SEC. 506G. STANDARDS FOR REGENERATIVE MEDICINE**  
12 **AND REGENERATIVE ADVANCED THERAPIES.**

13 “(a) IN GENERAL.—Not later than 2 years after the  
14 date of enactment of the 21st Century Cures Act, the Sec-  
15 retary, in consultation with the National Institute of  
16 Standards and Technology and stakeholders (including re-  
17 generative medicine and advanced therapies manufactur-  
18 ers and clinical trial sponsors, contract manufacturers,  
19 academic institutions, practicing clinicians, regenerative  
20 medicine and advanced therapies industry organizations,  
21 and standard setting organizations), shall facilitate an ef-  
22 fort to coordinate and prioritize the development of stand-  
23 ards and consensus definition of terms, through a public  
24 process, to support, through regulatory predictability, the  
25 development, evaluation, and review of regenerative medi-

1 cine therapies and regenerative advanced therapies, in-  
2 cluding with respect to the manufacturing processes and  
3 controls of such products.

4 “(b) ACTIVITIES.—

5 “(1) IN GENERAL.—In carrying out this sec-  
6 tion, the Secretary shall continue to—

7 “(A) identify opportunities to help advance  
8 the development of regenerative medicine thera-  
9 pies and regenerative advanced therapies;

10 “(B) identify opportunities for the develop-  
11 ment of laboratory regulatory science research  
12 and documentary standards that the Secretary  
13 determines would help support the development,  
14 evaluation, and review of regenerative medicine  
15 therapies and regenerative advanced therapies  
16 through regulatory predictability; and

17 “(C) work with stakeholders, such as those  
18 described in subsection (a), as appropriate, in  
19 the development of such standards.

20 “(2) REGULATIONS AND GUIDANCE.—Not later  
21 than 1 year after the development of standards as  
22 described in subsection (a), the Secretary shall re-  
23 view relevant regulations and guidance and, through  
24 a public process, update such regulations and guid-  
25 ance as the Secretary determines appropriate.

1           “(c) DEFINITIONS.—For purposes of this section, the  
2 terms ‘regenerative medicine therapy’ and ‘regenerative  
3 advanced therapy’ have the meanings given such terms in  
4 section 506(g).”.

5 **SEC. 3037. HEALTH CARE ECONOMIC INFORMATION.**

6           Section 502(a) of the Federal Food, Drug, and Cos-  
7 metic Act (21 U.S.C. 352(a)) is amended—

8           (1) by striking “(a) If its” and inserting  
9           “(a)(1) If its”;

10           (2) by striking “a formulary committee, or  
11 other similar entity, in the course of the committee  
12 or the entity carrying out its responsibilities for the  
13 selection of drugs for managed care or other similar  
14 organizations” and inserting “a payor, formulary  
15 committee, or other similar entity with knowledge  
16 and expertise in the area of health care economic  
17 analysis, carrying out its responsibilities for the se-  
18 lection of drugs for coverage or reimbursement”;

19           (3) by striking “directly relates” and inserting  
20           “relates”;

21           (4) by striking “and is based on competent and  
22 reliable scientific evidence. The requirements set  
23 forth in section 505(a) or in section 351(a) of the  
24 Public Health Service Act shall not apply to health  
25 care economic information provided to such a com-

1        mittee or entity in accordance with this paragraph”  
2        and inserting “, is based on competent and reliable  
3        scientific evidence, and includes, where applicable, a  
4        conspicuous and prominent statement describing any  
5        material differences between the health care eco-  
6        nomic information and the labeling approved for the  
7        drug under section 505 or under section 351 of the  
8        Public Health Service Act. The requirements set  
9        forth in section 505(a) or in subsections (a) and (k)  
10       of section 351 of the Public Health Service Act shall  
11       not apply to health care economic information pro-  
12       vided to such a payor, committee, or entity in ac-  
13       cordance with this paragraph”; and

14                (5) by striking “In this paragraph, the term”  
15       and all that follows and inserting the following:

16       “(2)(A) For purposes of this paragraph, the term  
17       ‘health care economic information’ means any analysis (in-  
18       cluding the clinical data, inputs, clinical or other assump-  
19       tions, methods, results, and other components underlying  
20       or comprising the analysis) that identifies, measures, or  
21       describes the economic consequences, which may be based  
22       on the separate or aggregated clinical consequences of the  
23       represented health outcomes, of the use of a drug. Such  
24       analysis may be comparative to the use of another drug,  
25       to another health care intervention, or to no intervention.

1       “(B) Such term does not include any analysis that  
2 relates only to an indication that is not approved under  
3 section 505 or under section 351 of the Public Health  
4 Service Act for such drug.”.

5 **SEC. 3038. COMBINATION PRODUCT INNOVATION.**

6       (a) IN GENERAL.—Section 503(g) of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is  
8 amended—

9           (1) by striking paragraph (3);

10          (2) by redesignating paragraph (2) as para-  
11 graph (7);

12          (3) by redesignating paragraphs (4) and (5) as  
13 paragraphs (8) and (9), respectively;

14          (4) by striking “(g)(1)” and all that follows  
15 through the end of paragraph (1) and inserting the  
16 following:

17       “(g)(1)(A) The Secretary shall, in accordance with  
18 this subsection, assign a primary agency center to regulate  
19 products that constitute a combination of a drug, device,  
20 or biological product.

21       “(B) The Secretary shall conduct the premarket re-  
22 view of any combination product under a single applica-  
23 tion, whenever appropriate.

24       “(C) For purposes of this subsection, the term ‘pri-  
25 mary mode of action’ means the single mode of action of

1 a combination product expected to make the greatest con-  
2 tribution to the overall intended therapeutic effects of the  
3 combination product.

4 “(D) The Secretary shall determine the primary  
5 mode of action of the combination product. If the Sec-  
6 retary determines that the primary mode of action is that  
7 of—

8 “(i) a drug (other than a biological product),  
9 the agency center charged with premarket review of  
10 drugs shall have primary jurisdiction;

11 “(ii) a device, the agency center charged with  
12 premarket review of devices shall have primary juris-  
13 diction; or

14 “(iii) a biological product, the agency center  
15 charged with premarket review of biological products  
16 shall have primary jurisdiction.

17 “(E) In determining the primary mode of action of  
18 a combination product, the Secretary shall not determine  
19 that the primary mode of action is that of a drug or bio-  
20 logical product solely because the combination product has  
21 any chemical action within or on the human body.

22 “(F) If a sponsor of a combination product disagrees  
23 with the determination under subparagraph (D)—

24 “(i) such sponsor may request, and the Sec-  
25 retary shall provide, a substantive rationale to such

1 sponsor that references scientific evidence provided  
2 by the sponsor and any other scientific evidence re-  
3 lied upon by the Secretary to support such deter-  
4 mination; and

5 “(ii)(I) the sponsor of the combination product  
6 may propose one or more studies (which may be  
7 nonclinical, clinical, or both) to establish the rel-  
8 evance, if any, of the chemical action in achieving  
9 the primary mode of action of such product;

10 “(II) if the sponsor proposes any such studies,  
11 the Secretary and the sponsor of such product shall  
12 collaborate and seek to reach agreement, within a  
13 reasonable time of such proposal, not to exceed 90  
14 calendar days, on the design of such studies; and

15 “(III) if an agreement is reached under sub-  
16 clause (II) and the sponsor conducts one or more of  
17 such studies, the Secretary shall consider the data  
18 resulting from any such study when reevaluating the  
19 determination of the primary mode of action of such  
20 product, and unless and until such reevaluation has  
21 occurred and the Secretary issues a new determina-  
22 tion, the determination of the Secretary under sub-  
23 paragraph (D) shall remain in effect.

24 “(2)(A)(i) To establish clarity and certainty for the  
25 sponsor, the sponsor of a combination product may re-



1 quest a meeting on such combination product. If the Sec-  
2 retary concludes that a determination of the primary mode  
3 of action pursuant to paragraph (1)(D) is necessary, the  
4 sponsor may request such meeting only after the Secretary  
5 makes such determination. If the sponsor submits a writ-  
6 ten meeting request, the Secretary shall, not later than  
7 75 calendar days after receiving such request, meet with  
8 the sponsor of such combination product.

9 “(ii) A meeting under clause (i) may—

10 “(I) address the standards and requirements  
11 for market approval or clearance of the combination  
12 product;

13 “(II) address other issues relevant to such com-  
14 bination product, such as requirements related to  
15 postmarket modification of such combination prod-  
16 uct and good manufacturing practices applicable to  
17 such combination product; and

18 “(III) identify elements under subclauses (I)  
19 and (II) that may be more appropriate for discus-  
20 sion and agreement with the Secretary at a later  
21 date given that scientific or other information is not  
22 available, or agreement is otherwise not feasible re-  
23 garding such elements, at the time a request for  
24 such meeting is made.

1       “(iii) Any agreement under this subparagraph shall  
2 be in writing and made part of the administrative record  
3 by the Secretary.

4       “(iv) Any such agreement shall remain in effect, ex-  
5 cept—

6               “(I) upon the written agreement of the Sec-  
7 retary and the sponsor or applicant; or

8               “(II) pursuant to a decision by the director of  
9 the reviewing division of the primary agency center,  
10 or a person more senior than such director, in con-  
11 sultation with consulting centers and the Office, as  
12 appropriate, that an issue essential to determining  
13 whether the standard for market clearance or other  
14 applicable standard under this Act or the Public  
15 Health Service Act applicable to the combination  
16 product has been identified since the agreement was  
17 reached, or that deviating from the agreement is  
18 otherwise justifiable based on scientific evidence, for  
19 public health reasons.

20       “(3) For purposes of conducting the premarket re-  
21 view of a combination product that contains an approved  
22 constituent part described in paragraph (4), the Secretary  
23 may require that the sponsor of such combination product  
24 submit to the Secretary only data or information that the  
25 Secretary determines is necessary to meet the standard

1 for clearance or approval, as applicable, under this Act  
2 or the Public Health Service Act, including any incre-  
3 mental risks and benefits posed by such combination prod-  
4 uct, using a risk-based approach and taking into account  
5 any prior finding of safety and effectiveness or substantial  
6 equivalence for the approved constituent part relied upon  
7 by the applicant in accordance with paragraph (5).

8 “(4) For purposes of paragraph (3), an approved con-  
9 stituent part is—

10 “(A) a drug constituent part of a combination  
11 product being reviewed in a single application or re-  
12 quest under section 515, 510(k), or 513(f)(2) (sub-  
13 mitted in accordance with paragraph (5)), that is an  
14 approved drug, provided such application or request  
15 complies with paragraph (5);

16 “(B) a device constituent part approved under  
17 section 515 that is referenced by the sponsor and  
18 that is available for use by the Secretary under sec-  
19 tion 520(h)(4); or

20 “(C) any constituent part that was previously  
21 approved, cleared, or classified under section 505,  
22 510(k), 513(f)(2), or 515 of this Act for which the  
23 sponsor has a right of reference or any constituent  
24 part that is a nonprescription drug, as defined in  
25 section 760(a)(2).

1           “(5)(A) If an application is submitted under section  
2 515 or 510(k) or a request is submitted under section  
3 513(f)(2), consistent with any determination made under  
4 paragraph (1)(D), for a combination product containing  
5 as a constituent part an approved drug—

6           “(i) the application or request shall include the  
7 certification or statement described in section  
8 505(b)(2); and

9           “(ii) the applicant or requester shall provide no-  
10 tice as described in section 505(b)(3).

11           “(B) For purposes of this paragraph and paragraph  
12 (4), the term ‘approved drug’ means an active ingre-  
13 dient—

14           “(i) that was in an application previously ap-  
15 proved under section 505(c);

16           “(ii) where such application is relied upon by  
17 the applicant submitting the application or request  
18 described in subparagraph (A);

19           “(iii) for which full reports of investigations  
20 that have been made to show whether such drug is  
21 safe for use and whether such drug is effective in  
22 use were not conducted by or for the applicant sub-  
23 mitting the application or request described in sub-  
24 paragraph (A); and

1           “(iv) for which the applicant submitting the ap-  
2           plication or request described in subparagraph (A)  
3           has not obtained a right of reference or use from the  
4           person by or for whom the investigations described  
5           in clause (iii) were conducted.

6           “(C) The following provisions shall apply with respect  
7           to an application or request described in subparagraph (A)  
8           to the same extent and in the same manner as if such  
9           application or request were an application described in sec-  
10          tion 505(b)(2) that referenced the approved drug:

11           “(i) Subparagraphs (A), (B), (C), and (D) of  
12          section 505(c)(3).

13           “(ii) Clauses (ii), (iii), and (iv) of section  
14          505(c)(3)(E).

15           “(iii) Subsections (b) and (c) of section 505A.

16           “(iv) Section 505E(a).

17           “(v) Section 527(a).

18          “(D) Notwithstanding any other provision of this  
19          subsection, an application or request for classification for  
20          a combination product described in subparagraph (A)  
21          shall be considered an application submitted under section  
22          505(b)(2) for purposes of section 271(e)(2)(A) of title 35,  
23          United States Code.

24          “(6) Nothing in this subsection shall be construed as  
25          prohibiting a sponsor from submitting separate applica-

1 tions for the constituent parts of a combination product,  
2 unless the Secretary determines that a single application  
3 is necessary.”;

4 (5) in paragraph (8) (as redesignated by para-  
5 graph (3))—

6 (A) in subparagraph (C)—

7 (i) by amending clause (i) to read as  
8 follows:

9 “(i) In carrying out this subsection, the Office shall  
10 help to ensure timely and effective premarket review that  
11 involves more than one agency center by coordinating such  
12 reviews, overseeing the timeliness of such reviews, and  
13 overseeing the alignment of feedback regarding such re-  
14 views.”;

15 (ii) in clause (ii), by inserting “and  
16 alignment” after “the timeliness” each  
17 place it appears; and

18 (iii) by adding at the end the fol-  
19 lowing new clauses:

20 “(iii) The Office shall ensure that, with respect to a  
21 combination product, a designated person or persons in  
22 the primary agency center is the primary point or points  
23 of contact for the sponsor of such combination product.  
24 The Office shall also coordinate communications to and  
25 from any consulting center involved in such premarket re-

1 view, if requested by such primary agency center or any  
2 such consulting center. Agency communications and com-  
3 mitments, to the extent consistent with other provisions  
4 of law and the requirements of all affected agency centers,  
5 from the primary agency center shall be considered as  
6 communication from the Secretary on behalf of all agency  
7 centers involved in the review.

8 “(iv) The Office shall, with respect to the premarket  
9 review of a combination product—

10 “(I) ensure that any meeting between the Sec-  
11 retary and the sponsor of such product is attended  
12 by each agency center involved in the review, as ap-  
13 propriate;

14 “(II) ensure that each consulting agency center  
15 has completed its premarket review and provided the  
16 results of such review to the primary agency center  
17 in a timely manner; and

18 “(III) ensure that each consulting center fol-  
19 lows the guidance described in clause (vi) and ad-  
20 vises, as appropriate, on other relevant regulations,  
21 guidances, and policies.

22 “(v) In seeking agency action with respect to a com-  
23 bination product, the sponsor of such product—

24 “(I) shall identify the product as a combination  
25 product; and

1           “(II) may request in writing the participation of  
2           representatives of the Office in meetings related to  
3           such combination product, or to have the Office oth-  
4           erwise engage on such regulatory matters concerning  
5           the combination product.

6           “(vi) Not later than 4 years after the date of enact-  
7           ment of the 21st Century Cures Act, and after a public  
8           comment period of not less than 60 calendar days, the  
9           Secretary shall issue a final guidance that describes—

10           “(I) the structured process for managing pre-  
11           submission interactions with sponsors developing  
12           combination products;

13           “(II) the best practices for ensuring that the  
14           feedback in such pre-submission interactions rep-  
15           resents the Agency’s best advice based on the infor-  
16           mation provided during such pre-submission inter-  
17           actions;

18           “(III) the information that is required to be  
19           submitted with a meeting request under paragraph  
20           (2), how such meetings relate to other types of meet-  
21           ings in the Food and Drug Administration, and the  
22           form and content of any agreement reached through  
23           a meeting under such paragraph (2);”;

24           (B) in subparagraph (G)—



1 (i) in the matter preceding clause (i),  
2 by inserting “(except with respect to clause  
3 (iv), beginning not later than one year  
4 after the date of the enactment of the 21st  
5 Century Cures Act)” after “enactment of  
6 this paragraph”;

7 (ii) in clause (ii), by striking “and” at  
8 the end;

9 (iii) in clause (iii), by striking the pe-  
10 riod at the end and inserting “; and”; and

11 (iv) by adding at the end the following  
12 new clause:

13 “(iv) identifying the percentage of combination  
14 products for which a dispute resolution, with respect  
15 to premarket review, was requested by the combina-  
16 tion product’s sponsor.”; and

17 (6) in paragraph (9) (as redesignated by para-  
18 graph (3))—

19 (A) in subparagraph (C)—

20 (i) in clause (i), by striking the  
21 comma at the end and inserting a semi-  
22 colon;

23 (ii) in clause (ii), by striking “, and”  
24 at the end and inserting a semicolon;

1 (iii) in clause (iii), by striking the pe-  
2 riod at the end and inserting “; and”;

3 (iv) by adding at the end the fol-  
4 lowing:

5 “(iv) de novo classification under sec-  
6 tion 513(a)(1).”; and

7 (B) by adding at the end the following:

8 “(D) The terms ‘premarket review’ and ‘re-  
9 views’ include all activities of the Food and Drug  
10 Administration conducted prior to approval or clear-  
11 ance of an application, notification, or request for  
12 classification submitted under section 505, 510(k),  
13 513(f)(2), 515, or 520 of this Act or under section  
14 351 of the Public Health Service Act, including with  
15 respect to investigational use of the product.”.

16 (b) INFORMATION FOR APPROVAL OF COMBINATION  
17 PRODUCTS.—Section 520(h)(4) of the Federal Food,  
18 Drug, and Cosmetic Act (21 U.S.C. 360j(h)(4)) is amend-  
19 ed—

20 (1) in subparagraph (A), by striking “Any in-  
21 formation” and inserting “Subject to subparagraph  
22 (C), any information”; and

23 (2) by adding at the end the following new sub-  
24 paragraph:

1           “(C) No information contained in an application for  
2 premarket approval filed with the Secretary pursuant to  
3 section 515(c) may be used to approve or clear any appli-  
4 cation submitted under section 515 or 510(k) or to classify  
5 a product under section 513(f)(2) for a combination prod-  
6 uct containing as a constituent part an approved drug (as  
7 defined in section 503(g)(5)(B)) unless—

8           “(i) the application includes the certification or  
9 statement referenced in section 503(g)(5)(A);

10           “(ii) the applicant provides notice as described  
11 in section 503(g)(5)(A); and

12           “(iii) the Secretary’s approval of such applica-  
13 tion is subject to the provisions in section  
14 503(g)(5)(C).”.

15       (c) VARIATIONS FROM CGMP STREAMLINED AP-  
16 PROACH.—Not later than 18 months after the date of en-  
17 actment of this Act, the Secretary of Health and Human  
18 Services (referred to in this subsection as the “Secretary”)  
19 shall identify types of combination products and manufac-  
20 turing processes with respect to which the Secretary pro-  
21 poses that good manufacturing processes may be adopted  
22 that vary from the requirements set forth in section 4.4  
23 of title 21, Code of Federal Regulations (or any successor  
24 regulations) or that the Secretary proposes can satisfy the  
25 requirements in section 4.4 through alternative or stream-

1 lined mechanisms. The Secretary shall identify such types,  
2 variations from such requirements, and such mechanisms,  
3 in a proposed list published in the Federal Register. After  
4 a public comment period regarding the appropriate good  
5 manufacturing practices for such types, the Secretary  
6 shall publish a final list in the Federal Register, notwith-  
7 standing section 553 of title 5, United States Code. The  
8 Secretary shall evaluate such types, variations, and mech-  
9 anisms using a risk-based approach. The Secretary shall  
10 periodically review such final list.

11 **Subtitle E—Antimicrobial**  
12 **Innovation and Stewardship**

13 **SEC. 3041. ANTIMICROBIAL RESISTANCE MONITORING.**

14 (a) IN GENERAL.—Section 319E of the Public  
15 Health Service Act (42 U.S.C. 247d–5) is amended—

16 (1) by redesignating subsections (f) and (g) as  
17 subsections (l) and (m), respectively; and

18 (2) by inserting after subsection (e), the fol-  
19 lowing:

20 “(f) MONITORING AT FEDERAL HEALTH CARE FA-  
21 CILITIES.—The Secretary shall encourage reporting on ag-  
22 gregate antimicrobial drug use and antimicrobial resist-  
23 ance to antimicrobial drugs and the implementation of  
24 antimicrobial stewardship programs by health care facili-  
25 ties of the Department of Defense, the Department of Vet-

1 erans Affairs, and the Indian Health Service and shall  
2 provide technical assistance to the Secretary of Defense  
3 and the Secretary of Veterans Affairs, as appropriate and  
4 upon request.

5 “(g) REPORT ON ANTIMICROBIAL RESISTANCE IN  
6 HUMANS AND USE OF ANTIMICROBIAL DRUGS.—Not  
7 later than 1 year after the date of enactment of the 21st  
8 Century Cures Act, and annually thereafter, the Secretary  
9 shall prepare and make publicly available data and infor-  
10 mation concerning—

11 “(1) aggregate national and regional trends of  
12 antimicrobial resistance in humans to antimicrobial  
13 drugs, including such drugs approved under section  
14 506(h) of the Federal Food, Drug, and Cosmetic  
15 Act;

16 “(2) antimicrobial stewardship, which may in-  
17 clude summaries of State efforts to address anti-  
18 microbial resistance in humans to antimicrobial  
19 drugs and antimicrobial stewardship; and

20 “(3) coordination between the Director of the  
21 Centers for Disease Control and Prevention and the  
22 Commissioner of Food and Drugs with respect to  
23 the monitoring of—

24 “(A) any applicable resistance under para-  
25 graph (1); and

1                   “(B) drugs approved under section 506(h)  
2                   of the Federal Food, Drug, and Cosmetic Act.

3           “(h) INFORMATION RELATED TO ANTIMICROBIAL  
4 STEWARDSHIP PROGRAMS.—The Secretary shall, as ap-  
5 propriate, disseminate guidance, educational materials, or  
6 other appropriate materials related to the development  
7 and implementation of evidence-based antimicrobial stew-  
8 ardsHIP programs or practices at health care facilities,  
9 such as nursing homes and other long-term care facilities,  
10 ambulatory surgical centers, dialysis centers, outpatient  
11 clinics, and hospitals, including community and rural hos-  
12 pitals.

13           “(i) SUPPORTING STATE-BASED ACTIVITIES TO  
14 COMBAT ANTIMICROBIAL RESISTANCE.—The Secretary  
15 shall continue to work with State and local public health  
16 departments on statewide or regional programs related to  
17 antimicrobial resistance. Such efforts may include activi-  
18 ties to related to—

19                   “(1) identifying patterns of bacterial and fungal  
20                   resistance in humans to antimicrobial drugs;

21                   “(2) preventing the spread of bacterial and  
22                   fungal infections that are resistant to antimicrobial  
23                   drugs; and

24                   “(3) promoting antimicrobial stewardship.

1       “(j) ANTIMICROBIAL RESISTANCE AND STEWARD-  
2 SHIP ACTIVITIES.—

3           “(1) IN GENERAL.—For the purposes of sup-  
4 porting stewardship activities, examining changes in  
5 antimicrobial resistance, and evaluating the effec-  
6 tiveness of section 506(h) of the Federal Food,  
7 Drug, and Cosmetic Act, the Secretary shall—

8           “(A) provide a mechanism for facilities to  
9 report data related to their antimicrobial stew-  
10 ardship activities (including analyzing the out-  
11 comes of such activities); and

12           “(B) evaluate—

13           “(i) antimicrobial resistance data  
14 using a standardized approach; and

15           “(ii) trends in the utilization of drugs  
16 approved under such section 506(h) with  
17 respect to patient populations.

18           “(2) USE OF SYSTEMS.—The Secretary shall  
19 use available systems, including the National  
20 Healthcare Safety Network or other systems identi-  
21 fied by the Secretary, to fulfill the requirements or  
22 conduct activities under this section.

23       “(k) ANTIMICROBIAL.—For purposes of subsections  
24 (f) through (j), the term ‘antimicrobial’ includes any anti-  
25 bacterial or antifungal drugs, and may include drugs that

1 eliminate or inhibit the growth of other microorganisms,  
2 as appropriate.”.

3 (b) AVAILABILITY OF DATA.—The Secretary shall  
4 make the data collected pursuant to this subsection public.  
5 Nothing in this subsection shall be construed as author-  
6 izing the Secretary to disclose any information that is a  
7 trade secret or confidential information subject to section  
8 552(b)(4) of title 5, United States Code, or section 1905  
9 of title 18, United States Code.

10 **SEC. 3042. LIMITED POPULATION PATHWAY.**

11 Section 506 of the Federal Food, Drug, and Cosmetic  
12 Act (21 U.S.C. 356), as amended by section 3033, is fur-  
13 ther amended by adding at the end the following:

14 “(h) LIMITED POPULATION PATHWAY FOR ANTI-  
15 BACTERIAL AND ANTIFUNGAL DRUGS.—

16 “(1) IN GENERAL.—The Secretary may approve  
17 an antibacterial or antifungal drug, alone or in com-  
18 bination with one or more other drugs, as a limited  
19 population drug pursuant to this subsection only  
20 if—

21 “(A) the drug is intended to treat a serious  
22 or life-threatening infection in a limited popu-  
23 lation of patients with unmet needs;

24 “(B) the standards for approval under sec-  
25 tion 505(c) and (d), or the standards for licen-



1           sure under section 351 of the Public Health  
2           Service Act, as applicable, are met; and

3                   “(C) the Secretary receives a written re-  
4           quest from the sponsor to approve the drug as  
5           a limited population drug pursuant to this sub-  
6           section.

7                   “(2) BENEFIT-RISK CONSIDERATION.—The Sec-  
8           retary’s determination of safety and effectiveness of  
9           an antibacterial or antifungal drug shall reflect the  
10          benefit-risk profile of such drug in the intended lim-  
11          ited population, taking into account the severity, rar-  
12          ity, or prevalence of the infection the drug is in-  
13          tended to treat and the availability or lack of alter-  
14          native treatment in such limited population. Such  
15          drug may be approved under this subsection not-  
16          withstanding a lack of evidence to fully establish a  
17          favorable benefit-risk profile in a population that is  
18          broader than the intended limited population.

19                   “(3) ADDITIONAL REQUIREMENTS.—A drug ap-  
20          proved under this subsection shall be subject to the  
21          following requirements, in addition to any other ap-  
22          plicable requirements of this Act:

23                           “(A) LABELING.—To indicate that the  
24          safety and effectiveness of a drug approved

1 under this subsection has been demonstrated  
2 only with respect to a limited population—

3 “(i) all labeling and advertising of an  
4 antibacterial or antifungal drug approved  
5 under this subsection shall contain the  
6 statement ‘Limited Population’ in a promi-  
7 nent manner and adjacent to, and not  
8 more prominent than—

9 “(I) the proprietary name of such  
10 drug, if any; or

11 “(II) if there is no proprietary  
12 name, the established name of the  
13 drug, if any, as defined in section  
14 503(e)(3), or, in the case of a drug  
15 that is a biological product, the proper  
16 name, as defined by regulation; and

17 “(ii) the prescribing information for  
18 the drug required by section 201.57 of title  
19 21, Code of Federal Regulations (or any  
20 successor regulation) shall also include the  
21 following statement: ‘This drug is indicated  
22 for use in a limited and specific population  
23 of patients.’

24 “(B) PROMOTIONAL MATERIAL.—The  
25 sponsor of an antibacterial or antifungal drug

1 subject to this subsection shall submit to the  
2 Secretary copies of all promotional materials re-  
3 lated to such drug at least 30 calendar days  
4 prior to dissemination of the materials.

5 “(4) OTHER PROGRAMS.—A sponsor of a drug  
6 that seeks approval of a drug under this subsection  
7 may also seek designation or approval, as applicable,  
8 of such drug under other applicable sections or sub-  
9 sections of this Act of the Public Health Service Act.

10 “(5) GUIDANCE.—Not later than 18 months  
11 after the date of enactment of the 21st Century  
12 Cures Act, the Secretary shall issue draft guidance  
13 describing criteria, processes, and other general con-  
14 siderations for demonstrating the safety and effec-  
15 tiveness of limited population antibacterial and  
16 antifungal drugs. The Secretary shall publish final  
17 guidance within 18 months of the close of the public  
18 comment period on such draft guidance. The Sec-  
19 retary may approve antibacterial and antifungal  
20 drugs under this subsection prior to issuing guid-  
21 ance under this paragraph.

22 “(6) ADVICE.—The Secretary shall provide  
23 prompt advice to the sponsor of a drug for which the  
24 sponsor seeks approval under this subsection to en-  
25 able the sponsor to plan a development program to

1 obtain the necessary data for such approval, and to  
2 conduct any additional studies that would be re-  
3 quired to gain approval of such drug for use in a  
4 broader population.

5 “(7) TERMINATION OF LIMITATIONS.—If, after  
6 approval of a drug under this subsection, the Sec-  
7 retary approves a broader indication for such drug  
8 under section 505(b) or section 351(a) of the Public  
9 Health Service Act, the Secretary may remove any  
10 postmarketing conditions, including requirements  
11 with respect to labeling and review of promotional  
12 materials under paragraph (3), applicable to the ap-  
13 proval of the drug under this subsection.

14 “(8) RULES OF CONSTRUCTION.—Nothing in  
15 this subsection shall be construed to alter the au-  
16 thority of the Secretary to approve drugs pursuant  
17 to this Act or section 351 of the Public Health Serv-  
18 ice Act, including the standards of evidence and ap-  
19 plicable conditions for approval under such Acts, the  
20 standards of approval of a drug under such Acts, or  
21 to alter the authority of the Secretary to monitor  
22 drugs pursuant to such Acts.

23 “(9) REPORTING AND ACCOUNTABILITY.—

24 “(A) BIENNIAL REPORTING.—The Sec-  
25 retary shall report to Congress not less often

1 than once every 2 years on the number of re-  
2 quests for approval, and the number of approv-  
3 als, of an antibacterial or antifungal drug under  
4 this subsection.

5 “(B) GAO REPORT.—Not later than De-  
6 cember 2021, the Comptroller General of the  
7 United States shall submit to the Committee on  
8 Energy and Commerce of the House of Rep-  
9 resentatives and the Committee on Health,  
10 Education, Labor and Pensions of the Senate a  
11 report on the coordination of activities required  
12 under section 319E of the Public Health Serv-  
13 ice Act. Such report shall include a review of  
14 such activities, and the extent to which the use  
15 of the pathway established under this sub-  
16 section has streamlined premarket approval for  
17 antibacterial or antifungal drugs for limited  
18 populations, if such pathway has functioned as  
19 intended, if such pathway has helped provide  
20 for safe and effective treatment for patients, if  
21 such premarket approval would be appropriate  
22 for other categories of drugs, and if the au-  
23 thorities under this subsection have affected  
24 antibacterial or antifungal resistance.”.

1 **SEC. 3043. PRESCRIBING AUTHORITY.**

2 Nothing in this subtitle, or an amendment made by  
3 this subtitle, shall be construed to restrict the prescribing  
4 of antimicrobial drugs or other products, including drugs  
5 approved under subsection (h) of section 506 of the Fed-  
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 356) (as  
7 added by section 3042), by health care professionals, or  
8 to limit the practice of health care.

9 **SEC. 3044. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**  
10 **FOR MICROORGANISMS; ANTIMICROBIAL**  
11 **SUSCEPTIBILITY TESTING DEVICES.**

12 (a) IN GENERAL.—Subchapter A of chapter V of the  
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351  
14 et seq.) is amended by inserting after section 511 the fol-  
15 lowing:

16 **“SEC. 511A. SUSCEPTIBILITY TEST INTERPRETIVE CRI-**  
17 **TERIA FOR MICROORGANISMS.**

18 “(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

19 “(1) PURPOSE.—The purpose of this section is  
20 to clarify the Secretary’s authority to—

21 “(A) efficiently update susceptibility test  
22 interpretive criteria for antimicrobial drugs  
23 when necessary for public health, due to, among  
24 other things, the constant evolution of micro-  
25 organisms that leads to the development of re-  
26 sistance to drugs that have been effective in de-

1           creasing morbidity and mortality for patients,  
2           which warrants unique management of anti-  
3           microbial drugs that is inappropriate for most  
4           other drugs in order to delay or prevent the de-  
5           velopment of further resistance to existing  
6           therapies;

7           “(B) provide for public notice of the avail-  
8           ability of recognized interpretive criteria and in-  
9           terpretive criteria standards; and

10          “(C) clear under section 510(k), classify  
11          under section 513(f)(2), or approve under sec-  
12          tion 515, antimicrobial susceptibility testing de-  
13          vices utilizing updated, recognized susceptibility  
14          test interpretive criteria to characterize the in  
15          vitro susceptibility of particular bacteria, fungi,  
16          or other microorganisms, as applicable, to anti-  
17          microbial drugs.

18          “(2) IDENTIFICATION OF CRITERIA.—The Sec-  
19          retary shall identify appropriate susceptibility test  
20          interpretive criteria with respect to antimicrobial  
21          drugs—

22          “(A) if such criteria are available on the  
23          date of approval of the drug under section 505  
24          of this Act or licensure of the drug under sec-

1           tion 351 of the Public Health Service Act (as  
2           applicable), upon such approval or licensure; or

3           “(B) if such criteria are unavailable on  
4           such date, on the date on which such criteria  
5           are available for such drug.

6           “(3) BASES FOR INITIAL IDENTIFICATION.—  
7           The Secretary shall identify appropriate suscepti-  
8           bility test interpretive criteria under paragraph (2),  
9           based on the Secretary’s review of, to the extent  
10          available and relevant—

11           “(A) preclinical and clinical data, including  
12           pharmacokinetic, pharmacodynamic, and epide-  
13           miological data;

14           “(B) the relationship of susceptibility test  
15           interpretive criteria to morbidity and mortality  
16           associated with the disease or condition for  
17           which such drug is used; and

18           “(C) such other evidence and information  
19           as the Secretary considers appropriate.

20          “(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA  
21          WEBSITE.—

22           “(1) IN GENERAL.—Not later than 1 year after  
23           the date of the enactment of the 21st Century Cures  
24           Act, the Secretary shall establish, and maintain  
25           thereafter, on the website of the Food and Drug Ad-



1       ministration, a dedicated website that contains a list  
2       of any appropriate new or updated susceptibility test  
3       interpretive criteria standards and interpretive cri-  
4       teria in accordance with paragraph (2) (referred to  
5       in this section as the ‘Interpretive Criteria Website’).

6               “(2) LISTING OF SUSCEPTIBILITY TEST INTER-  
7       PRETIVE CRITERIA STANDARDS AND INTERPRETIVE  
8       CRITERIA.—

9               “(A) IN GENERAL.—The list described in  
10       paragraph (1) shall consist of any new or up-  
11       dated susceptibility test interpretive criteria  
12       standards that are—

13               “(i) established by a nationally or  
14       internationally recognized standard devel-  
15       opment organization that—

16               “(I) establishes and maintains  
17       procedures to address potential con-  
18       flicts of interest and ensure trans-  
19       parent decisionmaking;

20               “(II) holds open meetings to en-  
21       sure that there is an opportunity for  
22       public input by interested parties, and  
23       establishes and maintains processes to  
24       ensure that such input is considered  
25       in decisionmaking; and

1                   “(III) permits its standards to be  
2                   made publicly available, through the  
3                   National Library of Medicine or an-  
4                   other similar source acceptable to the  
5                   Secretary; and

6                   “(ii) recognized in whole, or in part,  
7                   by the Secretary under subsection (c).

8                   “(B) OTHER LIST.—The Interpretive Cri-  
9                   teria Website shall, in addition to the list de-  
10                  scribed in subparagraph (A), include a list of  
11                  interpretive criteria, if any, that the Secretary  
12                  has determined to be appropriate with respect  
13                  to legally marketed antimicrobial drugs,  
14                  where—

15                  “(i) the Secretary does not recognize,  
16                  in whole or in part, an interpretive criteria  
17                  standard described under subparagraph  
18                  (A) otherwise applicable to such a drug;

19                  “(ii) the Secretary withdraws under  
20                  subsection (c)(1)(A) recognition of a stand-  
21                  ard, in whole or in part, otherwise applica-  
22                  ble to such a drug;

23                  “(iii) the Secretary approves an appli-  
24                  cation under section 505 of this Act or sec-  
25                  tion 351 of the Public Health Service Act,

1 as applicable, with respect to marketing of  
2 such a drug for which there are no rel-  
3 evant interpretive criteria included in a  
4 standard recognized by the Secretary  
5 under subsection (c); or

6 “(iv) because the characteristics of  
7 such a drug differ from other drugs with  
8 the same active ingredient, the interpretive  
9 criteria with respect to such drug—

10 “(I) differ from otherwise appli-  
11 cable interpretive criteria included in  
12 a standard listed under subparagraph  
13 (A) or interpretive criteria otherwise  
14 listed under this subparagraph; and

15 “(II) are determined by the Sec-  
16 retary to be appropriate for the drug.

17 “(C) REQUIRED STATEMENTS.—The Inter-  
18 pretive Criteria Website shall include state-  
19 ments conveying—

20 “(i) that the website provides informa-  
21 tion about the in vitro susceptibility of bac-  
22 teria, fungi, or other microorganisms, as  
23 applicable to a certain drug (or drugs);

24 “(ii) that—

1                   “(I) the safety and efficacy of  
2                   such drugs in treating clinical infec-  
3                   tions due to such bacteria, fungi, or  
4                   other microorganisms, as applicable,  
5                   may or may not have been established  
6                   in adequate and well-controlled clin-  
7                   ical trials in order for the suscepti-  
8                   bility information described in clause  
9                   (i) to be included on the website; and

10                   “(II) the clinical significance of  
11                   such susceptibility information in such  
12                   instances is unknown;

13                   “(iii) that the approved product label-  
14                   ing for specific drugs provides the uses for  
15                   which the Secretary has approved the  
16                   product; and

17                   “(iv) any other information that the  
18                   Secretary determines appropriate to ade-  
19                   quately convey the meaning of the data  
20                   supporting the recognition or listing of sus-  
21                   ceptibility test interpretive criteria stand-  
22                   ards or susceptibility test interpretive cri-  
23                   teria included on the website.

24                   “(3) NOTICE.—Not later than the date on  
25                   which the Interpretive Criteria Website is estab-

1 lished, the Secretary shall publish a notice of that  
2 establishment in the Federal Register.

3 “(4) INAPPLICABILITY OF MISBRANDING PROVI-  
4 SION.—The inclusion in the approved labeling of an  
5 antimicrobial drug of a reference or hyperlink to the  
6 Interpretive Criteria Website, in and of itself, shall  
7 not cause the drug to be misbranded in violation of  
8 section 502.

9 “(5) TRADE SECRETS AND CONFIDENTIAL IN-  
10 FORMATION.—Nothing in this section shall be con-  
11 strued as authorizing the Secretary to disclose any  
12 information that is a trade secret or confidential in-  
13 formation subject to section 552(b)(4) of title 5,  
14 United States Code.

15 “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-  
16 PRETIVE CRITERIA.—

17 “(1) EVALUATION AND PUBLICATION.—

18 “(A) IN GENERAL.—Beginning on the date  
19 of the establishment of the Interpretive Criteria  
20 Website, and at least every 6 months thereafter,  
21 the Secretary shall—

22 “(i) evaluate any appropriate new or  
23 updated susceptibility test interpretive cri-  
24 teria standards established by a nationally  
25 or internationally recognized standard de-

1                   velopment organization described in sub-  
2                   section (b)(2)(A)(i); and

3                   “(ii) publish on the public website of  
4                   the Food and Drug Administration a no-  
5                   tice—

6                   “(I) withdrawing recognition of  
7                   any different susceptibility test inter-  
8                   pretive criteria standard, in whole or  
9                   in part;

10                  “(II) recognizing the new or up-  
11                  dated standards;

12                  “(III) recognizing one or more  
13                  parts of the new or updated interpre-  
14                  tive criteria specified in such a stand-  
15                  ard and declining to recognize the re-  
16                  mainder of such standard; and

17                  “(IV) making any necessary up-  
18                  dates to the lists under subsection  
19                  (b)(2).

20                  “(B) UPON APPROVAL OF A DRUG.—Upon  
21                  the approval of an initial or supplemental appli-  
22                  cation for an antimicrobial drug under section  
23                  505 of this Act or section 351 of the Public  
24                  Health Service Act, as applicable, where such  
25                  approval is based on susceptibility test interpre-

1           tive criteria which differ from those contained  
2           in a standard recognized, or from those other-  
3           wise listed, by the Secretary pursuant to this  
4           subsection, or for which there are no relevant  
5           interpretive criteria standards recognized, or in-  
6           terpretive criteria otherwise listed, by the Sec-  
7           retary pursuant to this subsection, the Sec-  
8           retary shall update the lists under subpara-  
9           graphs (A) and (B) of subsection (b)(2) to in-  
10          clude the susceptibility test interpretive criteria  
11          upon which such approval was based.

12           “(2) BASES FOR UPDATING INTERPRETIVE CRI-  
13          TERIA STANDARDS.—In evaluating new or updated  
14          susceptibility test interpretive criteria standards  
15          under paragraph (1)(A), the Secretary may con-  
16          sider—

17                   “(A) the Secretary’s determination that  
18                   such a standard is not applicable to a particular  
19                   drug because the characteristics of the drug dif-  
20                   fer from other drugs with the same active in-  
21                   gredient;

22                   “(B) information provided by interested  
23                   third parties, including public comment on the  
24                   annual compilation of notices published under  
25                   paragraph (3);

1           “(C) any bases used to identify suscepti-  
2           bility test interpretive criteria under subsection  
3           (a)(2); and

4           “(D) such other information or factors as  
5           the Secretary determines appropriate.

6           “(3) ANNUAL COMPILATION OF NOTICES.—  
7           Each year, the Secretary shall compile the notices  
8           published under paragraph (1)(B) and publish such  
9           compilation in the Federal Register and provide for  
10          public comment. If the Secretary receives comments,  
11          the Secretary shall review such comments and, if the  
12          Secretary determines appropriate, update pursuant  
13          to this subsection susceptibility test interpretive cri-  
14          teria standards or criteria—

15                 “(A) recognized by the Secretary under  
16                 this subsection; or

17                 “(B) otherwise listed on the Interpretive  
18                 Criteria Website under subsection (b)(2).

19           “(4) RELATION TO SECTION 514(c).—Any sus-  
20           ceptibility test interpretive standard recognized  
21           under this subsection or any criteria otherwise listed  
22           under subsection (b)(2)(B) shall be deemed to be  
23           recognized as a standard by the Secretary under sec-  
24           tion 514(c)(1).



1           “(5) VOLUNTARY USE OF INTERPRETIVE CRI-  
2           TERIA.—Nothing in this section prohibits a person  
3           from seeking approval or clearance of a drug or de-  
4           vice, or changes to the drug or the device, on the  
5           basis of susceptibility test interpretive criteria which  
6           differ from those contained in a standard recognized,  
7           or from those otherwise listed, by the Secretary pur-  
8           suant to subsection (b)(2).

9           “(d) ANTIMICROBIAL DRUG LABELING.—

10           “(1) DRUGS MARKETED PRIOR TO ESTABLISH-  
11           MENT OF INTERPRETIVE CRITERIA WEBSITE.—

12           “(A) IN GENERAL.—With respect to an  
13           antimicrobial drug lawfully introduced or deliv-  
14           ered for introduction into interstate commerce  
15           for commercial distribution before the establish-  
16           ment of the Interpretive Criteria Website, a  
17           holder of an approved application under section  
18           505 of this Act or section 351 of the Public  
19           Health Service Act, as applicable, for each such  
20           drug, not later than 1 year after establishment  
21           of the Interpretive Criteria Website described in  
22           subsection (b)(1), shall remove susceptibility  
23           test interpretive criteria, if any, and related in-  
24           formation from the approved drug labeling and

1           replace it with a reference to the Interpretive  
2           Criteria Website.

3           “(B) LABELING CHANGES.—The labeling  
4           changes required by this section shall be consid-  
5           ered a minor change under section 314.70 of  
6           title 21, Code of Federal Regulations (or any  
7           successor regulations) that may be implemented  
8           through documentation in the next applicable  
9           annual report.

10          “(2) DRUGS MARKETED SUBSEQUENT TO ES-  
11          TABLISHMENT OF INTERPRETIVE CRITERIA  
12          WEBSITE.—With respect to antimicrobial drugs ap-  
13          proved on or after the date of the establishment of  
14          the Interpretive Criteria Website described in sub-  
15          section (b)(1), the labeling for such a drug shall in-  
16          clude, in lieu of susceptibility test interpretive cri-  
17          teria and related information, a reference to such  
18          Website.

19          “(e) SPECIAL CONDITION FOR MARKETING OF ANTI-  
20          MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

21          “(1) IN GENERAL.—Notwithstanding sections  
22          501, 502, 505, 510, 513, and 515, if the conditions  
23          specified in paragraph (2) are met (in addition to  
24          other applicable provisions under this chapter) with  
25          respect to an antimicrobial susceptibility testing de-

1 vice described in subsection (f)(1), the Secretary  
2 may authorize the marketing of such device for a  
3 use described in such subsection.

4 “(2) CONDITIONS APPLICABLE TO ANTI-  
5 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

6 The conditions specified in this paragraph are the  
7 following:

8 “(A) The device is used to make a deter-  
9 mination of susceptibility using susceptibility  
10 test interpretive criteria that are—

11 “(i) included in a standard recognized  
12 by the Secretary under subsection (c); or

13 “(ii) otherwise listed on the Interpre-  
14 tive Criteria Website under subsection  
15 (b)(2).

16 “(B) The labeling of such device includes  
17 statements conveying—

18 “(i) that the device provides informa-  
19 tion about the in vitro susceptibility of bac-  
20 teria, fungi, or other microorganisms, as  
21 applicable to antimicrobial drugs;

22 “(ii) that—

23 “(I) the safety and efficacy of  
24 such drugs in treating clinical infec-  
25 tions due to such bacteria, fungi, or

1 other microorganisms, as applicable,  
2 may or may not have been established  
3 in adequate and well-controlled clin-  
4 ical trials in order for the device to re-  
5 port the susceptibility of such bac-  
6 teria, fungi, or other microorganisms,  
7 as applicable, to such drugs; and

8 “(II) the clinical significance of  
9 such susceptibility information in  
10 those instances is unknown;

11 “(iii) that the approved labeling for  
12 drugs tested using such a device provides  
13 the uses for which the Secretary has ap-  
14 proved such drugs; and

15 “(iv) any other information the Sec-  
16 retary determines appropriate to ade-  
17 quately convey the meaning of the data  
18 supporting the recognition or listing of sus-  
19 ceptibility test interpretive criteria stand-  
20 ards or susceptibility test interpretive cri-  
21 teria described in subparagraph (A).

22 “(C) The antimicrobial susceptibility test-  
23 ing device meets all other requirements to be  
24 cleared under section 510(k), classified under

1 section 513(f)(2), or approved under section  
2 515.

3 “(f) DEFINITIONS.—In this section:

4 “(1) The term ‘antimicrobial susceptibility test-  
5 ing device’ means a device that utilizes susceptibility  
6 test interpretive criteria to determine and report the  
7 in vitro susceptibility of certain microorganisms to a  
8 drug (or drugs).

9 “(2) The term ‘qualified infectious disease  
10 product’ means a qualified infectious disease product  
11 designated under section 505E(d).

12 “(3) The term ‘susceptibility test interpretive  
13 criteria’ means—

14 “(A) one or more specific numerical values  
15 which characterize the susceptibility of bacteria  
16 or other microorganisms to the drug tested; and

17 “(B) related categorizations of such sus-  
18 ceptibility, including categorization of the drug  
19 as susceptible, intermediate, resistant, or such  
20 other term as the Secretary determines appro-  
21 priate.

22 “(4)(A) The term ‘antimicrobial drug’ means,  
23 subject to subparagraph (B), a systemic anti-  
24 bacterial or antifungal drug that—

1 “(i) is intended for human use in the treat-  
2 ment of a disease or condition caused by a bac-  
3 terium or fungus;

4 “(ii) may include a qualified infectious dis-  
5 ease product designated under section 505E(d);  
6 and

7 “(iii) is subject to section 503(b)(1).

8 “(B) If provided by the Secretary through regu-  
9 lations, such term may include—

10 “(i) drugs other than systemic anti-  
11 bacterial and antifungal drugs; and

12 “(ii) biological products (as such term is  
13 defined in section 351 of the Public Health  
14 Service Act) to the extent such products exhibit  
15 antimicrobial activity.

16 “(5) The term ‘interpretive criteria standard’  
17 means a compilation of susceptibility test interpre-  
18 tive criteria developed by a standard development or-  
19 ganization that meets the criteria set forth in sub-  
20 section (b)(2)(A)(i).

21 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-  
22 tion shall be construed to—

23 “(1) alter the standards of evidence under sub-  
24 section (c) or (d) of section 505 (including the sub-  
25 stantial evidence standard under section 505(d)) or

1 under section 351 of the Public Health Service Act  
2 (as applicable); or

3 “(2) with respect to clearing devices under sec-  
4 tion 510(k), classifying devices under section  
5 513(f)(2), or approving devices under section 515—

6 “(A) apply with respect to any drug, de-  
7 vice, or biological product, in any context other  
8 than an antimicrobial drug and an anti-  
9 microbial susceptibility testing device that uses  
10 susceptibility test interpretive criteria to charac-  
11 terize and report the susceptibility of certain  
12 bacteria, fungi, or other microorganisms, as ap-  
13 plicable, to such drug to reflect patient mor-  
14 bidity and mortality in accordance with this sec-  
15 tion; or

16 “(B) unless specifically stated, have any ef-  
17 fect on authorities provided under other sec-  
18 tions of this Act, including any regulations  
19 issued under such sections.”.

20 (b) CONFORMING AMENDMENTS.—

21 (1) REPEAL OF PRIOR RELATED AUTHORITY.—

22 Section 1111 of the Food and Drug Administration  
23 Amendments Act of 2007 (42 U.S.C. 247d–5a), re-  
24 lating to identification of clinically susceptible con-  
25 centrations of antimicrobials, is repealed.

1           (2) ADDITION TO CATEGORIES OF MISBRANDED  
2           DRUGS.—Section 502 of the Federal Food, Drug,  
3           and Cosmetic Act (21 U.S.C. 352) is amended by  
4           adding at the end the following:

5           “(dd) If it is an antimicrobial drug, as defined in sec-  
6           tion 511A(f), and its labeling fails to conform with the  
7           requirements under section 511A(d).”.

8           (3) RECOGNITION OF INTERPRETIVE CRITERIA  
9           STANDARD AS DEVICE STANDARD.—Section  
10          514(c)(1)(A) of the Federal Food, Drug, and Cos-  
11          metic Act (21 U.S.C. 360d(c)(1)(A)) is amended by  
12          inserting after “the Secretary shall, by publication in  
13          the Federal Register” the following: “(or, with re-  
14          spect to a susceptibility test interpretive criteria  
15          standard under section 511A, by posting on the In-  
16          terpretive Criteria Website in accordance with such  
17          section)”.

18          (c) REPORT TO CONGRESS.—Not later than 2 years  
19          after the date of enactment of this Act, the Secretary of  
20          Health and Human Services shall submit to the Com-  
21          mittee on Health, Education, Labor, and Pensions of the  
22          Senate and the Committee on Energy and Commerce of  
23          the House of Representatives a report on the progress  
24          made in implementing section 511A of the Federal Food,



1 Drug, and Cosmetic Act (21 U.S.C. 360a), as added by  
2 subsection (a).

3 (d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-  
4 TERIA WEBSITE.—Chapter 35 of title 44, United States  
5 Code, shall not apply to the collection of information from  
6 interested parties regarding updating the lists established  
7 under section 511A(b) of the Federal Food, Drug, and  
8 Cosmetic Act and posted on the Interpretive Criteria  
9 Website established under section 511A(c) of such Act.

10 **Subtitle F—Medical Device**  
11 **Innovations**

12 **SEC. 3051. BREAKTHROUGH DEVICES.**

13 (a) IN GENERAL.—Chapter V of the Federal Food,  
14 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
15 ed by inserting after section 515B, as added by section  
16 3034(b), the following:

17 **“SEC. 515C. BREAKTHROUGH DEVICES.**

18 “(a) PURPOSE.—The purpose of this section is to en-  
19 courage the Secretary, and provide the Secretary with suf-  
20 ficient authority, to apply efficient and flexible approaches  
21 to expedite the development of, and prioritize the Food  
22 and Drug Administration’s review of, devices that rep-  
23 resent breakthrough technologies.

24 “(b) ESTABLISHMENT OF PROGRAM.—The Secretary  
25 shall establish a program to expedite the development of,

1 and provide for the priority review for, devices, as deter-  
2 mined by the Secretary—

3 “(1) that provide for more effective treatment  
4 or diagnosis of life-threatening or irreversibly debili-  
5 tating human disease or conditions; and

6 “(2)(A) that represent breakthrough tech-  
7 nologies;

8 “(B) for which no approved or cleared alter-  
9 natives exist;

10 “(C) that offer significant advantages over ex-  
11 isting approved or cleared alternatives, including the  
12 potential, compared to existing approved alter-  
13 natives, to reduce or eliminate the need for hos-  
14 pitalization, improve patient quality of life, facilitate  
15 patients’ ability to manage their own care (such as  
16 through self-directed personal assistance), or estab-  
17 lish long-term clinical efficiencies; or

18 “(D) the availability of which is in the best in-  
19 terest of patients.

20 “(c) REQUEST FOR DESIGNATION.—A sponsor of a  
21 device may request that the Secretary designate such de-  
22 vice for expedited development and priority review under  
23 this section. Any such request for designation may be  
24 made at any time prior to the submission of an application

1 under section 515(c), a notification under section 510(k),  
2 or a petition for classification under section 513(f)(2).

3 “(d) DESIGNATION PROCESS.—

4 “(1) IN GENERAL.—Not later than 60 calendar  
5 days after the receipt of a request under subsection  
6 (c), the Secretary shall determine whether the device  
7 that is the subject of the request meets the criteria  
8 described in subsection (b). If the Secretary deter-  
9 mines that the device meets the criteria, the Sec-  
10 retary shall designate the device for expedited devel-  
11 opment and priority review.

12 “(2) REVIEW.—Review of a request under sub-  
13 section (c) shall be undertaken by a team that is  
14 composed of experienced staff and senior managers  
15 of the Food and Drug Administration.

16 “(3) WITHDRAWAL.—The Secretary may not  
17 withdraw a designation granted under this section  
18 on the basis of the criteria under subsection (b) no  
19 longer applying because of the subsequent clearance  
20 or approval of another device that—

21 “(A) was designated under this section; or

22 “(B) was given priority review under sec-  
23 tion 515(d)(5), as in effect prior to the date of  
24 enactment of the 21st Century Cures Act.

1           “(e) EXPEDITED DEVELOPMENT AND PRIORITY RE-  
2 VIEW.—

3           “(1) ACTIONS.—For purposes of expediting the  
4 development and review of devices designated under  
5 subsection (d) the Secretary shall—

6           “(A) assign a team of staff, including a  
7 team leader with appropriate subject matter ex-  
8 pertise and experience, for each device for  
9 which a request is submitted under subsection  
10 (c);

11           “(B) provide for oversight of the team by  
12 senior agency personnel to facilitate the effi-  
13 cient development of the device and the efficient  
14 review of any submission described in sub-  
15 section (c) for the device;

16           “(C) adopt an efficient process for timely  
17 dispute resolution;

18           “(D) provide for interactive and timely  
19 communication with the sponsor of the device  
20 during the development program and review  
21 process;

22           “(E) expedite the Secretary’s review of  
23 manufacturing and quality systems compliance,  
24 as applicable;

1           “(F) disclose to the sponsor, not less than  
2           5 business days in advance, the topics of any  
3           consultation the Secretary intends to undertake  
4           with external experts or an advisory committee  
5           concerning the sponsor’s device and provide the  
6           sponsor the opportunity to recommend such ex-  
7           ternal experts;

8           “(G) provide for advisory committee input,  
9           as the Secretary determines appropriate (in-  
10          cluding in response to the request of the spon-  
11          sor) for applications submitted under section  
12          515(c); and

13          “(H) assign staff to be available within a  
14          reasonable time to address questions by institu-  
15          tional review committees concerning the condi-  
16          tions and clinical testing requirements applica-  
17          ble to the investigational use of the device pur-  
18          suant to an exemption under section 520(g).

19          “(2) ADDITIONAL ACTIONS.—In addition to the  
20          actions described in paragraph (1), for purposes of  
21          expediting the development and review of devices  
22          designated under subsection (d), the Secretary, in  
23          collaboration with the device sponsor, may, as appro-  
24          priate—

1           “(A) coordinate with the sponsor regarding  
2           early agreement on a data development plan;

3           “(B) take steps to ensure that the design  
4           of clinical trials is as efficient and flexible as  
5           practicable, when scientifically appropriate;

6           “(C) facilitate, when scientifically appro-  
7           priate, expedited and efficient development and  
8           review of the device through utilization of time-  
9           ly postmarket data collection with regard to ap-  
10          plication for approval under section 515(c); and

11          “(D) agree in writing to clinical protocols  
12          that the Secretary will consider binding on the  
13          Secretary and the sponsor, subject to—

14               “(i) changes to such protocols agreed  
15               to in writing by the sponsor and the Sec-  
16               retary; or

17               “(ii) a decision, made by the director  
18               of the office responsible for reviewing the  
19               device submission, that a substantial sci-  
20               entific issue essential to determining the  
21               safety or effectiveness of such device exists,  
22               provided that such decision is in writing,  
23               and is made only after the Secretary pro-  
24               vides to the device sponsor or applicant an  
25               opportunity for a meeting at which the di-

1           rector and the sponsor or applicant are  
2           present and at which the director docu-  
3           ments the substantial scientific issue.

4           “(f) PRIORITY REVIEW GUIDANCE.—

5           “(1) CONTENT.—Not later than 1 year after  
6           the date of enactment of the 21st Century Cures  
7           Act, the Secretary shall issue guidance on the imple-  
8           mentation of this section. Such guidance shall—

9           “(A) set forth the process by which a per-  
10          son may seek a designation under subsection  
11          (d);

12          “(B) provide a template for requests under  
13          subsection (c);

14          “(C) identify the criteria the Secretary will  
15          use in evaluating a request for designation  
16          under this section; and

17          “(D) identify the criteria and processes the  
18          Secretary will use to assign a team of staff, in-  
19          cluding team leaders, to review devices des-  
20          ignated for expedited development and priority  
21          review, including any training required for such  
22          personnel to ensure effective and efficient re-  
23          view.

1           “(2) PROCESS.—Prior to finalizing the guid-  
2           ance under paragraph (1), the Secretary shall seek  
3           public comment on a proposed guidance.

4           “(g) RULE OF CONSTRUCTION.—Nothing in this sec-  
5           tion shall be construed to affect—

6           “(1) the criteria and standards for evaluating  
7           an application pursuant to section 515(c), a report  
8           and request for classification under section  
9           513(f)(2), or a report under section 510(k), includ-  
10          ing the recognition of valid scientific evidence as de-  
11          scribed in section 513(a)(3)(B) and consideration  
12          and application of the least burdensome means of  
13          evaluating device effectiveness or demonstrating sub-  
14          stantial equivalence between devices with differing  
15          technological characteristics, as applicable;

16          “(2) the authority of the Secretary with respect  
17          to clinical holds under section 520(g)(8)(A);

18          “(3) the authority of the Secretary to act on an  
19          application pursuant to section 515(d) before com-  
20          pletion of an establishment inspection, as the Sec-  
21          retary determines appropriate; or

22          “(4) the authority of the Secretary with respect  
23          to postmarket surveillance under sections 519(h)  
24          and 522.”.



1 (b) DOCUMENTATION AND REVIEW OF SIGNIFICANT  
2 DECISIONS.—Section 517A(a)(1) of the Federal Food,  
3 Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)(1)) is  
4 amended by inserting “a request for designation under  
5 section 515C,” after “application under section 515,”.

6 (c) TERMINATION OF PREVIOUS PROGRAM.—

7 (1) IN GENERAL.—Section 515(d) of the Fed-  
8 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
9 360e(d)) is amended—

10 (A) by striking paragraph (5); and

11 (B) by redesignating paragraph (6) as  
12 paragraph (5).

13 (2) CONFORMING AMENDMENT.—Section  
14 737(5) of the Federal Food, Drug, and Cosmetics  
15 Act (21 U.S.C. 379i(5)) is amended by striking  
16 “515(d)(6)” and inserting “515(d)(5)”.

17 (d) REPORT.—On January 1, 2019, the Secretary of  
18 Health and Human Services shall issue a report to the  
19 Committee on Health, Education, Labor, and Pensions of  
20 the Senate and the Committee on Energy and Commerce  
21 of the House of Representatives—

22 (1) on the program under section 515C of the  
23 Federal Food, Drug, and Cosmetic Act, as added by  
24 subsection (a), in bringing safe and effective devices

1 included in such program to patients as soon as possible;  
2 and

3 (2) that includes recommendations, if any, to  
4 strengthen the program to better meet patient device  
5 needs in a manner as timely as possible.

6 **SEC. 3052. HUMANITARIAN DEVICE EXEMPTION.**

7 (a) IN GENERAL.—Section 520(m) of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—  
9 ed—

10 (1) in paragraph (1) by striking “fewer than  
11 4,000” and inserting “not more than 8,000”;

12 (2) in paragraph (2)(A) by striking “fewer than  
13 4,000” and inserting “not more than 8,000”; and

14 (3) in paragraph (6)(A)(ii), by striking “4,000”  
15 and inserting “8,000”.

16 (b) GUIDANCE DOCUMENT ON PROBABLE BENEFIT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human  
17 Services, acting through the Commissioner of Food and  
18 Drugs, shall publish a draft guidance that defines the criteria for establishing “probable benefit” as that term is  
19 used in section 520(m)(2)(C) of the Federal Food, Drug,  
20 and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).  
21  
22  
23

1 **SEC. 3053. RECOGNITION OF STANDARDS.**

2 (a) IN GENERAL.—Section 514(c) of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) is  
4 amended—

5 (1) in paragraph (1), by inserting after sub-  
6 paragraph (B) the following new subparagraphs:

7 “(C)(i) Any person may submit a request for recogni-  
8 tion under subparagraph (A) of all or part of an appro-  
9 priate standard established by a nationally or internation-  
10 ally recognized standard organization.

11 “(ii) Not later than 60 calendar days after the Sec-  
12 retary receives such a request, the Secretary shall—

13 “(I) make a determination to recognize all,  
14 part, or none of the standard that is the subject of  
15 the request; and

16 “(II) issue to the person who submitted such  
17 request a response in writing that states the Sec-  
18 retary’s rationale for that determination, including  
19 the scientific, technical, regulatory, or other basis for  
20 such determination.

21 “(iii) The Secretary shall make a response issued  
22 under clause (ii)(II) publicly available, in such a manner  
23 as the Secretary determines appropriate.

24 “(iv) The Secretary shall take such actions as may  
25 be necessary to implement all or part of a standard recog-

1 nized under clause (ii)(I), in accordance with subpara-  
2 graph (A).

3 “(D) The Secretary shall make publicly available, in  
4 such manner as the Secretary determines appropriate, the  
5 rationale for recognition under subparagraph (A) of all,  
6 part, or none of a standard, including the scientific, tech-  
7 nical, regulatory, or other basis for the decision regarding  
8 such recognition.”; and

9 (2) by adding at the end the following:

10 “(4) The Secretary shall provide to all employees of  
11 the Food and Drug Administration who review premarket  
12 submissions for devices periodic training on the concept  
13 and use of recognized standards for purposes of meeting  
14 a premarket submission requirement or other applicable  
15 requirement under this Act, including standards relevant  
16 to an employee’s area of device review.”.

17 (b) GUIDANCE.—The Secretary of Health and  
18 Human Services, acting through the Commissioner of  
19 Food and Drugs, shall review and update, if necessary,  
20 previously published guidance and standard operating pro-  
21 cedures identifying the principles for recognizing stand-  
22 ards, and for withdrawing the recognition of standards,  
23 under section 514(c) of the Federal Food, Drug, and Cos-  
24 metic Act (21 U.S.C. 360d(c)), taking into account the  
25 experience with and reliance on a standard by foreign reg-

1 ulatory authorities and the device industry, and whether  
2 recognition of a standard will promote harmonization  
3 among regulatory authorities in the regulation of devices.

4 **SEC. 3054. CERTAIN CLASS I AND CLASS II DEVICES.**

5 (a) CLASS I DEVICES.—Section 510(l) of the Federal  
6 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is  
7 amended—

8 (1) by striking “A report under subsection (k)”  
9 and inserting “(1) A report under subsection (k)”;  
10 and

11 (2) by adding at the end the following new  
12 paragraph:

13 “(2) Not later than 120 calendar days after the date  
14 of enactment of the 21st Century Cures Act and at least  
15 once every 5 years thereafter, as the Secretary determines  
16 appropriate, the Secretary shall identify, through publica-  
17 tion in the Federal Register, any type of class I device  
18 that the Secretary determines no longer requires a report  
19 under subsection (k) to provide reasonable assurance of  
20 safety and effectiveness. Upon such publication—

21 “(A) each type of class I device so identified  
22 shall be exempt from the requirement for a report  
23 under subsection (k); and

1           “(B) the classification regulation applicable to  
2           each such type of device shall be deemed amended  
3           to incorporate such exemption.”.

4           (b) CLASS II DEVICES.—Section 510(m) of the Fed-  
5           eral Food, Drug, and Cosmetic Act (21 U.S.C. 360(m))  
6           is amended—

7           (1) by striking “(m)(1)” and all that follows  
8           through “by the Secretary.” and inserting the fol-  
9           lowing:

10          “(m)(1) The Secretary shall—

11           “(A) not later than 90 days after the date of  
12           enactment of the 21st Century Cures Act and at  
13           least once every 5 years thereafter, as the Secretary  
14           determines appropriate—

15           “(i) publish in the Federal Register a no-  
16           tice that contains a list of each type of class II  
17           device that the Secretary determines no longer  
18           requires a report under subsection (k) to pro-  
19           vide reasonable assurance of safety and effec-  
20           tiveness; and

21           “(ii) provide for a period of not less than  
22           60 calendar days for public comment beginning  
23           on the date of the publication of such notice;  
24           and

1           “(B) not later than 210 calendar days after the  
2           date of enactment of the 21st Century Cures Act,  
3           publish in the Federal Register a list representing  
4           the Secretary’s final determination with respect to  
5           the devices contained in the list published under sub-  
6           paragraph (A).”; and

7           (2) in paragraph (2)—

8           (A) by striking “1 day after the date of  
9           publication of a list under this subsection,” and  
10          inserting “1 calendar day after the date of pub-  
11          lication of the final list under paragraph  
12          (1)(B),”; and

13          (B) by striking “30-day period” and in-  
14          serting “60-calendar-day period”; and

15          (C) by adding at the end the following new  
16          paragraph:

17          “(3) Upon the publication of the final list under para-  
18          graph (1)(B)—

19                 “(A) each type of class II device so listed shall  
20                 be exempt from the requirement for a report under  
21                 subsection (k); and

22                 “(B) the classification regulation applicable to  
23                 each such type of device shall be deemed amended  
24                 to incorporate such exemption.”.

1 **SEC. 3055. CLASSIFICATION PANELS.**

2 (a) CLASSIFICATION PANELS.—Paragraph (5) of sec-  
3 tion 513(b) of the Federal Food, Drug, and Cosmetic Act  
4 (21 U.S.C. 360c(b)) is amended—

5 (1) by striking “(5)” and inserting “(5)(A)”;

6 and

7 (2) by adding at the end the following:

8 “(B) When a device is specifically the subject of re-  
9 view by a classification panel, the Secretary shall—

10 “(i) ensure that adequate expertise is rep-  
11 resented on the classification panel to assess—

12 “(I) the disease or condition which the de-  
13 vice is intended to cure, treat, mitigate, prevent,  
14 or diagnose; and

15 “(II) the technology of the device; and

16 “(ii) provide an opportunity for the person  
17 whose device is specifically the subject of panel re-  
18 view to provide recommendations on the expertise  
19 needed among the voting members of the panel.

20 “(C) For purposes of subparagraph (B)(i), the term  
21 ‘adequate expertise’ means that the membership of the  
22 classification panel includes—

23 “(i) two or more voting members, with a spe-  
24 cialty or other expertise clinically relevant to the de-  
25 vice under review; and



1           “(ii) at least one voting member who is knowl-  
2           edgeable about the technology of the device.

3           “(D) The Secretary shall provide an annual oppor-  
4           tunity for patients, representatives of patients, and spon-  
5           sors of medical device submissions to provide rec-  
6           ommendations for individuals with appropriate expertise  
7           to fill voting member positions on classification panels.”.

8           (b) PANEL REVIEW PROCESS.—Section 513(b)(6) of  
9           the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
10          360c(b)(6)) is amended—

11           (1) in subparagraph (A)(iii), by inserting before  
12           the period at the end “, including, subject to the dis-  
13           cretion of the panel chairperson, by designating a  
14           representative who will be provided a time during  
15           the panel meeting to address the panel for the pur-  
16           pose of correcting misstatements of fact or providing  
17           clarifying information, and permitting the person or  
18           representative to call on experts within the person’s  
19           organization to address such specific issues in the  
20           time provided”; and

21           (2) by striking subparagraph (B) and inserting  
22           the following new subparagraph:

23           “(B)(i) Any meeting of a classification panel with re-  
24           spect to the review of a device shall—

1           “(I) provide adequate time for initial presen-  
2           tations by the person whose device is specifically the  
3           subject of such review and by the Secretary; and

4           “(II) encourage free and open participation by  
5           all interested persons.

6           “(ii) Following the initial presentations described in  
7           clause (i), the panel may—

8           “(I) pose questions to a designated representa-  
9           tive described in subparagraph (A)(iii); and

10           “(II) consider the responses to such questions  
11           in the panel’s review of the device.”.

12   **SEC. 3056. INSTITUTIONAL REVIEW BOARD FLEXIBILITY.**

13           Section 520 of the Federal Food, Drug, and Cosmetic  
14   Act (21 U.S.C. 360j) is amended—

15           (1) in subsection (g)(3)—

16           (A) in subparagraph (A)(i)—

17           (i) by striking “local”; and

18           (ii) by striking “which has been”; and

19           (B) in subparagraph (B), by striking “a  
20           local institutional” and inserting “an institu-  
21           tional”; and

22           (2) in subsection (m)(4)—

23           (A) by striking subparagraph (A) and in-  
24           serting the following:

1           “(A) in facilities in which clinical testing of de-  
2           vices is supervised by an institutional review com-  
3           mittee established in accordance with the regulations  
4           of the Secretary; and”;

5           (B) in subparagraph (B), by striking “a  
6           local institutional” and inserting “an institu-  
7           tional”; and

8           (C) in the matter following subparagraph  
9           (B), by striking “local”.

10 **SEC. 3057. CLIA WAIVER IMPROVEMENTS.**

11           (a) DRAFT REVISED GUIDANCE.—Not later than 1  
12           year after the date of the enactment of this Act, the Sec-  
13           retary of Health and Human Services, acting through the  
14           Commissioner of Food and Drugs, shall publish a draft  
15           guidance that—

16           (1) revises “Section V. Demonstrating Insignifi-  
17           cant Risk of an Erroneous Result – Accuracy” of  
18           the guidance entitled “Recommendations for Clinical  
19           Laboratory Improvement Amendments of 1988  
20           (CLLA) Waiver Applications for Manufacturers of In  
21           Vitro Diagnostic Devices” and dated January 30,  
22           2008; and

23           (2) includes the appropriate use of comparable  
24           performance between a waived user and a mod-

1 erately complex laboratory user to demonstrate accu-  
2 racy.

3 (b) **FINAL REVISED GUIDANCE.**—The Secretary of  
4 Health and Human Services, acting through the Commis-  
5 sioner of Food and Drugs, shall finalize the draft guidance  
6 published under subsection (a) not later than 1 year after  
7 the comment period for such draft guidance closes.

8 **SEC. 3058. LEAST BURDENSOME DEVICE REVIEW.**

9 (a) **IN GENERAL.**—Section 513 of the Federal Food,  
10 Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by  
11 adding at the end the following:

12 “(j) **TRAINING AND OVERSIGHT OF LEAST BURDEN-**  
13 **SOME REQUIREMENTS.**—

14 “(1) The Secretary shall—

15 “(A) ensure that each employee of the  
16 Food and Drug Administration who is involved  
17 in the review of premarket submissions, includ-  
18 ing supervisors, receives training regarding the  
19 meaning and implementation of the least bur-  
20 densome requirements under subsections  
21 (a)(3)(D) and (i)(1)(D) of this section and sec-  
22 tion 515(c)(5); and

23 “(B) periodically assess the implementa-  
24 tion of the least burdensome requirements, in-  
25 cluding the employee training under subpara-

1 graph (A), to ensure that the least burdensome  
2 requirements are fully and consistently applied.

3 “(2) Not later than 18 months after the date  
4 of enactment of the 21st Century Cures Act, the om-  
5 budsman for any organizational unit of the Food  
6 and Drug Administration responsible for the pre-  
7 market review of devices shall—

8 “(A) conduct an audit of the training de-  
9 scribed in paragraph (1)(A), including the effec-  
10 tiveness of such training in implementing the  
11 least burdensome requirements;

12 “(B) include in such audit interviews of  
13 persons who are representatives of the device  
14 industry regarding their experiences in the de-  
15 vice premarket review process, including with  
16 respect to the application of least burdensome  
17 concepts to premarket review and decision-  
18 making;

19 “(C) include in such audit a list of the  
20 measurement tools the Secretary uses to assess  
21 the implementation of the least burdensome re-  
22 quirements, including under paragraph (1)(B)  
23 and section 517A(a)(3), and may also provide  
24 feedback on the effectiveness of such tools in

1 the implementation of the least burdensome re-  
2 quirements;

3 “(D) summarize the findings of such audit  
4 in a final audit report; and

5 “(E) within 30 calendar days of completion  
6 of such final audit report, make such final audit  
7 report available—

8 “(i) to the Committee on Health,  
9 Education, Labor, and Pensions of the  
10 Senate and the Committee on Energy and  
11 Commerce of the House of Representa-  
12 tives; and

13 “(ii) on the Internet website of the  
14 Food and Drug Administration.”.

15 (b) **PREMARKET APPLICATIONS.**—Section 515(c) of  
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17 360e(c)) is amended by adding at the end the following:

18 “(5)(A) In requesting additional information with re-  
19 spect to an application under this section, the Secretary  
20 shall consider the least burdensome appropriate means  
21 necessary to demonstrate a reasonable assurance of device  
22 safety and effectiveness.

23 “(B) For purposes of subparagraph (A), the term  
24 ‘necessary’ means the minimum required information that  
25 would support a determination by the Secretary that an

1 application provides a reasonable assurance of the safety  
2 and effectiveness of the device.

3 “(C) For purposes of this paragraph, the Secretary  
4 shall consider the role of postmarket information in deter-  
5 mining the least burdensome means of demonstrating a  
6 reasonable assurance of device safety and effectiveness.

7 “(D) Nothing in this paragraph alters the standards  
8 for premarket approval of a device.”.

9 (c) RATIONALE FOR SIGNIFICANT DECISIONS RE-  
10 GARDING DEVICES.—Section 517A(a) of the Federal  
11 Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)) is  
12 amended by adding at the end the following:

13 “(3) APPLICATION OF LEAST BURDENSOME RE-  
14 QUIREMENTS.—The substantive summary required  
15 under this subsection shall include a brief statement  
16 regarding how the least burdensome requirements  
17 were considered and applied consistent with section  
18 513(i)(1)(D), section 513(a)(3)(D), and section  
19 515(c)(5), as applicable.”.

20 **SEC. 3059. CLEANING INSTRUCTIONS AND VALIDATION**  
21 **DATA REQUIREMENT.**

22 (a) IN GENERAL.—Section 510 of the Federal Food,  
23 Drug, and Cosmetic Act (21 U.S.C. 360) is amended by  
24 adding at the end the following:

25 “(q) REUSABLE MEDICAL DEVICES.—

1           “(1) IN GENERAL.—Not later than 180 days  
2 after the date of enactment of the 21st Century  
3 Cures Act, the Secretary shall identify and publish  
4 a list of reusable device types for which reports  
5 under subsection (k) are required to include—

6           “(A) instructions for use, which have been  
7 validated in a manner specified by the Sec-  
8 retary; and

9           “(B) validation data, the types of which  
10 shall be specified by the Secretary;  
11 regarding cleaning, disinfection, and sterilization,  
12 and for which a substantial equivalence determina-  
13 tion may be based.

14           “(2) REVISION OF LIST.—The Secretary shall  
15 revise the list under paragraph (2), as the Secretary  
16 determines appropriate, with notice in the Federal  
17 Register.

18           “(3) CONTENT OF REPORTS.—Reports under  
19 subsection (k) that are submitted after the publica-  
20 tion of the list described in paragraph (1), for de-  
21 vices or types of devices included on such list, shall  
22 include such instructions for use and validation  
23 data.”.

24           (b) DEVICE MODIFICATIONS.—The Secretary of  
25 Health and Human Services, acting through the Commis-



1 sioner of Food and Drugs, shall issue final guidance re-  
2 garding when a premarket notification under section  
3 510(k) of the Federal Food, Drug, and Cosmetic Act (21  
4 U.S.C. 360(k)) is required to be submitted for a modifica-  
5 tion or change to a legally marketed device. Such final  
6 guidance shall be issued not later than 1 year after the  
7 date on which the comment period closes for the draft  
8 guidance on such subject.

9 **SEC. 3060. CLARIFYING MEDICAL SOFTWARE REGULATION.**

10 (a) IN GENERAL.—Section 520 of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by  
12 adding at the end the following:

13 “(o) REGULATION OF MEDICAL AND CERTAIN DECI-  
14 SIONS SUPPORT SOFTWARE.—

15 “(1) The term device, as defined in section  
16 201(h), shall not include a software function that is  
17 intended—

18 “(A) for administrative support of a health  
19 care facility, including the processing and main-  
20 tenance of financial records, claims or billing  
21 information, appointment schedules, business  
22 analytics, information about patient popu-  
23 lations, admissions, practice and inventory man-  
24 agement, analysis of historical claims data to  
25 predict future utilization or cost-effectiveness,

1 determination of health benefit eligibility, popu-  
2 lation health management, and laboratory  
3 workflow;

4 “(B) for maintaining or encouraging a  
5 healthy lifestyle and is unrelated to the diag-  
6 nosis, cure, mitigation, prevention, or treatment  
7 of a disease or condition;

8 “(C) to serve as electronic patient records,  
9 including patient-provided information, to the  
10 extent that such records are intended to trans-  
11 fer, store, convert formats, or display the equiv-  
12 alent of a paper medical chart, so long as—

13 “(i) such records were created, stored,  
14 transferred, or reviewed by health care  
15 professionals, or by individuals working  
16 under supervision of such professionals;

17 “(ii) such records are part of health  
18 information technology that is certified  
19 under section 3001(c)(5) of the Public  
20 Health Service Act; and

21 “(iii) such function is not intended to  
22 interpret or analyze patient records, in-  
23 cluding medical image data, for the pur-  
24 pose of the diagnosis, cure, mitigation, pre-

1                   vention, or treatment of a disease or condi-  
2                   tion;

3                   “(D) for transferring, storing, converting  
4                   formats, or displaying clinical laboratory test or  
5                   other device data and results, findings by a  
6                   health care professional with respect to such  
7                   data and results, general information about  
8                   such findings, and general background informa-  
9                   tion about such laboratory test or other device,  
10                  unless such function is intended to interpret or  
11                  analyze clinical laboratory test or other device  
12                  data, results, and findings; or

13                  “(E) unless the function is intended to ac-  
14                  quire, process, or analyze a medical image or a  
15                  signal from an in vitro diagnostic device or a  
16                  pattern or signal from a signal acquisition sys-  
17                  tem, for the purpose of—

18                         “(i) displaying, analyzing, or printing  
19                         medical information about a patient or  
20                         other medical information (such as peer-re-  
21                         viewed clinical studies and clinical practice  
22                         guidelines);

23                         “(ii) supporting or providing rec-  
24                         ommendations to a health care professional

1 about prevention, diagnosis, or treatment  
2 of a disease or condition; and

3 “(iii) enabling such health care profes-  
4 sional to independently review the basis for  
5 such recommendations that such software  
6 presents so that it is not the intent that  
7 such health care professional rely primarily  
8 on any of such recommendations to make  
9 a clinical diagnosis or treatment decision  
10 regarding an individual patient.

11 “(2) In the case of a product with multiple  
12 functions that contains—

13 “(A) at least one software function that  
14 meets the criteria under paragraph (1) or that  
15 otherwise does not meet the definition of device  
16 under section 201(h); and

17 “(B) at least one function that does not  
18 meet the criteria under paragraph (1) and that  
19 otherwise meets the definition of a device under  
20 section 201(h),

21 the Secretary shall not regulate the software func-  
22 tion of such product described in subparagraph (A)  
23 as a device. Notwithstanding the preceding sentence,  
24 when assessing the safety and effectiveness of the  
25 device function or functions of such product de-

1       scribed in subparagraph (B), the Secretary may as-  
2       sess the impact that the software function or func-  
3       tions described in subparagraph (A) have on such  
4       device function or functions.

5           “(3)(A) Notwithstanding paragraph (1), a soft-  
6       ware function described in subparagraph (C), (D),  
7       or (E) of paragraph (1) shall not be excluded from  
8       the definition of device under section 201(h) if—

9           “(i) the Secretary makes a finding that use  
10       of such software function would be reasonably  
11       likely to have serious adverse health con-  
12       sequences; and

13           “(ii) the software function has been identi-  
14       fied in a final order issued by the Secretary  
15       under subparagraph (B).

16           “(B) Subparagraph (A) shall apply only if the  
17       Secretary—

18           “(i) publishes a notification and proposed  
19       order in the Federal Register;

20           “(ii) includes in such notification the Sec-  
21       retary’s finding, including the rationale and  
22       identification of the evidence on which such  
23       finding was based, as described in subpara-  
24       graph (A)(i); and

1           “(iii) provides for a period of not less than  
2           30 calendar days for public comment before  
3           issuing a final order or withdrawing such pro-  
4           posed order.

5           “(C) In making a finding under subparagraph  
6           (A)(i) with respect to a software function, the Sec-  
7           retary shall consider—

8                   “(i) the likelihood and severity of patient  
9                   harm if the software function were to not per-  
10                  form as intended;

11                  “(ii) the extent to which the software func-  
12                  tion is intended to support the clinical judgment  
13                  of a health care professional;

14                  “(iii) whether there is a reasonable oppor-  
15                  tunity for a health care professional to review  
16                  the basis of the information or treatment rec-  
17                  ommendation provided by the software function;  
18                  and

19                  “(iv) the intended user and user environ-  
20                  ment, such as whether a health care profes-  
21                  sional will use a software function of a type de-  
22                  scribed in subparagraph (E) of paragraph (1).

23           “(4) Nothing in this subsection shall be con-  
24           strued as limiting the authority of the Secretary  
25           to—

1           “(A) exercise enforcement discretion as to  
2           any device subject to regulation under this Act;

3           “(B) regulate software used in the manu-  
4           facture and transfusion of blood and blood com-  
5           ponents to assist in the prevention of disease in  
6           humans; or

7           “(C) regulate software as a device under  
8           this Act if such software meets the criteria  
9           under section 513(a)(1)(C).”.

10       (b) REPORTS.—The Secretary of Health and Human  
11       Services (referred to in this subsection as the “Sec-  
12       retary”), after consultation with agencies and offices of  
13       the Department of Health and Human Services involved  
14       in health information technology, shall publish a report,  
15       not later than 2 years after the date of enactment of this  
16       Act and every 2 years thereafter, that—

17           (1) includes input from outside experts, such as  
18           representatives of patients, consumers, health care  
19           providers, startup companies, health plans or other  
20           third-party payers, venture capital investors, infor-  
21           mation technology vendors, health information tech-  
22           nology vendors, small businesses, purchasers, em-  
23           ployers, and other stakeholders with relevant exper-  
24           tise, as determined by the Secretary;

1           (2) examines information available to the Sec-  
2           retary on any risks and benefits to health associated  
3           with software functions described in section  
4           520(o)(1) of the Federal Food, Drug, and Cosmetic  
5           Act (21 U.S.C. 360j) (as amended by subsection  
6           (a)); and

7           (3) summarizes findings regarding the impact  
8           of such software functions on patient safety, includ-  
9           ing best practices to promote safety, education, and  
10          competency related to such functions.

11          (c) CLASSIFICATION OF ACCESSORIES.—Section  
12          513(b) of the Federal Food, Drug, and Cosmetic Act (21  
13          U.S.C. 360c(b)) is amended by adding at the end the fol-  
14          lowing:

15          “(9) The Secretary shall classify an accessory under  
16          this section based on the intended use of the accessory,  
17          notwithstanding the classification of any other device with  
18          which such accessory is intended to be used.”.

19          (d) CONFORMING AMENDMENT.—Section 201(h) of  
20          the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
21          321(h)) is amended by adding at the end the following:  
22          “The term ‘device’ does not include software functions ex-  
23          cluded pursuant to section 520(o).”.



1     **Subtitle G—Improving Scientific**  
2     **Expertise and Outreach at FDA**

3     **SEC. 3071. SILVIO O. CONTE SENIOR BIOMEDICAL RE-**  
4                   **SEARCH AND BIOMEDICAL PRODUCT ASSESS-**  
5                   **MENT SERVICE.**

6           (a) **HIRING AND RETENTION AUTHORITY.**—Section  
7     228 of the Public Health Service Act (42 U.S.C. 237) is  
8     amended—

9           (1) in the section heading, by inserting “**AND**  
10           **BIOMEDICAL PRODUCT ASSESSMENT**” after  
11           “**RESEARCH**”;

12           (2) in subsection (a)—

13           (A) in paragraph (1), by striking “Silvio  
14           O. Conte Senior Biomedical Research Service,  
15           not to exceed 500 members” and inserting  
16           “Silvio O. Conte Senior Biomedical Research  
17           and Biomedical Product Assessment Service (in  
18           this section referred to as the ‘Service’), not to  
19           exceed 2,000 members, the purpose of which is  
20           to recruit and retain outstanding and qualified  
21           scientific and technical experts in the fields of  
22           biomedical research, clinical research evalua-  
23           tion, and biomedical product assessment”;

24           (B) by amending paragraph (2) to read as  
25           follows:

1           “(2) The authority established in paragraph (1) may  
2 not be construed to require the Secretary to reduce the  
3 number of employees serving under any other employment  
4 system in order to offset the number of members serving  
5 in the Service.”; and

6                       (C) by adding at the end the following:

7           “(3) The Secretary shall assign experts under this  
8 section to agencies within the Department of Health and  
9 Human Services taking into account the need for the ex-  
10 pertise of such expert.”;

11                   (3) in subsection (b)—

12                       (A) in the matter preceding paragraph (1),  
13 by striking “or clinical research evaluation” and  
14 inserting “, clinical research evaluation, or bio-  
15 medical product assessment”; and

16                       (B) in paragraph (1), by inserting “or a  
17 doctoral or master’s level degree in engineering,  
18 bioinformatics, or a related or emerging field,”  
19 after the comma;

20                   (4) in subsection (d)(2), by striking “and shall  
21 not exceed the rate payable for level I of the Execu-  
22 tive Schedule unless approved by the President  
23 under section 5377(d)(2) of title 5, United States  
24 Code” and inserting “and shall not exceed the  
25 amount of annual compensation (excluding expenses)

1 specified in section 102 of title 3, United States  
2 Code”;

3 (5) by striking subsection (e); and

4 (6) by redesignating subsections (f) and (g) as  
5 subsections (e) and (f), respectively.

6 (b) GAO STUDY.—

7 (1) IN GENERAL.—The Comptroller General of  
8 the United States shall conduct a study of the effec-  
9 tiveness of the amendments to section 228 of the  
10 Public Health Service Act (42 U.S.C. 237) made by  
11 subsection (a) and the impact of such amendments,  
12 if any, on all agencies or departments of the Depart-  
13 ment of Health and Human Services, and, not later  
14 than 4 years after the date of enactment of this Act,  
15 shall submit a report based on such study to the  
16 Committee on Health, Education, Labor, and Pen-  
17 sions of the Senate and the Committee on Energy  
18 and Commerce of the House of Representatives.

19 (2) CONTENT OF STUDY AND REPORT.—The  
20 study and report under paragraph (1) shall include  
21 an examination of the extent to which recruitment  
22 and retention of outstanding and qualified scientific,  
23 medical, or technical experts in the fields of bio-  
24 medical research, clinical research evaluation, and  
25 biomedical product assessment have improved or

1 otherwise have been affected by the amendments to  
2 section 228 of the Public Health Service Act (42  
3 U.S.C. 237) made by subsection (a), including by  
4 determining, during the period between the date of  
5 enactment of this Act and the completion of the  
6 study—

7 (A) the total number of members recruited  
8 and retained under the Senior Biomedical Re-  
9 search and Biomedical Product Assessment  
10 Service under such section 228, and the effect  
11 of increasing the number of members eligible  
12 for such Service;

13 (B) the number of members of such Senior  
14 Biomedical Research and Biomedical Product  
15 Assessment Service hired with a doctoral level  
16 degree in biomedicine or a related field, and the  
17 number of such members hired with a doctoral  
18 or master's level degree in engineering,  
19 bioinformatics, or a related or emerging field;  
20 and

21 (C) the number of Senior Biomedical Re-  
22 search and Biomedical Product Assessment  
23 Service members that have been hired by each  
24 agency or department of the Department of  
25 Health and Human Services, and how such De-

1           partment assigns such members to each agency  
2           or department.

3 **SEC. 3072. HIRING AUTHORITY FOR SCIENTIFIC, TECH-**  
4 **NICAL, AND PROFESSIONAL PERSONNEL.**

5           (a) IN GENERAL.—The Federal Food, Drug, and  
6 Cosmetic Act is amended by inserting after section 714  
7 (21 U.S.C. 379d–3) the following:

8 **“SEC. 714A. HIRING AUTHORITY FOR SCIENTIFIC, TECH-**  
9 **NICAL, AND PROFESSIONAL PERSONNEL.**

10          “(a) IN GENERAL.—The Secretary may, notwith-  
11 standing title 5, United States Code, governing appoint-  
12 ments in the competitive service, appoint outstanding and  
13 qualified candidates to scientific, technical, or professional  
14 positions that support the development, review, and regu-  
15 lation of medical products. Such positions shall be within  
16 the competitive service.

17          “(b) COMPENSATION.—

18               “(1) IN GENERAL.—Notwithstanding any other  
19 provision of law, including any requirement with re-  
20 spect to General Schedule pay rates under sub-  
21 chapter III of chapter 53 of title 5, United States  
22 Code, and consistent with the requirements of para-  
23 graph (2), the Commissioner of Food and Drugs  
24 may determine and fix—

1           “(A) the annual rate of pay of any indi-  
2           vidual appointed under subsection (a); and

3           “(B) for purposes of retaining qualified  
4           employees, the annual rate of pay for any quali-  
5           fied scientific, technical, or professional per-  
6           sonnel appointed to a position described in sub-  
7           section (a) before the date of enactment of the  
8           21st Century Cures Act.

9           “(2) LIMITATION.—The annual rate of pay es-  
10          tablished pursuant to paragraph (1) may not exceed  
11          the amount of annual compensation (excluding ex-  
12          penses) specified in section 102 of title 3, United  
13          States Code.

14          “(3) PUBLIC AVAILABILITY.—The annual rate  
15          of pay provided to an individual in accordance with  
16          this section shall be publicly available information.

17          “(c) RULE OF CONSTRUCTION.—The authorities  
18          under this section shall not be construed to affect the au-  
19          thority provided under section 714.

20          “(d) REPORT ON WORKFORCE PLANNING.—

21                 “(1) IN GENERAL.—Not later than 18 months  
22                 after the date of enactment of the 21st Century  
23                 Cures Act, the Secretary shall submit a report on  
24                 workforce planning to the Committee on Health,  
25                 Education, Labor, and Pensions of the Senate and

1 the Committee on Energy and Commerce of the  
2 House of Representatives that examines the extent  
3 to which the Food and Drug Administration has a  
4 critical need for qualified individuals for scientific,  
5 technical, or professional positions, including—

6 “(A) an analysis of the workforce needs at  
7 the Food and Drug Administration and the  
8 Secretary’s strategic plan for addressing such  
9 needs, including through use of the authority  
10 under this section; and

11 “(B) a recruitment and retention plan for  
12 hiring qualified scientific, technical, and profes-  
13 sional candidates, which may include the use  
14 of—

15 “(i) recruitment through nongovern-  
16 mental recruitment or placement agencies;

17 “(ii) recruitment through academic in-  
18 stitutions;

19 “(iii) recruitment or hiring bonuses, if  
20 applicable;

21 “(iv) recruitment using targeted direct  
22 hiring authorities; and

23 “(v) retention of qualified scientific,  
24 technical, and professional employees using

1           the authority under this section, or other  
2           applicable authorities of the Secretary.

3           “(2) RECOMMENDATIONS.—The report under  
4           paragraph (1) may include the recommendations of  
5           the Commissioner of Food and Drugs that would  
6           help the Food and Drug Administration to better re-  
7           cruit and retain qualified individuals for scientific,  
8           technical, or professional positions at the agency.”.

9           (b) GAO STUDY AND REPORT.—

10           (1) IN GENERAL.—The Comptroller General of  
11           the United States shall conduct a study of the abil-  
12           ity of the Food and Drug Administration to hire,  
13           train, and retain qualified scientific, technical, and  
14           professional staff, not including contractors, nec-  
15           essary to fulfill the mission of the Food and Drug  
16           Administration to protect and promote public health.  
17           Not later than January 1, 2022, the Comptroller  
18           General shall submit a report on such study to the  
19           Committee on Health, Education, Labor, and Pen-  
20           sions of the Senate and the Committee on Energy  
21           and Commerce of the House of Representatives.

22           (2) CONTENTS OF STUDY.—The Comptroller  
23           General shall include in the study and report under  
24           paragraph (1)—



1 (A) information about the progress of the  
2 Food and Drug Administration in recruiting  
3 and retaining qualified scientific, technical, and  
4 professional staff outstanding in the field of  
5 biomedical research, clinical research evalua-  
6 tion, and biomedical product assessment;

7 (B) the extent to which critical staffing  
8 needs exist at the Food and Drug Administra-  
9 tion, and barriers to hiring, training, and re-  
10 taining qualified staff, if any;

11 (C) an examination of the recruitment and  
12 retention strategies of the Food and Drug Ad-  
13 ministration, including examining any strategic  
14 workforce plan, focused on improving scientific,  
15 technical, and professional staff recruitment  
16 and retention; and

17 (D) recommendations for potential im-  
18 provements that would address staffing needs  
19 of the Food and Drug Administration.

20 **SEC. 3073. ESTABLISHMENT OF FOOD AND DRUG ADMINIS-**  
21 **TRATION INTERCENTER INSTITUTES.**

22 (a) IN GENERAL.—Chapter X of the Federal Food,  
23 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-  
24 ed by adding at the end the following:

1 **“SEC. 1014. FOOD AND DRUG ADMINISTRATION INTER-**  
2 **CENTER INSTITUTES.**

3 “(a) IN GENERAL.—The Secretary shall establish one  
4 or more Intercenter Institutes within the Food and Drug  
5 Administration (referred to in this section as an ‘Insti-  
6 tute’) for a major disease area or areas. With respect to  
7 the major disease area of focus of an Institute, such Insti-  
8 tute shall develop and implement processes for coordina-  
9 tion of activities, as applicable to such major disease area  
10 or areas, among the Center for Drug Evaluation and Re-  
11 search, the Center for Biologics Evaluation and Research,  
12 and the Center for Devices and Radiological Health (for  
13 the purposes of this section, referred to as the ‘Centers’).  
14 Such activities may include—

15 “(1) coordination of staff from the Centers with  
16 diverse product expertise in the diagnosis, cure, miti-  
17 gation, treatment, or prevention of the specific dis-  
18 eases relevant to the major disease area of focus of  
19 the Institute;

20 “(2) streamlining, where appropriate, the re-  
21 view of medical products to diagnose, cure, mitigate,  
22 treat, or prevent the specific diseases relevant to the  
23 major disease area of focus of the Institute, applying  
24 relevant standards under sections 505, 510(k),  
25 513(f)(2), and 515 of this Act and section 351 of

1 the Public Health Service Act, and other applicable  
2 authorities;

3 “(3) promotion of scientific programs within  
4 the Centers related to the major disease area of  
5 focus of the Institute;

6 “(4) development of programs and enhancement  
7 of strategies to recruit, train, and provide continuing  
8 education opportunities for the personnel of the Cen-  
9 ters with expertise related to the major disease area  
10 of focus of the Institute;

11 “(5) enhancement of the interactions of the  
12 Centers with patients, sponsors, and the external  
13 biomedical community regarding the major disease  
14 area of focus of the Institute; and

15 “(6) facilitation of the collaborative relation-  
16 ships of the Centers with other agencies within the  
17 Department of Health and Human Services regard-  
18 ing the major disease area of focus of the Institute.

19 “(b) PUBLIC PROCESS.—The Secretary shall provide  
20 a period for public comment during the time that each  
21 Institute is being implemented.

22 “(c) TIMING.—The Secretary shall establish at least  
23 one Institute under subsection (a) before the date that is  
24 1 year after the date of enactment of the 21st Century  
25 Cures Act.

1           “(d) **TERMINATION OF INSTITUTES.**—The Secretary  
2 may terminate any Institute established pursuant to this  
3 section if the Secretary determines such Institute is no  
4 longer benefitting the public health. Not less than 60 days  
5 prior to so terminating an Institute, the Secretary shall  
6 provide public notice, including the rationale for such ter-  
7 mination.”.

8           (b) **TECHNICAL AMENDMENTS.**—Chapter X of the  
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391  
10 et seq.) is amended—

11           (1) by redesignating section 1012 as section  
12           1013; and

13           (2) by redesignating the second section 1011  
14           (with respect to improving the training of State,  
15           local, territorial, and tribal food safety officials), as  
16           added by section 209(a) of the FDA Food Safety  
17           Modernization Act (Public Law 111–353), as section  
18           1012.

19 **SEC. 3074. SCIENTIFIC ENGAGEMENT.**

20           (a) **IN GENERAL.**—Scientific meetings that are at-  
21 tended by scientific or medical personnel, or other profes-  
22 sionals, of the Department of Health and Human Services  
23 for whom attendance at such meeting is directly related  
24 to their professional duties and the mission of the Depart-  
25 ment—

1           (1) shall not be considered conferences for the  
2 purposes of complying with Federal reporting re-  
3 quirements contained in annual appropriations Acts  
4 or in this section; and

5           (2) shall not be considered conferences for pur-  
6 poses of a restriction contained in an annual appro-  
7 priations Act, based on Office of Management and  
8 Budget Memorandum M-12-12 or any other regula-  
9 tion restricting travel to such meeting.

10          (b) LIMITATION.—Nothing in this section shall be  
11 construed to exempt travel for scientific meetings from  
12 Federal regulations relating to travel.

13          (c) REPORTS.—Not later than 90 days after the end  
14 of the fiscal year, each operating division of the Depart-  
15 ment of Health and Human Services shall prepare, and  
16 post on an Internet website of the operating division, an  
17 annual report on scientific meeting attendance and related  
18 travel spending for each fiscal year. Such report shall in-  
19 clude—

20           (1) general information concerning the scientific  
21 meeting activities involved;

22           (2) information concerning the total amount ex-  
23 pended for such meetings;

24           (3) a description of all such meetings that were  
25 attended by scientific or medical personnel, or other

1 professionals, of each such operating division where  
2 the total amount expended by the operating division  
3 associated with each such meeting were in excess of  
4 \$30,000, including—

5 (A) the total amount of meeting expenses  
6 incurred by the operating division for such  
7 meeting;

8 (B) the location of such meeting;

9 (C) the date of such meeting;

10 (D) a brief explanation on how such meet-  
11 ing advanced the mission of the operating divi-  
12 sion; and

13 (E) the total number of individuals whose  
14 travel expenses or other scientific meeting ex-  
15 penses were paid by the operating division; and

16 (4) with respect to any such meeting where the  
17 total expenses to the operating division exceeded  
18 \$150,000, a description of the exceptional cir-  
19 cumstances that necessitated the expenditure of such  
20 amounts.

21 **SEC. 3075. DRUG SURVEILLANCE.**

22 (a) NEW DRUGS.—Section 505(k)(5) of the Federal  
23 Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)(5)), as  
24 amended by section 2074, is further amended—

1           (1) in subparagraph (A), by striking “, bi-week-  
2           ly screening” and inserting “screenings”;

3           (2) in subparagraph (B), as redesignated by  
4           section 2074(1)(C), by striking the period at the end  
5           and inserting “; and”; and

6           (3) by adding at the end the following:

7           “(C) make available on the Internet website of  
8           the Food and Drug Administration—

9           “(i) guidelines, developed with input from  
10           experts qualified by scientific training and expe-  
11           rience to evaluate the safety and effectiveness of  
12           drugs, that detail best practices for drug safety  
13           surveillance using the Adverse Event Reporting  
14           System; and

15           “(ii) criteria for public posting of adverse  
16           event signals.”.

17           (b) FAERS REVISION.—Section 505(r)(2)(D) of the  
18           Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19           355(r)(2)(D)) is amended by striking “, by 18 months”  
20           and all that follows through the semicolon at the end of  
21           the subparagraph and inserting “and making publicly  
22           available on the Internet website established under para-  
23           graph (1) best practices for drug safety surveillance activi-  
24           ties for drugs approved under this section or section 351  
25           of the Public Health Service Act;”.

1 (c) RISK EVALUATION AND MITIGATION STRATE-  
2 GIES.—Section 505–1(f)(5) of the Federal Food, Drug,  
3 and Cosmetic Act (21 U.S.C. 355–1(f)(5)) is amended—

4 (1) in the matter preceding subparagraph (A),  
5 by inserting “or other advisory committee” after  
6 “(or successor committee)”; and

7 (2) in subparagraph (B), by striking “at least  
8 annually,” and inserting “periodically”.

9 **SEC. 3076. REAGAN-UDALL FOUNDATION FOR THE FOOD**  
10 **AND DRUG ADMINISTRATION.**

11 (a) BOARD OF DIRECTORS.—

12 (1) COMPOSITION AND SIZE.—Section  
13 770(d)(1)(C) of the Federal Food, Drug, and Cos-  
14 metic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

15 (A) by redesignating clause (ii) as clause  
16 (iii);

17 (B) by inserting after clause (i) the fol-  
18 lowing:

19 “(ii) ADDITIONAL MEMBERS.—The  
20 Board, through amendments to the bylaws  
21 of the Foundation, may provide that the  
22 number of voting members of the Board  
23 shall be a number (to be specified in such  
24 amendment) greater than 14. Any Board  
25 positions that are established by any such



1 amendment shall be appointed (by majority  
2 vote) by the individuals who, as of the date  
3 of such amendment, are voting members of  
4 the Board and persons so appointed may  
5 represent any of the categories specified in  
6 subclauses (I) through (V) of clause (i), so  
7 long as no more than 30 percent of the  
8 total voting members of the Board (includ-  
9 ing members whose positions are estab-  
10 lished by such amendment) are representa-  
11 tives of the general pharmaceutical, device,  
12 food, cosmetic, and biotechnology indus-  
13 tries.”; and

14 (C) in clause (iii)(I), as redesignated by  
15 subparagraph (A), by striking “The ex officio  
16 members shall ensure” and inserting “The ex  
17 officio members, acting pursuant to clause (i),  
18 and the Board, acting pursuant to clause (ii),  
19 shall ensure”.

20 (2) FEDERAL EMPLOYEES ALLOWED TO SERVE  
21 ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C)  
22 of the Federal Food, Drug, and Cosmetic Act (21  
23 U.S.C. 379dd(d)(1)(C)), as redesignated by para-  
24 graph (1)(A), is amended by adding at the end the  
25 following: “For purposes of this section, the term

1 ‘employee of the Federal Government’ does not in-  
2 clude a special Government employee, as that term  
3 is defined in section 202(a) of title 18, United  
4 States Code.”.

5 (3) STAGGERED TERMS.—Subparagraph (A) of  
6 section 770(d)(3) of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended  
8 to read as follows:

9 “(A) TERM.—The term of office of each  
10 member of the Board appointed under para-  
11 graph (1)(C)(i), and the term of office of any  
12 member of the Board whose position is estab-  
13 lished pursuant to paragraph (1)(C)(ii), shall be  
14 4 years, except that—

15 “(i) the terms of offices for the mem-  
16 bers of the Board initially appointed under  
17 paragraph (1)(C)(i) shall expire on a stag-  
18 gered basis as determined by the ex officio  
19 members; and

20 “(ii) the terms of office for the per-  
21 sons initially appointed to positions estab-  
22 lished pursuant to paragraph (1)(C)(ii)  
23 may be made to expire on a staggered  
24 basis, as determined by the individuals  
25 who, as of the date of the amendment es-

1                   tablishing such positions, are members of  
2                   the Board.”.

3           (b) EXECUTIVE DIRECTOR COMPENSATION.—Section  
4 770(g)(2) of the Federal Food, Drug, and Cosmetic Act  
5 (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall  
6 not be greater than the compensation of the Commis-  
7 sioner”.

8           (c) SEPARATION OF FUNDS.—Section 770(m) of the  
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
10 379dd(m)) is amended by striking “are held in separate  
11 accounts from funds received from entities under sub-  
12 section (i)” and inserting “are managed as individual pro-  
13 grammatic funds under subsection (i), according to best  
14 accounting practices”.

## 15                   **Subtitle H—Medical** 16                   **Countermeasures Innovation**

### 17   **SEC. 3081. MEDICAL COUNTERMEASURE GUIDELINES.**

18           Section 319F–2 of the Public Health Service Act (42  
19 U.S.C. 247d–6b) is amended—

20                   (1) in subsection (a), by adding at the end the  
21                   following:

22                   “(3) UTILIZATION GUIDELINES.—The Secretary  
23                   shall ensure timely and accurate recommended utili-  
24                   zation guidelines for qualified countermeasures (as  
25                   defined in section 319F–1), qualified pandemic and

1 epidemic products (as defined in section 319F–3),  
2 and security countermeasures (as defined in sub-  
3 section (c)), including for such products in the  
4 stockpile.”; and

5 (2) in subsection (g)—

6 (A) by amending paragraph (4) to read as  
7 follows:

8 “(4) REPORT ON SECURITY COUNTERMEASURE  
9 PROCUREMENT.—Not later than March 1 of each  
10 year in which the Secretary determines that the  
11 amount of funds available for procurement of secu-  
12 rity countermeasures is less than \$1,500,000,000,  
13 the Secretary shall submit to the Committee on Ap-  
14 propriations and the Committee on Health, Edu-  
15 cation, Labor, and Pensions of the Senate and the  
16 Committee on Appropriations and the Committee on  
17 Energy and Commerce of the House of Representa-  
18 tives a report detailing the amount of such funds  
19 available for procurement and the impact such  
20 amount of funding will have—

21 “(A) in meeting the security counter-  
22 measure needs identified under this section; and

23 “(B) on the annual Public Health Emer-  
24 gency Medical Countermeasures Enterprise and

1 Strategy Implementation Plan (pursuant to sec-  
2 tion 2811(d)).”.

3 **SEC. 3082. CLARIFYING BARDA CONTRACTING AUTHORITY.**

4 (a) IN GENERAL.—Section 319F–2(g) of the Public  
5 Health Service Act (42 U.S.C. 247d–6b(g)) is amended  
6 by adding at the end the following:

7 “(5) CLARIFICATION ON CONTRACTING AU-  
8 THORITY.—The Secretary, acting through the Direc-  
9 tor of the Biomedical Advanced Research and Devel-  
10 opment Authority, shall carry out the programs  
11 funded by the special reserve fund (for the procure-  
12 ment of security countermeasures under subsection  
13 (c) and for carrying out section 319L), including the  
14 execution of procurement contracts, grants, and co-  
15 operative agreements pursuant to this section and  
16 section 319L.”.

17 (b) BARDA CONTRACTING AUTHORITY.—Section  
18 319L(c)(3) of the Public Health Service Act (42 U.S.C.  
19 247d–7c) is amended by inserting “, including the execu-  
20 tion of procurement contracts, grants, and cooperative  
21 agreements pursuant to this section” before the period.

22 **SEC. 3083. COUNTERMEASURE BUDGET PLAN.**

23 Section 2811(b)(7) of the Public Health Service Act  
24 (42 U.S.C. 300hh–10(b)(7)) is amended—

1           (1) in the matter preceding subparagraph (A),  
2           by striking the first sentence and inserting “De-  
3           velop, and update not later than March 1 of each  
4           year, a coordinated 5-year budget plan based on the  
5           medical countermeasure priorities described in sub-  
6           section (d), including with respect to chemical, bio-  
7           logical, radiological, and nuclear agent or agents  
8           that may present a threat to the Nation, including  
9           such agents that are novel or emerging infectious  
10          diseases, and the corresponding efforts to develop  
11          qualified countermeasures (as defined in section  
12          319F–1), security countermeasures (as defined in  
13          section 319F–2), and qualified pandemic or epidemic  
14          products (as defined in section 319F–3) for each  
15          such threat.”;

16          (2) in subparagraph (C), by striking “; and”  
17          and inserting a semicolon;

18          (3) in subparagraph (D), by striking “to the  
19          appropriate committees of Congress upon request.”  
20          and inserting “, not later than March 15 of each  
21          year, to the Committee on Appropriations and the  
22          Committee on Health, Education, Labor, and Pen-  
23          sions of the Senate and the Committee on Appro-  
24          priations and the Committee on Energy and Com-  
25          merce of the House of Representatives; and”;

1 (4) by adding at the end the following:

2 “(E) not later than March 15 of each year,  
3 be made publicly available in a manner that  
4 does not compromise national security.”.

5 **SEC. 3084. MEDICAL COUNTERMEASURES INNOVATION.**

6 Section 319L(c)(4) of the Public Health Service Act  
7 (42 U.S.C. 247d–7e(c)(4)) is amended by adding at the  
8 end the following:

9 “(E) MEDICAL COUNTERMEASURES INNO-  
10 VATION PARTNER.—

11 “(i) IN GENERAL.—To support the  
12 purposes described in paragraph (2), the  
13 Secretary, acting through the Director of  
14 BARDA, may enter into an agreement (in-  
15 cluding through the use of grants, con-  
16 tracts, cooperative agreements, or other  
17 transactions as described in paragraph (5))  
18 with an independent, nonprofit entity to—

19 “(I) foster and accelerate the de-  
20 velopment and innovation of medical  
21 countermeasures and technologies  
22 that may assist advanced research  
23 and the development of qualified  
24 countermeasures and qualified pan-  
25 demic or epidemic products, including

1 through the use of strategic venture  
2 capital practices and methods;

3 “(II) promote the development of  
4 new and promising technologies that  
5 address urgent medical counter-  
6 measure needs, as identified by the  
7 Secretary;

8 “(III) address unmet public  
9 health needs that are directly related  
10 to medical countermeasure require-  
11 ments, such as novel antimicrobials  
12 for multidrug resistant organisms and  
13 multiuse platform technologies for  
14 diagnostics, prophylaxis, vaccines, and  
15 therapeutics; and

16 “(IV) provide expert consultation  
17 and advice to foster viable medical  
18 countermeasure innovators, including  
19 helping qualified countermeasure  
20 innovators navigate unique industry  
21 challenges with respect to developing  
22 chemical, biological, radiological, and  
23 nuclear countermeasure products.

24 “(ii) ELIGIBILITY.—



1                   “(I) IN GENERAL.—To be eligible  
2 to enter into an agreement under  
3 clause (i) an entity shall—

4                   “(aa) be an independent,  
5 nonprofit entity;

6                   “(bb) have a demonstrated  
7 record of being able to create  
8 linkages between innovators and  
9 investors and leverage such part-  
10 nerships and resources for the  
11 purpose of addressing identified  
12 strategic needs of the Federal  
13 Government;

14                   “(cc) have experience in pro-  
15 moting novel technology innova-  
16 tion;

17                   “(dd) be problem-driven and  
18 solution-focused based on the  
19 needs, requirements, and prob-  
20 lems identified by the Secretary  
21 under clause (iv);

22                   “(ee) demonstrate the abil-  
23 ity, or the potential ability, to  
24 promote the development of med-  
25 ical countermeasure products;

1                   “(ff) demonstrate expertise,  
2                   or the capacity to develop or ac-  
3                   quire expertise, related to tech-  
4                   nical and regulatory consider-  
5                   ations with respect to medical  
6                   countermeasures; and

7                   “(gg) not be within the De-  
8                   partment of Health and Human  
9                   Services.

10                  “(II) PARTNERING EXPERI-  
11                  ENCE.—In selecting an entity with  
12                  which to enter into an agreement  
13                  under clause (i), the Secretary shall  
14                  place a high value on the dem-  
15                  onstrated experience of the entity in  
16                  partnering with the Federal Govern-  
17                  ment to meet identified strategic  
18                  needs.

19                  “(iii) NOT AGENCY.—An entity that  
20                  enters into an agreement under clause (i)  
21                  shall not be deemed to be a Federal agency  
22                  for any purpose, including for any purpose  
23                  under title 5, United States Code.

24                  “(iv) DIRECTION.—Pursuant to an  
25                  agreement entered into under this subpara-

1 graph, the Secretary, acting through the  
2 Director of BARDA, shall provide direc-  
3 tion to the entity that enters into an agree-  
4 ment under clause (i). As part of this  
5 agreement the Director of BARDA shall—

6 “(I) communicate the medical  
7 countermeasure needs, requirements,  
8 and problems to be addressed by the  
9 entity under the agreement;

10 “(II) develop a description of  
11 work to be performed by the entity  
12 under the agreement;

13 “(III) provide technical feedback  
14 and appropriate oversight over work  
15 carried out by the entity under the  
16 agreement, including subsequent de-  
17 velopment and partnerships consistent  
18 with the needs and requirements set  
19 forth in this subparagraph;

20 “(IV) ensure fair consideration of  
21 products developed under the agree-  
22 ment in order to maintain competition  
23 to the maximum practical extent, as  
24 applicable and appropriate under ap-  
25 plicable provisions of this section; and

1                   “(V) ensure, as a condition of the  
2 agreement that the entity—

3                   “(aa) has in place a com-  
4 prehensive set of policies that  
5 demonstrate a commitment to  
6 transparency and accountability;

7                   “(bb) protects against con-  
8 flicts of interest through a com-  
9 prehensive set of policies that ad-  
10 dress potential conflicts of inter-  
11 est, ethics, disclosure, and report-  
12 ing requirements;

13                   “(cc) provides monthly ac-  
14 counting on the use of funds pro-  
15 vided under such agreement; and

16                   “(dd) provides on a quar-  
17 terly basis, reports regarding the  
18 progress made toward meeting  
19 the identified needs set forth in  
20 the agreement.

21                   “(v) SUPPLEMENT NOT SUPPLANT.—  
22 Activities carried out under this subpara-  
23 graph shall supplement, and not supplant,  
24 other activities carried out under this sec-  
25 tion.

1           “(vi) NO ESTABLISHMENT OF ENTI-  
2           TY.—To prevent unnecessary duplication  
3           and target resources effectively, nothing in  
4           this subparagraph shall be construed to  
5           authorize the Secretary to establish within  
6           the Department of Health and Human  
7           Services an entity for the purposes of car-  
8           rying out this subparagraph.

9           “(vii) TRANSPARENCY AND OVER-  
10          SIGHT.—Upon request, the Secretary shall  
11          provide to Congress the information pro-  
12          vided to the Secretary under clause  
13          (iv)(V)(dd).

14          “(viii) INDEPENDENT EVALUATION.—  
15          Not later than 4 years after the date of en-  
16          actment of the 21st Century Cures Act,  
17          the Comptroller General of the United  
18          States shall conduct an independent eval-  
19          uation, and submit to the Secretary and  
20          the appropriate committees of Congress a  
21          report, concerning the activities conducted  
22          under this subparagraph. Such report shall  
23          include recommendations with respect to  
24          any agreement or activities carried out  
25          pursuant to this subparagraph.

1                   “(ix) SUNSET.—This subparagraph  
2                   shall have no force or effect after Sep-  
3                   tember 30, 2022.”.

4 **SEC. 3085. STREAMLINING PROJECT BIOSHIELD PROCURE-**  
5 **MENT.**

6           Section 319F–2(c) of the Public Health Service Act  
7 (42 U.S.C. 247d–6b(c)) is amended—

8                   (1) in paragraph (4)(A)(ii), by striking “make  
9                   a recommendation under paragraph (6) that the spe-  
10                  cial reserve fund as defined in subsection (h) be  
11                  made available for the procurement of such counter-  
12                  measure” and inserting “and subject to the avail-  
13                  ability of appropriations, make available the special  
14                  reserve fund as defined in subsection (h) for pro-  
15                  curement of such countermeasure, as applicable”;

16                  (2) in paragraph (6)—

17                         (A) by striking subparagraphs (A), (B),  
18                         and (E);

19                         (B) by redesignating subparagraphs (C)  
20                         and (D) as subparagraphs (A) and (B), respec-  
21                         tively;

22                         (C) by amending subparagraph (A), as so  
23                         redesignated, to read as follows:

24                                 “(A) NOTICE TO APPROPRIATE CONGRES-  
25                                 SIONAL COMMITTEES.—The Secretary shall no-

1           tify the Committee on Appropriations and the  
2           Committee on Health, Education, Labor, and  
3           Pensions of the Senate and the Committee on  
4           Appropriations and the Committee on Energy  
5           and Commerce of the House of Representatives  
6           of each decision to make available the special  
7           reserve fund as defined in subsection (h) for  
8           procurement of a security countermeasure, in-  
9           cluding, where available, the number of, the na-  
10          ture of, and other information concerning po-  
11          tential suppliers of such countermeasure, and  
12          whether other potential suppliers of the same or  
13          similar countermeasures were considered and  
14          rejected for procurement under this section and  
15          the reasons for each such rejection.”; and

16                 (D) in the heading, by striking “REC-  
17                 COMMENDATION FOR PRESIDENT’S APPROVAL”  
18                 and inserting “RECOMMENDATIONS FOR PRO-  
19                 CUREMENT”; and

20                 (3) in paragraph (7)—

21                         (A) by striking subparagraphs (A) and (B)  
22                         and inserting the following:

23                                 “(A) PAYMENTS FROM SPECIAL RESERVE  
24                                 FUND.—The special reserve fund as defined in  
25                                 subsection (h) shall be available for payments

1 made by the Secretary to a vendor for procure-  
2 ment of a security countermeasure in accord-  
3 ance with the provisions of this paragraph.”;  
4 and

5 (B) by redesignating subparagraph (C) as  
6 subparagraph (B).

7 **SEC. 3086. ENCOURAGING TREATMENTS FOR AGENTS THAT**  
8 **PRESENT A NATIONAL SECURITY THREAT.**

9 Subchapter E of chapter V of the Federal Food,  
10 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is  
11 amended by inserting after section 565 the following:

12 **“SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREAT-**  
13 **MENTS FOR AGENTS THAT PRESENT NA-**  
14 **TIONAL SECURITY THREATS.**

15 “(a) DEFINITIONS.—In this section:

16 “(1) HUMAN DRUG APPLICATION.—The term  
17 ‘human drug application’ has the meaning given  
18 such term in section 735(1).

19 “(2) PRIORITY REVIEW.—The term ‘priority re-  
20 view’, with respect to a human drug application,  
21 means review and action by the Secretary on such  
22 application not later than 6 months after receipt by  
23 the Secretary of such application, as described in the  
24 Manual of Policies and Procedures in the Food and  
25 Drug Administration and goals identified in the let-



1       ters described in section 101(b) of the Food and  
2       Drug Administration Safety and Innovation Act.

3           “(3) PRIORITY REVIEW VOUCHER.—The term  
4       ‘priority review voucher’ means a voucher issued by  
5       the Secretary to the sponsor of a material threat  
6       medical countermeasure application that entitles the  
7       holder of such voucher to priority review of a single  
8       human drug application submitted under section  
9       505(b)(1) or section 351(a) of the Public Health  
10      Service Act after the date of approval of the mate-  
11      rial threat medical countermeasure application.

12           “(4) MATERIAL THREAT MEDICAL COUNTER-  
13      MEASURE APPLICATION.—The term ‘material threat  
14      medical countermeasure application’ means an appli-  
15      cation that—

16           “(A) is a human drug application for a  
17      drug intended for use—

18           “(i) to prevent, or treat harm from a  
19      biological, chemical, radiological, or nuclear  
20      agent identified as a material threat under  
21      section 319F–2(c)(2)(A)(ii) of the Public  
22      Health Service Act; or

23           “(ii) to mitigate, prevent, or treat  
24      harm from a condition that may result in  
25      adverse health consequences or death and

1           may be caused by administering a drug, or  
2           biological product against such agent; and

3           “(B) the Secretary determines eligible for  
4           priority review;

5           “(C) is approved after the date of enact-  
6           ment of the 21st Century Cures Act; and

7           “(D) is for a human drug, no active ingre-  
8           dient (including any ester or salt of the active  
9           ingredient) of which has been approved in any  
10          other application under section 505(b)(1) or  
11          section 351(a) of the Public Health Service Act.

12         “(b) PRIORITY REVIEW VOUCHER.—

13           “(1) IN GENERAL.—The Secretary shall award  
14           a priority review voucher to the sponsor of a mate-  
15           rial threat medical countermeasure application upon  
16           approval by the Secretary of such material threat  
17           medical countermeasure application.

18           “(2) TRANSFERABILITY.—The sponsor of a ma-  
19           terial threat medical countermeasure application  
20           that receives a priority review voucher under this  
21           section may transfer (including by sale) the entitle-  
22           ment to such voucher to a sponsor of a human drug  
23           for which an application under section 505(b)(1) or  
24           section 351(a) of the Public Health Service Act will  
25           be submitted after the date of the approval of the

1 material threat medical countermeasure application.  
2 There is no limit on the number of times a priority  
3 review voucher may be transferred before such  
4 voucher is used.

5 “(3) NOTIFICATION.—

6 “(A) IN GENERAL.—The sponsor of a  
7 human drug application shall notify the Sec-  
8 retary not later than 90 calendar days prior to  
9 submission of the human drug application that  
10 is the subject of a priority review voucher of an  
11 intent to submit the human drug application,  
12 including the date on which the sponsor intends  
13 to submit the application. Such notification  
14 shall be a legally binding commitment to pay  
15 for the user fee to be assessed in accordance  
16 with this section.

17 “(B) TRANSFER AFTER NOTICE.—The  
18 sponsor of a human drug application that pro-  
19 vides notification of the intent of such sponsor  
20 to use the voucher for the human drug applica-  
21 tion under subparagraph (A) may transfer the  
22 voucher after such notification is provided, if  
23 such sponsor has not yet submitted the human  
24 drug application described in the notification.

25 “(c) PRIORITY REVIEW USER FEE.—

1           “(1) IN GENERAL.—The Secretary shall estab-  
2           lish a user fee program under which a sponsor of a  
3           human drug application that is the subject of a pri-  
4           ority review voucher shall pay to the Secretary a fee  
5           determined under paragraph (2). Such fee shall be  
6           in addition to any fee required to be submitted by  
7           the sponsor under chapter VII.

8           “(2) FEE AMOUNT.—The amount of the pri-  
9           ority review user fee shall be determined each fiscal  
10          year by the Secretary and based on the average cost  
11          incurred by the agency in the review of a human  
12          drug application subject to priority review in the  
13          previous fiscal year.

14          “(3) ANNUAL FEE SETTING.—The Secretary  
15          shall establish, before the beginning of each fiscal  
16          year beginning after September 30, 2016, for that  
17          fiscal year, the amount of the priority review user  
18          fee.

19          “(4) PAYMENT.—

20                 “(A) IN GENERAL.—The priority review  
21                 user fee required by this subsection shall be due  
22                 upon the submission of a human drug applica-  
23                 tion under section 505(b)(1) or section 351(a)  
24                 of the Public Health Service Act for which the  
25                 priority review voucher is used.

1           “(B) COMPLETE APPLICATION.—An appli-  
2 cation described under subparagraph (A) for  
3 which the sponsor requests the use of a priority  
4 review voucher shall be considered incomplete if  
5 the fee required by this subsection and all other  
6 applicable user fees are not paid in accordance  
7 with the Secretary’s procedures for paying such  
8 fees.

9           “(C) NO WAIVERS, EXEMPTIONS, REDUC-  
10 TIONS, OR REFUNDS.—The Secretary may not  
11 grant a waiver, exemption, reduction, or refund  
12 of any fees due and payable under this section.

13           “(5) OFFSETTING COLLECTIONS.—Fees col-  
14 lected pursuant to this subsection for any fiscal  
15 year—

16           “(A) shall be deposited and credited as off-  
17 setting collections to the account providing ap-  
18 propriations to the Food and Drug Administra-  
19 tion; and

20           “(6) shall not be collected for any fiscal year  
21 except to the extent provided in advance in appro-  
22 priation Acts.

23           “(d) NOTICE OF ISSUANCE OF VOUCHER AND AP-  
24 PROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary  
25 shall publish a notice in the Federal Register and on the

1 Internet website of the Food and Drug Administration not  
2 later than 30 calendar days after the occurrence of each  
3 of the following:

4           “(1) The Secretary issues a priority review  
5 voucher under this section.

6           “(2) The Secretary approves a drug pursuant  
7 to an application submitted under section 505(b) of  
8 this Act or section 351(a) of the Public Health Serv-  
9 ice Act for which the sponsor of the application used  
10 a priority review voucher issued under this section.

11          “(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing  
12 in this section precludes a sponsor who seeks a priority  
13 review voucher under this section from participating in  
14 any other incentive program, including under this Act, ex-  
15 cept that no sponsor of a material threat medical counter-  
16 measure application may receive more than one priority  
17 review voucher issued under any section of this Act with  
18 respect to such drug.

19          “(f) RELATION TO OTHER PROVISIONS.—The provi-  
20 sions of this section shall supplement, not supplant, any  
21 other provisions of this Act or the Public Health Service  
22 Act that encourage the development of medical counter-  
23 measures.

1 “(g) SUNSET.—The Secretary may not award any  
2 priority review vouchers under subsection (b) after Octo-  
3 ber 1, 2023.”.

4 **SEC. 3087. PAPERWORK REDUCTION ACT WAIVER DURING**  
5 **A PUBLIC HEALTH EMERGENCY.**

6 Section 319 of the Public Health Service Act (42  
7 U.S.C. 247d) is amended by adding at the end the fol-  
8 lowing:

9 “(f) DETERMINATION WITH RESPECT TO PAPER-  
10 WORK REDUCTION ACT WAIVER DURING A PUBLIC  
11 HEALTH EMERGENCY.—

12 “(1) DETERMINATION.—If the Secretary deter-  
13 mines, after consultation with such public health of-  
14 ficials as may be necessary, that—

15 “(A)(i) the criteria set forth for a public  
16 health emergency under paragraph (1) or (2) of  
17 subsection (a) has been met; or

18 “(ii) a disease or disorder, including a  
19 novel and emerging public health threat, is sig-  
20 nificantly likely to become a public health emer-  
21 gency; and

22 “(B) the circumstances of such public  
23 health emergency, or potential for such signifi-  
24 cantly likely public health emergency, including  
25 the specific preparation for and response to

1           such public health emergency or threat, neces-  
2           sitate a waiver from the requirements of sub-  
3           chapter I of chapter 35 of title 44, United  
4           States Code (commonly referred to as the Pa-  
5           perwork Reduction Act),  
6           then the requirements of such subchapter I with re-  
7           spect to voluntary collection of information shall not  
8           be applicable during the immediate investigation of,  
9           and response to, such public health emergency dur-  
10          ing the period of such public health emergency or  
11          the period of time necessary to determine if a dis-  
12          ease or disorder, including a novel and emerging  
13          public health threat, will become a public health  
14          emergency as provided for in this paragraph. The re-  
15          quirements of such subchapter I with respect to vol-  
16          untary collection of information shall not be applica-  
17          ble during the immediate postresponse review re-  
18          garding such public health emergency if such imme-  
19          diate postresponse review does not exceed a reason-  
20          able length of time.

21           “(2) **TRANSPARENCY.**—If the Secretary deter-  
22          mines that a waiver is necessary under paragraph  
23          (1), the Secretary shall promptly post on the Inter-  
24          net website of the Department of Health and  
25          Human Services a brief justification for such waiver,



1 the anticipated period of time such waiver will be in  
2 effect, and the agencies and offices within the De-  
3 partment of Health and Human Services to which  
4 such waiver shall apply, and update such informa-  
5 tion posted on the Internet website of the Depart-  
6 ment of Health and Human Services, as applicable.

7 “(3) EFFECTIVENESS OF WAIVER.—Any waiver  
8 under this subsection shall take effect on the date on  
9 which the Secretary posts information on the Inter-  
10 net website as provided for in this subsection.

11 “(4) TERMINATION OF WAIVER.—Upon deter-  
12 mining that the circumstances necessitating a waiver  
13 under paragraph (1) no longer exist, the Secretary  
14 shall promptly update the Internet website of the  
15 Department of Health and Human Services to re-  
16 flect the termination of such waiver.

17 “(5) LIMITATIONS.—

18 “(A) PERIOD OF WAIVER.—The period of  
19 a waiver under paragraph (1) shall not exceed  
20 the period of time for the related public health  
21 emergency, including a public health emergency  
22 declared pursuant to subsection (a), and any  
23 immediate postresponse review regarding the  
24 public health emergency consistent with the re-  
25 quirements of this subsection.

1           “(B) SUBSEQUENT COMPLIANCE.—An ini-  
2           tiative subject to a waiver under paragraph (1)  
3           that is ongoing after the date on which the  
4           waiver expires, shall be subject to the require-  
5           ments of subchapter I of chapter 35 of title 44,  
6           United States Code, and the Secretary shall en-  
7           sure that compliance with such requirements  
8           occurs in as timely a manner as possible based  
9           on the applicable circumstances, but not to ex-  
10          ceed 30 calendar days after the expiration of  
11          the applicable waiver.”.

12 **SEC. 3088. CLARIFYING FOOD AND DRUG ADMINISTRATION**  
13 **EMERGENCY USE AUTHORIZATION.**

14          (a) AUTHORIZATION FOR MEDICAL PRODUCTS FOR  
15 USE IN EMERGENCIES.—Section 564 of the Federal Food,  
16 Drug, and Cosmetic Act (21 U.S.C. 360bbb-3) is amend-  
17 ed—

18           (1) in subsection (a)(2)—

19               (A) in subparagraph (A)—

20                   (i) by striking “or 515” and inserting  
21                   “512, or 515”; and

22                   (ii) by inserting “or conditionally ap-  
23                   proved under section 571 of this Act” after  
24                   “Public Health Service Act”; and

1 (B) in subparagraph (B), by inserting  
2 “conditionally approved under section 571,”  
3 after “approved,” each place the term appears;

4 (2) in subsection (b)(4), by striking the second  
5 comma after “determination”;

6 (3) in subsection (e)(3)(B), by striking “section  
7 503(b)” and inserting “subsection (b) or (f) of sec-  
8 tion 503 or under section 504”;

9 (4) in subsection (f)(2)—

10 (A) by inserting “, or an animal to which,”  
11 after “to a patient to whom”; and

12 (B) by inserting “or by the veterinarian  
13 caring for such animal, as applicable” after “at-  
14 tending physician”;

15 (5) in subsection (g)(1), by inserting “condi-  
16 tional approval under section 571,” after “ap-  
17 proval,”;

18 (6) in subsection (h)(1), by striking “or section  
19 520(g)” and inserting “512(j), or 520(g)”; and

20 (7) in subsection (k), by striking “section  
21 520(g),” and inserting “512(j), or 520(g)”.

22 (b) NEW ANIMAL DRUGS.—Section 512(a)(1) of the  
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
24 360b(a)(1)) is amended—

1 (1) in subparagraph (B), by striking “or” at  
2 the end;

3 (2) in subparagraph (C), by striking the period  
4 and inserting “; or”; and

5 (3) by inserting after subparagraph (C) the fol-  
6 lowing:

7 “(D) there is in effect an authorization pursu-  
8 ant to section 564 with respect to such use or in-  
9 tended use of such drug, and such drug, its labeling,  
10 and such use conform to any conditions of such au-  
11 thorization.”.

12 (c) EMERGENCY USE OF MEDICAL PRODUCTS.—Sec-  
13 tion 564A of the Federal Food, Drug, and Cosmetic Act  
14 (21 U.S.C. 360bbb–3a) is amended—

15 (1) in subsection (a)(1)(A), by inserting “, con-  
16 ditionally approved under section 571,” after “chap-  
17 ter”; and

18 (2) in subsection (d), by striking “sections  
19 503(b) and 520(e)” and inserting “subsections (b)  
20 and (f) of section 503, section 504, and section  
21 520(e)”.

22 (d) PRODUCTS HELD FOR EMERGENCY USE.—Sec-  
23 tion 564B(2) of the Federal Food, Drug, and Cosmetic  
24 Act (21 U.S.C. 360bbb–3b(2)) is amended—

25 (1) in subparagraph (A)—

1 (A) by inserting “or conditionally approved  
2 under section 571 of this Act” after “Public  
3 Health Service Act”; and

4 (B) by striking “or 515” and inserting  
5 “512, or 515”; and

6 (2) in subparagraph (B), by striking “or 520”  
7 and inserting “512, or 520”.

8 **Subtitle I—Vaccine Access,**  
9 **Certainty, and Innovation**

10 **SEC. 3091. PREDICTABLE REVIEW TIMELINES OF VACCINES**

11 **BY THE ADVISORY COMMITTEE ON IMMUNI-**  
12 **ZATION PRACTICES.**

13 (a) **CONSIDERATION OF NEW VACCINES.**—Upon the  
14 licensure of any vaccine or any new indication for a vac-  
15 cine, the Advisory Committee on Immunization Practices  
16 (in this section referred to as the “Advisory Committee”)  
17 shall, as appropriate, consider the use of the vaccine at  
18 its next regularly scheduled meeting.

19 (b) **ADDITIONAL INFORMATION.**—If the Advisory  
20 Committee does not make a recommendation with respect  
21 to the use of a vaccine at the Advisory Committee’s first  
22 regularly scheduled meeting after the licensure of the vac-  
23 cine or any new indication for the vaccine, the Advisory  
24 Committee shall provide an update on the status of such  
25 committee’s review.

1 (c) CONSIDERATION FOR BREAKTHROUGH THERA-  
2 PIES AND FOR POTENTIAL USE DURING PUBLIC HEALTH  
3 EMERGENCY.—The Advisory Committee shall make rec-  
4 ommendations with respect to the use of certain vaccines  
5 in a timely manner, as appropriate, including vaccines  
6 that—

7 (1) are designated as a breakthrough therapy  
8 under section 506 of the Federal Food, Drug, and  
9 Cosmetic Act (21 U.S.C. 356) and licensed under  
10 section 351 of the Public Health Service Act (42  
11 U.S.C. 262); or

12 (2) could be used in a public health emergency.

13 (d) DEFINITION.—In this section, the terms “Advi-  
14 sory Committee on Immunization Practices” and “Advi-  
15 sory Committee” mean the Advisory Committee on Immu-  
16 nization Practices established by the Secretary pursuant  
17 to section 222 of the Public Health Service Act (42 U.S.C.  
18 217a), acting through the Director of the Centers for Dis-  
19 ease Control and Prevention.”.

20 **SEC. 3092. REVIEW OF PROCESSES AND CONSISTENCY OF**  
21 **ADVISORY COMMITTEE ON IMMUNIZATION**  
22 **PRACTICES RECOMMENDATIONS.**

23 (a) REVIEW.—The Director of the Centers for Dis-  
24 ease Control and Prevention shall conduct a review of the  
25 processes used by the Advisory Committee on Immuniza-

1 tion Practices in formulating and issuing recommenda-  
2 tions pertaining to vaccines, including with respect to con-  
3 sistency.

4 (b) CONSIDERATIONS.—The review under subsection  
5 (a) shall include an assessment of—

6 (1) the criteria used to evaluate new and exist-  
7 ing vaccines, including the identification of any  
8 areas for which flexibility in evaluating such criteria  
9 is necessary and the reason for such flexibility;

10 (2) the Grading of Recommendations, Assess-  
11 ment, Development, and Evaluation (GRADE) ap-  
12 proach to the review and analysis of scientific and  
13 economic data, including the scientific basis for such  
14 approach; and

15 (3) the extent to which the processes used by  
16 the work groups of the Advisory Committee on Im-  
17 munization Practices are consistent among such  
18 groups, including the identification of reasons for  
19 any variation.

20 (c) STAKEHOLDERS.—In carrying out the review  
21 under subsection (a), the Director of the Centers for Dis-  
22 ease Control and Prevention shall solicit input from vac-  
23 cine stakeholders.

24 (d) REPORT.—Not later than 18 months after the  
25 date of enactment of this Act, the Director of the Centers

1 for Disease Control and Prevention shall submit to the  
2 appropriate committees of the Congress, and make pub-  
3 licly available, a report on the results of the review under  
4 subsection (a), including any recommendations on improv-  
5 ing the consistency of the processes described in such sub-  
6 section.

7 (e) DEFINITION.—In this section, the term “Advisory  
8 Committee on Immunization Practices” means the Advi-  
9 sory Committee on Immunization Practices established by  
10 the Secretary of Health and Human Services pursuant to  
11 section 222 of the Public Health Service Act (42 U.S.C.  
12 217a), acting through the Director of the Centers for Dis-  
13 ease Control and Prevention.

14 **SEC. 3093. ENCOURAGING VACCINE INNOVATION.**

15 (a) VACCINE MEETINGS.—The Director of the Cen-  
16 ters for Disease Control and Prevention shall ensure that  
17 appropriate staff within the relevant centers and divisions  
18 of the Office of Infectious Diseases, and others, as appro-  
19 priate, coordinate with respect to the public health needs,  
20 epidemiology, and program planning and implementation  
21 considerations related to immunization, including with re-  
22 gard to meetings with stakeholders related to such topics.

23 (b) REPORT ON VACCINE INNOVATION.—

24 (1) IN GENERAL.—Not later than 1 year after  
25 the date of enactment of this Act, the Secretary of



1 Health and Human Services (referred to in this sec-  
2 tion as the “Secretary”), in collaboration with ap-  
3 propriate agencies or offices within the Department  
4 of Health and Human Services, including the Na-  
5 tional Institutes of Health, the Centers for Disease  
6 Control and Prevention, the Food and Drug Admin-  
7 istration, and the Biomedical Advanced Research  
8 and Development Authority, shall submit to the  
9 Committee on Health, Education, Labor, and Pen-  
10 sions of the Senate and the Committee on Energy  
11 and Commerce of the House of Representatives, and  
12 post publicly on the Internet website of the Depart-  
13 ment of Health and Human Services, a report on  
14 ways to promote innovation in the development of  
15 vaccines that minimize the burden of infectious dis-  
16 ease.

17 (2) CONTENTS.—The report described in para-  
18 graph (1) shall review the current status of vaccine  
19 development and, as appropriate—

20 (A) consider the optimal process to deter-  
21 mine which vaccines would be beneficial to pub-  
22 lic health and how information on such vaccines  
23 is disseminated to key stakeholders;

1 (B) examine and identify whether obstacles  
2 exist that inhibit the development of beneficial  
3 vaccines; and

4 (C) make recommendations about how best  
5 to remove any obstacles identified under sub-  
6 paragraph (B) in order to promote and  
7 incentivize vaccine innovation and development.

8 (3) CONSULTATION.—In preparing the report  
9 under this subsection, the Secretary may consult  
10 with—

11 (A) representatives of relevant Federal  
12 agencies and departments, including the De-  
13 partment of Defense and the Department of  
14 Veterans Affairs;

15 (B) academic researchers;

16 (C) developers and manufacturers of vac-  
17 cines;

18 (D) medical and public health practi-  
19 tioners;

20 (E) representatives of patient, policy, and  
21 advocacy organizations; and

22 (F) representatives of other entities, as the  
23 Secretary determines appropriate.

24 (c) UPDATES RELATED TO MATERNAL IMMUNIZA-  
25 TION.—

1           (1) ADDITIONAL VACCINES.—Section 2114(e)  
2 of the Public Health Service Act (42 U.S.C. 300aa–  
3 14(e)) is amended by adding at the end the fol-  
4 lowing:

5           “(3) VACCINES RECOMMENDED FOR USE IN  
6 PREGNANT WOMEN.—The Secretary shall revise the  
7 Vaccine Injury Table included in subsection (a),  
8 through the process described in subsection (c), to  
9 include vaccines recommended by the Centers for  
10 Disease Control and Prevention for routine adminis-  
11 tration in pregnant women and the information de-  
12 scribed in subparagraphs (B) and (C) of paragraph  
13 (2) with respect to such vaccines.”.

14           (2) PETITION CONTENT.—Section 2111 of the  
15 Public Health Service Act (42 U.S.C. 300aa–11) is  
16 amended by adding at the end the following:

17           “(f) MATERNAL IMMUNIZATION.—

18           “(1) IN GENERAL.—Notwithstanding any other  
19 provision of law, for purposes of this subtitle, both  
20 a woman who received a covered vaccine while preg-  
21 nant and any child who was in utero at the time  
22 such woman received the vaccine shall be considered  
23 persons to whom the covered vaccine was adminis-  
24 tered and persons who received the covered vaccine.

1           “(2) DEFINITION.—As used in this subsection,  
2           the term ‘child’ shall have the meaning given that  
3           term by subsections (a) and (b) of section 8 of title  
4           1, United States Code, except that, for purposes of  
5           this subsection, such section 8 shall be applied as if  
6           the term ‘include’ in subsection (a) of such section  
7           were replaced with the term ‘mean’.”

8           (3) PETITIONERS.—Section 2111(b)(2) of the  
9           Public Health Service Act (42 U.S.C. 300aa–  
10          11(b)(2)) is amended by adding “A covered vaccine  
11          administered to a pregnant woman shall constitute  
12          more than one administration, one to the mother  
13          and one to each child (as such term is defined in  
14          subsection (f)(2)) who was in utero at the time such  
15          woman was administered the vaccine.” at the end.

## 16   **Subtitle J—Technical Corrections**

### 17   **SEC. 3101. TECHNICAL CORRECTIONS.**

18          (a) FFDCA.—

19               (1) REFERENCES.—Except as otherwise ex-  
20               pressly provided, whenever in this subsection an  
21               amendment is expressed in terms of an amendment  
22               to a section or other provision, the reference shall be  
23               considered to be made to that section or other provi-  
24               sion of the Federal Food, Drug, and Cosmetic Act  
25               (21 U.S.C. 301 et seq.).

1 (2) AMENDMENTS.—

2 (A) PROHIBITED ACTS.—Section 301(r)  
3 (21 U.S.C. 331(r)) is amended by inserting “,  
4 drug,” after “device” each place the term ap-  
5 pears.

6 (B) NEW DRUGS.—Section 505 (21 U.S.C.  
7 355) is amended—

8 (i) in subsection (d), in the last sen-  
9 tence, by striking “premarket approval”  
10 and inserting “marketing approval”; and

11 (ii) in subsection (q)(5)(A), by strik-  
12 ing “subsection (b)(2) or (j) of the Act or  
13 351(k)” and inserting “subsection (b)(2)  
14 or (j) of this section or section 351(k)”.

15 (C) RISK EVALUATION AND MITIGATION  
16 STRATEGIES.—Section 505–1(h)(21 U.S.C.  
17 355–1(h)) is amended—

18 (i) in paragraph (2)(A)(iii)—

19 (I) in the clause heading, by  
20 striking “LABEL” and inserting “LA-  
21 BELING”;

22 (II) by striking “label” each  
23 place the term appears and inserting  
24 “labeling”; and

1 (III) by striking “sponsor” and  
2 inserting “responsible person”; and  
3 (ii) in paragraph (8), by striking “and  
4 (7).” and inserting “and (7)”.

5 (D) PEDIATRIC STUDY PLANS.—Section  
6 505B (21 U.S.C. 355c) is amended—

7 (i) in subsection (e)—

8 (I) in paragraph (2)—

9 (aa) in subparagraph (A),  
10 by inserting “study” after “ini-  
11 tial pediatric” each place the  
12 term appears; and

13 (bb) in subparagraph (B), in  
14 the subparagraph heading, by  
15 striking “INITIAL PLAN” and in-  
16 serting “INITIAL PEDIATRIC  
17 STUDY PLAN”;

18 (II) in paragraph (5), in the  
19 paragraph heading, by inserting  
20 “AGREED INITIAL PEDIATRIC STUDY”  
21 before “PLAN”; and

22 (III) in paragraph (6), by strik-  
23 ing “agreed initial pediatric plan” and  
24 inserting “agreed initial pediatric  
25 study plan”; and

1 (ii) in subsection (f)(1), by inserting  
2 “and any significant amendments to such  
3 plans,” after “agreed initial pediatric study  
4 plans,”.

5 (E) DISCONTINUANCE OR INTERRUPTION  
6 IN THE PRODUCTION OF LIVE-SAVING DRUGS.—  
7 Section 506C (21 U.S.C. 356c) is amended—

8 (i) in subsection (e), by striking “dis-  
9 continuation” and inserting “discontinu-  
10 ance”; and

11 (ii) in subsection (g)(1), by striking  
12 “section 505(j) that could help” and in-  
13 serting “section 505(j), that could help”.

14 (F) ANNUAL REPORTING ON DRUG SHORT-  
15 AGES.—Section 506C–1(a) (21 U.S.C. 331(a))  
16 is amended, in the matter before paragraph  
17 (1)—

18 (i) by striking “Not later than the end  
19 of calendar year 2013, and not later than  
20 the end of each calendar year thereafter,”  
21 and inserting “Not later than March 31 of  
22 each calendar year,”; and

23 (ii) by inserting “, with respect to the  
24 preceding calendar year,” after “a report”.

1 (G) DRUG SHORTAGE LIST.—Section  
2 506E(b)(3)(E) (21 U.S.C. 356e(b)(3)(E)) is  
3 amended by striking “discontinuation” and in-  
4 serting “discontinuance”.

5 (H) INSPECTIONS OF ESTABLISHMENTS.—  
6 Section 510(h) (21 U.S.C. 360(h)) is amend-  
7 ed—

8 (i) in paragraph (4), in the matter  
9 preceding subparagraph (A), by striking  
10 “establishing the risk-based scheduled”  
11 and inserting “establishing a risk-based  
12 schedule”; and

13 (ii) in paragraph (6)—

14 (I) in subparagraph (A), by strik-  
15 ing “fiscal” and inserting “calendar”  
16 each place the term appears; and

17 (II) in subparagraph (B), by  
18 striking “an active ingredient of a  
19 drug, a finished drug product, or an  
20 excipient of a drug” and inserting “an  
21 active ingredient of a drug or a fin-  
22 ished drug product”.

23 (I) CLASSIFICATION OF DEVICES IN-  
24 TENDED FOR HUMAN USE.—Section



1           513(f)(2)(A) (21 U.S.C. 360c(f)(2)(A)) is  
2 amended—

3           (i) in clause (i), by striking “within  
4 30 days”; and

5           (ii) in clause (iv), by striking “low-  
6 moderate” and inserting “low to mod-  
7 erate”.

8           (J) PREMARKET APPROVAL.—Section  
9 515(a)(1) (21 U.S.C. 360e(a)(1)) is amended  
10 by striking “subject to a an order” and insert-  
11 ing “subject to an order”.

12           (K) PROGRAM TO IMPROVE THE DEVICE  
13 RECALL SYSTEM.—Section 518A (21 U.S.C.  
14 360h–1) is amended—

15           (i) by striking subsection (c); and

16           (ii) by redesignating subsection (d) as  
17 subsection (c).

18           (L) UNIQUE DEVICE IDENTIFIER.—Section  
19 519(f) (21 U.S.C. 360i(f)) is amended by strik-  
20 ing “and life sustaining” and inserting “or life  
21 sustaining”.

22           (M) PRIORITY REVIEW TO ENCOURAGE  
23 TREATMENTS FOR TROPICAL DISEASES.—Sec-  
24 tion 524(c)(4)(A) of the Federal Food, Drug,  
25 and Cosmetic Act (21 U.S.C. 360n(c)(4)(A)) is

1 amended by striking “Services Act” and insert-  
2 ing “Service Act”.

3 (N) PRIORITY REVIEW FOR QUALIFIED IN-  
4 FECTIOUS DISEASE PRODUCTS.—Section 524A  
5 (21 U.S.C. 360n–1) is amended—

6 (i) by striking “If the Secretary” and  
7 inserting the following:

8 “(a) IN GENERAL.—If the Secretary”;

9 (ii) by striking “any” and inserting  
10 “the first”; and

11 (iii) by adding at the end the fol-  
12 lowing:

13 “(b) CONSTRUCTION.—Nothing in this section shall  
14 prohibit the Secretary from giving priority review to a  
15 human drug application or efficacy supplement submitted  
16 for approval under section 505(b) that otherwise meets the  
17 criteria for the Secretary to grant priority review.”.

18 (O) CONSULTATION WITH EXTERNAL EX-  
19 PERTS ON RARE DISEASES, TARGETED THERA-  
20 PIES, AND GENETIC TARGETING OF TREAT-  
21 MENTS.—Section 569(a)(2)(A) (21 U.S.C.  
22 360bbb–8(a)(2)(A)) is amended, in the first  
23 sentence, by striking “subsection (c)” and in-  
24 serting “subsection (b)”.

1 (P) OPTIMIZING GLOBAL CLINICAL  
2 TRIALS.—Section 569A(c) (21 U.S.C. 360bbb–  
3 8a(c)) is amended by inserting “or under the  
4 Public Health Service Act” after “this Act”.

5 (Q) USE OF CLINICAL INVESTIGATION  
6 DATA FROM OUTSIDE THE UNITED STATES.—  
7 Section 569B (21 U.S.C. 360bbb–8b) is amend-  
8 ed by striking “drug or device” and inserting  
9 “drug, biological product, or device” each place  
10 the term appears.

11 (R) MEDICAL GASES DEFINITIONS.—Sec-  
12 tion 575(1)(H) (21 U.S.C. 360ddd(1)(H)) is  
13 amended—

14 (i) by inserting “for a new drug” after  
15 “any period of exclusivity”; and

16 (ii) by inserting “or any period of ex-  
17 clusivity for a new animal drug under sec-  
18 tion 512(c)(2)(F),” after “section 505A,”.

19 (S) REGULATION OF MEDICAL GASES.—  
20 Section 576(a) (21 U.S.C. 360ddd–1(a)) is  
21 amended—

22 (i) in the matter preceding subpara-  
23 graph (A) of paragraph (1), by inserting  
24 “who seeks to initially introduce or deliver  
25 for introduction a designated medical gas

1                   into interstate commerce” after “any per-  
2                   son”; and

3                   (ii) in paragraph (3)—

4                   (I) in subparagraph (A)—

5                   (aa) in clause (i)(VIII), by  
6                   inserting “for a new drug” after  
7                   “any period of exclusivity”; and

8                   (bb) in clause (ii), in the  
9                   matter preceding subclause (I),  
10                  by inserting “the” before “final  
11                  use”; and

12                  (II) in subparagraph (B)—

13                  (aa) in clause (i), by insert-  
14                  ing “for a new drug” after “any  
15                  period of exclusivity”; and

16                  (bb) in clause (ii), by insert-  
17                  ing a comma after “drug prod-  
18                  uct”.

19                  (T) INAPPLICABILITY OF DRUG FEES TO  
20                  DESIGNATED MEDICAL GASES.—Section 577  
21                  (21 U.S.C. 360ddd–2) is amended by inserting  
22                  “or 740(a)” after “section 736(a)”.

23                  (U) CONFLICTS OF INTEREST.—Section  
24                  712(e)(1)(B) (21 U.S.C. 379d–1(e)(1)(B)) is

1 amended by striking “services” and inserting  
2 “service”.

3 (V) AUTHORITY TO ASSESS AND USE BIO-  
4 SIMILAR BIOLOGICAL PRODUCT FEES.—Section  
5 744H(a) (21 U.S.C. 379j–52(a)) is amended—

6 (i) in paragraph (1)(A)(v), by striking  
7 “Biosimilars User Fee Act of 2012” and  
8 inserting “Biosimilar User Fee Act of  
9 2012”; and

10 (ii) in paragraph (2)(B), by striking  
11 “Biosimilars User Fee Act of 2012” and  
12 inserting “Biosimilar User Fee Act of  
13 2012”.

14 (W) REGISTRATION OF COMMERCIAL IM-  
15 PORTERS.—

16 (i) AMENDMENT.—Section 801(s)(2)  
17 (21 U.S.C. 381(s)(2)) is amended by add-  
18 ing at the end the following:

19 “(D) EFFECTIVE DATE.—In establishing  
20 the effective date of the regulations under sub-  
21 paragraph (A), the Secretary shall, in consulta-  
22 tion with the Secretary of Homeland Security  
23 acting through U.S. Customs and Border Pro-  
24 tection, as determined appropriate by the Sec-  
25 retary of Health and Human Services, provide

1 a reasonable period of time for an importer of  
2 a drug to comply with good importer practices,  
3 taking into account differences among import-  
4 ers and types of imports, including based on the  
5 level of risk posed by the imported product.”.

6 (ii) CONFORMING AMENDMENT.—Sec-  
7 tion 714 of the Food and Drug Adminis-  
8 tration Safety and Innovation Act (Public  
9 Law 112–144; 126 Stat. 1074) is amended  
10 by striking subsection (d).

11 (X) RECOGNITION OF FOREIGN GOVERN-  
12 MENT INSPECTIONS.—Section 809(a)(2) (21  
13 U.S.C. 384e(a)(2)) is amended by striking  
14 “conduction” and inserting “conducting”.

15 (b) FDASIA.—

16 (1) FINDINGS RELATING TO DRUG AP-  
17 PROVAL.—Section 901(a)(1)(A) of the Food and  
18 Drug Administration Safety and Innovation Act  
19 (Public Law 112–144; 21 U.S.C. 356 note) is  
20 amended by striking “serious and life-threatening  
21 diseases” and inserting “serious or life-threatening  
22 diseases”.

23 (2) REPORTING OF INCLUSION OF DEMO-  
24 GRAPHIC SUBGROUPS.—Section 907 of the Food and  
25 Drug Administration Safety and Innovation Act

1 (Public Law 112–144; 126 Stat. 1092, 1093) is  
2 amended—

3 (A) in the section heading, by striking  
4 “**BIOLOGICS**” in the heading and inserting  
5 “**BIOLOGICAL PRODUCTS**”; and

6 (B) in subsection (a)(2)(B), by striking  
7 “applications for new drug applications” and  
8 inserting “new drug applications”.

9 (3) **COMBATING PRESCRIPTION DRUG ABUSE.**—  
10 Section 1122 of the Food and Drug Administration  
11 Safety and Innovation Act (Public Law 112–144;  
12 126 Stat. 1112, 1113) is amended—

13 (A) in subsection (a)(2), by striking  
14 “dependance” and inserting “dependence”; and

15 (B) in subsection (c), by striking “promul-  
16 gate” and inserting “issue”.

17 **SEC. 3102. COMPLETED STUDIES.**

18 The Federal Food, Drug, and Cosmetic Act is amend-  
19 ed—

20 (1) in section 505(k)(5) (21 U.S.C.  
21 355(k)(5))—

22 (A) in subparagraph (A), by inserting  
23 “and” after the semicolon;

24 (B) by striking subparagraph (B); and

1 (C) by redesignating subparagraph (C) as  
2 subparagraph (B);  
3 (2) in section 505A (21 U.S.C. 355a), by strik-  
4 ing subsection (p);  
5 (3) in section 505B (21 U.S.C. 355c)—  
6 (A) by striking subsection (l); and  
7 (B) by redesignating subsection (m) as  
8 subsection (l); and  
9 (4) in section 523 (21 U.S.C. 360m), by strik-  
10 ing subsection (d).

## 11 **TITLE IV—DELIVERY**

### 12 **SEC. 4001. ASSISTING DOCTORS AND HOSPITALS IN IM-** 13 **PROVING QUALITY OF CARE FOR PATIENTS.**

14 (a) **IN GENERAL.**—The Health Information Tech-  
15 nology for Economic and Clinical Health Act (title XIII  
16 of division A of Public Law 111–5) is amended—

17 (1) by adding at the end of part 1 of subtitle  
18 A the following:

### 19 **“SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IM-** 20 **PROVING QUALITY OF CARE FOR PATIENTS.**

21 **“(a) REDUCTION IN BURDENS GOAL.**—The Sec-  
22 retary of Health and Human Services (referred to in this  
23 section as the ‘Secretary’), in consultation with providers  
24 of health services, health care suppliers of services, health  
25 care payers, health professional societies, health informa-



1 tion technology developers, health care quality organiza-  
2 tions, health care accreditation organizations, public  
3 health entities, States, and other appropriate entities,  
4 shall, in accordance with subsection (b)—

5           “(1) establish a goal with respect to the reduc-  
6 tion of regulatory or administrative burdens (such as  
7 documentation requirements) relating to the use of  
8 electronic health records;

9           “(2) develop a strategy for meeting the goal es-  
10 tablished under paragraph (1); and

11           “(3) develop recommendations for meeting the  
12 goal established under paragraph (1).

13           “(b) STRATEGY AND RECOMMENDATIONS.—

14           “(1) IN GENERAL.—To achieve the goal estab-  
15 lished under subsection (a)(1), the Secretary, in con-  
16 sultation with the entities described in such sub-  
17 section, shall, not later than 1 year after the date  
18 of enactment of the 21st Century Cures Act, develop  
19 a strategy and recommendations to meet the goal in  
20 accordance with this subsection.

21           “(2) STRATEGY.—The strategy developed under  
22 paragraph (1) shall address the regulatory and ad-  
23 ministrative burdens (such as documentation re-  
24 quirements) relating to the use of electronic health

1 records. Such strategy shall include broad public  
2 comment and shall prioritize—

3 “(A)(i) incentives for meaningful use of  
4 certified EHR technology for eligible profes-  
5 sionals and hospitals under sections 1848(a)(7)  
6 and 1886(b)(3)(B)(ix), respectively, of the So-  
7 cial Security Act (42 U.S.C. 1395w–4(a)(7),  
8 1395ww(b)(3)(B)(ix));

9 “(ii) the program for making payments  
10 under section 1903(a)(3)(F) of the Social Secu-  
11 rity Act (42 U.S.C. 1396b(a)(3)(F)) to encour-  
12 age the adoption and use of certified EHR  
13 technology by Medicaid providers;

14 “(iii) the Merit-based Incentive Payment  
15 System under section 1848(q) of the Social Se-  
16 curity Act (42 U.S.C. 1395w–4(q));

17 “(iv) alternative payment models (as de-  
18 fined in section 1833(z)(3)(C) of the Social Se-  
19 curity Act (42 U.S.C. 1395l(z)(3)(C));

20 “(v) the Hospital Value-Based Purchasing  
21 Program under section 1886(o) of the Social  
22 Security Act (42 U.S.C. 1395ww(o)); and

23 “(vi) other value-based payment programs,  
24 as the Secretary determines appropriate;

1           “(B) health information technology certifi-  
2           cation;

3           “(C) standards and implementation speci-  
4           fications, as appropriate;

5           “(D) activities that provide individuals ac-  
6           cess to their electronic health information;

7           “(E) activities related to protecting the  
8           privacy of electronic health information;

9           “(F) activities related to protecting the se-  
10          curity of electronic health information;

11          “(G) activities related to facilitating health  
12          and clinical research;

13          “(H) activities related to public health;

14          “(I) activities related to aligning and sim-  
15          plifying quality measures across Federal pro-  
16          grams and other payers;

17          “(J) activities related to reporting clinical  
18          data for administrative purposes; and

19          “(K) other areas, as the Secretary deter-  
20          mines appropriate.

21          “(3) RECOMMENDATIONS.—The recommenda-  
22          tions developed under paragraph (1) shall address—

23                 “(A) actions that improve the clinical doc-  
24                 umentation experience;

25                 “(B) actions that improve patient care;

1           “(C) actions to be taken by the Secretary  
2           and by other entities; and

3           “(D) other areas, as the Secretary deter-  
4           mines appropriate, to reduce the reporting bur-  
5           den required of health care providers.

6           “(4) FACA.—The Federal Advisory Committee  
7           Act (5 U.S.C. App.) shall not apply to the develop-  
8           ment of the goal, strategies, or recommendations de-  
9           scribed in this section.

10          “(c) APPLICATION OF CERTAIN REGULATORY RE-  
11          QUIREMENTS.—A physician (as defined in section  
12          1861(r)(1) of the Social Security Act), to the extent con-  
13          sistent with applicable State law, may delegate electronic  
14          medical record documentation requirements specified in  
15          regulations promulgated by the Centers for Medicare &  
16          Medicaid Services to a person performing a scribe function  
17          who is not such physician if such physician has signed and  
18          verified the documentation.”; and

19                 (2) in the table of contents in section 13001(b),  
20          by inserting after the item relating to section 13102  
21          the following:

                  “13103. Assisting doctors and hospitals in improving the quality and care for  
                  patients.”.

22          (b) CERTIFICATION OF HEALTH INFORMATION  
23          TECHNOLOGY FOR MEDICAL SPECIALTIES AND SITES OF  
24          SERVICE.—Section 3001(c)(5) of the Public Health Serv-

1 ice Act (42 U.S.C. 300jj–11(e)(5)) is amended by adding  
2 at the end the following:

3 “(C) HEALTH INFORMATION TECHNOLOGY  
4 FOR MEDICAL SPECIALTIES AND SITES OF  
5 SERVICE.—

6 “(i) IN GENERAL.—The National Co-  
7 ordinator shall encourage, keep, or recog-  
8 nize, through existing authorities, the vol-  
9 untary certification of health information  
10 technology under the program developed  
11 under subparagraph (A) for use in medical  
12 specialties and sites of service for which no  
13 such technology is available or where more  
14 technological advancement or integration is  
15 needed.

16 “(ii) SPECIFIC MEDICAL SPECIAL-  
17 TIES.—The Secretary shall accept public  
18 comment on specific medical specialties  
19 and sites of service, in addition to those  
20 described in clause (i), for the purpose of  
21 selecting additional specialties and sites of  
22 service as necessary.

23 “(iii) HEALTH INFORMATION TECH-  
24 NOLOGY FOR PEDIATRICS.—Not later than  
25 18 months after the date of enactment of

1 the 21st Century Cures Act, the Secretary,  
2 in consultation with relevant stakeholders,  
3 shall make recommendations for the vol-  
4 untary certification of health information  
5 technology for use by pediatric health pro-  
6 viders to support the health care of chil-  
7 dren. Not later than 2 years after the date  
8 of enactment of the 21st Century Cures  
9 Act, the Secretary shall adopt certification  
10 criteria under section 3004 to support the  
11 voluntary certification of health informa-  
12 tion technology for use by pediatric health  
13 providers to support the health care of  
14 children.”.

15 (c) MEANINGFUL USE STATISTICS.—

16 (1) IN GENERAL.—Not later than 6 months  
17 after the date of enactment of this Act, the Sec-  
18 retary of Health and Human Services shall submit  
19 to the HIT Advisory Committee of the Office of the  
20 National Coordinator for Health Information Tech-  
21 nology, a report concerning attestation statistics for  
22 the Medicare and Medicaid EHR Meaningful Use  
23 Incentive programs to assist in informing standards  
24 adoption and related practices. Such statistics shall  
25 include attestation information delineated by State,

1 including, to the extent practicable, the number of  
2 providers who did not meet the minimum criteria  
3 necessary to attest for the Medicare and Medicaid  
4 EHR Meaningful Use Incentive programs for a cal-  
5 endar year, and shall be made publicly available on  
6 the Internet website of the Secretary on at least a  
7 quarterly basis.

8 (2) **AUTHORITY TO ALTER FORMAT.**—The Sec-  
9 retary of Health and Human Services may alter the  
10 format of the reports on the attestation of eligible  
11 health care professionals following the first perform-  
12 ance year of the Merit-based Incentive Payment Sys-  
13 tem to account for changes arising from the imple-  
14 mentation of such payment system.

15 **SEC. 4002. TRANSPARENT REPORTING ON USABILITY, SE-**  
16 **CURITY, AND FUNCTIONALITY.**

17 (a) **ENHANCEMENTS TO CERTIFICATION.**—Section  
18 3001(c)(5) of the Public Health Service Act (42 U.S.C.  
19 300jj–11), as amended by section 4001(b), is further  
20 amended by adding at the end the following:

21 “(D) **CONDITIONS OF CERTIFICATION.**—  
22 Not later than 1 year after the date of enact-  
23 ment of the 21st Century Cures Act, the Sec-  
24 retary, through notice and comment rule-  
25 making, shall require, as a condition of certifi-

1 cation and maintenance of certification for pro-  
2 grams maintained or recognized under this  
3 paragraph, consistent with other conditions and  
4 requirements under this title, that the health  
5 information technology developer or entity—

6 “(i) does not take any action that con-  
7 stitutes information blocking as defined in  
8 section 3022(a);

9 “(ii) provides assurances satisfactory  
10 to the Secretary that such developer or en-  
11 tity, unless for legitimate purposes speci-  
12 fied by the Secretary, will not take any ac-  
13 tion described in clause (i) or any other ac-  
14 tion that may inhibit the appropriate ex-  
15 change, access, and use of electronic health  
16 information;

17 “(iii) does not prohibit or restrict  
18 communication regarding—

19 “(I) the usability of the health  
20 information technology;

21 “(II) the interoperability of the  
22 health information technology;

23 “(III) the security of the health  
24 information technology;



1                   “(IV) relevant information re-  
2                   garding users’ experiences when using  
3                   the health information technology;

4                   “(V) the business practices of de-  
5                   velopers of health information tech-  
6                   nology related to exchanging elec-  
7                   tronic health information; and

8                   “(VI) the manner in which a user  
9                   of the health information technology  
10                  has used such technology;

11                  “(iv) has published application pro-  
12                  gramming interfaces and allows health in-  
13                  formation from such technology to be  
14                  accessed, exchanged, and used without spe-  
15                  cial effort through the use of application  
16                  programming interfaces or successor tech-  
17                  nology or standards, as provided for under  
18                  applicable law, including providing access  
19                  to all data elements of a patient’s elec-  
20                  tronic health record to the extent permis-  
21                  sible under applicable privacy laws;

22                  “(v) has successfully tested the real  
23                  world use of the technology for interoper-  
24                  ability (as defined in section 3000) in the

1 type of setting in which such technology  
2 would be marketed;

3 “(vi) provides to the Secretary an at-  
4 testation that the developer or entity—

5 “(I) has not engaged in any of  
6 the conduct described in clause (i);

7 “(II) has provided assurances  
8 satisfactory to the Secretary in ac-  
9 cordance with clause (ii);

10 “(III) does not prohibit or re-  
11 strict communication as described in  
12 clause (iii);

13 “(IV) has published information  
14 in accordance with clause (iv);

15 “(V) ensures that its technology  
16 allows for health information to be ex-  
17 changed, accessed, and used, in the  
18 manner described in clause (iv); and

19 “(VI) has undertaken real world  
20 testing as described in clause (v); and

21 “(vii) submits reporting criteria in ac-  
22 cordance with section 3009A(b).”.

23 “(E) COMPLIANCE WITH CONDITIONS OF  
24 CERTIFICATION.—The Secretary may encourage  
25 compliance with the conditions of certification

1 described in subparagraph (D) and take action  
2 to discourage noncompliance, as appropriate.”.

3 (b) EHR SIGNIFICANT HARDSHIP EXCEPTION.—

4 (1) APPLICATION TO ELIGIBLE PROFES-  
5 SIONALS.—

6 (A) IN CASE OF DECERTIFICATION.—Sec-  
7 tion 1848(a)(7)(B) of the Social Security Act  
8 (42 U.S.C. 1395w-4(a)(7)(B)) is amended by  
9 inserting after the first sentence the following  
10 new sentence: “The Secretary shall exempt an  
11 eligible professional from the application of the  
12 payment adjustment under subparagraph (A)  
13 with respect to a year, subject to annual re-  
14 newal, if the Secretary determines that compli-  
15 ance with the requirement for being a meaning-  
16 ful EHR user is not possible because the cer-  
17 tified EHR technology used by such profes-  
18 sional has been decertified under a program  
19 kept or recognized pursuant to section  
20 3001(c)(5) of the Public Health Service Act.”.

21 (B) CONTINUED APPLICATION UNDER  
22 MIPS.—Section 1848(o)(2)(D) of the Social Se-  
23 curity Act (42 U.S.C. 1395w-4(o)(2)(D)) is  
24 amended by adding at the end the following  
25 new sentence: “The provisions of subparagraphs

1 (B) and (D) of subsection (a)(7), shall apply to  
2 assessments of MIPS eligible professionals  
3 under subsection (q) with respect to the per-  
4 formance category described in subsection  
5 (q)(2)(A)(iv) in an appropriate manner which  
6 may be similar to the manner in which such  
7 provisions apply with respect to payment ad-  
8 justments made under subsection (a)(7)(A).”.

9 (2) APPLICATION TO ELIGIBLE HOSPITALS.—

10 Section 1886(b)(3)(B)(ix)(II) of the Social Security  
11 Act (42 U.S.C. 1395ww(b)(3)(B)(ix)(II)) is amended  
12 by inserting after the first sentence the following  
13 new sentence: “The Secretary shall exempt an eligi-  
14 ble hospital from the application of the payment ad-  
15 justment under subclause (I) with respect to a fiscal  
16 year, subject to annual renewal, if the Secretary de-  
17 termines that compliance with the requirement for  
18 being a meaningful EHR user is not possible be-  
19 cause the certified EHR technology used by such  
20 hospital is decertified under a program kept or rec-  
21 ognized pursuant to section 3001(c)(5) of the Public  
22 Health Service Act.”.

23 (c) ELECTRONIC HEALTH RECORD REPORTING PRO-  
24 GRAM.—Subtitle A of title XXX of the Public Health

1 Service Act (42 U.S.C. 300jj–11 et seq.) is amended by  
2 adding at the end the following:

3 **“SEC. 3009A. ELECTRONIC HEALTH RECORD REPORTING**  
4 **PROGRAM.**

5 “(a) REPORTING CRITERIA.—

6 “(1) CONVENING OF STAKEHOLDERS.—Not  
7 later than 1 year after the date of enactment of the  
8 21st Century Cures Act, the Secretary shall convene  
9 stakeholders, as described in paragraph (2), for the  
10 purpose of developing the reporting criteria in ac-  
11 cordance with paragraph (3).

12 “(2) DEVELOPMENT OF REPORTING CRI-  
13 TERIA.—The reporting criteria under this subsection  
14 shall be developed through a public, transparent  
15 process that reflects input from relevant stake-  
16 holders, including—

17 “(A) health care providers, including pri-  
18 mary care and specialty care health care profes-  
19 sionals;

20 “(B) hospitals and hospital systems;

21 “(C) health information technology devel-  
22 opers;

23 “(D) patients, consumers, and their advo-  
24 cates;

1           “(E) data sharing networks, such as health  
2 information exchanges;

3           “(F) authorized certification bodies and  
4 testing laboratories;

5           “(G) security experts;

6           “(H) relevant manufacturers of medical  
7 devices;

8           “(I) experts in health information tech-  
9 nology market economics;

10           “(J) public and private entities engaged in  
11 the evaluation of health information technology  
12 performance;

13           “(K) quality organizations, including the  
14 consensus based entity described in section  
15 1890 of the Social Security Act;

16           “(L) experts in human factors engineering  
17 and the measurement of user-centered design;  
18 and

19           “(M) other entities or individuals, as the  
20 Secretary determines appropriate.

21           “(3) CONSIDERATIONS FOR REPORTING CRI-  
22 TERIA.—The reporting criteria developed under this  
23 subsection—

24           “(A) shall include measures that reflect  
25 categories including—

- 1 “(i) security;
- 2 “(ii) usability and user-centered de-
- 3 sign;
- 4 “(iii) interoperability;
- 5 “(iv) conformance to certification test-
- 6 ing; and
- 7 “(v) other categories, as appropriate
- 8 to measure the performance of electronic
- 9 health record technology;
- 10 “(B) may include categories such as—
- 11 “(i) enabling the user to order and
- 12 view the results of laboratory tests, imag-
- 13 ing tests, and other diagnostic tests;
- 14 “(ii) submitting, editing, and retriev-
- 15 ing data from registries such as clinician-
- 16 led clinical data registries;
- 17 “(iii) accessing and exchanging infor-
- 18 mation and data from and through health
- 19 information exchanges;
- 20 “(iv) accessing and exchanging infor-
- 21 mation and data from medical devices;
- 22 “(v) accessing and exchanging infor-
- 23 mation and data held by Federal, State,
- 24 and local agencies and other applicable en-
- 25 tities useful to a health care provider or

1 other applicable user in the furtherance of  
2 patient care;

3 “(vi) accessing and exchanging infor-  
4 mation from other health care providers or  
5 applicable users;

6 “(vii) accessing and exchanging pa-  
7 tient generated information;

8 “(viii) providing the patient or an au-  
9 thorized designee with a complete copy of  
10 their health information from an electronic  
11 record in a computable format;

12 “(ix) providing accurate patient infor-  
13 mation for the correct patient, including  
14 exchanging such information, and avoiding  
15 the duplication of patients records; and

16 “(x) other categories regarding per-  
17 formance, accessibility, as the Secretary  
18 determines appropriate; and

19 “(C) shall be designed to ensure that small  
20 and startup health information technology de-  
21 velopers are not unduly disadvantaged by the  
22 reporting criteria.

23 “(4) MODIFICATIONS.—After the reporting cri-  
24 teria have been developed under paragraph (3), the  
25 Secretary may convene stakeholders and conduct a



1 public comment period for the purpose of modifying  
2 the reporting criteria developed under such para-  
3 graph.

4 “(b) PARTICIPATION.—As a condition of maintaining  
5 certification under section 3001(e)(5)(D), a developer of  
6 certified electronic health records shall submit to an ap-  
7 propriate recipient of a grant, contract, or agreement  
8 under subsection (c)(1) responses to the criteria developed  
9 under subsection (a), with respect to all certified tech-  
10 nology offered by such developer.

11 “(c) REPORTING PROGRAM.—

12 “(1) IN GENERAL.—Not later than 1 year after  
13 the date of enactment of the 21st Century Cures  
14 Act, the Secretary shall award grants, contracts, or  
15 agreements to independent entities on a competitive  
16 basis to support the convening of stakeholders as de-  
17 scribed in subsection (a)(2), collect the information  
18 required to be reported in accordance with the cri-  
19 teria established as described subsection (a)(3), and  
20 develop and implement a process in accordance with  
21 paragraph (5) and report such information to the  
22 Secretary.

23 “(2) APPLICATIONS.—An independent entity  
24 that seeks a grant, contract, or agreement under  
25 this subsection shall submit an application to the

1 Secretary at such time, in such manner, and con-  
2 taining such information as the Secretary may rea-  
3 sonably require, including a description of—

4 “(A) the proposed method for reviewing  
5 and summarizing information gathered based  
6 on reporting criteria established under sub-  
7 section (a);

8 “(B) if applicable, the intended focus on a  
9 specific subset of certified electronic health  
10 record technology users, such as health care  
11 providers, including primary care, specialty  
12 care, and care provided in rural settings; hos-  
13 pitals and hospital systems; and patients, con-  
14 sumers, and patients and consumer advocates;

15 “(C) the plan for widely distributing re-  
16 ports described in paragraph (6);

17 “(D) the period for which the grant, con-  
18 tract, or agreement is requested, which may be  
19 up to 2 years; and

20 “(E) the budget for reporting program  
21 participation, and whether the eligible inde-  
22 pendent entity intends to continue participation  
23 after the period of the grant, contract, or agree-  
24 ment.

1           “(3) CONSIDERATIONS FOR INDEPENDENT EN-  
2           TITIES.—In awarding grants, contracts, and agree-  
3           ments under paragraph (1), the Secretary shall give  
4           priority to independent entities with appropriate ex-  
5           pertise in health information technology usability,  
6           interoperability, and security (especially entities with  
7           such expertise in electronic health records) with re-  
8           spect to—

9                   “(A) health care providers, including pri-  
10                  mary care, specialty care, and care provided in  
11                  rural settings;

12                   “(B) hospitals and hospital systems; and

13                   “(C) patients, consumers, and patient and  
14                  consumer advocates.

15           “(4) LIMITATIONS.—

16                   “(A) ASSESSMENT AND REDETERMINA-  
17                  TION.—Not later than 4 years after the date of  
18                  enactment of the 21st Century Cures Act and  
19                  every 2 years thereafter, the Secretary, in con-  
20                  sultation with stakeholders, shall—

21                   “(i) assess performance of the recipi-  
22                  ents of the grants, contracts, and agree-  
23                  ments under paragraph (1) based on qual-  
24                  ity and usability of reports described in  
25                  paragraph (6); and

1                   “(ii) re-determine grants, contracts,  
2                   and agreements as necessary.

3                   “(B) PROHIBITIONS ON PARTICIPATION.—

4                   The Secretary may not award a grant, contract,  
5                   or cooperative agreement under paragraph (1)  
6                   to—

7                   “(i) a proprietor of certified health in-  
8                   formation technology or a business affiliate  
9                   of such a proprietor;

10                   “(ii) a developer of certified health in-  
11                   formation technology; or

12                   “(iii) a State or local government  
13                   agency.

14                   “(5) FEEDBACK.—Based on reporting criteria  
15                   established under subsection (a), the recipients of  
16                   grants, contracts, and agreements under paragraph  
17                   (1) shall develop and implement a process to collect  
18                   and verify confidential feedback on such criteria  
19                   from—

20                   “(A) health care providers, patients, and  
21                   other users of certified electronic health record  
22                   technology; and

23                   “(B) developers of certified electronic  
24                   health record technology.

25                   “(6) REPORTS.—

1           “(A) DEVELOPMENT OF REPORTS.—Each  
2 recipient of a grant, contract, or agreement  
3 under paragraph (1) shall report on the infor-  
4 mation reported to such recipient pursuant to  
5 subsection (a) and the user feedback collected  
6 under paragraph (5) by preparing summary re-  
7 ports and detailed reports of such information.

8           “(B) DISTRIBUTION OF REPORTS.—Each  
9 recipient of a grant, contract, or agreement  
10 under paragraph (1) shall submit the reports  
11 prepared under subparagraph (A) to the Sec-  
12 retary for public distribution in accordance with  
13 subsection (d).

14       “(d) PUBLICATION.—The Secretary shall distribute  
15 widely, as appropriate, and publish, on the Internet  
16 website of the Office of the National Coordinator—

17           “(1) the reporting criteria developed under sub-  
18 section (a); and

19           “(2) the summary and detailed reports under  
20 subsection (c)(6).

21       “(e) REVIEW.—Each recipient of a grant, contract,  
22 or agreement under paragraph (1) shall develop and im-  
23 plement a process through which participating electronic  
24 health record technology developers may review and rec-  
25 ommend changes to the reports created under subsection

1 (c)(6) for products developed by such developer prior to  
2 the publication of such report under subsection (d).

3 “(f) **ADDITIONAL RESOURCES.**—The Secretary may  
4 provide additional resources on the Internet website of the  
5 Office of the National Coordinator to better inform con-  
6 sumers of health information technology. Such reports  
7 may be carried out through partnerships with private or-  
8 ganizations with appropriate expertise.”.

9 (d) **AUTHORIZATION OF APPROPRIATIONS.**—There is  
10 authorized to be appropriated \$15,000,000 for purposes  
11 of carrying out subparagraph (D) of section 3001(e)(5)  
12 of the Public Health Service Act (42 U.S.C. 300jj–11) (as  
13 added by subsection (a)) and section 3009A of the Public  
14 Health Service Act (as added by subsection (b)), including  
15 for purposes of administering any contracts, grants, or  
16 agreements, to remain available until expended.

17 **SEC. 4003. INTEROPERABILITY.**

18 (a) **DEFINITION.**—Section 3000 of the Public Health  
19 Service Act (42 U.S.C. 300jj) is amended—

20 (1) by redesignating paragraphs (10) through  
21 (14), as paragraphs (11) through (15), respectively;  
22 and

23 (2) by inserting after paragraph (9) the fol-  
24 lowing:

1           “(10) INTEROPERABILITY.—The term ‘inter-  
2           operability’, with respect to health information tech-  
3           nology, means such health information technology  
4           that—

5                   “(A) enables the secure exchange of elec-  
6                   tronic health information with, and use of elec-  
7                   tronic health information from, other health in-  
8                   formation technology without special effort on  
9                   the part of the user;

10                   “(B) allows for complete access, exchange,  
11                   and use of all electronically accessible health in-  
12                   formation for authorized use under applicable  
13                   State or Federal law; and

14                   “(C) does not constitute information block-  
15                   ing as defined in section 3022(a).”.

16           (b) SUPPORT FOR INTEROPERABLE NETWORK EX-  
17           CHANGE.—Section 3001(c) of the Public Health Service  
18           Act (42 U.S.C. 300jj–11(c)) is amended by adding at the  
19           end the following:

20                   “(9) SUPPORT FOR INTEROPERABLE NET-  
21                   WORKS EXCHANGE.—

22                   “(A) IN GENERAL.—The National Coordi-  
23                   nator shall, in collaboration with the National  
24                   Institute of Standards and Technology and  
25                   other relevant agencies within the Department

1 of Health and Human Services, for the purpose  
2 of ensuring full network-to-network exchange of  
3 health information, convene public-private and  
4 public-public partnerships to build consensus  
5 and develop or support a trusted exchange  
6 framework, including a common agreement  
7 among health information networks nationally.  
8 Such convention may occur at a frequency de-  
9 termined appropriate by the Secretary.

10 “(B) ESTABLISHING A TRUSTED EX-  
11 CHANGE FRAMEWORK.—

12 “(i) IN GENERAL.—Not later than 6  
13 months after the date of enactment of the  
14 21st Century Cures Act, the National Co-  
15 ordinator shall convene appropriate public  
16 and private stakeholders to develop or sup-  
17 port a trusted exchange framework for  
18 trust policies and practices and for a com-  
19 mon agreement for exchange between  
20 health information networks. The common  
21 agreement may include—

22 “(I) a common method for au-  
23 thenticating trusted health informa-  
24 tion network participants;



1                   “(II) a common set of rules for  
2                   trusted exchange;

3                   “(III) organizational and oper-  
4                   ational policies to enable the exchange  
5                   of health information among net-  
6                   works, including minimum conditions  
7                   for such exchange to occur; and

8                   “(IV) a process for filing and ad-  
9                   judicating noncompliance with the  
10                  terms of the common agreement.

11                  “(ii) TECHNICAL ASSISTANCE.—The  
12                  National Coordinator, in collaboration with  
13                  the National Institute of Standards and  
14                  Technology, shall provide technical assist-  
15                  ance on how to implement the trusted ex-  
16                  change framework and common agreement  
17                  under this paragraph.

18                  “(iii) PILOT TESTING.—The National  
19                  Coordinator, in consultation with the Na-  
20                  tional Institute of Standards and Tech-  
21                  nology, shall provide for the pilot testing of  
22                  the trusted exchange framework and com-  
23                  mon agreement established or supported  
24                  under this subsection (as authorized under  
25                  section 13201 of the Health Information

1 Technology for Economic and Clinical  
2 Health Act). The National Coordinator, in  
3 consultation with the National Institute of  
4 Standards and Technology, may delegate  
5 pilot testing activities under this clause to  
6 independent entities with appropriate ex-  
7 pertise.

8 “(C) PUBLICATION OF A TRUSTED EX-  
9 CHANGE FRAMEWORK AND COMMON AGREE-  
10 MENT.—Not later than 1 year after convening  
11 stakeholders under subparagraph (A), the Na-  
12 tional Coordinator shall publish on its public  
13 Internet website, and in the Federal register,  
14 the trusted exchange framework and common  
15 agreement developed or supported under sub-  
16 paragraph (B). Such trusted exchange frame-  
17 work and common agreement shall be published  
18 in a manner that protects proprietary and secu-  
19 rity information, including trade secrets and  
20 any other protected intellectual property.

21 “(D) DIRECTORY OF PARTICIPATING  
22 HEALTH INFORMATION NETWORKS.—

23 “(i) IN GENERAL.—Not later than 2  
24 years after convening stakeholders under  
25 subparagraph (A), and annually thereafter,

1 the National Coordinator shall publish on  
2 its public Internet website a list of the  
3 health information networks that have  
4 adopted the common agreement and are  
5 capable of trusted exchange pursuant to  
6 the common agreement developed or sup-  
7 ported under paragraph (B).

8 “(ii) PROCESS.—The Secretary shall,  
9 through notice and comment rulemaking,  
10 establish a process for health information  
11 networks that voluntarily elect to adopt the  
12 trusted exchange framework and common  
13 agreement to attest to such adoption of the  
14 framework and agreement.

15 “(E) APPLICATION OF THE TRUSTED EX-  
16 CHANGE FRAMEWORK AND COMMON AGREE-  
17 MENT.—As appropriate, Federal agencies con-  
18 tracting or entering into agreements with health  
19 information exchange networks may require  
20 that as each such network upgrades health in-  
21 formation technology or trust and operational  
22 practices, such network may adopt, where avail-  
23 able, the trusted exchange framework and com-  
24 mon agreement published under subparagraph  
25 (C).

1 “(F) RULE OF CONSTRUCTION.—

2 “(i) GENERAL ADOPTION.—Nothing  
3 in this paragraph shall be construed to re-  
4 quire a health information network to  
5 adopt the trusted exchange framework or  
6 common agreement.

7 “(ii) ADOPTION WHEN EXCHANGE OF  
8 INFORMATION IS WITHIN NETWORK.—  
9 Nothing in this paragraph shall be con-  
10 strued to require a health information net-  
11 work to adopt the trusted exchange frame-  
12 work or common agreement for the ex-  
13 change of electronic health information be-  
14 tween participants of the same network.

15 “(iii) EXISTING FRAMEWORKS AND  
16 AGREEMENTS.—The trusted exchange  
17 framework and common agreement pub-  
18 lished under subparagraph (C) shall take  
19 into account existing trusted exchange  
20 frameworks and agreements used by health  
21 information networks to avoid the disrup-  
22 tion of existing exchanges between partici-  
23 pants of health information networks.

24 “(iv) APPLICATION BY FEDERAL  
25 AGENCIES.—Notwithstanding clauses (i),

1 (ii), and (iii), Federal agencies may require  
2 the adoption of the trusted exchange  
3 framework and common agreement pub-  
4 lished under subparagraph (C) for health  
5 information exchanges contracting with or  
6 entering into agreements pursuant to sub-  
7 paragraph (E).

8 “(v) CONSIDERATION OF ONGOING  
9 WORK.—In carrying out this paragraph,  
10 the Secretary shall ensure the consider-  
11 ation of activities carried out by public and  
12 private organizations related to exchange  
13 between health information exchanges to  
14 avoid duplication of efforts.”.

15 (c) PROVIDER DIGITAL CONTACT INFORMATION  
16 INDEX.—

17 (1) IN GENERAL.—Not later than 3 years after  
18 the date of enactment of this Act, the Secretary of  
19 Health and Human Services (referred to in this sub-  
20 section as the “Secretary”) shall, directly or through  
21 a partnership with a private entity, establish a pro-  
22 vider digital contact information index to provide  
23 digital contact information for health professionals  
24 and health facilities.

1           (2) USE OF EXISTING INDEX.—In establishing  
2           the initial index under paragraph (1), the Secretary  
3           may utilize an existing provider directory to make  
4           such digital contact information available.

5           (3) CONTACT INFORMATION.—An index estab-  
6           lished under this subsection shall ensure that con-  
7           tact information is available at the individual health  
8           care provider level and at the health facility or prac-  
9           tice level.

10          (4) RULE OF CONSTRUCTION.—

11           (A) IN GENERAL.—The purpose of this  
12           subsection is to encourage the exchange of elec-  
13           tronic health information by providing the most  
14           useful, reliable, and comprehensive index of pro-  
15           viders possible. In furthering such purpose, the  
16           Secretary shall include all health professionals  
17           and health facilities applicable to provide a use-  
18           ful, reliable, and comprehensive index for use in  
19           the exchange of health information.

20           (B) LIMITATION.—In no case shall exclu-  
21           sion from the index of providers be used as a  
22           measure to achieve objectives other the objec-  
23           tives described in subparagraph (A).

1 (d) STANDARDS DEVELOPMENT ORGANIZATIONS.—  
2 Section 3004 of the Public Health Service Act (42 U.S.C.  
3 300jj–14) is amended by adding at the end the following:

4 “(c) DEFERENCE TO STANDARDS DEVELOPMENT  
5 ORGANIZATIONS.—In adopting and implementing stand-  
6 ards under this section, the Secretary shall give deference  
7 to standards published by standards development organi-  
8 zations and voluntary consensus-based standards bodies.”.

9 (e) HEALTH INFORMATION TECHNOLOGY ADVISORY  
10 COMMITTEE.—

11 (1) IN GENERAL.—Title XXX of the Public  
12 Health Service Act (42 U.S.C. 300jj et seq.) is  
13 amended by striking sections 3002 (42 U.S.C.  
14 300jj–12) and 3003 (42 U.S.C. 300jj–13) and in-  
15 serting the following:

16 **“SEC. 3002. HEALTH INFORMATION TECHNOLOGY ADVI-  
17 SORY COMMITTEE.**

18 “(a) ESTABLISHMENT.—There is established a  
19 Health Information Technology Advisory Committee (re-  
20 ferred to in this section as the ‘HIT Advisory Committee’)  
21 to recommend to the National Coordinator, consistent  
22 with the implementation of the strategic plan described  
23 in section 3001(c)(3), policies, and, for purposes of adop-  
24 tion under section 3004, standards, implementation speci-  
25 fications, and certification criteria, relating to the imple-

1 mentation of a health information technology infrastruc-  
2 ture, nationally and locally, that advances the electronic  
3 access, exchange, and use of health information. Such  
4 Committee shall serve to unify the roles of, and replace,  
5 the HIT Policy Committee and the HIT Standards Com-  
6 mittee, as in existence before the date of the enactment  
7 of the 21st Century Cures Act.

8 “(b) DUTIES.—

9 “(1) RECOMMENDATIONS ON POLICY FRAME-  
10 WORK TO ADVANCE AN INTEROPERABLE HEALTH IN-  
11 FORMATION TECHNOLOGY INFRASTRUCTURE.—

12 “(A) IN GENERAL.—The HIT Advisory  
13 Committee shall recommend to the National  
14 Coordinator a policy framework for adoption by  
15 the Secretary consistent with the strategic plan  
16 under section 3001(c)(3) for advancing the tar-  
17 get areas described in this subsection. Such pol-  
18 icy framework shall seek to prioritize achieving  
19 advancements in the target areas specified in  
20 subparagraph (B) of paragraph (2) and may, to  
21 the extent consistent with this section, incor-  
22 porate policy recommendations made by the  
23 HIT Policy Committee, as in existence before  
24 the date of the enactment of the 21st Century  
25 Cures Act.



1           “(B) UPDATES.—The HIT Advisory Com-  
2           mittee shall propose updates to such rec-  
3           ommendations to the policy framework and  
4           make new recommendations, as appropriate.

5           “(2) GENERAL DUTIES AND TARGET AREAS.—

6           “(A) IN GENERAL.—The HIT Advisory  
7           Committee shall recommend to the National  
8           Coordinator for purposes of adoption under sec-  
9           tion 3004, standards, implementation specifica-  
10          tions, and certification criteria and an order of  
11          priority for the development, harmonization,  
12          and recognition of such standards, specifica-  
13          tions, and certification criteria. Such rec-  
14          ommendations shall include recommended  
15          standards, architectures, and software schemes  
16          for access to electronic individually identifiable  
17          health information across disparate systems in-  
18          cluding user vetting, authentication, privilege  
19          management, and access control.

20          “(B) PRIORITY TARGET AREAS.—For pur-  
21          poses of this section, the HIT Advisory Com-  
22          mittee shall make recommendations under sub-  
23          paragraph (A) with respect to at least each of  
24          the following target areas:

1                   “(i) Achieving a health information  
2                   technology infrastructure, nationally and  
3                   locally, that allows for the electronic ac-  
4                   cess, exchange, and use of health informa-  
5                   tion, including through technology that  
6                   provides accurate patient information for  
7                   the correct patient, including exchanging  
8                   such information, and avoids the duplica-  
9                   tion of patient records.

10                   “(ii) The promotion and protection of  
11                   privacy and security of health information  
12                   in health information technology, including  
13                   technologies that allow for an accounting  
14                   of disclosures and protections against dis-  
15                   closures of individually identifiable health  
16                   information made by a covered entity for  
17                   purposes of treatment, payment, and  
18                   health care operations (as such terms are  
19                   defined for purposes of the regulation pro-  
20                   mulgated under section 264(e) of the  
21                   Health Insurance Portability and Account-  
22                   ability Act of 1996), including for the seg-  
23                   mentation and protection from disclosure  
24                   of specific and sensitive individually identi-  
25                   fiable health information with the goal of

1 minimizing the reluctance of patients to  
2 seek care.

3 “(iii) The facilitation of secure access  
4 by an individual to such individual’s pro-  
5 tected health information and access to  
6 such information by a family member,  
7 caregiver, or guardian acting on behalf of  
8 a patient, including due to age-related and  
9 other disability, cognitive impairment, or  
10 dementia.

11 “(iv) Subject to subparagraph (D),  
12 any other target area that the HIT Advi-  
13 sory Committee identifies as an appro-  
14 priate target area to be considered under  
15 this subparagraph.

16 “(C) ADDITIONAL TARGET AREAS.—For  
17 purposes of this section, the HIT Advisory  
18 Committee may make recommendations under  
19 subparagraph (A), in addition to areas de-  
20 scribed in subparagraph (B), with respect to  
21 any of the following areas:

22 “(i) The use of health information  
23 technology to improve the quality of health  
24 care, such as by promoting the coordina-  
25 tion of health care and improving con-

1                   tinuity of health care among health care  
2                   providers, reducing medical errors, improv-  
3                   ing population health, reducing chronic dis-  
4                   ease, and advancing research and edu-  
5                   cation.

6                   “(ii) The use of technologies that ad-  
7                   dress the needs of children and other vul-  
8                   nerable populations.

9                   “(iii) The use of electronic systems to  
10                  ensure the comprehensive collection of pa-  
11                  tient demographic data, including at a  
12                  minimum, race, ethnicity, primary lan-  
13                  guage, and gender information.

14                  “(iv) The use of self-service, telemedi-  
15                  cine, home health care, and remote moni-  
16                  toring technologies.

17                  “(v) The use of technologies that meet  
18                  the needs of diverse populations.

19                  “(vi) The use of technologies that  
20                  support—

21                         “(I) data for use in quality and  
22                         public reporting programs;

23                         “(II) public health; or

24                         “(III) drug safety.

1                   “(vii) The use of technologies that  
2                   allow individually identifiable health infor-  
3                   mation to be rendered unusable,  
4                   unreadable, or indecipherable to unauthor-  
5                   ized individuals when such information is  
6                   transmitted in a health information net-  
7                   work or transported outside of the secure  
8                   facilities or systems where the disclosing  
9                   covered entity is responsible for security  
10                  conditions.

11                  “(viii) The use of a certified health in-  
12                  formation technology for each individual in  
13                  the United States.

14                  “(D) AUTHORITY FOR TEMPORARY ADDI-  
15                  TIONAL PRIORITY TARGET AREAS.—For pur-  
16                  poses of subparagraph (B)(iv), the HIT Advi-  
17                  sory Committee may identify an area to be con-  
18                  sidered for purposes of recommendations under  
19                  this subsection as a target area described in  
20                  subparagraph (B) if—

21                         “(i) the area is so identified for pur-  
22                         poses of responding to new circumstances  
23                         that have arisen in the health information  
24                         technology community that affect the  
25                         interoperability, privacy, or security of

1 health information, or affect patient safety;  
2 and

3 “(ii) at least 30 days prior to treating  
4 such area as if it were a target area de-  
5 scribed in subparagraph (B), the National  
6 Coordinator provides adequate notice to  
7 Congress of the intent to treat such area  
8 as so described.

9 “(E) FOCUS OF COMMITTEE WORK.—It is  
10 the sense of Congress that the HIT Advisory  
11 Committee shall focus its work on the priority  
12 areas described in subparagraph (B) before pro-  
13 ceeding to other work under subparagraph (C).

14 “(3) RULES RELATING TO RECOMMENDATIONS  
15 FOR STANDARDS, IMPLEMENTATION SPECIFICA-  
16 TIONS, AND CERTIFICATION CRITERIA.—

17 “(A) IN GENERAL.—The HIT Advisory  
18 Committee shall recommend to the National  
19 Coordinator standards, implementation speci-  
20 fications, and certification criteria described in  
21 subsection (a), which may include standards,  
22 implementation specifications, and certification  
23 criteria that have been developed, harmonized,  
24 or recognized by the HIT Advisory Committee  
25 or predecessor committee. The HIT Advisory

1           Committee shall update such recommendations  
2           and make new recommendations as appropriate,  
3           including in response to a notification sent  
4           under section 3004(a)(2)(B). Such rec-  
5           ommendations shall be consistent with the lat-  
6           est recommendations made by the Committee.

7           “(B) HARMONIZATION.—The HIT Advi-  
8           sory Committee may recognize harmonized or  
9           updated standards from an entity or entities for  
10          the purpose of harmonizing or updating stand-  
11          ards and implementation specifications in order  
12          to achieve uniform and consistent implementa-  
13          tion of the standards and implementation speci-  
14          fication.

15          “(C) PILOT TESTING OF STANDARDS AND  
16          IMPLEMENTATION SPECIFICATIONS.—In the de-  
17          velopment, harmonization, or recognition of  
18          standards and implementation specifications,  
19          the HIT Advisory Committee for purposes of  
20          recommendations under paragraph (2)(B),  
21          shall, as appropriate, provide for the testing of  
22          such standards and specifications by the Na-  
23          tional Institute for Standards and Technology  
24          under section 13201(a) of the Health Informa-

1           tion Technology for Economic and Clinical  
2           Health Act.

3           “(D) CONSISTENCY.—The standards, im-  
4           plementation specifications, and certification  
5           criteria recommended under paragraph (2)(B)  
6           shall be consistent with the standards for infor-  
7           mation transactions and data elements adopted  
8           pursuant to section 1173 of the Social Security  
9           Act.

10          “(E) SPECIAL RULE RELATED TO INTER-  
11          OPERABILITY.—Any recommendation made by  
12          the HIT Advisory Committee after the date of  
13          the enactment of this subparagraph with re-  
14          spect to interoperability of health information  
15          technology shall be consistent with interoper-  
16          ability as described in section 3000.

17          “(4) FORUM.—The HIT Advisory Committee  
18          shall serve as a forum for the participation of a  
19          broad range of stakeholders with specific expertise in  
20          policies, including technical expertise, relating to the  
21          matters described in paragraphs (1), (2), and (3) to  
22          provide input on the development, harmonization,  
23          and recognition of standards, implementation speci-  
24          fications, and certification criteria necessary for the  
25          development and adoption of health information



1       technology infrastructure nationally and locally that  
2       allows for the electronic access, exchange, and use of  
3       health information.

4           “(5) SCHEDULE.—Not later than 30 days after  
5       the date on which the HIT Advisory Committee first  
6       meets, such HIT Advisory Committee shall develop  
7       a schedule for the assessment of policy recommenda-  
8       tions developed under paragraph (1). The HIT Advi-  
9       sory Committee shall update such schedule annually.  
10       The Secretary shall publish such schedule in the  
11       Federal Register.

12           “(6) PUBLIC INPUT.—The HIT Advisory Com-  
13       mittee shall conduct open public meetings and de-  
14       velop a process to allow for public comment on the  
15       schedule described in paragraph (5) and rec-  
16       ommendations described in this subsection. Under  
17       such process comments shall be submitted in a time-  
18       ly manner after the date of publication of a rec-  
19       ommendation under this subsection.

20           “(c) MEASURED PROGRESS IN ADVANCING PRIORITY  
21       AREAS.—

22           “(1) IN GENERAL.—For purposes of this sec-  
23       tion, the National Coordinator, in collaboration with  
24       the Secretary, shall establish, and update as appro-  
25       priate, objectives and benchmarks for advancing and

1 measuring the advancement of the priority target  
2 areas described in subsection (b)(2)(B).

3 “(2) ANNUAL PROGRESS REPORTS ON ADVANC-  
4 ING INTEROPERABILITY.—

5 “(A) IN GENERAL.—The HIT Advisory  
6 Committee, in consultation with the National  
7 Coordinator, shall annually submit to the Sec-  
8 retary and Congress a report on the progress  
9 made during the preceding fiscal year in—

10 “(i) achieving a health information  
11 technology infrastructure, nationally and  
12 locally, that allows for the electronic ac-  
13 cess, exchange, and use of health informa-  
14 tion; and

15 “(ii) meeting the objectives and  
16 benchmarks described in paragraph (1).

17 “(B) CONTENT.—Each such report shall  
18 include, for a fiscal year—

19 “(i) a description of the work con-  
20 ducted by the HIT Advisory Committee  
21 during the preceding fiscal year with re-  
22 spect to the areas described in subsection  
23 (b)(2)(B);

24 “(ii) an assessment of the status of  
25 the infrastructure described in subpara-

1 graph (A), including the extent to which  
2 electronic health information is appro-  
3 priately and readily available to enhance  
4 the access, exchange, and the use of elec-  
5 tronic health information between users  
6 and across technology offered by different  
7 developers;

8 “(iii) the extent to which advance-  
9 ments have been achieved with respect to  
10 areas described in subsection (b)(2)(B);

11 “(iv) an analysis identifying existing  
12 gaps in policies and resources for—

13 “(I) achieving the objectives and  
14 benchmarks established under para-  
15 graph (1); and

16 “(II) furthering interoperability  
17 throughout the health information  
18 technology infrastructure;

19 “(v) recommendations for addressing  
20 the gaps identified in clause (iii); and

21 “(vi) a description of additional initia-  
22 tives as the HIT Advisory Committee and  
23 National Coordinator determine appro-  
24 priate.

1           “(3) SIGNIFICANT ADVANCEMENT DETERMINA-  
2           TION.—The Secretary shall periodically, based on  
3           the reports submitted under this subsection, review  
4           the target areas described in subsection (b)(2)(B),  
5           and, based on the objectives and benchmarks estab-  
6           lished under paragraph (1), the Secretary shall de-  
7           termine if significant advancement has been achieved  
8           with respect to such an area. Such determination  
9           shall be taken into consideration by the HIT Advi-  
10          sory Committee when determining to what extent  
11          the Committee makes recommendations for an area  
12          other than an area described in subsection  
13          (b)(2)(B).

14          “(d) MEMBERSHIP AND OPERATIONS.—

15                 “(1) IN GENERAL.—The National Coordinator  
16                 shall take a leading position in the establishment  
17                 and operations of the HIT Advisory Committee.

18                 “(2) MEMBERSHIP.—The membership of the  
19                 HIT Advisory Committee shall—

20                         “(A) include at least 25 members, of  
21                         which—

22                                 “(i) no fewer than 2 members are ad-  
23                                 vocates for patients or consumers of health  
24                                 information technology;

1                   “(ii) 3 members are appointed by the  
2                   Secretary, 1 of whom shall be appointed to  
3                   represent the Department of Health and  
4                   Human Services and 1 of whom shall be a  
5                   public health official;

6                   “(iii) 2 members are appointed by the  
7                   majority leader of the Senate;

8                   “(iv) 2 members are appointed by the  
9                   minority leader of the Senate;

10                  “(v) 2 members are appointed by the  
11                  Speaker of the House of Representatives;

12                  “(vi) 2 members are appointed by the  
13                  minority leader of the House of Represent-  
14                  atives; and

15                  “(vii) such other members are ap-  
16                  pointed by the Comptroller General of the  
17                  United States; and

18                  “(B) at least reflect providers, ancillary  
19                  health care workers, consumers, purchasers,  
20                  health plans, health information technology de-  
21                  velopers, researchers, patients, relevant Federal  
22                  agencies, and individuals with technical exper-  
23                  tise on health care quality, system functions,  
24                  privacy, security, and on the electronic ex-

1 change and use of health information, including  
2 the use standards for such activity.

3 “(3) PARTICIPATION.—The members of the  
4 HIT Advisory Committee shall represent a balance  
5 among various sectors of the health care system so  
6 that no single sector unduly influences the rec-  
7 ommendations of the Committee.

8 “(4) TERMS.—

9 “(A) IN GENERAL.—The terms of the  
10 members of the HIT Advisory Committee shall  
11 be for 3 years, except that the Secretary shall  
12 designate staggered terms of the members first  
13 appointed.

14 “(B) VACANCIES.—Any member appointed  
15 to fill a vacancy in the membership of the HIT  
16 Advisory Committee that occurs prior to the ex-  
17 piration of the term for which the member’s  
18 predecessor was appointed shall be appointed  
19 only for the remainder of that term. A member  
20 may serve after the expiration of that member’s  
21 term until a successor has been appointed. A  
22 vacancy in the HIT Advisory Committee shall  
23 be filled in the manner in which the original ap-  
24 pointment was made.

1           “(C) LIMITS.—Members of the HIT Advi-  
2           sory Committee shall be limited to two 3-year  
3           terms, for a total of not to exceed 6 years of  
4           service on the Committee.

5           “(5) OUTSIDE INVOLVEMENT.—The HIT Advi-  
6           sory Committee shall ensure an opportunity for the  
7           participation in activities of the Committee of out-  
8           side advisors, including individuals with expertise in  
9           the development of policies and standards for the  
10          electronic exchange and use of health information,  
11          including in the areas of health information privacy  
12          and security.

13          “(6) QUORUM.—A majority of the members of  
14          the HIT Advisory Committee shall constitute a  
15          quorum for purposes of voting, but a lesser number  
16          of members may meet and hold hearings.

17          “(7) CONSIDERATION.—The National Coordi-  
18          nator shall ensure that the relevant and available  
19          recommendations and comments from the National  
20          Committee on Vital and Health Statistics are con-  
21          sidered in the development of policies.

22          “(8) ASSISTANCE.—For the purposes of car-  
23          rying out this section, the Secretary may provide or  
24          ensure that financial assistance is provided by the  
25          HIT Advisory Committee to defray in whole or in

1 part any membership fees or dues charged by such  
2 Committee to those consumer advocacy groups and  
3 not-for-profit entities that work in the public interest  
4 as a party of their mission.

5 “(e) APPLICATION OF FACA.—The Federal Advisory  
6 Committee Act (5 U.S.C. App.), other than section 14 of  
7 such Act, shall apply to the HIT Advisory Committee.

8 “(f) PUBLICATION.—The Secretary shall provide for  
9 publication in the Federal Register and the posting on the  
10 Internet website of the Office of the National Coordinator  
11 for Health Information Technology of all policy rec-  
12 ommendations made by the HIT Advisory Committee  
13 under this section.”.

14 (2) TECHNICAL AND CONFORMING AMEND-  
15 MENTS.—Title XXX of the Public Health Service  
16 Act (42 U.S.C. 300jj et seq.) is amended—

17 (A) by striking—

18 (i) “HIT Policy Committee” and  
19 “HIT Standards Committee” each place  
20 that such terms appear (other than within  
21 the term “HIT Policy Committee and the  
22 HIT Standards Committee” or within the  
23 term “HIT Policy Committee or the HIT  
24 Standards Committee”) and inserting  
25 “HIT Advisory Committee”;



1 (ii) “HIT Policy Committee and the  
2 HIT Standards Committee” each place  
3 that such term appears and inserting  
4 “HIT Advisory Committee”; and

5 (iii) “HIT Policy Committee or the  
6 HIT Standards Committee” each place  
7 that such term appears and inserting  
8 “HIT Advisory Committee”;

9 (B) in section 3000 (42 U.S.C. 300jj)—

10 (i) by striking paragraphs (7) and (8)  
11 and redesignating paragraphs (9) through  
12 (14) as paragraphs (8) through (13), re-  
13 spectively; and

14 (ii) by inserting after paragraph (6)  
15 the following paragraph:

16 “(7) HIT ADVISORY COMMITTEE.—The term  
17 ‘HIT Advisory Committee’ means such Committee  
18 established under section 3002(a).”;

19 (C) in section 3001(c) (42 U.S.C. 300jj–  
20 11(c))—

21 (i) in paragraph (1)(A), by striking  
22 “under section 3003” and inserting “under  
23 section 3002”;

24 (ii) in paragraph (2), by striking sub-  
25 paragraph (B) and inserting the following:

1           “(B) HIT ADVISORY COMMITTEE.—The  
2           National Coordinator shall be a leading member  
3           in the establishment and operations of the HIT  
4           Advisory Committee and shall serve as a liaison  
5           between that Committee and the Federal Gov-  
6           ernment.”;

7           (D) in section 3004(b)(3) (42 U.S.C.  
8           300jj–14(b)(3)), by striking “3003(b)(2)” and  
9           inserting “3002(b)(4)”;

10          (E) in section 3007(b) (42 U.S.C. 300jj–  
11          17(b)), by striking “3003(a)” and inserting  
12          “3002(a)(2)”;

13          (F) in section 3008 (42 U.S.C. 300jj–  
14          18)—

15                 (i) in subsection (b), by striking “or  
16                 3003”; and

17                 (ii) in subsection (c), by striking  
18                 “3003(b)(1)(A)” and inserting  
19                 “3002(b)(2)”.

20          (3) TRANSITION TO THE HIT ADVISORY COM-  
21          MITTEE.—The Secretary of Health and Human  
22          Services shall provide for an orderly and timely tran-  
23          sition to the HIT Advisory Committee established  
24          under amendments made by this section.

1 (f) PRIORITIES FOR ADOPTION OF STANDARDS, IM-  
2 PLEMENTATION SPECIFICATIONS, AND CERTIFICATION  
3 CRITERIA.—Title XXX of the Public Health Service Act  
4 (42 U.S.C. 300jj et seq.), as amended by subsection (e),  
5 is further amended by inserting after section 3002 the fol-  
6 lowing:

7 **“SEC. 3003. SETTING PRIORITIES FOR STANDARDS ADOPTI-**  
8 **ON.**

9 “(a) IDENTIFYING PRIORITIES.—

10 “(1) IN GENERAL.—Not later than 6 months  
11 after the date on which the HIT Advisory Com-  
12 mittee first meets, the National Coordinator shall  
13 periodically convene the HIT Advisory Committee  
14 to—

15 “(A) identify priority uses of health infor-  
16 mation technology, focusing on priorities—

17 “(i) arising from the implementation  
18 of the incentive programs for the meaning-  
19 ful use of certified EHR technology, the  
20 Merit-based Incentive Payment System, Al-  
21 ternative Payment Models, the Hospital  
22 Value-Based Purchasing Program, and any  
23 other value-based payment program deter-  
24 mined appropriate by the Secretary;

1                   “(ii) related to the quality of patient  
2                   care;  
3                   “(iii) related to public health;  
4                   “(iv) related to clinical research;  
5                   “(v) related to the privacy and secu-  
6                   rity of electronic health information;  
7                   “(vi) related to innovation in the field  
8                   of health information technology;  
9                   “(vii) related to patient safety;  
10                   “(viii) related to the usability of  
11                   health information technology;  
12                   “(ix) related to individuals’ access to  
13                   electronic health information; and  
14                   “(x) other priorities determined ap-  
15                   propriate by the Secretary;  
16                   “(B) identify existing standards and imple-  
17                   mentation specifications that support the use  
18                   and exchange of electronic health information  
19                   needed to meet the priorities identified in sub-  
20                   paragraph (A); and  
21                   “(C) publish a report summarizing the  
22                   findings of the analysis conducted under sub-  
23                   paragraphs (A) and (B) and make appropriate  
24                   recommendations.

1           “(2) PRIORITIZATION.—In identifying such  
2 standards and implementation specifications under  
3 paragraph (1)(B), the HIT Advisory Committee  
4 shall prioritize standards and implementation speci-  
5 fications developed by consensus-based standards de-  
6 velopment organizations.

7           “(3) GUIDELINES FOR REVIEW OF EXISTING  
8 STANDARDS AND SPECIFICATIONS.—In consultation  
9 with the consensus-based entity described in section  
10 1890 of the Social Security Act and other appro-  
11 priate Federal agencies, the analysis of existing  
12 standards under paragraph (1)(B) shall include an  
13 evaluation of the need for a core set of common data  
14 elements and associated value sets to enhance the  
15 ability of certified health information technology to  
16 capture, use, and exchange structured electronic  
17 health information.

18           “(b) REVIEW OF ADOPTED STANDARDS.—

19           “(1) IN GENERAL.—Beginning 5 years after the  
20 date of enactment of the 21st Century Cures Act  
21 and every 3 years thereafter, the National Coordi-  
22 nator shall convene stakeholders to review the exist-  
23 ing set of adopted standards and implementation  
24 specifications and make recommendations with re-  
25 spect to whether to—

1           “(A) maintain the use of such standards  
2           and implementation specifications; or

3           “(B) phase out such standards and imple-  
4           mentation specifications.

5           “(2) PRIORITIES.—The HIT Advisory Com-  
6           mittee, in collaboration with the National Institute  
7           for Standards and Technology, shall annually and  
8           through the use of public input, review and publish  
9           priorities for the use of health information tech-  
10          nology, standards, and implementation specifications  
11          to support those priorities.

12          “(c) RULE OF CONSTRUCTION.—Nothing in this sec-  
13          tion shall be construed to prevent the use or adoption of  
14          novel standards that improve upon the existing health in-  
15          formation technology infrastructure and facilitate the se-  
16          cure exchange of health information.”.

17          **SEC. 4004. INFORMATION BLOCKING.**

18          Subtitle C of title XXX of the Public Health Service  
19          Act (42 U.S.C. 300jj–51 et seq.) is amended by adding  
20          at the end the following:

21          **“SEC. 3022. INFORMATION BLOCKING.**

22                 “(a) DEFINITION.—

23                         “(1) IN GENERAL.—In this section, the term  
24                         ‘information blocking’ means a practice that—

1           “(A) except as required by law or specified  
2           by the Secretary pursuant to rulemaking under  
3           paragraph (3), is likely to interfere with, pre-  
4           vent, or materially discourage access, exchange,  
5           or use of electronic health information; and

6           “(B)(i) if conducted by a health informa-  
7           tion technology developer, exchange, or network,  
8           such developer, exchange, or network knows, or  
9           should know, that such practice is likely to  
10          interfere with, prevent, or materially discourage  
11          the access, exchange, or use of electronic health  
12          information; or

13          “(ii) if conducted by a health care pro-  
14          vider, such provider knows that such practice is  
15          unreasonable and is likely to interfere with, pre-  
16          vent, or materially discourage access, exchange,  
17          or use of electronic health information.

18          “(2) PRACTICES DESCRIBED.—The information  
19          blocking practices described in paragraph (1) may  
20          include—

21                 “(A) practices that restrict authorized ac-  
22                 cess, exchange, or use under applicable State or  
23                 Federal law of such information for treatment  
24                 and other permitted purposes under such appli-

1 cable law, including transitions between cer-  
2 tified health information technologies;

3 “(B) implementing health information  
4 technology in nonstandard ways that are likely  
5 to substantially increase the complexity or bur-  
6 den of accessing, exchanging, or using elec-  
7 tronic health information; and

8 “(C) implementing health information  
9 technology in ways that are likely to—

10 “(i) restrict the access, exchange, or  
11 use of electronic health information with  
12 respect to exporting complete information  
13 sets or in transitioning between health in-  
14 formation technology systems; or

15 “(ii) lead to fraud, waste, or abuse, or  
16 impede innovations and advancements in  
17 health information access, exchange, and  
18 use, including care delivery enabled by  
19 health information technology.

20 “(3) RULEMAKING.—The Secretary, through  
21 rulemaking, shall identify reasonable and necessary  
22 activities that do not constitute information blocking  
23 for purposes of paragraph (1).

24 “(4) NO ENFORCEMENT BEFORE EXCEPTION  
25 IDENTIFIED.—The term ‘information blocking’ does



1 not include any practice or conduct occurring prior  
2 to the date that is 30 days after the date of enact-  
3 ment of the 21st Century Cures Act.

4 “(5) CONSULTATION.—The Secretary may con-  
5 sult with the Federal Trade Commission in promul-  
6 gating regulations under this subsection, to the ex-  
7 tent that such regulations define practices that are  
8 necessary to promote competition and consumer wel-  
9 fare.

10 “(6) APPLICATION.—The term ‘information  
11 blocking’, with respect to an individual or entity,  
12 shall not include an act or practice other than an act  
13 or practice committed by such individual or entity.

14 “(7) CLARIFICATION.—In carrying out this sec-  
15 tion, the Secretary shall ensure that health care pro-  
16 viders are not penalized for the failure of developers  
17 of health information technology or other entities of-  
18 fering health information technology to such pro-  
19 viders to ensure that such technology meets the re-  
20 quirements to be certified under this title.

21 “(b) INSPECTOR GENERAL AUTHORITY.—

22 “(1) IN GENERAL.—The inspector general of  
23 the Department of Health and Human Services (re-  
24 ferred to in this section as the ‘Inspector General’)  
25 may investigate any claim that—

1           “(A) a health information technology de-  
2           veloper of certified health information tech-  
3           nology or other entity offering certified health  
4           information technology—

5                   “(i) submitted a false attestation  
6                   under section 3001(c)(5)(D)(vii); or

7                   “(ii) engaged in information blocking;

8           “(B) a health care provider engaged in in-  
9           formation blocking; or

10           “(C) a health information exchange or net-  
11           work engaged in information blocking.

12           “(2) PENALTIES.—

13                   “(A) DEVELOPERS, NETWORKS, AND EX-  
14                   CHANGES.—Any individual or entity described  
15                   in subparagraph (A) or (C) of paragraph (1)  
16                   that the Inspector General, following an inves-  
17                   tigation conducted under this subsection, deter-  
18                   mines to have committed information blocking  
19                   shall be subject to a civil monetary penalty de-  
20                   termined by the Secretary for all such violations  
21                   identified through such investigation, which  
22                   may not exceed \$1,000,000 per violation. Such  
23                   determination shall take into account factors  
24                   such as the nature and extent of the informa-  
25                   tion blocking and harm resulting from such in-

1           formation blocking, including, where applicable,  
2           the number of patients affected, the number of  
3           providers affected, and the number of days the  
4           information blocking persisted.

5           “(B) PROVIDERS.—Any individual or enti-  
6           ty described in subparagraph (B) of paragraph  
7           (1) determined by the Inspector General to  
8           have committed information blocking shall be  
9           referred to the appropriate agency to be subject  
10          to appropriate disincentives using authorities  
11          under applicable Federal law, as the Secretary  
12          sets forth through notice and comment rule-  
13          making.

14          “(C) PROCEDURE.—The provisions of sec-  
15          tion 1128A of the Social Security Act (other  
16          than subsections (a) and (b) of such section)  
17          shall apply to a civil money penalty applied  
18          under this paragraph in the same manner as  
19          such provisions apply to a civil money penalty  
20          or proceeding under such section 1128A(a).

21          “(D) RECOVERED PENALTY FUNDS.—The  
22          amounts recovered under this paragraph shall  
23          be allocated as follows:

24                  “(i) ANNUAL OPERATING EX-  
25                  PENSES.—Each year following the estab-

1           lishment of the authority under this sub-  
2           section, the Office of the Inspector General  
3           shall provide to the Secretary an estimate  
4           of the costs to carry out investigations  
5           under this section. Such estimate may in-  
6           clude reasonable reserves to account for  
7           variance in annual amounts recovered  
8           under this paragraph. There is authorized  
9           to be appropriated for purposes of carrying  
10          out this section an amount equal to the  
11          amount specified in such estimate for the  
12          fiscal year.

13                   “(ii) APPLICATION TO OTHER PRO-  
14                   GRAMS.—The amounts recovered under  
15                   this paragraph and remaining after  
16                   amounts are made available under clause  
17                   (i) shall be transferred to the Federal Hos-  
18                   pital Insurance Trust Fund under section  
19                   1817 of the Social Security Act and the  
20                   Federal Supplementary Medical Insurance  
21                   Trust Fund under section 1841 of such  
22                   Act, in such proportion as the Secretary  
23                   determines appropriate.

24                   “(E) AUTHORIZATION OF APPROPRIA-  
25                   TIONS.—There is authorized to be appropriated

1 to the Office of the Inspector General to carry  
2 out this section \$10,000,000, to remain avail-  
3 able until expended.

4 “(3) RESOLUTION OF CLAIMS.—

5 “(A) IN GENERAL.—The Office of the In-  
6 spector General, if such Office determines that  
7 a consultation regarding the health privacy and  
8 security rules promulgated under section 264(c)  
9 of the Health Insurance Portability and Ac-  
10 countability Act of 1996 (42 U.S.C. 1320d–2  
11 note) will resolve an information blocking claim,  
12 may refer such instances of information block-  
13 ing to the Office for Civil Rights of the Depart-  
14 ment of Health and Human Services for resolu-  
15 tion.

16 “(B) LIMITATION ON LIABILITY.—If a  
17 health care provider or health information tech-  
18 nology developer makes information available  
19 based on a good faith reliance on consultations  
20 with the Office for Civil Rights of the Depart-  
21 ment of Health and Human Services pursuant  
22 to a referral under subparagraph (A), with re-  
23 spect to such information, the health care pro-  
24 vider or developer shall not be liable for such

1 disclosure or disclosures made pursuant to sub-  
2 paragraph (A).

3 “(c) IDENTIFYING BARRIERS TO EXCHANGE OF  
4 CERTIFIED HEALTH INFORMATION TECHNOLOGY.—

5 “(1) TRUSTED EXCHANGE DEFINED.—In this  
6 section, the term ‘trusted exchange’ with respect to  
7 certified electronic health records means that the  
8 certified electronic health record technology has the  
9 technical capability to enable secure health informa-  
10 tion exchange between users and multiple certified  
11 electronic health record technology systems.

12 “(2) GUIDANCE.—The National Coordinator, in  
13 consultation with the Office for Civil Rights of the  
14 Department of Health and Human Services, shall  
15 issue guidance on common legal, governance, and se-  
16 curity barriers that prevent the trusted exchange of  
17 electronic health information.

18 “(3) REFERRAL.—The National Coordinator  
19 and the Office for Civil Rights of the Department of  
20 Health and Human Services may refer to the In-  
21 spector General instances or patterns of refusal to  
22 exchange health information with an individual or  
23 entity using certified electronic health record tech-  
24 nology that is technically capable of trusted ex-

1 change and under conditions when exchange is le-  
2 gally permissible.

3 “(d) ADDITIONAL PROVISIONS.—

4 “(1) INFORMATION SHARING PROVISIONS.—The  
5 National Coordinator may serve as a technical con-  
6 sultant to the Inspector General and the Federal  
7 Trade Commission for purposes of carrying out this  
8 section. The National Coordinator may, notwith-  
9 standing any other provision of law, share informa-  
10 tion related to claims or investigations under sub-  
11 section (b) with the Federal Trade Commission for  
12 purposes of such investigations and shall share in-  
13 formation with the Inspector General, as required by  
14 law.

15 “(2) PROTECTION FROM DISCLOSURE OF IN-  
16 FORMATION.—Any information that is received by  
17 the National Coordinator in connection with a claim  
18 or suggestion of possible information blocking and  
19 that could reasonably be expected to facilitate identi-  
20 fication of the source of the information—

21 “(A) shall not be disclosed by the National  
22 Coordinator except as may be necessary to  
23 carry out the purpose of this section;

24 “(B) shall be exempt from mandatory dis-  
25 closure under section 552 of title 5, United

1 States Code, as provided by subsection (b)(3) of  
2 such section; and

3 “(C) may be used by the Inspector General  
4 or Federal Trade Commission for reporting  
5 purposes to the extent that such information  
6 could not reasonably be expected to facilitate  
7 identification of the source of such information.

8 “(3) STANDARDIZED PROCESS.—

9 “(A) IN GENERAL.—The National Coordi-  
10 nator shall implement a standardized process  
11 for the public to submit reports on claims of—

12 “(i) health information technology  
13 products or developers of such products (or  
14 other entities offering such products to  
15 health care providers) not being interoper-  
16 able or resulting in information blocking;

17 “(ii) actions described in subsection  
18 (b)(1) that result in information blocking  
19 as described in subsection (a); and

20 “(iii) any other act described in sub-  
21 section (a).

22 “(B) COLLECTION OF INFORMATION.—The  
23 standardized process implemented under sub-  
24 paragraph (A) shall provide for the collection of  
25 such information as the originating institution,



1 location, type of transaction, system and  
2 version, timestamp, terminating institution, lo-  
3 cations, system and version, failure notice, and  
4 other related information.

5 “(4) NONDUPLICATION OF PENALTY STRUC-  
6 TURES.—In carrying out this subsection, the Sec-  
7 retary shall, to the extent possible, ensure that pen-  
8 alties do not duplicate penalty structures that would  
9 otherwise apply with respect to information blocking  
10 and the type of individual or entity involved as of  
11 the day before the date of the enactment of this sec-  
12 tion.”.

13 **SEC. 4005. LEVERAGING ELECTRONIC HEALTH RECORDS**  
14 **TO IMPROVE PATIENT CARE.**

15 (a) REQUIREMENT RELATING TO REGISTRIES.—

16 (1) IN GENERAL.—To be certified in accordance  
17 with title XXX of the Public Health Service Act (42  
18 U.S.C. 300jj et seq.), electronic health records shall  
19 be capable of transmitting to, and where applicable,  
20 receiving and accepting data from, registries in ac-  
21 cordance with standards recognized by the Office of  
22 the National Coordinator for Health Information  
23 Technology, including clinician-led clinical data reg-  
24 istries, that are also certified to be technically capa-  
25 ble of receiving and accepting from, and where appli-

1 cable, transmitting data to certified electronic health  
2 record technology in accordance with such stand-  
3 ards.

4 (2) RULE OF CONSTRUCTION.—Nothing in this  
5 subsection shall be construed to require the certifi-  
6 cation of registries beyond the technical capability to  
7 exchange data in accordance with applicable recog-  
8 nized standards.

9 (b) DEFINITION.—For purposes of this Act, the term  
10 “clinician-led clinical data registry” means a clinical data  
11 repository—

12 (1) that is established and operated by a clini-  
13 cian-led or controlled, tax-exempt (pursuant to sec-  
14 tion 501(c) of the Internal Revenue Code of 1986),  
15 professional society or other similar clinician-led or  
16 -controlled organization, or such organization’s con-  
17 trolled affiliate, devoted to the care of a population  
18 defined by a particular disease, condition, exposure  
19 or therapy;

20 (2) that is designed to collect detailed, stand-  
21 ardized data on an ongoing basis for medical proce-  
22 dures, services, or therapies for particular diseases,  
23 conditions, or exposures;

24 (3) that provides feedback to participants who  
25 submit reports to the repository;

1 (4) that meets standards for data quality in-  
2 cluding—

3 (A) systematically collecting clinical and  
4 other health care data, using standardized data  
5 elements and having procedures in place to  
6 verify the completeness and validity of those  
7 data; and

8 (B) being subject to regular data checks or  
9 audits to verify completeness and validity; and

10 (5) that provides ongoing participant training  
11 and support.

12 (c) TREATMENT OF HEALTH INFORMATION TECH-  
13 NOLOGY DEVELOPERS WITH RESPECT TO PATIENT SAFE-  
14 TY ORGANIZATIONS.—

15 (1) IN GENERAL.—In applying part C of title  
16 IX of the Public Health Service Act (42 U.S.C.  
17 299b–21 et seq.), a health information technology  
18 developer shall be treated as a provider (as defined  
19 in section 921 of such Act) for purposes of reporting  
20 and conducting patient safety activities concerning  
21 improving clinical care through the use of health in-  
22 formation technology that could result in improved  
23 patient safety, health care quality, or health care  
24 outcomes.



1 health information exchange organizations and net-  
2 works and health care providers, health plans, and  
3 other appropriate entities with the goal of offering  
4 patients access to their electronic health information  
5 in a single, longitudinal format that is easy to un-  
6 derstand, secure, and may be updated automatically.

7 “(2) EDUCATION OF PROVIDERS.—The Sec-  
8 retary, in coordination with the Office for Civil  
9 Rights of the Department of Health and Human  
10 Services, shall—

11 “(A) educate health care providers on ways  
12 of leveraging the capabilities of health informa-  
13 tion exchanges (or other relevant platforms) to  
14 provide patients with access to their electronic  
15 health information;

16 “(B) clarify misunderstandings by health  
17 care providers about using health information  
18 exchanges (or other relevant platforms) for pa-  
19 tient access to electronic health information;  
20 and

21 “(C) to the extent practicable, educate pro-  
22 viders about health information exchanges (or  
23 other relevant platforms) that employ some or  
24 all of the capabilities described in paragraph  
25 (1).

1           “(3) REQUIREMENTS.—In carrying out para-  
2           graph (1), the Secretary, in coordination with the  
3           Office for Civil Rights, shall issue guidance to health  
4           information exchanges related to best practices to  
5           ensure that the electronic health information pro-  
6           vided to patients is—

7                   “(A) private and secure;

8                   “(B) accurate;

9                   “(C) verifiable; and

10                   “(D) where a patient’s authorization to ex-  
11           change information is required by law, easily  
12           exchanged pursuant to such authorization.

13           “(4) RULE OF CONSTRUCTION.—Nothing in  
14           this subsection shall be construed to preempt State  
15           laws applicable to patient consent for the access of  
16           information through a health information exchange  
17           (or other relevant platform) that provide protections  
18           to patients that are greater than the protections oth-  
19           erwise provided for under applicable Federal law.

20           “(d) EFFORTS TO PROMOTE ACCESS TO HEALTH IN-  
21           FORMATION.—The National Coordinator and the Office  
22           for Civil Rights of the Department of Health and Human  
23           Services shall jointly promote patient access to health in-  
24           formation in a manner that would ensure that such infor-  
25           mation is available in a form convenient for the patient,

1 in a reasonable manner, without burdening the health care  
2 provider involved.

3 “(e) ACCESSIBILITY OF PATIENT RECORDS.—

4 “(1) ACCESSIBILITY AND UPDATING OF INFOR-  
5 MATION.—

6 “(A) IN GENERAL.—The Secretary, in con-  
7 sultation with the National Coordinator, shall  
8 promote policies that ensure that a patient’s  
9 electronic health information is accessible to  
10 that patient and the patient’s designees, in a  
11 manner that facilitates communication with the  
12 patient’s health care providers and other indi-  
13 viduals, including researchers, consistent with  
14 such patient’s consent.

15 “(B) UPDATING EDUCATION ON ACCESS-  
16 ING AND EXCHANGING PERSONAL HEALTH IN-  
17 FORMATION.—To promote awareness that an  
18 individual has a right of access to inspect, ob-  
19 tain a copy of, and transmit to a third party a  
20 copy of such individual’s protected health infor-  
21 mation pursuant to the Health Information  
22 Portability and Accountability Act, Privacy  
23 Rule (subpart E of part 164 of title 45, Code  
24 of Federal Regulations), the Director of the Of-  
25 fice for Civil Rights, in consultation with the

1 National Coordinator, shall assist individuals  
2 and health care providers in understanding a  
3 patient’s rights to access and protect personal  
4 health information under the Health Insurance  
5 Portability and Accountability Act of 1996  
6 (Public Law 104–191), including providing best  
7 practices for requesting personal health infor-  
8 mation in a computable format, including using  
9 patient portals or third-party applications and  
10 common cases when a provider is permitted to  
11 exchange and provide access to health informa-  
12 tion.”.

13 “(2) CERTIFYING USABILITY FOR PATIENTS.—  
14 In carrying out certification programs under section  
15 3001(c)(5), the National Coordinator may require  
16 that—

17 “(A) the certification criteria support—

18 “(i) patient access to their electronic  
19 health information, including in a single  
20 longitudinal format that is easy to under-  
21 stand, secure, and may be updated auto-  
22 matically;

23 “(ii) the patient’s ability to electroni-  
24 cally communicate patient-reported infor-



1                   mation (such as family history and medical  
2                   history); and

3                   “(iii) patient access to their personal  
4                   electronic health information for research  
5                   at the option of the patient; and

6                   “(B) the HIT Advisory Committee develop  
7                   and prioritize standards, implementation speci-  
8                   fications, and certification criteria required to  
9                   help support patient access to electronic health  
10                  information, patient usability, and support for  
11                  technologies that offer patients access to their  
12                  electronic health information in a single, longi-  
13                  tudinal format that is easy to understand, se-  
14                  cure, and may be updated automatically.”.

15                  (b) ACCESS TO INFORMATION IN AN ELECTRONIC  
16                  FORMAT.—Section 13405(e) of the Health Information  
17                  Technology for Economic and Clinical Health Act (42  
18                  U.S.C. 17935) is amended—

19                   (1) in paragraph (1), by striking “and” at the  
20                   end;

21                   (2) by redesignating paragraph (2) as para-  
22                   graph (3); and

23                   (3) by inserting after paragraph (1), the fol-  
24                   lowing:

1           “(2) if the individual makes a request to a busi-  
2           ness associate for access to, or a copy of, protected  
3           health information about the individual, or if an in-  
4           dividual makes a request to a business associate to  
5           grant such access to, or transmit such copy directly  
6           to, a person or entity designated by the individual,  
7           a business associate may provide the individual with  
8           such access or copy, which may be in an electronic  
9           form, or grant or transmit such access or copy to  
10          such person or entity designated by the individual;  
11          and”.

12 **SEC. 4007. GAO STUDY ON PATIENT MATCHING.**

13          (a) IN GENERAL.—Not later than 1 year after the  
14          date of enactment of this Act, the Comptroller General  
15          of the United States shall conduct a study to—

16                (1) review the policies and activities of the Of-  
17                fice of the National Coordinator for Health Informa-  
18                tion Technology and other relevant stakeholders,  
19                which may include standards development organiza-  
20                tions, experts in the technical aspects of health in-  
21                formation technology, health information technology  
22                developers, providers of health services, health care  
23                suppliers, health care payers, health care quality or-  
24                ganizations, States, health information technology  
25                policy experts, and other appropriate entities, to en-

1       sure appropriate patient matching to protect patient  
2       privacy and security with respect to electronic health  
3       records and the exchange of electronic health infor-  
4       mation; and

5               (2) survey ongoing efforts related to the policies  
6       and activities described in paragraph (1) and the ef-  
7       fectiveness of such efforts occurring in the private  
8       sector.

9       (b) AREAS OF CONCENTRATION.—In conducting the  
10      study under subsection (a), the Comptroller General  
11      shall—

12             (1) evaluate current methods used in certified  
13      electronic health records for patient matching based  
14      on performance related to factors such as—

- 15                     (A) the privacy of patient information;  
16                     (B) the security of patient information;  
17                     (C) improving matching rates;  
18                     (D) reducing matching errors; and  
19                     (E) reducing duplicate records; and

20             (2) determine whether the Office of the Na-  
21      tional Coordinator for Health Information Tech-  
22      nology could improve patient matching by taking  
23      steps including—

- 24                     (A) defining additional data elements to  
25                     assist in patient data matching;

1 (B) agreeing on a required minimum set of  
2 elements that need to be collected and ex-  
3 changed;

4 (C) requiring electronic health records to  
5 have the ability to make certain fields required  
6 and use specific standards; and

7 (D) other options recommended by the rel-  
8 evant stakeholders consulted pursuant to sub-  
9 section (a).

10 (c) REPORT.—Not later than 2 years after the date  
11 of enactment of this Act, the Comptroller General shall  
12 submit to the appropriate committees of Congress a report  
13 concerning the findings of the study conducted under sub-  
14 section (a).

15 **SEC. 4008. GAO STUDY ON PATIENT ACCESS TO HEALTH IN-**  
16 **FORMATION.**

17 (a) STUDY.—

18 (1) IN GENERAL.—The Comptroller General of  
19 the United States (referred to in this section as the  
20 “Comptroller General”) shall build on prior Govern-  
21 ment Accountability Office studies and other lit-  
22 erature review and conduct a study to review patient  
23 access to their own protected health information, in-  
24 cluding barriers to such patient access and complica-  
25 tions or difficulties providers experience in providing

1 access to patients. In conducting such study, the  
2 Comptroller General shall consider the increase in  
3 adoption of health information technology and the  
4 increasing prevalence of protected health information  
5 that is maintained electronically.

6 (2) AREAS OF CONCENTRATION.—In conducting  
7 the review under paragraph (1), the Comptroller  
8 General shall consider—

9 (A) instances when covered entities charge  
10 individuals, including patients, third parties,  
11 and health care providers, for record requests,  
12 including records that are requested in an elec-  
13 tronic format;

14 (B) examples of the amounts and types of  
15 fees charged to individuals for record requests,  
16 including instances when the record is re-  
17 quested to be transmitted to a third party;

18 (C) the extent to which covered entities are  
19 unable to provide the access requested by indi-  
20 viduals in the form and format requested by the  
21 individual, including examples of such in-  
22 stances;

23 (D) instances in which third parties may  
24 request protected health information through  
25 patients' individual right of access, including in-

1           stances where such requests may be used to cir-  
2           cumvent appropriate fees that may be charged  
3           to third parties;

4           (E) opportunities that permit covered enti-  
5           ties to charge appropriate fees to third parties  
6           for patient records while providing patients with  
7           access to their protected health information at  
8           low or no cost;

9           (F) the ability of providers to distinguish  
10          between requests originating from an individual  
11          that require limitation to a cost-based fee and  
12          requests originating from third parties that  
13          may not be limited to cost-based fees; and

14          (G) other circumstances that may inhibit  
15          the ability of providers to provide patients with  
16          access to their records, and the ability of pa-  
17          tients to gain access to their records.

18          (b) REPORT.—Not later than 18 months after the  
19          date of enactment of this Act, the Comptroller General  
20          shall submit a report to Congress on the findings of the  
21          study conducted under subsection (a).

1 **SEC. 4009. STREAMLINING TRANSFERS USED FOR EDU-**  
2 **CATIONAL PURPOSES.**

3 (a) IN GENERAL.—Section 1128G(e)(10)(B) of the  
4 Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is  
5 amended—

6 (1) in clause (iii), by inserting “, including  
7 peer-reviewed journals, journal reprints, journal sup-  
8 plements, medical conference reports, and medical  
9 textbooks” after “patient use”; and

10 (2) by adding at the end the following new  
11 clause:

12 “(xiii) In the case of a covered recipi-  
13 ent who is a physician, an indirect pay-  
14 ment or transfer of value to the covered re-  
15 cipient—

16 “(I) for speaking at, or preparing  
17 educational materials for, an edu-  
18 cational event for physicians or other  
19 health care professionals that does not  
20 commercially promote a covered drug,  
21 device, biological, or medical supply;  
22 or

23 “(II) that serves the sole purpose  
24 of providing the covered recipient with  
25 medical education, such as by pro-  
26 viding the covered recipient with the

1                   tuition required to attend an edu-  
2                   cational event or with materials pro-  
3                   vided to physicians at an educational  
4                   event.”.

5           (b) **EFFECTIVE DATE.**—The amendments made by  
6 this section shall apply with respect to payments and  
7 transfers of value made on or after the date of enactment  
8 of this Act.

9   **SEC. 4010. IMPROVING MEDICARE LOCAL COVERAGE DE-**  
10                                   **TERMINATIONS.**

11           (a) **IN GENERAL.**—Section 1862(l)(5) of the Social  
12 Security Act (42 U.S.C. 1395y(l)(5)) is amended by add-  
13 ing at the end the following new subparagraph:

14                           “(D) **LOCAL COVERAGE DETERMINA-**  
15                           **TIONS.**—The Secretary shall require each Medi-  
16                           care administrative contractor that develops a  
17                           local coverage determination to make available  
18                           on the Internet website of such contractor and  
19                           on the Medicare Internet website, at least 45  
20                           days before the effective date of such deter-  
21                           mination, the following information:

22                                   “(i) Such determination in its en-  
23                                   tirety.

24                                   “(ii) Where and when the proposed  
25                                   determination was first made public.



1                   “(iii) Hyperlinks to the proposed de-  
2                   termination and a response to comments  
3                   submitted to the contractor with respect to  
4                   such proposed determination.

5                   “(iv) A summary of evidence that was  
6                   considered by the contractor during the de-  
7                   velopment of such determination and a list  
8                   of the sources of such evidence.

9                   “(v) An explanation of the rationale  
10                  that supports such determination.”.

11               (b) **EFFECTIVE DATE.**—The amendment made by  
12 subsection (a) shall apply with respect to local coverage  
13 determinations that are proposed or revised on or after  
14 the date that is 180 days after the date of enactment of  
15 this Act.

16 **SEC. 4011. MEDICARE PHARMACEUTICAL AND TECH-**  
17 **NOLOGY OMBUDSMAN.**

18               Section 1808 of the Social Security Act (42 U.S.C.  
19 1395b–9) is amended by adding at the end the following  
20 new subsection:

21               “(d) **PHARMACEUTICAL AND TECHNOLOGY OMBUDS-**  
22 **MAN.**—

23                   “(1) **IN GENERAL.**—Not later than 12 months  
24                   after the date of enactment of this paragraph, the  
25                   Secretary shall provide for a pharmaceutical and

1 technology ombudsman within the Centers for Medi-  
2 care & Medicaid Services who shall receive and re-  
3 spond to complaints, grievances, and requests that—

4 “(A) are from entities that manufacture  
5 pharmaceutical, biotechnology, medical device,  
6 or diagnostic products that are covered or for  
7 which coverage is being sought under this title;  
8 and

9 “(B) are with respect to coverage, coding,  
10 or payment under this title for such products.

11 “(2) APPLICATION.—The second sentence of  
12 subsection (c)(2) shall apply to the ombudsman  
13 under subparagraph (A) in the same manner as such  
14 sentence applies to the Medicare Beneficiary Om-  
15 budsman under subsection (c).”.

16 **SEC. 4012. MEDICARE SITE-OF-SERVICE PRICE TRANS-**  
17 **PARENCY.**

18 Section 1834 of the Social Security Act (42 U.S.C.  
19 1395m) is amended by adding at the end the following  
20 new subsection:

21 “(t) SITE-OF-SERVICE PRICE TRANSPARENCY.—

22 “(1) IN GENERAL.—In order to facilitate price  
23 transparency with respect to items and services for  
24 which payment may be made either to a hospital  
25 outpatient department or to an ambulatory surgical

1 center under this title, the Secretary shall, for 2018  
2 and each year thereafter, make available to the pub-  
3 lic via a searchable Internet website, with respect to  
4 an appropriate number of such items and services—

5 “(A) the estimated payment amount for  
6 the item or service under the outpatient depart-  
7 ment fee schedule under subsection (t) of sec-  
8 tion 1833 and the ambulatory surgical center  
9 payment system under subsection (i) of such  
10 section; and

11 “(B) the estimated amount of beneficiary  
12 liability applicable to the item or service.

13 “(2) CALCULATION OF ESTIMATED BENE-  
14 FICIARY LIABILITY.—For purposes of paragraph  
15 (1)(B), the estimated amount of beneficiary liability,  
16 with respect to an item or service, is the amount for  
17 such item or service for which an individual who  
18 does not have coverage under a Medicare supple-  
19 mental policy certified under section 1882 or any  
20 other supplemental insurance coverage is respon-  
21 sible.

22 “(3) IMPLEMENTATION.—In carrying out this  
23 subsection, the Secretary—

24 “(A) shall include in the notice described  
25 in section 1804(a) a notification of the avail-

1 ability of the estimated amounts made available  
2 under paragraph (1); and

3 “(B) may utilize mechanisms in existence  
4 on the date of enactment of this subsection,  
5 such as the portion of the Internet website of  
6 the Centers for Medicare & Medicaid Services  
7 on which information comparing physician per-  
8 formance is posted (commonly referred to as  
9 the Physician Compare Internet website), to  
10 make available such estimated amounts under  
11 such paragraph.

12 “(4) FUNDING.—For purposes of implementing  
13 this subsection, the Secretary shall provide for the  
14 transfer, from the Federal Supplementary Medical  
15 Insurance Trust Fund under section 1841 to the  
16 Centers for Medicare & Medicaid Services Program  
17 Management Account, of \$6,000,000 for fiscal year  
18 2017, to remain available until expended.”.

19 **SEC. 4013. TELEHEALTH SERVICES IN MEDICARE.**

20 (a) PROVISION OF INFORMATION BY CENTERS FOR  
21 MEDICARE & MEDICAID SERVICES.—Not later than 1  
22 year after the date of enactment of this Act, the Adminis-  
23 trator of the Centers for Medicare & Medicaid Services  
24 shall provide to the committees of jurisdiction of the

1 House of Representatives and the Senate information on  
2 the following:

3 (1) The populations of Medicare beneficiaries,  
4 such as those who are dually eligible for the Medi-  
5 care program under title XVIII of the Social Secu-  
6 rity Act (42 U.S.C. 1395 et seq.) and the Medicaid  
7 program under title XIX of such Act (42 U.S.C.  
8 1396 et seq.) and those with chronic conditions,  
9 whose care may be improved most in terms of qual-  
10 ity and efficiency by the expansion, in a manner that  
11 meets or exceeds the existing in-person standard of  
12 care under the Medicare program under such title  
13 XVIII, of telehealth services under section  
14 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

15 (2) Activities by the Center for Medicare and  
16 Medicaid Innovation which examine the use of tele-  
17 health services in models, projects, or initiatives  
18 funded through section 1115A of such Act (42  
19 U.S.C. 1315a).

20 (3) The types of high-volume services (and re-  
21 lated diagnoses) under such title XVIII which might  
22 be suitable to be furnished using telehealth.

23 (4) Barriers that might prevent the expansion  
24 of telehealth services under section 1834(m)(4) of  
25 the Social Security Act (42 U.S.C. 1395m(m)(4))

1 beyond such services that are in effect as of the date  
2 of enactment of this Act.

3 (b) PROVISION OF INFORMATION BY MEDPAC.—Not  
4 later than March 15, 2018, the Medicare Payment Advi-  
5 sory Commission established under section 1805 of the So-  
6 cial Security Act (42 U.S.C. 1395b–6) shall, using quan-  
7 titative and qualitative research methods, provide informa-  
8 tion to the committees of jurisdiction of the House of Rep-  
9 resentatives and the Senate that identifies—

10 (1) the telehealth services for which payment  
11 can be made, as of the date of enactment of this  
12 Act, under the fee-for-service program under parts A  
13 and B of title XVIII of such Act;

14 (2) the telehealth services for which payment  
15 can be made, as of such date, under private health  
16 insurance plans; and

17 (3) with respect to services identified under  
18 paragraph (2) but not under paragraph (1), ways in  
19 which payment for such services might be incor-  
20 porated into such fee-for-service program (including  
21 any recommendations for ways to accomplish this in-  
22 corporation).

23 (c) SENSE OF CONGRESS.—It is the sense of Con-  
24 gress that—

1 (1) eligible originating sites should be expanded  
2 beyond those originating sites described in section  
3 1834(m)(4)(C) of the Social Security Act (42 U.S.C.  
4 1395m(m)(4)(C)); and

5 (2) any expansion of telehealth services under  
6 the Medicare program under title XVIII of such Act  
7 should—

8 (A) recognize that telemedicine is the deliv-  
9 ery of safe, effective, quality health care serv-  
10 ices, by a health care provider, using technology  
11 as the mode of care delivery;

12 (B) meet or exceed the conditions of cov-  
13 erage and payment with respect to the Medicare  
14 program if the service was furnished in person,  
15 including standards of care, unless specifically  
16 addressed in subsequent legislation; and

17 (C) involve clinically appropriate means to  
18 furnish such services.

## 19 **TITLE V—SAVINGS**

### 20 **SEC. 5001. SAVINGS IN THE MEDICARE IMPROVEMENT** 21 **FUND.**

22 Section 1898(b)(1) of the Social Security Act (42  
23 U.S.C. 1395iii(b)(1)), as amended by section 704(h) of the  
24 Comprehensive Addiction and Recovery Act of 2016, is

1 amended by striking “\$140,000,000” and inserting  
2 “\$270,000,000”.

3 **SEC. 5002. MEDICAID REIMBURSEMENT TO STATES FOR DU-**  
4 **RABLE MEDICAL EQUIPMENT.**

5 Section 1903(i)(27) of the Social Security Act (42  
6 U.S.C. 1396b(i)(27)) is amended by striking “January 1,  
7 2019” and inserting “January 1, 2018”.

8 **SEC. 5003. PENALTIES FOR VIOLATIONS OF GRANTS, CON-**  
9 **TRACTS, AND OTHER AGREEMENTS.**

10 (a) IN GENERAL.—Section 1128A of the Social Secu-  
11 rity Act (42 U.S.C. 1320a–7a) is amended by adding at  
12 the end the following new subsections:

13 “(o) Any person (including an organization, agency,  
14 or other entity, but excluding a program beneficiary, as  
15 defined in subsection (q)(4)) that, with respect to a grant,  
16 contract, or other agreement for which the Secretary pro-  
17 vides funding—

18 “(1) knowingly presents or causes to be pre-  
19 sented a specified claim (as defined in subsection  
20 (r)) under such grant, contract, or other agreement  
21 that the person knows or should know is false or  
22 fraudulent;

23 “(2) knowingly makes, uses, or causes to be  
24 made or used any false statement, omission, or mis-  
25 representation of a material fact in any application,



1 proposal, bid, progress report, or other document  
2 that is required to be submitted in order to directly  
3 or indirectly receive or retain funds provided in  
4 whole or in part by such Secretary pursuant to such  
5 grant, contract, or other agreement;

6 “(3) knowingly makes, uses, or causes to be  
7 made or used, a false record or statement material  
8 to a false or fraudulent specified claim under such  
9 grant, contract, or other agreement;

10 “(4) knowingly makes, uses, or causes to be  
11 made or used, a false record or statement material  
12 to an obligation (as defined in subsection (s)) to pay  
13 or transmit funds or property to such Secretary with  
14 respect to such grant, contract, or other agreement,  
15 or knowingly conceals or knowingly and improperly  
16 avoids or decreases an obligation to pay or transmit  
17 funds or property to such Secretary with respect to  
18 such grant, contract, or other agreement; or

19 “(5) fails to grant timely access, upon reason-  
20 able request (as defined by such Secretary in regula-  
21 tions), to the Inspector General of the Department,  
22 for the purpose of audits, investigations, evaluations,  
23 or other statutory functions of such Inspector Gen-  
24 eral in matters involving such grants, contracts, or  
25 other agreements;

1 shall be subject, in addition to any other penalties that  
2 may be prescribed by law, to a civil money penalty in cases  
3 under paragraph (1), of not more than \$10,000 for each  
4 specified claim; in cases under paragraph (2), not more  
5 than \$50,000 for each false statement, omission, or mis-  
6 representation of a material fact; in cases under para-  
7 graph (3), not more than \$50,000 for each false record  
8 or statement; in cases under paragraph (4), not more than  
9 \$50,000 for each false record or statement or \$10,000 for  
10 each day that the person knowingly conceals or knowingly  
11 and improperly avoids or decreases an obligation to pay;  
12 or in cases under paragraph (5), not more than \$15,000  
13 for each day of the failure described in such paragraph.  
14 In addition, in cases under paragraphs (1) and (3), such  
15 a person shall be subject to an assessment of not more  
16 than 3 times the amount claimed in the specified claim  
17 described in such paragraph in lieu of damages sustained  
18 by the United States or a specified State agency because  
19 of such specified claim, and in cases under paragraphs (2)  
20 and (4), such a person shall be subject to an assessment  
21 of not more than 3 times the total amount of the funds  
22 described in paragraph (2) or (4), respectively (or, in the  
23 case of an obligation to transmit property to the Secretary  
24 described in paragraph (4), of the value of the property  
25 described in such paragraph) in lieu of damages sustained

1 by the United States or a specified State agency because  
2 of such case. In addition, the Secretary may make a deter-  
3 mination in the same proceeding to exclude the person  
4 from participation in the Federal health care programs (as  
5 defined in section 1128B(f)(1)) and to direct the appro-  
6 priate State agency to exclude the person from participa-  
7 tion in any State health care program.

8 “(p) The provisions of subsections (e), (d), (g), and  
9 (h) shall apply to a civil money penalty or assessment  
10 under subsection (o) in the same manner as such provi-  
11 sions apply to a penalty, assessment, or proceeding under  
12 subsection (a). In applying subsection (d), each reference  
13 to a claim under such subsection shall be treated as in-  
14 cluding a reference to a specified claim (as defined in sub-  
15 section (r)).

16 “(q) For purposes of this subsection and subsections  
17 (o) and (p):

18 “(1) The term ‘Department’ means the Depart-  
19 ment of Health and Human Services.

20 “(2) The term ‘material’ means having a nat-  
21 ural tendency to influence, or be capable of influ-  
22 encing, the payment or receipt of money or property.

23 “(3) The term ‘other agreement’ includes a co-  
24 operative agreement, scholarship, fellowship, loan,  
25 subsidy, payment for a specified use, donation agree-

1       ment, award, or subaward (regardless of whether  
2       one or more of the persons entering into the agree-  
3       ment is a contractor or subcontractor).

4           “(4) The term ‘program beneficiary’ means, in  
5       the case of a grant, contract, or other agreement de-  
6       signed to accomplish the objective of awarding or  
7       otherwise furnishing benefits or assistance to indi-  
8       viduals and for which the Secretary provides fund-  
9       ing, an individual who applies for, or who receives,  
10      such benefits or assistance from such grant, con-  
11      tract, or other agreement. Such term does not in-  
12      clude, with respect to such grant, contract, or other  
13      agreement, an officer, employee, or agent of a per-  
14      son or entity that receives such grant or that enters  
15      into such contract or other agreement.

16           “(5) The term ‘recipient’ includes a sub-  
17      recipient or subcontractor.

18           “(6) The term ‘specified State agency’ means  
19      an agency of a State government established or des-  
20      ignated to administer or supervise the administra-  
21      tion of a grant, contract, or other agreement funded  
22      in whole or in part by the Secretary.

23           “(r) For purposes of this section, the term ‘specified  
24      claim’ means any application, request, or demand under  
25      a grant, contract, or other agreement for money or prop-

1 erty, whether or not the United States or a specified State  
2 agency has title to the money or property, that is not a  
3 claim (as defined in subsection (i)(2)) and that—

4 “(1) is presented or caused to be presented to  
5 an officer, employee, or agent of the Department or  
6 agency thereof, or of any specified State agency; or

7 “(2) is made to a contractor, grantee, or any  
8 other recipient if the money or property is to be  
9 spent or used on the Department’s behalf or to ad-  
10 vance a Department program or interest, and if the  
11 Department—

12 “(A) provides or has provided any portion  
13 of the money or property requested or de-  
14 manded; or

15 “(B) will reimburse such contractor, grant-  
16 ee, or other recipient for any portion of the  
17 money or property which is requested or de-  
18 manded.

19 “(s) For purposes of subsection (o), the term ‘obliga-  
20 tion’ means an established duty, whether or not fixed, aris-  
21 ing from an express or implied contractual, grantor-grant-  
22 ee, or licensor-licensee relationship, for a fee-based or  
23 similar relationship, from statute or regulation, or from  
24 the retention of any overpayment.”.

1 (b) CONFORMING AMENDMENTS.—Section 1128A of  
2 the Social Security Act (42 U.S.C. 1320a–7a) is amend-  
3 ed—

4 (1) in subsection (e), by inserting “or specified  
5 claim” after “claim” in the first sentence; and

6 (2) in subsection (f)—

7 (A) in the matter preceding paragraph

8 (1)—

9 (i) by inserting “or specified claim (as  
10 defined in subsection (r))” after “district  
11 where the claim”; and

12 (ii) by inserting “(or, with respect to  
13 a person described in subsection (o), the  
14 person)” after “claimant”; and

15 (B) in the matter following paragraph (4),  
16 by inserting “(or, in the case of a penalty or as-  
17 sessment under subsection (o), by a specified  
18 State agency (as defined in subsection (q)(6)),”  
19 after “or a State agency”.

20 **SEC. 5004. REDUCING OVERPAYMENTS OF INFUSION**  
21 **DRUGS.**

22 (a) TREATMENT OF INFUSION DRUGS FURNISHED  
23 THROUGH DURABLE MEDICAL EQUIPMENT.—Section  
24 1842(o)(1) of the Social Security Act (42 U.S.C.  
25 1395u(o)(1)) is amended—

1 (1) in subparagraph (C), by inserting “(and in-  
2 cluding a drug or biological described in subpara-  
3 graph (D)(i) furnished on or after January 1,  
4 2017)” after “2005”; and

5 (2) in subparagraph (D)—

6 (A) by striking “infusion drugs” and in-  
7 serting “infusion drugs or biologicals” each  
8 place it appears; and

9 (B) in clause (i)—

10 (i) by striking “2004” and inserting  
11 “2004, and before January 1, 2017”; and

12 (ii) by striking “for such drug”.

13 (b) NONINCLUSION OF DME INFUSION DRUGS  
14 UNDER DME COMPETITIVE ACQUISITION PROGRAMS.—

15 (1) IN GENERAL.—Section 1847(a)(2)(A) of the  
16 Social Security Act (42 U.S.C. 1395w-3(a)(2)(A)) is  
17 amended—

18 (A) by striking “and excluding” and in-  
19 serting “, excluding”; and

20 (B) by inserting before the period at the  
21 end the following: “, and excluding drugs and  
22 biologicals described in section 1842(o)(1)(D)”.

23 (2) CONFORMING AMENDMENT.—Section  
24 1842(o)(1)(D)(ii) of the Social Security Act (42  
25 U.S.C. 1395u(o)(1)(D)(ii)) is amended by striking

1 “2007” and inserting “2007, and before the date of  
2 the enactment of the 21st Century Cures Act.”.

3 **SEC. 5005. INCREASING OVERSIGHT OF TERMINATION OF**  
4 **MEDICAID PROVIDERS.**

5 (a) INCREASED OVERSIGHT AND REPORTING.—

6 (1) STATE REPORTING REQUIREMENTS.—Sec-  
7 tion 1902(kk) of the Social Security Act (42 U.S.C.  
8 1396a(kk)) is amended—

9 (A) by redesignating paragraph (8) as  
10 paragraph (9); and

11 (B) by inserting after paragraph (7) the  
12 following new paragraph:

13 “(8) PROVIDER TERMINATIONS.—

14 “(A) IN GENERAL.—Beginning on July 1,  
15 2018, in the case of a notification under sub-  
16 section (a)(41) with respect to a termination for  
17 a reason specified in section 455.101 of title 42,  
18 Code of Federal Regulations (as in effect on  
19 November 1, 2015) or for any other reason  
20 specified by the Secretary, of the participation  
21 of a provider of services or any other person  
22 under the State plan (or under a waiver of the  
23 plan), the State, consistent with subparagraph  
24 (B), submits to the Secretary with respect to  
25 any such provider or person, as appropriate—



1                   “(i) the name of such provider or per-  
2                   son;

3                   “(ii) the provider type of such pro-  
4                   vider or person;

5                   “(iii) the specialty of such provider’s  
6                   or person’s practice;

7                   “(iv) the date of birth, Social Security  
8                   number, national provider identifier (if ap-  
9                   plicable), Federal taxpayer identification  
10                  number, and the State license or certifi-  
11                  cation number of such provider or person  
12                  (if applicable);

13                  “(v) the reason for the termination;

14                  “(vi) a copy of the notice of termi-  
15                  nation sent to the provider or person;

16                  “(vii) the date on which such termi-  
17                  nation is effective, as specified in the no-  
18                  tice; and

19                  “(viii) any other information required  
20                  by the Secretary.

21                  “(B) EFFECTIVE DATE DEFINED.—For  
22                  purposes of this paragraph, the term ‘effective  
23                  date’ means, with respect to a termination de-  
24                  scribed in subparagraph (A), the later of—

1           “(i) the date on which such termi-  
2           nation is effective, as specified in the no-  
3           tice of such termination; or

4           “(ii) the date on which all appeal  
5           rights applicable to such termination have  
6           been exhausted or the timeline for any  
7           such appeal has expired.”.

8           (2) CONTRACT REQUIREMENT FOR MANAGED  
9           CARE ENTITIES.—Section 1932(d) of the Social Se-  
10          curity Act (42 U.S.C. 1396u–2(d)) is amended by  
11          adding at the end the following new paragraph:

12          “(5) CONTRACT REQUIREMENT FOR MANAGED  
13          CARE ENTITIES.—With respect to any contract with  
14          a managed care entity under section 1903(m) or  
15          1905(t)(3) (as applicable), no later than July 1,  
16          2018, such contract shall include a provision that  
17          providers of services or persons terminated (as de-  
18          scribed in section 1902(kk)(8)) from participation  
19          under this title, title XVIII, or title XXI shall be  
20          terminated from participating under this title as a  
21          provider in any network of such entity that serves  
22          individuals eligible to receive medical assistance  
23          under this title.”.

24          (3) TERMINATION NOTIFICATION DATABASE.—  
25          Section 1902 of the Social Security Act (42 U.S.C.

1 1396a) is amended by adding at the end the fol-  
2 lowing new subsection:

3 “(ll) TERMINATION NOTIFICATION DATABASE.—In  
4 the case of a provider of services or any other person  
5 whose participation under this title or title XXI is termi-  
6 nated (as described in subsection (kk)(8)), the Secretary  
7 shall, not later than 30 days after the date on which the  
8 Secretary is notified of such termination under subsection  
9 (a)(41) (as applicable), review such termination and, if the  
10 Secretary determines appropriate, include such termi-  
11 nation in any database or similar system developed pursu-  
12 ant to section 6401(b)(2) of the Patient Protection and  
13 Affordable Care Act (42 U.S.C. 1395cc note; Public Law  
14 111–148).”.

15 (4) NO FEDERAL FUNDS FOR ITEMS AND SERV-  
16 ICES FURNISHED BY TERMINATED PROVIDERS.—  
17 Section 1903 of the Social Security Act (42 U.S.C.  
18 1396b) is amended—

19 (A) in subsection (i)(2)—

20 (i) in subparagraph (A), by striking  
21 the comma at the end and inserting a  
22 semicolon;

23 (ii) in subparagraph (B), by striking  
24 “or” at the end; and

1 (iii) by adding at the end the fol-  
2 lowing new subparagraph:

3 “(D) beginning on July 1, 2018, under the  
4 plan by any provider of services or person  
5 whose participation in the State plan is termi-  
6 nated (as described in section 1902(kk)(8))  
7 after the date that is 60 days after the date on  
8 which such termination is included in the data-  
9 base or other system under section 1902(ll);  
10 or”; and

11 (B) in subsection (m), by inserting after  
12 paragraph (2) the following new paragraph:

13 “(3) No payment shall be made under this title to  
14 a State with respect to expenditures incurred by the State  
15 for payment for services provided by a managed care enti-  
16 ty (as defined under section 1932(a)(1)) under the State  
17 plan under this title (or under a waiver of the plan) unless  
18 the State—

19 “(A) beginning on July 1, 2018, has a contract  
20 with such entity that complies with the requirement  
21 specified in section 1932(d)(5); and

22 “(B) beginning on January 1, 2018, complies  
23 with the requirement specified in section  
24 1932(d)(6)(A).”.

1           (5) DEVELOPMENT OF UNIFORM TERMINOLOGY  
2           FOR REASONS FOR PROVIDER TERMINATION.—Not  
3           later than July 1, 2017, the Secretary of Health and  
4           Human Services shall, in consultation with the  
5           heads of State agencies administering State Med-  
6           icaid plans (or waivers of such plans), issue regula-  
7           tions establishing uniform terminology to be used  
8           with respect to specifying reasons under subpara-  
9           graph (A)(v) of paragraph (8) of section 1902(kk)  
10          of the Social Security Act (42 U.S.C. 1396a(kk)), as  
11          added by paragraph (1), for the termination (as de-  
12          scribed in such paragraph (8)) of the participation  
13          of certain providers in the Medicaid program under  
14          title XIX of such Act or the Children’s Health In-  
15          surance Program under title XXI of such Act.

16          (6) CONFORMING AMENDMENT.—Section  
17          1902(a)(41) of the Social Security Act (42 U.S.C.  
18          1396a(a)(41)) is amended by striking “provide that  
19          whenever” and inserting “provide, in accordance  
20          with subsection (kk)(8) (as applicable), that when-  
21          ever”.

22          (b) INCREASING AVAILABILITY OF MEDICAID PRO-  
23          VIDER INFORMATION.—

24          (1) FFS PROVIDER ENROLLMENT.—Section  
25          1902(a) of the Social Security Act (42 U.S.C.

1 1396a(a)) is amended by inserting after paragraph  
2 (77) the following new paragraph:

3 “(78) provide that, not later than January 1,  
4 2017, in the case of a State that pursuant to its  
5 State plan or waiver of the plan for medical assist-  
6 ance pays for medical assistance on a fee-for-service  
7 basis, the State shall require each provider fur-  
8 nishing items and services to, or ordering, pre-  
9 scribing, referring, or certifying eligibility for, serv-  
10 ices for individuals eligible to receive medical assist-  
11 ance under such plan to enroll with the State agency  
12 and provide to the State agency the provider’s iden-  
13 tifying information, including the name, specialty,  
14 date of birth, Social Security number, national pro-  
15 vider identifier (if applicable), Federal taxpayer  
16 identification number, and the State license or cer-  
17 tification number of the provider (if applicable);”.

18 (2) MANAGED CARE PROVIDER ENROLLMENT.—  
19 Section 1932(d) of the Social Security Act (42  
20 U.S.C. 1396u–2(d)), as amended by subsection  
21 (a)(2), is amended by adding at the end the fol-  
22 lowing new paragraph:

23 “(6) ENROLLMENT OF PARTICIPATING PRO-  
24 VIDERS.—

1           “(A) IN GENERAL.—Beginning not later  
2 than January 1, 2018, a State shall require  
3 that, in order to participate as a provider in the  
4 network of a managed care entity that provides  
5 services to, or orders, prescribes, refers, or cer-  
6 tifies eligibility for services for, individuals who  
7 are eligible for medical assistance under the  
8 State plan under this title (or under a waiver  
9 of the plan) and who are enrolled with the enti-  
10 ty, the provider is enrolled consistent with sec-  
11 tion 1902(kk) with the State agency admin-  
12 istering the State plan under this title. Such  
13 enrollment shall include providing to the State  
14 agency the provider’s identifying information,  
15 including the name, specialty, date of birth, So-  
16 cial Security number, national provider identi-  
17 fier, Federal taxpayer identification number,  
18 and the State license or certification number of  
19 the provider.

20           “(B) RULE OF CONSTRUCTION.—Nothing  
21 in subparagraph (A) shall be construed as re-  
22 quiring a provider described in such subpara-  
23 graph to provide services to individuals who are  
24 not enrolled with a managed care entity under  
25 this title.”.

1 (c) COORDINATION WITH CHIP.—

2 (1) IN GENERAL.—Section 2107(e)(1) of the  
3 Social Security Act (42 U.S.C. 1397gg(e)(1)) is  
4 amended—

5 (A) by redesignating subparagraphs (B),  
6 (C), (D), (E), (F), (G), (H), (I), (J), (K), (L),  
7 (M), (N), and (O) as subparagraphs (D), (E),  
8 (F), (G), (H), (I), (J), (K), (M), (N), (O), (P),  
9 (Q), and (R), respectively;

10 (B) by inserting after subparagraph (A)  
11 the following new subparagraphs:

12 “(B) Section 1902(a)(39) (relating to ter-  
13 mination of participation of certain providers).

14 “(C) Section 1902(a)(78) (relating to en-  
15 rollment of providers participating in State  
16 plans providing medical assistance on a fee-for-  
17 service basis).”;

18 (C) by inserting after subparagraph (K)  
19 (as redesignated by subparagraph (A)) the fol-  
20 lowing new subparagraph:

21 “(L) Section 1903(m)(3) (relating to limi-  
22 tation on payment with respect to managed  
23 care).”; and

24 (D) in subparagraph (P) (as redesignated  
25 by subparagraph (A)), by striking “(a)(2)(C)



1           and (h)” and inserting “(a)(2)(C) (relating to  
2           Indian enrollment), (d)(5) (relating to contract  
3           requirement for managed care entities), (d)(6)  
4           (relating to enrollment of providers partici-  
5           pating with a managed care entity), and (h)  
6           (relating to special rules with respect to Indian  
7           enrollees, Indian health care providers, and In-  
8           dian managed care entities)”.

9           (2) EXCLUDING FROM MEDICAID PROVIDERS  
10          EXCLUDED FROM CHIP.—Section 1902(a)(39) of the  
11          Social Security Act (42 U.S.C. 1396a(a)(39)) is  
12          amended by striking “title XVIII or any other State  
13          plan under this title” and inserting “title XVIII, any  
14          other State plan under this title (or waiver of the  
15          plan), or any State child health plan under title XXI  
16          (or waiver of the plan) and such termination is in-  
17          cluded by the Secretary in any database or similar  
18          system developed pursuant to section 6401(b)(2) of  
19          the Patient Protection and Affordable Care Act”.

20          (d) RULE OF CONSTRUCTION.—Nothing in this sec-  
21          tion shall be construed as changing or limiting the appeal  
22          rights of providers or the process for appeals of States  
23          under the Social Security Act.

24          (e) OIG REPORT.—Not later than March 31, 2020,  
25          the Inspector General of the Department of Health and

1 Human Services shall submit to Congress a report on the  
2 implementation of the amendments made by this section.

3 Such report shall include the following:

4           (1) An assessment of the extent to which pro-  
5 viders who are included under subsection (ll) of sec-  
6 tion 1902 of the Social Security Act (42 U.S.C.  
7 1396a) (as added by subsection (a)(3)) in the data-  
8 base or similar system referred to in such subsection  
9 are terminated (as described in paragraph (8) of  
10 subsection (kk) of such section, as added by sub-  
11 section (a)(1)) from participation in all State plans  
12 under title XIX of such Act (or waivers of such  
13 plans).

14           (2) Information on the amount of Federal fi-  
15 nancial participation paid to States under section  
16 1903 of such Act in violation of the limitation on  
17 such payment specified in subparagraph (D) of sub-  
18 section (i)(2) of such section and paragraph (3) of  
19 subsection (m) of such section, as added by sub-  
20 section (a)(4).

21           (3) An assessment of the extent to which con-  
22 tracts with managed care entities under title XIX of  
23 such Act comply with the requirement specified in  
24 paragraph (5) of section 1932(d) of such Act, as  
25 added by subsection (a)(2).

1           (4) An assessment of the extent to which pro-  
2           viders have been enrolled under section 1902(a)(78)  
3           or 1932(d)(6)(A) of such Act (42 U.S.C.  
4           1396a(a)(78), 1396u-2(d)(6)(A)) with State agen-  
5           cies administering State plans under title XIX of  
6           such Act (or waivers of such plans).

7   **SEC. 5006. REQUIRING PUBLICATION OF FEE-FOR-SERVICE**  
8                           **PROVIDER DIRECTORY.**

9           (a) IN GENERAL.—Section 1902(a) of the Social Se-  
10          curity Act (42 U.S.C. 1396a(a)) is amended—

11           (1) in paragraph (81), by striking “and” at the  
12          end;

13           (2) in paragraph (82), by striking the period at  
14          the end and inserting “; and”; and

15           (3) by inserting after paragraph (82) the fol-  
16          lowing new paragraph:

17           “(83) provide that, not later than January 1,  
18          2017, in the case of a State plan (or waiver of the  
19          plan) that provides medical assistance on a fee-for-  
20          service basis or through a primary care case-man-  
21          agement system described in section 1915(b)(1)  
22          (other than a primary care case management entity  
23          (as defined by the Secretary)), the State shall pub-  
24          lish (and update on at least an annual basis) on the  
25          public website of the State agency administering the

1 State plan, a directory of the physicians described in  
2 subsection (mm) and, at State option, other pro-  
3 viders described in such subsection that—

4 “(A) includes—

5 “(i) with respect to each such physi-  
6 cian or provider—

7 “(I) the name of the physician or  
8 provider;

9 “(II) the specialty of the physi-  
10 cian or provider;

11 “(III) the address at which the  
12 physician or provider provides serv-  
13 ices; and

14 “(IV) the telephone number of  
15 the physician or provider; and

16 “(ii) with respect to any such physi-  
17 cian or provider participating in such a  
18 primary care case-management system, in-  
19 formation regarding—

20 “(I) whether the physician or  
21 provider is accepting as new patients  
22 individuals who receive medical assist-  
23 ance under this title; and

24 “(II) the physician’s or provider’s  
25 cultural and linguistic capabilities, in-

1 including the languages spoken by the  
2 physician or provider or by the skilled  
3 medical interpreter providing interpre-  
4 tation services at the physician's or  
5 provider's office; and

6 “(B) may include, at State option, with re-  
7 spect to each such physician or provider—

8 “(i) the Internet website of such phy-  
9 sician or provider; or

10 “(ii) whether the physician or provider  
11 is accepting as new patients individuals  
12 who receive medical assistance under this  
13 title.”.

14 (b) DIRECTORY PHYSICIAN OR PROVIDER DE-  
15 SCRIBED.—Section 1902 of the Social Security Act (42  
16 U.S.C. 1396a), as amended by section 5005(a)(3), is fur-  
17 ther amended by adding at the end the following new sub-  
18 section:

19 “(mm) DIRECTORY PHYSICIAN OR PROVIDER DE-  
20 SCRIBED.—A physician or provider described in this sub-  
21 section is—

22 “(1) in the case of a physician or provider of  
23 a provider type for which the State agency, as a con-  
24 dition on receiving payment for items and services  
25 furnished by the physician or provider to individuals

1 eligible to receive medical assistance under the State  
2 plan, requires the enrollment of the physician or pro-  
3 vider with the State agency, a physician or a pro-  
4 vider that—

5 “(A) is enrolled with the agency as of the  
6 date on which the directory is published or up-  
7 dated (as applicable) under subsection (a)(83);  
8 and

9 “(B) received payment under the State  
10 plan in the 12-month period preceding such  
11 date; and

12 “(2) in the case of a physician or provider of  
13 a provider type for which the State agency does not  
14 require such enrollment, a physician or provider that  
15 received payment under the State plan (or a waiver  
16 of the plan) in the 12-month period preceding the  
17 date on which the directory is published or updated  
18 (as applicable) under subsection (a)(83).”.

19 (c) RULE OF CONSTRUCTION.—

20 (1) IN GENERAL.—The amendment made by  
21 subsection (a) shall not be construed to apply in the  
22 case of a State (as defined for purposes of title XIX  
23 of the Social Security Act) in which all the individ-  
24 uals enrolled in the State plan under such title (or  
25 under a waiver of such plan), other than individuals

1 described in paragraph (2), are enrolled with a med-  
2 icaid managed care organization (as defined in sec-  
3 tion 1903(m)(1)(A) of such Act (42 U.S.C.  
4 1396b(m)(1)(A))), including prepaid inpatient health  
5 plans and prepaid ambulatory health plans (as de-  
6 fined by the Secretary of Health and Human Serv-  
7 ices).

8 (2) INDIVIDUALS DESCRIBED.—An individual  
9 described in this paragraph is an individual who is  
10 an Indian (as defined in section 4 of the Indian  
11 Health Care Improvement Act (25 U.S.C. 1603)) or  
12 an Alaska Native.

13 (d) EXCEPTION FOR STATE LEGISLATION.—In the  
14 case of a State plan under title XIX of the Social Security  
15 Act (42 U.S.C. 1396 et seq.), which the Secretary of  
16 Health and Human Services determines requires State  
17 legislation in order for the respective plan to meet one or  
18 more additional requirements imposed by amendments  
19 made by this section, the respective plan shall not be re-  
20 garded as failing to comply with the requirements of such  
21 title solely on the basis of its failure to meet such an addi-  
22 tional requirement before the first day of the first calendar  
23 quarter beginning after the close of the first regular ses-  
24 sion of the State legislature that begins after the date of  
25 enactment of this Act. For purposes of the previous sen-

1 tence, in the case of a State that has a 2-year legislative  
2 session, each year of the session shall be considered to be  
3 a separate regular session of the State legislature.

4 **SEC. 5007. FAIRNESS IN MEDICAID SUPPLEMENTAL NEEDS**  
5 **TRUSTS.**

6 (a) IN GENERAL.—Section 1917(d)(4)(A) of the So-  
7 cial Security Act (42 U.S.C. 1396p(d)(4)(A)) is amended  
8 by inserting “the individual,” after “for the benefit of such  
9 individual by”.

10 (b) EFFECTIVE DATE.—The amendment made by  
11 subsection (a) shall apply to trusts established on or after  
12 the date of the enactment of this Act.

13 **SEC. 5008. ELIMINATING FEDERAL FINANCIAL PARTICIPA-**  
14 **TION WITH RESPECT TO EXPENDITURES**  
15 **UNDER MEDICAID FOR AGENTS USED FOR**  
16 **COSMETIC PURPOSES OR HAIR GROWTH.**

17 (a) IN GENERAL.—Section 1903(i)(21) of the Social  
18 Security Act (42 U.S.C. 1396b(i)(21)) is amended by in-  
19 serting “section 1927(d)(2)(C) (relating to drugs when  
20 used for cosmetic purposes or hair growth), except where  
21 medically necessary, and” after “drugs described in”.

22 (b) EFFECTIVE DATE.—The amendment made by  
23 subsection (a) shall apply with respect to calendar quar-  
24 ters beginning on or after the date of the enactment of  
25 this Act.



1 **SEC. 5009. AMENDMENT TO THE PREVENTION AND PUBLIC**  
2 **HEALTH FUND.**

3 Section 4002(b) of the Patient Protection and Af-  
4 fordable Care Act (42 U.S.C. 300u-11(b)) is amended—

5 (1) in paragraph (3), by striking  
6 “\$1,250,000,000” and inserting “\$900,000,000”;

7 (2) in paragraph (4), by striking  
8 “\$1,500,000,000” and inserting “\$1,000,000,000”;

9 and

10 (3) by striking paragraph (5) and inserting the  
11 following:

12 “(5) for fiscal year 2022, \$1,500,000,000;

13 “(6) for fiscal year 2023, \$1,000,000,000;

14 “(7) for fiscal year 2024, \$1,700,000,000; and

15 “(8) for fiscal year 2025 and each fiscal year  
16 thereafter, \$2,000,000,000.”.

17 **SEC. 5010. STRATEGIC PETROLEUM RESERVE DRAWDOWN.**

18 (a) DRAWDOWN AND SALE.—

19 (1) IN GENERAL.—Notwithstanding section 161  
20 of the Energy Policy and Conservation Act (42  
21 U.S.C. 6241), except as provided in subsections (b)  
22 and (c), the Secretary of Energy shall drawdown  
23 and sell from the Strategic Petroleum Reserve—

24 (A) 10,000,000 barrels of crude oil during  
25 fiscal year 2017;

1 (B) 9,000,000 barrels of crude oil during  
2 fiscal year 2018; and

3 (C) 6,000,000 barrels of crude oil during  
4 fiscal year 2019.

5 (2) DEPOSIT OF AMOUNTS RECEIVED FROM  
6 SALE.—Amounts received from a sale under para-  
7 graph (1) shall be deposited in the general fund of  
8 the Treasury during the fiscal year in which the sale  
9 occurs.

10 (b) EMERGENCY PROTECTION.—The Secretary shall  
11 not draw down and sell crude oil under this section in  
12 quantities that would limit the authority to sell petroleum  
13 products under section 161(h) of the Energy Policy and  
14 Conservation Act (42 U.S.C. 6241(h)) in the full quantity  
15 authorized by that subsection.

16 (c) STRATEGIC PETROLEUM DRAWDOWN LIMITA-  
17 TIONS.—Subparagraphs (C) and (D) of section 161(h)(2)  
18 of the Energy Policy and Conservation Act (42 U.S.C.  
19 6241(h)(2)(C) and (D)) are both amended by striking  
20 “500,000,000” and inserting “450,000,000”.

21 **SEC. 5011. RESCISSION OF PORTION OF ACA TERRITORY**  
22 **FUNDING.**

23 Of the unobligated amounts available under section  
24 1323(c)(1) of the Patient Protection and Affordable Care

1 Act (42 U.S.C. 18043(c)(1)), \$464,000,000 is rescinded  
2 immediately upon the date of the enactment of this Act.

3 **SEC. 5012. MEDICARE COVERAGE OF HOME INFUSION**  
4 **THERAPY.**

5 (a) IN GENERAL.—Section 1861 of the Social Secu-  
6 rity Act (42 U.S.C. 1395x) is amended—

7 (1) in subsection (s)(2)—

8 (A) by striking “and” at the end of sub-  
9 paragraph (EE);

10 (B) by inserting “and” at the end of sub-  
11 paragraph (FF); and

12 (C) by inserting at the end the following  
13 new subparagraph:

14 “(GG) home infusion therapy (as defined in  
15 subsection (iii)(1));”; and

16 (2) by adding at the end the following new sub-  
17 section:

18 “(iii) HOME INFUSION THERAPY.—(1) The term  
19 ‘home infusion therapy’ means the items and services de-  
20 scribed in paragraph (2) furnished by a qualified home  
21 infusion therapy supplier (as defined in paragraph (3)(D))  
22 which are furnished in the individual’s home (as defined  
23 in paragraph (3)(B)) to an individual—

24 “(A) who is under the care of an applicable pro-  
25 vider (as defined in paragraph (3)(A)); and

1           “(B) with respect to whom a plan prescribing  
2           the type, amount, and duration of infusion therapy  
3           services that are to be furnished such individual has  
4           been established by a physician (as defined in sub-  
5           section (r)(1)) and is periodically reviewed by a phy-  
6           sician (as so defined) in coordination with the fur-  
7           nishing of home infusion drugs (as defined in para-  
8           graph (3)(C)) under part B.

9           “(2) The items and services described in this para-  
10          graph are the following:

11           “(A) Professional services, including nursing  
12           services, furnished in accordance with the plan.

13           “(B) Training and education (not otherwise  
14           paid for as durable medical equipment (as defined in  
15           subsection (n)), remote monitoring, and monitoring  
16           services for the provision of home infusion therapy  
17           and home infusion drugs furnished by a qualified  
18           home infusion therapy supplier.

19           “(3) For purposes of this subsection:

20           “(A) The term ‘applicable provider’ means—

21                   “(i) a physician;

22                   “(ii) a nurse practitioner; and

23                   “(iii) a physician assistant.

1           “(B) The term ‘home’ means a place of resi-  
2           dence used as the home of an individual (as defined  
3           for purposes of subsection (n)).

4           “(C) The term ‘home infusion drug’ means a  
5           parenteral drug or biological administered intra-  
6           venously, or subcutaneously for an administration  
7           period of 15 minutes or more, in the home of an in-  
8           dividual through a pump that is an item of durable  
9           medical equipment (as defined in subsection (n)).  
10          Such term does not include the following:

11                   “(i) Insulin pump systems.

12                   “(ii) A self-administered drug or biological  
13                   on a self-administered drug exclusion list.

14           “(D)(i) The term ‘qualified home infusion ther-  
15           apy supplier’ means a pharmacy, physician, or other  
16           provider of services or supplier licensed by the State  
17           in which the pharmacy, physician, or provider or  
18           services or supplier furnishes items or services and  
19           that—

20                   “(I) furnishes infusion therapy to individ-  
21                   uals with acute or chronic conditions requiring  
22                   administration of home infusion drugs;

23                   “(II) ensures the safe and effective provi-  
24                   sion and administration of home infusion ther-  
25                   apy on a 7-day-a-week, 24-hour-a-day basis;

1           “(III) is accredited by an organization des-  
2           signed by the Secretary pursuant to section  
3           1834(u)(5); and

4           “(IV) meets such other requirements as  
5           the Secretary determines appropriate, taking  
6           into account the standards of care for home in-  
7           fusion therapy established by Medicare Advan-  
8           tage plans under part C and in the private sec-  
9           tor.

10          “(ii) A qualified home infusion therapy supplier  
11          may subcontract with a pharmacy, physician, pro-  
12          vider of services, or supplier to meet the require-  
13          ments of this subparagraph.”.

14          (b) PAYMENT AND RELATED REQUIREMENTS FOR  
15          HOME INFUSION THERAPY.—Section 1834 of the Social  
16          Security Act (42 U.S.C. 1395m), as amended by section  
17          4012, is further amended by adding at the end the fol-  
18          lowing new subsection:

19          “(u) PAYMENT AND RELATED REQUIREMENTS FOR  
20          HOME INFUSION THERAPY.—

21                  “(1) PAYMENT.—

22                          “(A) SINGLE PAYMENT.—

23                                  “(i) IN GENERAL.—Subject to clause  
24                                  (iii) and subparagraphs (B) and (C), the  
25                                  Secretary shall implement a payment sys-

1           tem under which a single payment is made  
2           under this title to a qualified home infu-  
3           sion therapy supplier for items and serv-  
4           ices described in subparagraphs (A) and  
5           (B) of section 1861(iii)(2)) furnished by a  
6           qualified home infusion therapy supplier  
7           (as defined in section 1861(iii)(3)(D)) in  
8           coordination with the furnishing of home  
9           infusion drugs (as defined in section  
10          1861(iii)(3)(C)) under this part.

11           “(ii) UNIT OF SINGLE PAYMENT.—A  
12          unit of single payment under the payment  
13          system implemented under this subpara-  
14          graph is for each infusion drug administra-  
15          tion calendar day in the individual’s home.  
16          The Secretary shall, as appropriate, estab-  
17          lish single payment amounts for types of  
18          infusion therapy, including to take into ac-  
19          count variation in utilization of nursing  
20          services by therapy type.

21           “(iii) LIMITATION.—The single pay-  
22          ment amount determined under this sub-  
23          paragraph after application of subpara-  
24          graph (B) and paragraph (3) shall not ex-  
25          ceed the amount determined under the fee

1 schedule under section 1848 for infusion  
2 therapy services furnished in a calendar  
3 day if furnished in a physician office set-  
4 ting, except such single payment shall not  
5 reflect more than 5 hours of infusion for a  
6 particular therapy in a calendar day.

7 “(B) REQUIRED ADJUSTMENTS.—The Sec-  
8 retary shall adjust the single payment amount  
9 determined under subparagraph (A) for home  
10 infusion therapy services under section  
11 1861(iii)(1) to reflect other factors such as—

12 “(i) a geographic wage index and  
13 other costs that may vary by region; and

14 “(ii) patient acuity and complexity of  
15 drug administration.

16 “(C) DISCRETIONARY ADJUSTMENTS.—

17 “(i) IN GENERAL.—Subject to clause  
18 (ii), the Secretary may adjust the single  
19 payment amount determined under sub-  
20 paragraph (A) (after application of sub-  
21 paragraph (B)) to reflect outlier situations  
22 and other factors as the Secretary deter-  
23 mines appropriate.

24 “(ii) REQUIREMENT OF BUDGET NEU-  
25 TRALITY.—Any adjustment under this sub-



1 paragraph shall be made in a budget neu-  
2 tral manner.

3 “(2) CONSIDERATIONS.—In developing the pay-  
4 ment system under this subsection, the Secretary  
5 may consider the costs of furnishing infusion ther-  
6 apy in the home, consult with home infusion therapy  
7 suppliers, consider payment amounts for similar  
8 items and services under this part and part A, and  
9 consider payment amounts established by Medicare  
10 Advantage plans under part C and in the private in-  
11 surance market for home infusion therapy (including  
12 average per treatment day payment amounts by type  
13 of home infusion therapy).

14 “(3) ANNUAL UPDATES.—

15 “(A) IN GENERAL.—Subject to subpara-  
16 graph (B), the Secretary shall update the single  
17 payment amount under this subsection from  
18 year to year beginning in 2022 by increasing  
19 the single payment amount from the prior year  
20 by the percentage increase in the Consumer  
21 Price Index for all urban consumers (United  
22 States city average) for the 12-month period  
23 ending with June of the preceding year.

24 “(B) ADJUSTMENT.—For each year, the  
25 Secretary shall reduce the percentage increase

1 described in subparagraph (A) by the produc-  
2 tivity adjustment described in section  
3 1886(b)(3)(B)(xi)(II). The application of the  
4 preceding sentence may result in a percentage  
5 being less than 0.0 for a year, and may result  
6 in payment being less than such payment rates  
7 for the preceding year.

8 “(4) AUTHORITY TO APPLY PRIOR AUTHORIZA-  
9 TION.—The Secretary may, as determined appro-  
10 priate by the Secretary, apply prior authorization for  
11 home infusion therapy services under section  
12 1861(iii)(1).

13 “(5) ACCREDITATION OF QUALIFIED HOME IN-  
14 FUSION THERAPY SUPPLIERS.—

15 “(A) FACTORS FOR DESIGNATION OF AC-  
16 CREDITATION ORGANIZATIONS.—The Secretary  
17 shall consider the following factors in desig-  
18 nating accreditation organizations under sub-  
19 paragraph (B) and in reviewing and modifying  
20 the list of accreditation organizations des-  
21 ignated pursuant to subparagraph (C):

22 “(i) The ability of the organization to  
23 conduct timely reviews of accreditation ap-  
24 plications.

1                   “(ii) The ability of the organization to  
2                   take into account the capacities of sup-  
3                   pliers located in a rural area (as defined in  
4                   section 1886(d)(2)(D)).

5                   “(iii) Whether the organization has  
6                   established reasonable fees to be charged  
7                   to suppliers applying for accreditation.

8                   “(iv) Such other factors as the Sec-  
9                   retary determines appropriate.

10                  “(B) DESIGNATION.—Not later than Janu-  
11                  ary 1, 2021, the Secretary shall designate orga-  
12                  nizations to accredit suppliers furnishing home  
13                  infusion therapy. The list of accreditation orga-  
14                  nizations so designated may be modified pursu-  
15                  ant to subparagraph (C).

16                  “(C) REVIEW AND MODIFICATION OF LIST  
17                  OF ACCREDITATION ORGANIZATIONS.—

18                  “(i) IN GENERAL.—The Secretary  
19                  shall review the list of accreditation organi-  
20                  zations designated under subparagraph (B)  
21                  taking into account the factors under sub-  
22                  paragraph (A). Taking into account the re-  
23                  sults of such review, the Secretary may, by  
24                  regulation, modify the list of accreditation

1 organizations designated under subpara-  
2 graph (B).

3 “(ii) SPECIAL RULE FOR ACCREDITA-  
4 TIONS DONE PRIOR TO REMOVAL FROM  
5 LIST OF DESIGNATED ACCREDITATION OR-  
6 GANIZATIONS.—In the case where the Sec-  
7 retary removes an organization from the  
8 list of accreditation organizations des-  
9 ignated under subparagraph (B), any sup-  
10 plier that is accredited by the organization  
11 during the period beginning on the date on  
12 which the organization is designated as an  
13 accreditation organization under subpara-  
14 graph (B) and ending on the date on  
15 which the organization is removed from  
16 such list shall be considered to have been  
17 accredited by an organization designated  
18 by the Secretary under subparagraph (B)  
19 for the remaining period such accreditation  
20 is in effect.

21 “(D) RULE FOR ACCREDITATIONS MADE  
22 PRIOR TO DESIGNATION.—In the case of a sup-  
23 plier that is accredited before January 1, 2021,  
24 by an accreditation organization designated by  
25 the Secretary under subparagraph (B) as of

1           January 1, 2019, such supplier shall be consid-  
2           ered to have been accredited by an organization  
3           designated by the Secretary under such para-  
4           graph as of January 1, 2023, for the remaining  
5           period such accreditation is in effect.

6           “(6) NOTIFICATION OF INFUSION THERAPY OP-  
7           TIONS AVAILABLE PRIOR TO FURNISHING HOME IN-  
8           FUSION THERAPY.—Prior to the furnishing of home  
9           infusion therapy to an individual, the physician who  
10          establishes the plan described in section 1861(iii)(1)  
11          for the individual shall provide notification (in a  
12          form, manner, and frequency determined appro-  
13          priate by the Secretary) of the options available  
14          (such as home, physician’s office, hospital outpatient  
15          department) for the furnishing of infusion therapy  
16          under this part.”.

17          (c) CONFORMING AMENDMENTS.—

18                 (1)           PAYMENT           REFERENCE.—Section  
19           1833(a)(1) of the Social Security Act (42 U.S.C.  
20           1395l(a)(1)) is amended—

21                         (A) by striking “and” before “(AA)”; and

22                         (B) by inserting before the semicolon at  
23           the end the following: “, and (BB) with respect  
24           to home infusion therapy, the amount paid shall  
25           be an amount equal to 80 percent of the lesser

1 of the actual charge for the services or the  
2 amount determined under section 1834(u)”.

3 (2) DIRECT PAYMENT.—The first sentence of  
4 section 1842(b)(6) of the Social Security Act (42  
5 U.S.C. 1395u(b)(6)) is amended—

6 (A) by striking “and” before “(H)”; and

7 (B) by inserting before the period at the  
8 end the following: “, and (I) in the case of  
9 home infusion therapy, payment shall be made  
10 to the qualified home infusion therapy sup-  
11 plier”.

12 (3) EXCLUSION FROM HOME HEALTH SERV-  
13 ICES.—Section 1861(m) of the Social Security Act  
14 (42 U.S.C. 1395x(m)) is amended, in the first sen-  
15 tence, by inserting the following before the period at  
16 the end: “and home infusion therapy (as defined in  
17 subsection (iii)(i))”.

18 (d) EFFECTIVE DATE.—The amendments made by  
19 this section shall apply to items and services furnished on  
20 or after January 1, 2021.

21 **DIVISION B—HELPING FAMILIES**  
22 **IN MENTAL HEALTH CRISIS**

23 **SEC. 6000. SHORT TITLE.**

24 This division may be cited as the “Helping Families  
25 in Mental Health Crisis Reform Act of 2016”.

1 **TITLE VI—STRENGTHENING**  
2 **LEADERSHIP AND ACCOUNT-**  
3 **ABILITY**

4 **Subtitle A—Leadership**

5 **SEC. 6001. ASSISTANT SECRETARY FOR MENTAL HEALTH**  
6 **AND SUBSTANCE USE.**

7 (a) ASSISTANT SECRETARY.—Section 501(c) of the  
8 Public Health Service Act (42 U.S.C. 290aa(c)) is amend-  
9 ed to read as follows:

10 “(c) ASSISTANT SECRETARY AND DEPUTY ASSIST-  
11 ANT SECRETARY.—

12 “(1) ASSISTANT SECRETARY.—The Administra-  
13 tion shall be headed by an official to be known as  
14 the Assistant Secretary for Mental Health and Sub-  
15 stance Use (hereinafter in this title referred to as  
16 the ‘Assistant Secretary’) who shall be appointed by  
17 the President, by and with the advice and consent  
18 of the Senate.

19 “(2) DEPUTY ASSISTANT SECRETARY.—The As-  
20 sistant Secretary, with the approval of the Secretary,  
21 may appoint a Deputy Assistant Secretary and may  
22 employ and prescribe the functions of such officers  
23 and employees, including attorneys, as are necessary  
24 to administer the activities to be carried out through  
25 the Administration.”.

1 (b) TRANSFER OF AUTHORITIES.—The Secretary of  
2 Health and Human Services shall delegate to the Assist-  
3 ant Secretary for Mental Health and Substance Use all  
4 duties and authorities that—

5 (1) as of the day before the date of enactment  
6 of this Act, were vested in the Administrator of the  
7 Substance Abuse and Mental Health Services Ad-  
8 ministration; and

9 (2) are not terminated by this Act.

10 (c) CONFORMING AMENDMENTS.—Title V of the  
11 Public Health Service Act (42 U.S.C. 290aa et seq.), as  
12 amended by the previous provisions of this section, is fur-  
13 ther amended—

14 (1) by striking “Administrator of the Substance  
15 Abuse and Mental Health Services Administration”  
16 each place it appears and inserting “Assistant Sec-  
17 retary for Mental Health and Substance Use”; and

18 (2) by striking “Administrator” or “ADMINIS-  
19 TRATOR” each place it appears (including in any  
20 headings) and inserting “Assistant Secretary” or  
21 “ASSISTANT SECRETARY”, respectively, except where  
22 the term “Administrator” appears—

23 (A) in each of subsections (e) and (f) of  
24 section 501 of such Act (42 U.S.C. 290aa), in-



1 including the headings of such subsections, within  
2 the term “Associate Administrator”;

3 (B) in section 507(b)(6) of such Act (42  
4 U.S.C. 290bb(b)(6)), within the term “Adminis-  
5 trator of the Health Resources and Services Ad-  
6 ministration”;

7 (C) in section 507(b)(6) of such Act (42  
8 U.S.C. 290bb(b)(6)), within the term “Adminis-  
9 trator of the Centers for Medicare & Medicaid  
10 Services”;

11 (D) in section 519B(c)(1)(B) of such Act  
12 (42 U.S.C. 290bb–25b(c)(1)(B)), within the  
13 term “Administrator of the National Highway  
14 Traffic Safety Administration”; or

15 (E) in each of sections 519B(c)(1)(B),  
16 520C(a), and 520D(a) of such Act (42 U.S.C.  
17 290bb–25b(c)(1)(B), 290bb–34(a), 290bb–  
18 35(a)), within the term “Administrator of the  
19 Office of Juvenile Justice and Delinquency Pre-  
20 vention”.

21 (d) REFERENCES.—After executing subsections (a),  
22 (b), and (c), any reference in statute, regulation, or guid-  
23 ance to the Administrator of the Substance Abuse and  
24 Mental Health Services Administration shall be construed

1 to be a reference to the Assistant Secretary for Mental  
2 Health and Substance Use.

3 **SEC. 6002. STRENGTHENING THE LEADERSHIP OF THE SUB-**  
4 **STANCE ABUSE AND MENTAL HEALTH SERV-**  
5 **ICES ADMINISTRATION.**

6 Section 501 of the Public Health Service Act (42  
7 U.S.C. 290aa), as amended by section 6001, is further  
8 amended—

9 (1) in subsection (b)—

10 (A) in the subsection heading, by striking  
11 “AGENCIES” and inserting “CENTERS”; and

12 (B) in the matter preceding paragraph (1),  
13 by striking “entities” and inserting “Centers”;

14 (2) in subsection (d)—

15 (A) in paragraph (1)—

16 (i) by striking “agencies” each place  
17 the term appears and inserting “Centers”;  
18 and

19 (ii) by striking “such agency” and in-  
20 serting “such Center”;

21 (B) in paragraph (2)—

22 (i) by striking “agencies” and insert-  
23 ing “Centers”;

1 (ii) by striking “with respect to sub-  
2 stance abuse” and inserting “with respect  
3 to substance use disorders”; and

4 (iii) by striking “and individuals who  
5 are substance abusers” and inserting “and  
6 individuals with substance use disorders”;

7 (C) in paragraph (5), by striking “sub-  
8 stance abuse” and inserting “substance use dis-  
9 order”;

10 (D) in paragraph (6)—

11 (i) by striking “the Centers for Dis-  
12 ease Control” and inserting “the Centers  
13 for Disease Control and Prevention,”;

14 (ii) by striking “Administration de-  
15 velop” and inserting “Administration, de-  
16 velop”;

17 (iii) by striking “HIV or tuberculosis  
18 among substance abusers and individuals  
19 with mental illness” and inserting “HIV,  
20 hepatitis, tuberculosis, and other commu-  
21 nicable diseases among individuals with  
22 mental or substance use disorders,”; and

23 (iv) by striking “illnesses” at the end  
24 and inserting “diseases or disorders”;

1 (E) in paragraph (7), by striking “abuse  
2 utilizing anti-addiction medications, including  
3 methadone” and inserting “use disorders, in-  
4 cluding services that utilize drugs or devices ap-  
5 proved or cleared by the Food and Drug Ad-  
6 ministration for the treatment of substance use  
7 disorders”;

8 (F) in paragraph (8)—

9 (i) by striking “Agency for Health  
10 Care Policy Research” and inserting  
11 “Agency for Healthcare Research and  
12 Quality”; and

13 (ii) by striking “treatment and pre-  
14 vention” and inserting “prevention and  
15 treatment”;

16 (G) in paragraph (9)—

17 (i) by inserting “and maintenance”  
18 after “development”;

19 (ii) by striking “Agency for Health  
20 Care Policy Research” and inserting  
21 “Agency for Healthcare Research and  
22 Quality”; and

23 (iii) by striking “treatment and pre-  
24 vention services” and inserting “preven-  
25 tion, treatment, and recovery support serv-

1           ices and are appropriately incorporated  
2           into programs carried out by the Adminis-  
3           tration”;

4           (H) in paragraph (10), by striking “abuse”  
5           and inserting “use disorder”;

6           (I) by striking paragraph (11) and insert-  
7           ing the following:

8           “(11) work with relevant agencies of the De-  
9           partment of Health and Human Services on inte-  
10          grating mental health promotion and substance use  
11          disorder prevention with general health promotion  
12          and disease prevention and integrating mental and  
13          substance use disorders treatment services with  
14          physical health treatment services;”;

15          (J) in paragraph (13)—

16               (i) in the matter preceding subpara-  
17               graph (A), by striking “this title, assure  
18               that” and inserting “this title or part B of  
19               title XIX, or grant programs otherwise  
20               funded by the Administration”;

21               (ii) in subparagraph (A)—

22                       (I) by inserting “require that”  
23                       before “all grants”; and

24                       (II) by striking “and” at the end;

1 (iii) by redesignating subparagraph  
2 (B) as subparagraph (C);

3 (iv) by inserting after subparagraph  
4 (A) the following:

5 “(B) ensure that the director of each Cen-  
6 ter of the Administration consistently docu-  
7 ments the application of criteria when awarding  
8 grants and the ongoing oversight of grantees  
9 after such grants are awarded;”;

10 (v) in subparagraph (C), as so redес-  
11 igned—

12 (I) by inserting “require that”  
13 before “all grants”; and

14 (II) in clause (ii), by inserting  
15 “and” after the semicolon at the end;  
16 and

17 (vi) by adding at the end the fol-  
18 lowing:

19 “(D) inform a State when any funds are  
20 awarded through such a grant to any entity  
21 within such State;”;

22 (K) in paragraph (16), by striking “abuse  
23 and mental health information” and inserting  
24 “use disorder information, including evidence-  
25 based and promising best practices for preven-

1           tion, treatment, and recovery support services  
2           for individuals with mental and substance use  
3           disorders,”;

4                   (L) in paragraph (17)—

5                           (i) by striking “substance abuse” and  
6                           inserting “substance use disorder”; and

7                           (ii) by striking “and” at the end;

8                   (M) in paragraph (18), by striking the pe-  
9           riod and inserting a semicolon; and

10                   (N) by adding at the end the following:

11                   “(19) consult with State, local, and tribal gov-  
12           ernments, nongovernmental entities, and individuals  
13           with mental illness, particularly adults with a serious  
14           mental illness, children with a serious emotional dis-  
15           turbance, and the family members of such adults  
16           and children, with respect to improving community-  
17           based and other mental health services;

18                   “(20) collaborate with the Secretary of Defense  
19           and the Secretary of Veterans Affairs to improve the  
20           provision of mental and substance use disorder serv-  
21           ices provided by the Department of Defense and the  
22           Department of Veterans Affairs to members of the  
23           Armed Forces, veterans, and the family members of  
24           such members and veterans, including through the  
25           provision of services using the telehealth capabilities

1 of the Department of Defense and the Department  
2 of Veterans Affairs;

3 “(21) collaborate with the heads of relevant  
4 Federal agencies and departments, States, commu-  
5 nities, and nongovernmental experts to improve men-  
6 tal and substance use disorders services for chron-  
7 ically homeless individuals, including by designing  
8 strategies to provide such services in supportive  
9 housing;

10 “(22) work with States and other stakeholders  
11 to develop and support activities to recruit and re-  
12 tain a workforce addressing mental and substance  
13 use disorders;

14 “(23) collaborate with the Attorney General  
15 and representatives of the criminal justice system to  
16 improve mental and substance use disorders services  
17 for individuals who have been arrested or incarcer-  
18 ated;

19 “(24) after providing an opportunity for public  
20 input, set standards for grant programs under this  
21 title for mental and substance use disorders services  
22 and prevention programs, which standards may ad-  
23 dress—

24 “(A) the capacity of the grantee to imple-  
25 ment the award;



1           “(B) requirements for the description of  
2           the program implementation approach;

3           “(C) the extent to which the grant plan  
4           submitted by the grantee as part of its applica-  
5           tion must explain how the grantee will reach  
6           the population of focus and provide a statement  
7           of need, which may include information on how  
8           the grantee will increase access to services and  
9           a description of measurable objectives for im-  
10          proving outcomes;

11          “(D) the extent to which the grantee must  
12          collect and report on required performance  
13          measures; and

14          “(E) the extent to which the grantee is  
15          proposing to use evidence-based practices; and

16          “(25) advance, through existing programs, the  
17          use of performance metrics, including those based on  
18          the recommendations on performance metrics from  
19          the Assistant Secretary for Planning and Evaluation  
20          under section 6021(d) of the Helping Families in  
21          Mental Health Crisis Reform Act of 2016.”; and

22          (3) in subsection (m), by adding at the end the  
23          following:

24          “(4) EMERGENCY RESPONSE.—Amounts made  
25          available for carrying out this subsection shall re-

1 main available through the end of the fiscal year fol-  
2 lowing the fiscal year for which such amounts are  
3 appropriated.”.

4 **SEC. 6003. CHIEF MEDICAL OFFICER.**

5 Section 501 of the Public Health Service Act (42  
6 U.S.C. 290aa), as amended by sections 6001 and 6002,  
7 is further amended—

8 (1) by redesignating subsections (g) through (j)  
9 and subsections (k) through (o) as subsections (h)  
10 through (k) and subsections (m) through (q), respec-  
11 tively;

12 (2) in subsection (e)(3)(C), by striking “sub-  
13 section (k)” and inserting “subsection (m)”;

14 (3) in subsection (f)(2)(C)(iii), by striking “sub-  
15 section (k)” and inserting “subsection (m)”;

16 (4) by inserting after subsection (f) the fol-  
17 lowing:

18 “(g) CHIEF MEDICAL OFFICER.—

19 “(1) IN GENERAL.—The Assistant Secretary,  
20 with the approval of the Secretary, shall appoint a  
21 Chief Medical Officer to serve within the Adminis-  
22 tration.

23 “(2) ELIGIBLE CANDIDATES.—The Assistant  
24 Secretary shall select the Chief Medical Officer from  
25 among individuals who—

1           “(A) have a doctoral degree in medicine or  
2           osteopathic medicine;

3           “(B) have experience in the provision of  
4           mental or substance use disorder services;

5           “(C) have experience working with mental  
6           or substance use disorder programs;

7           “(D) have an understanding of biological,  
8           psychosocial, and pharmaceutical treatments of  
9           mental or substance use disorders; and

10          “(E) are licensed to practice medicine in  
11          one or more States.

12          “(3) DUTIES.—The Chief Medical Officer  
13          shall—

14               “(A) serve as a liaison between the Admin-  
15               istration and providers of mental and substance  
16               use disorders prevention, treatment, and recov-  
17               ery services;

18               “(B) assist the Assistant Secretary in the  
19               evaluation, organization, integration, and co-  
20               ordination of programs operated by the Admin-  
21               istration;

22               “(C) promote evidence-based and prom-  
23               ising best practices, including culturally and lin-  
24               guistically appropriate practices, as appropriate,  
25               for the prevention and treatment of, and recov-

1           ery from, mental and substance use disorders,  
2           including serious mental illness and serious  
3           emotional disturbances;

4           “(D) participate in regular strategic plan-  
5           ning with the Administration;

6           “(E) coordinate with the Assistant Sec-  
7           retary for Planning and Evaluation to assess  
8           the use of performance metrics to evaluate ac-  
9           tivities within the Administration related to  
10          mental and substance use disorders; and

11          “(F) coordinate with the Assistant Sec-  
12          retary to ensure mental and substance use dis-  
13          orders grant programs within the Administra-  
14          tion consistently utilize appropriate perform-  
15          ance metrics and evaluation designs.”.

16 **SEC. 6004. IMPROVING THE QUALITY OF BEHAVIORAL**  
17 **HEALTH PROGRAMS.**

18          Section 505 of the Public Health Service Act (42  
19 U.S.C. 290aa-4), as amended by section 6001(c), is  
20 amended—

21           (1) by striking the section designation and  
22          heading and inserting the following:

1 **“SEC. 505. CENTER FOR BEHAVIORAL HEALTH STATISTICS**  
2 **AND QUALITY.”;**

3 (2) by redesignating subsections (a) through (d)  
4 as subsections (b) through (e), respectively;

5 (3) before subsection (b), as redesignated by  
6 paragraph (2), by inserting the following:

7 “(a) IN GENERAL.—The Assistant Secretary shall  
8 maintain within the Administration a Center for Behav-  
9 ioral Health Statistics and Quality (in this section referred  
10 to as the ‘Center’). The Center shall be headed by a Direc-  
11 tor (in this section referred to as the ‘Director’) appointed  
12 by the Secretary from among individuals with extensive  
13 experience and academic qualifications in research and  
14 analysis in behavioral health care or related fields.”;

15 (4) in subsection (b), as redesignated by para-  
16 graph (2)—

17 (A) by redesignating paragraphs (1) and  
18 (2) as subparagraphs (A) and (B), respectively;

19 (B) by striking “The Secretary, acting”  
20 and all that follows through “year on—” and  
21 inserting “The Director shall—

22 “(1) coordinate the Administration’s integrated  
23 data strategy, including by collecting data each year  
24 on—”;

1 (C) in the subparagraph (B), as redesignig-  
2 nated by subparagraph (A), by striking “Assist-  
3 ant Secretary” and inserting “Director”; and

4 (D) by adding at the end the following new  
5 paragraphs:

6 “(2) provide statistical and analytical support  
7 for activities of the Administration;

8 “(3) recommend a core set of performance  
9 metrics to evaluate activities supported by the Ad-  
10 ministration; and

11 “(4) coordinate with the Assistant Secretary,  
12 the Assistant Secretary for Planning and Evalua-  
13 tion, and the Chief Medical Officer appointed under  
14 section 501(g), as appropriate, to improve the qual-  
15 ity of services provided by programs of the Adminis-  
16 tration and the evaluation of activities carried out by  
17 the Administration.”.

18 (5) in subsection (c), as so redesignated—

19 (A) by striking “With respect to the activi-  
20 ties” and inserting “MENTAL HEALTH.—With  
21 respect to the activities”;

22 (B) by striking “Assistant Secretary” each  
23 place it appears and inserting “Director”; and

24 (C) by striking “subsection (a)” and in-  
25 serting “subsection (b)(1)”;

1 (6) in subsection (d), as so redesignated—

2 (A) by striking the subsection designation  
3 and all that follows through “With respect to  
4 the activities” and inserting the following:

5 “(d) SUBSTANCE ABUSE.—

6 “(1) IN GENERAL.—With respect to the activi-  
7 ties”;

8 (B) in paragraph (1)—

9 (i) in the matter before subparagraph

10 (A)—

11 (I) by striking “subsection (a)”  
12 and inserting “subsection (b)(1)”; and

13 (II) by striking “Assistant Sec-  
14 retary” each place it appears and in-  
15 serting “Director”; and

16 (ii) in subparagraph (B), by inserting  
17 “in coordination with the Centers for Dis-  
18 ease Control and Prevention” before the  
19 semicolon at the end; and

20 (C) in paragraph (2), by striking “ANNUAL  
21 SURVEYS” and inserting “ANNUAL SURVEYS;  
22 PUBLIC AVAILABILITY OF DATA.—Annual sur-  
23 veys”; and

24 (7) in subsection (e), as so redesignated—

1 (A) by striking “After consultation” and  
2 inserting “CONSULTATION.—After consulta-  
3 tion”; and

4 (B) by striking “Assistant Secretary shall  
5 develop” and inserting “Assistant Secretary  
6 shall use existing standards and best practices  
7 to develop”.

8 **SEC. 6005. STRATEGIC PLAN.**

9 Section 501 of the Public Health Service Act (42  
10 U.S.C. 290aa), as amended by sections 6001 through  
11 6003, is further amended by inserting after subsection (k),  
12 as redesignated by section 6003, the following:

13 “(l) STRATEGIC PLAN.—

14 “(1) IN GENERAL.—Not later than September  
15 30, 2018, and every 4 years thereafter, the Assistant  
16 Secretary shall develop and carry out a strategic  
17 plan in accordance with this subsection for the plan-  
18 ning and operation of activities carried out by the  
19 Administration, including evidence-based programs.

20 “(2) COORDINATION.—In developing and car-  
21 rying out the strategic plan under this subsection,  
22 the Assistant Secretary shall take into consideration  
23 the findings and recommendations of the Assistant  
24 Secretary for Planning and Evaluation under section  
25 6021(d) of the Helping Families in Mental Health



1 Crisis Reform Act of 2016 and the report of the  
2 Interdepartmental Serious Mental Illness Coordinating  
3 Committee under section 6031 of such Act.

4 “(3) PUBLICATION OF PLAN.—Not later than  
5 September 30, 2018, and every 4 years thereafter,  
6 the Assistant Secretary shall—

7 “(A) submit the strategic plan developed  
8 under paragraph (1) to the Committee on En-  
9 ergy and Commerce and the Committee on Ap-  
10 propriations of the House of Representatives  
11 and the Committee on Health, Education,  
12 Labor, and Pensions and the Committee on Ap-  
13 propriations of the Senate; and

14 “(B) post such plan on the Internet  
15 website of the Administration.

16 “(4) CONTENTS.—The strategic plan developed  
17 under paragraph (1) shall—

18 “(A) identify strategic priorities, goals, and  
19 measurable objectives for mental and substance  
20 use disorders activities and programs operated  
21 and supported by the Administration, including  
22 priorities to prevent or eliminate the burden of  
23 mental and substance use disorders;

24 “(B) identify ways to improve the quality  
25 of services for individuals with mental and sub-

1           stance use disorders, and to reduce homeless-  
2           ness, arrest, incarceration, violence, including  
3           self-directed violence, and unnecessary hos-  
4           pitalization of individuals with a mental or sub-  
5           stance use disorder, including adults with a se-  
6           rious mental illness or children with a serious  
7           emotional disturbance;

8                   “(C) ensure that programs provide, as ap-  
9                   propriate, access to effective and evidence-based  
10                  prevention, diagnosis, intervention, treatment,  
11                  and recovery services, including culturally and  
12                  linguistically appropriate services, as appro-  
13                  priate, for individuals with a mental or sub-  
14                  stance use disorder;

15                  “(D) identify opportunities to collaborate  
16                  with the Health Resources and Services Admin-  
17                  istration to develop or improve—

18                          “(i) initiatives to encourage individ-  
19                          uals to pursue careers (especially in rural  
20                          and underserved areas and with rural and  
21                          underserved populations) as psychiatrists,  
22                          including child and adolescent psychia-  
23                          trists, psychologists, psychiatric nurse  
24                          practitioners, physician assistants, clinical  
25                          social workers, certified peer support spe-

1 cialists, licensed professional counselors, or  
2 other licensed or certified mental health or  
3 substance use disorder professionals, in-  
4 cluding such professionals specializing in  
5 the diagnosis, evaluation, or treatment of  
6 adults with a serious mental illness or chil-  
7 dren with a serious emotional disturbance;  
8 and

9 “(ii) a strategy to improve the recruit-  
10 ment, training, and retention of a work-  
11 force for the treatment of individuals with  
12 mental or substance use disorders, or co-  
13 occurring disorders;

14 “(E) identify opportunities to improve col-  
15 laboration with States, local governments, com-  
16 munities, and Indian tribes and tribal organiza-  
17 tions (as such terms are defined in section 4 of  
18 the Indian Self-Determination and Education  
19 Assistance Act); and

20 “(F) specify a strategy to disseminate evi-  
21 dence-based and promising best practices re-  
22 lated to prevention, diagnosis, early interven-  
23 tion, treatment, and recovery services related to  
24 mental illness, particularly for adults with a se-  
25 rious mental illness and children with a serious

1 emotional disturbance, and for individuals with  
2 a substance use disorder.”.

3 **SEC. 6006. BIENNIAL REPORT CONCERNING ACTIVITIES**  
4 **AND PROGRESS.**

5 (a) IN GENERAL.—Section 501 of the Public Health  
6 Service Act (42 U.S.C. 290aa), as so amended, is further  
7 amended by amending subsection (m), as redesignated by  
8 section 6003, to read as follows:

9 “(m) BIENNIAL REPORT CONCERNING ACTIVITIES  
10 AND PROGRESS.—Not later than September 30, 2020,  
11 and every 2 years thereafter, the Assistant Secretary shall  
12 prepare and submit to the Committee on Energy and  
13 Commerce and the Committee on Appropriations of the  
14 House of Representatives and the Committee on Health,  
15 Education, Labor, and Pensions and the Committee on  
16 Appropriations of the Senate, and post on the Internet  
17 website of the Administration, a report containing at a  
18 minimum—

19 “(1) a review of activities conducted or sup-  
20 ported by the Administration, including progress to-  
21 ward strategic priorities, goals, and objectives identi-  
22 fied in the strategic plan developed under subsection  
23 (l);

24 “(2) an assessment of programs and activities  
25 carried out by the Assistant Secretary, including the

1 extent to which programs and activities under this  
2 title and part B of title XIX meet identified goals  
3 and performance measures developed for the respec-  
4 tive programs and activities;

5 “(3) a description of the progress made in ad-  
6 dressing gaps in mental and substance use disorders  
7 prevention, treatment, and recovery services and im-  
8 proving outcomes by the Administration, including  
9 with respect to serious mental illnesses, serious emo-  
10 tional disturbances, and co-occurring disorders;

11 “(4) a description of the manner in which the  
12 Administration coordinates and partners with other  
13 Federal agencies and departments related to mental  
14 and substance use disorders, including activities re-  
15 lated to—

16 “(A) the implementation and dissemination  
17 of research findings into improved programs,  
18 including with respect to how advances in seri-  
19 ous mental illness and serious emotional dis-  
20 turbance research have been incorporated into  
21 programs;

22 “(B) the recruitment, training, and reten-  
23 tion of a mental and substance use disorders  
24 workforce;

1           “(C) the integration of mental disorder  
2           services, substance use disorder services, and  
3           physical health services;

4           “(D) homelessness; and

5           “(E) veterans;

6           “(5) a description of the manner in which the  
7           Administration promotes coordination by grantees  
8           under this title, and part B of title XIX, with State  
9           or local agencies; and

10          “(6) a description of the activities carried out  
11          under section 501A(e), with respect to mental and  
12          substance use disorders, including—

13                 “(A) the number and a description of  
14                 grants awarded;

15                 “(B) the total amount of funding for  
16                 grants awarded;

17                 “(C) a description of the activities sup-  
18                 ported through such grants, including outcomes  
19                 of programs supported; and

20                 “(D) information on how the National  
21                 Mental Health and Substance Use Policy Lab-  
22                 oratory is consulting with the Assistant Sec-  
23                 retary for Planning and Evaluation and collabo-  
24                 rating with the Center for Substance Abuse  
25                 Treatment, the Center for Substance Abuse

1           Prevention, the Center for Behavioral Health  
2           Statistics and Quality, and the Center for Men-  
3           tal Health Services to carry out such activities;  
4           and

5           “(7) recommendations made by the Assistant  
6           Secretary for Planning and Evaluation under section  
7           6021 of the Helping Families in Mental Health Cri-  
8           sis Reform Act of 2016 to improve programs within  
9           the Administration, and actions taken in response to  
10          such recommendations to improve programs within  
11          the Administration.

12          The Assistant Secretary may meet reporting requirements  
13          established under this title by providing the contents of  
14          such reports as an addendum to the biennial report estab-  
15          lished under this subsection, notwithstanding the timeline  
16          of other reporting requirements in this title. Nothing in  
17          this subsection shall be construed to alter the content re-  
18          quirements of such reports or authorize the Assistant Sec-  
19          retary to alter the timeline of any such reports to be less  
20          frequent than biennially, unless as specified in this title.”.

21          (b) CONFORMING AMENDMENT.—Section 508(p) of  
22          the Public Health Service Act (42 U.S.C. 290bb–1(p)) is  
23          amended by striking “section 501(k)” and inserting “sec-  
24          tion 501(m)”.

1 **SEC. 6007. AUTHORITIES OF CENTERS FOR MENTAL**  
2 **HEALTH SERVICES, SUBSTANCE ABUSE PRE-**  
3 **VENTION, AND SUBSTANCE ABUSE TREAT-**  
4 **MENT.**

5 (a) CENTER FOR MENTAL HEALTH SERVICES.—Sec-  
6 tion 520(b) of the Public Health Service Act (42 U.S.C.  
7 290bb–31(b)) is amended—

8 (1) by redesignating paragraphs (3) through  
9 (15) as paragraphs (4) through (16), respectively;

10 (2) by inserting after paragraph (2) the fol-  
11 lowing:

12 “(3) collaborate with the Director of the Na-  
13 tional Institute of Mental Health and the Chief Med-  
14 ical Officer, appointed under section 501(g), to en-  
15 sure that, as appropriate, programs related to the  
16 prevention and treatment of mental illness and the  
17 promotion of mental health and recovery support are  
18 carried out in a manner that reflects the best avail-  
19 able science and evidence-based practices, including  
20 culturally and linguistically appropriate services, as  
21 appropriate;”;

22 (3) in paragraph (5), as so redesignated, by in-  
23 serting “, including through programs that reduce  
24 risk and promote resiliency” before the semicolon;

25 (4) in paragraph (6), as so redesignated, by in-  
26 serting “in collaboration with the Director of the



1 National Institute of Mental Health,” before “de-  
2 velop”;

3 (5) in paragraph (8), as so redesignated, by in-  
4 serting “, increase meaningful participation of indi-  
5 viduals with mental illness in programs and activi-  
6 ties of the Administration,” before “and protect the  
7 legal”;

8 (6) in paragraph (10), as so redesignated, by  
9 striking “professional and paraprofessional per-  
10 sonnel pursuant to section 303” and inserting  
11 “health paraprofessional personnel and health pro-  
12 fessionals”;

13 (7) in paragraph (11), as so redesignated, by  
14 inserting “and tele-mental health” after “rural men-  
15 tal health”;

16 (8) in paragraph (12), as so redesignated, by  
17 striking “establish a clearinghouse for mental health  
18 information to assure the widespread dissemination  
19 of such information” and inserting “disseminate  
20 mental health information, including evidence-based  
21 practices,”;

22 (9) in paragraph (15), as so redesignated, by  
23 striking “and” at the end;

24 (10) in paragraph (16), as so redesignated, by  
25 striking the period and inserting “; and”; and

1 (11) by adding at the end the following:

2 “(17) ensure the consistent documentation of  
3 the application of criteria when awarding grants and  
4 the ongoing oversight of grantees after such grants  
5 are awarded.”.

6 (b) DIRECTOR OF THE CENTER FOR SUBSTANCE  
7 ABUSE PREVENTION.—Section 515 of the Public Health  
8 Service Act (42 U.S.C. 290bb–21) is amended—

9 (1) in the section heading, by striking “OF-  
10 FICE” and inserting “CENTER”;

11 (2) in subsection (a)—

12 (A) by striking “an Office” and inserting  
13 “a Center”; and

14 (B) by striking “The Office” and inserting  
15 “The Prevention Center”; and

16 (3) in subsection (b)—

17 (A) in paragraph (1), by inserting  
18 “through the reduction of risk and the pro-  
19 motion of resiliency” before the semicolon;

20 (B) by redesignating paragraphs (3)  
21 through (11) as paragraphs (4) through (12),  
22 respectively;

23 (C) by inserting after paragraph (2) the  
24 following:

1           “(3) collaborate with the Director of the Na-  
2           tional Institute on Drug Abuse, the Director of the  
3           National Institute on Alcohol Abuse and Alcoholism,  
4           and States to promote the study of substance abuse  
5           prevention and the dissemination and implementa-  
6           tion of research findings that will improve the deliv-  
7           ery and effectiveness of substance abuse prevention  
8           activities;”;

9           (D) in paragraph (4), as so redesignated,  
10           by striking “literature on the adverse effects of  
11           cocaine free base (known as crack)” and insert-  
12           ing “educational information on the effects of  
13           drugs abused by individuals, including drugs  
14           that are emerging as abused drugs”;

15           (E) in paragraph (6), as so redesignated—

16           (i) by striking “substance abuse coun-  
17           selors” and inserting “health professionals  
18           who provide substance use and misuse pre-  
19           vention and treatment services”; and

20           (ii) by striking “drug abuse education,  
21           prevention,” and inserting “illicit drug use  
22           education and prevention”;

23           (F) by amending paragraph (7), as so re-  
24           designated, to read as follows:

1           “(7) in cooperation with the Director of the  
2           Centers for Disease Control and Prevention, develop  
3           and disseminate educational materials to increase  
4           awareness for individuals at greatest risk for sub-  
5           stance use disorders to prevent the transmission of  
6           communicable diseases, such as HIV, hepatitis, tu-  
7           berculosis, and other communicable diseases;”;

8           (G) in paragraph (9), as so redesignated—

9                   (i) by striking “to discourage” and in-  
10                   serting “that reduce the risk of”; and

11                   (ii) by inserting before the semicolon  
12                   “and promote resiliency”;

13           (H) in paragraph (11), as so redesignated,  
14           by striking “and” after the semicolon;

15           (I) in paragraph (12), as so redesignated,  
16           by striking the period and inserting a semi-  
17           colon; and

18           (J) by adding at the end the following:

19                   “(13) ensure the consistent documentation of  
20                   the application of criteria when awarding grants and  
21                   the ongoing oversight of grantees after such grants  
22                   are awarded; and

23                   “(14) assist and support States in preventing il-  
24                   licit drug use, including emerging illicit drug use  
25                   issues.”.

1           (c) DIRECTOR OF THE CENTER FOR SUBSTANCE  
2 ABUSE TREATMENT.—Section 507 of the Public Health  
3 Service Act (42 U.S.C. 290bb) is amended—

4           (1) in subsection (a)—

5                 (A) by striking “treatment of substance  
6 abuse” and inserting “treatment of substance  
7 use disorders”; and

8                 (B) by striking “abuse treatment systems”  
9 and inserting “use disorder treatment systems”;  
10 and

11           (2) in subsection (b)—

12                 (A) in paragraph (1), by striking “abuse”  
13 and inserting “use disorder”;

14                 (B) in paragraph (3), by striking “abuse”  
15 and inserting “use disorder”;

16                 (C) in paragraph (4), by striking “individ-  
17 uals who abuse drugs” and inserting “individ-  
18 uals who illicitly use drugs”;

19                 (D) in paragraph (9), by striking “carried  
20 out by the Director”;

21                 (E) by striking paragraph (10);

22                 (F) by redesignating paragraphs (11)  
23 through (14) as paragraphs (10) through (13),  
24 respectively;

1 (G) in paragraph (12), as so redesignated,  
2 by striking “; and” and inserting a semicolon;  
3 and

4 (H) by striking paragraph (13), as so re-  
5 designated, and inserting the following:

6 “(13) ensure the consistent documentation of  
7 the application of criteria when awarding grants and  
8 the ongoing oversight of grantees after such grants  
9 are awarded; and

10 “(14) work with States, providers, and individ-  
11 uals in recovery, and their families, to promote the  
12 expansion of recovery support services and systems  
13 of care oriented toward recovery.”.

14 **SEC. 6008. ADVISORY COUNCILS.**

15 Section 502(b) of the Public Health Service Act (42  
16 U.S.C. 290aa-1(b)) is amended—

17 (1) in paragraph (2)—

18 (A) in subparagraph (E), by striking  
19 “and” after the semicolon;

20 (B) by redesignating subparagraph (F) as  
21 subparagraph (J); and

22 (C) by inserting after subparagraph (E),  
23 the following:

24 “(F) the Chief Medical Officer, appointed  
25 under section 501(g);

1           “(G) the Director of the National Institute  
2 of Mental Health for the advisory councils ap-  
3 pointed under subsections (a)(1)(A) and  
4 (a)(1)(D);

5           “(H) the Director of the National Institute  
6 on Drug Abuse for the advisory councils ap-  
7 pointed under subsections (a)(1)(A), (a)(1)(B),  
8 and (a)(1)(C);

9           “(I) the Director of the National Institute  
10 on Alcohol Abuse and Alcoholism for the advi-  
11 sory councils appointed under subsections  
12 (a)(1)(A), (a)(1)(B), and (a)(1)(C); and”;

13 (2) in paragraph (3), by adding at the end the  
14 following:

15           “(C) Not less than half of the members of  
16 the advisory council appointed under subsection  
17 (a)(1)(D)—

18           “(i) shall—

19                   “(I) have a medical degree;

20                   “(II) have a doctoral degree in  
21 psychology; or

22                   “(III) have an advanced degree  
23 in nursing or social work from an ac-  
24 credited graduate school or be a cer-  
25 tified physician assistant; and

1                   “(ii) shall specialize in the mental  
2 health field.

3                   “(D) Not less than half of the members of  
4 the advisory councils appointed under sub-  
5 sections (a)(1)(B) and (a)(1)(C)—

6                   “(i) shall—

7                           “(I) have a medical degree;

8                           “(II) have a doctoral degree; or

9                           “(III) have an advanced degree  
10 in nursing, public health, behavioral  
11 or social sciences, or social work from  
12 an accredited graduate school or be a  
13 certified physician assistant; and

14                   “(ii) shall have experience in the pro-  
15 vision of substance use disorder services or  
16 the development and implementation of  
17 programs to prevent substance misuse.”.

18 **SEC. 6009. PEER REVIEW.**

19           Section 504(b) of the Public Health Service Act (42  
20 U.S.C. 290aa–3(b)) is amended by adding at the end the  
21 following: “In the case of any such peer review group that  
22 is reviewing a grant, cooperative agreement, or contract  
23 related to mental illness treatment, not less than half of  
24 the members of such peer review group shall be licensed  
25 and experienced professionals in the prevention, diagnosis,



1 or treatment of, or recovery from, mental illness or co-  
2 occurring mental illness and substance use disorders and  
3 have a medical degree, a doctoral degree in psychology,  
4 or an advanced degree in nursing or social work from an  
5 accredited program, and the Secretary, in consultation  
6 with the Assistant Secretary, shall, to the extent possible,  
7 ensure such peer review groups include broad geographic  
8 representation, including both urban and rural representa-  
9 tives.”.

## 10 **Subtitle B—Oversight and** 11 **Accountability**

### 12 **SEC. 6021. IMPROVING OVERSIGHT OF MENTAL AND SUB-** 13 **STANCE USE DISORDERS PROGRAMS** 14 **THROUGH THE ASSISTANT SECRETARY FOR** 15 **PLANNING AND EVALUATION.**

16 (a) IN GENERAL.—The Secretary of Health and  
17 Human Services, acting through the Assistant Secretary  
18 for Planning and Evaluation, shall ensure efficient and ef-  
19 fective planning and evaluation of mental and substance  
20 use disorders prevention and treatment programs and re-  
21 lated activities.

22 (b) EVALUATION STRATEGY.—In carrying out sub-  
23 section (a), the Assistant Secretary for Planning and  
24 Evaluation shall, not later than 180 days after the date  
25 of enactment of this Act, develop a strategy for conducting

1 ongoing evaluations that identifies priority programs to be  
2 evaluated by the Assistant Secretary for Planning and  
3 Evaluation and priority programs to be evaluated by other  
4 relevant offices and agencies within the Department of  
5 Health and Human Services. The strategy shall—

6 (1) include a plan for evaluating programs re-  
7 lated to mental and substance use disorders, includ-  
8 ing co-occurring disorders, across agencies, as appro-  
9 priate, including programs related to—

10 (A) prevention, intervention, treatment,  
11 and recovery support services, including such  
12 services for adults with a serious mental illness  
13 or children with a serious emotional disturb-  
14 ance;

15 (B) the reduction of homelessness and in-  
16 carceration among individuals with a mental or  
17 substance use disorder; and

18 (C) public health and health services; and

19 (2) include a plan for assessing the use of per-  
20 formance metrics to evaluate activities carried out by  
21 entities receiving grants, contracts, or cooperative  
22 agreements related to mental and substance use dis-  
23 orders prevention and treatment services under title  
24 V or title XIX of the Public Health Service Act (42  
25 U.S.C. 290aa et seq.; 42 U.S.C. 300w et seq.).

1           (c) CONSULTATION.—In carrying out this section, the  
2 Assistant Secretary for Planning and Evaluation shall  
3 consult, as appropriate, with the Assistant Secretary for  
4 Mental Health and Substance Use, the Chief Medical Offi-  
5 cer of the Substance Abuse and Mental Health Services  
6 Administration appointed under section 501(g) of the  
7 Public Health Service Act (42 U.S.C. 290aa(g)), as  
8 amended by section 6003, the Behavioral Health Coordi-  
9 nating Council of the Department of Health and Human  
10 Services, other agencies within the Department of Health  
11 and Human Services, and other relevant Federal depart-  
12 ments and agencies.

13           (d) RECOMMENDATIONS.—In carrying out this sec-  
14 tion, the Assistant Secretary for Planning and Evaluation  
15 shall provide recommendations to the Secretary of Health  
16 and Human Services, the Assistant Secretary for Mental  
17 Health and Substance Use, and the Congress on improv-  
18 ing the quality of prevention and treatment programs and  
19 activities related to mental and substance use disorders,  
20 including recommendations for the use of performance  
21 metrics. The Assistant Secretary for Mental Health and  
22 Substance Use shall include such recommendations in the  
23 biennial report required by subsection 501(m) of the Pub-  
24 lic Health Service Act, as redesignated by section 6003  
25 of this Act.

1 **SEC. 6022. REPORTING FOR PROTECTION AND ADVOCACY**  
2 **ORGANIZATIONS.**

3 (a) PUBLIC AVAILABILITY OF REPORTS.—Section  
4 105(a)(7) of the Protection and Advocacy for Individuals  
5 with Mental Illness Act (42 U.S.C. 10805(a)(7)) is  
6 amended by striking “is located a report” and inserting  
7 “is located, and make publicly available, a report”.

8 (b) DETAILED ACCOUNTING.—Section 114(a) of the  
9 Protection and Advocacy for Individuals with Mental Ill-  
10 ness Act (42 U.S.C. 10824(a)) is amended—

11 (1) in paragraph (3), by striking “and” at the  
12 end;

13 (2) in paragraph (4), by striking the period at  
14 the end and inserting “; and”; and

15 (3) by adding at the end the following:

16 “(5) using data from the existing required an-  
17 nual program progress reports submitted by each  
18 system funded under this title, a detailed accounting  
19 for each such system of how funds are spent,  
20 disaggregated according to whether the funds were  
21 received from the Federal Government, the State  
22 government, a local government, or a private enti-  
23 ty.”.

24 **SEC. 6023. GAO STUDY.**

25 (a) IN GENERAL.—Not later than 18 months after  
26 the date of enactment of this Act, the Comptroller General

1 of the United States, in consultation with the Secretary  
2 of Health and Human Services and the Assistant Sec-  
3 retary for Mental Health and Substance Use, shall con-  
4 duct an independent evaluation, and submit a report, to  
5 the Committee on Health, Education, Labor, and Pen-  
6 sions of the Senate and the Committee on Energy and  
7 Commerce of the House of Representatives, on programs  
8 funded by allotments made under title I of the Protection  
9 and Advocacy for Individuals with Mental Illness Act (42  
10 U.S.C. 10801 et seq.).

11 (b) CONTENTS.—The report and evaluation required  
12 under subsection (a) shall include—

13 (1) a review of the programs described in such  
14 subsection that are carried out by State agencies  
15 and such programs that are carried out by private,  
16 nonprofit organizations; and

17 (2) a review of the compliance of the programs  
18 described in subsection (a) with statutory and regu-  
19 latory responsibilities, such as—

20 (A) responsibilities relating to family en-  
21 gagement;

22 (B) responsibilities relating to the griev-  
23 ance procedure for clients or prospective clients  
24 of the system to assure that individuals with  
25 mental illness have full access to the services of

1 the system, for individuals who have received or  
2 are receiving mental health services, and for  
3 family members of such individuals with mental  
4 illness, or representatives of such individuals or  
5 family members, to assure that the eligible sys-  
6 tem is operating in compliance with the provi-  
7 sions of the Protection and Advocacy for Indi-  
8 viduals with Mental Illness Act, as required to  
9 be established by section 105(a)(9) of such Act  
10 (42 U.S.C. 10805(a)(9));

11 (C) investigation of alleged abuse and ne-  
12 glect of persons with mental illness;

13 (D) availability of adequate medical and  
14 behavioral health treatment;

15 (E) denial of rights for persons with men-  
16 tal illness; and

17 (F) compliance with the Federal prohibi-  
18 tion on lobbying.

19 **Subtitle C—Interdepartmental Se-**  
20 **rious Mental Illness Coordi-**  
21 **nating Committee**

22 **SEC. 6031. INTERDEPARTMENTAL SERIOUS MENTAL ILL-**  
23 **NESS COORDINATING COMMITTEE.**

24 (a) ESTABLISHMENT.—

1           (1) IN GENERAL.—Not later than 3 months  
2 after the date of enactment of this Act, the Sec-  
3 retary of Health and Human Services, or the des-  
4 ignee of the Secretary, shall establish a committee to  
5 be known as the Interdepartmental Serious Mental  
6 Illness Coordinating Committee (in this section re-  
7 ferred to as the “Committee”).

8           (2) FEDERAL ADVISORY COMMITTEE ACT.—Ex-  
9 cept as provided in this section, the provisions of the  
10 Federal Advisory Committee Act (5 U.S.C. App.)  
11 shall apply to the Committee.

12          (b) MEETINGS.—The Committee shall meet not fewer  
13 than 2 times each year.

14          (c) RESPONSIBILITIES.—Not later than 1 year after  
15 the date of enactment of this Act, and 5 years after such  
16 date of enactment, the Committee shall submit to Con-  
17 gress and any other relevant Federal department or agen-  
18 cy a report including—

19           (1) a summary of advances in serious mental  
20 illness and serious emotional disturbance research  
21 related to the prevention of, diagnosis of, interven-  
22 tion in, and treatment and recovery of serious men-  
23 tal illnesses, serious emotional disturbances, and ad-  
24 vances in access to services and support for adults

1 with a serious mental illness or children with a seri-  
2 ous emotional disturbance;

3 (2) an evaluation of the effect Federal pro-  
4 grams related to serious mental illness have on pub-  
5 lic health, including public health outcomes such  
6 as—

7 (A) rates of suicide, suicide attempts, inci-  
8 dence and prevalence of serious mental ill-  
9 nesses, serious emotional disturbances, and sub-  
10 stance use disorders, overdose, overdose deaths,  
11 emergency hospitalizations, emergency room  
12 boarding, preventable emergency room visits,  
13 interaction with the criminal justice system,  
14 homelessness, and unemployment;

15 (B) increased rates of employment and en-  
16 rollment in educational and vocational pro-  
17 grams;

18 (C) quality of mental and substance use  
19 disorders treatment services; or

20 (D) any other criteria as may be deter-  
21 mined by the Secretary; and

22 (3) specific recommendations for actions that  
23 agencies can take to better coordinate the adminis-  
24 tration of mental health services for adults with a



1 serious mental illness or children with a serious emo-  
2 tional disturbance.

3 (d) COMMITTEE EXTENSION.—Upon the submission  
4 of the second report under subsection (c), the Secretary  
5 shall submit a recommendation to Congress on whether  
6 to extend the operation of the Committee.

7 (e) MEMBERSHIP.—

8 (1) FEDERAL MEMBERS.—The Committee shall  
9 be composed of the following Federal representa-  
10 tives, or the designees of such representatives—

11 (A) the Secretary of Health and Human  
12 Services, who shall serve as the Chair of the  
13 Committee;

14 (B) the Assistant Secretary for Mental  
15 Health and Substance Use;

16 (C) the Attorney General;

17 (D) the Secretary of Veterans Affairs;

18 (E) the Secretary of Defense;

19 (F) the Secretary of Housing and Urban  
20 Development;

21 (G) the Secretary of Education;

22 (H) the Secretary of Labor;

23 (I) the Administrator of the Centers for  
24 Medicare & Medicaid Services; and

25 (J) the Commissioner of Social Security.

1           (2) NON-FEDERAL MEMBERS.—The Committee  
2 shall also include not less than 14 non-Federal pub-  
3 lic members appointed by the Secretary of Health  
4 and Human Services, of which—

5           (A) at least 2 members shall be an indi-  
6 vidual who has received treatment for a diag-  
7 nosis of a serious mental illness;

8           (B) at least 1 member shall be a parent or  
9 legal guardian of an adult with a history of a  
10 serious mental illness or a child with a history  
11 of a serious emotional disturbance;

12           (C) at least 1 member shall be a represent-  
13 ative of a leading research, advocacy, or service  
14 organization for adults with a serious mental  
15 illness;

16           (D) at least 2 members shall be—

17           (i) a licensed psychiatrist with experi-  
18 ence in treating serious mental illnesses;

19           (ii) a licensed psychologist with experi-  
20 ence in treating serious mental illnesses  
21 or serious emotional disturbances;

22           (iii) a licensed clinical social worker  
23 with experience treating serious mental ill-  
24 nesses or serious emotional disturbances;

25           or

1 (iv) a licensed psychiatric nurse, nurse  
2 practitioner, or physician assistant with ex-  
3 perience in treating serious mental ill-  
4 nesses or serious emotional disturbances;

5 (E) at least 1 member shall be a licensed  
6 mental health professional with a specialty in  
7 treating children and adolescents with a serious  
8 emotional disturbance;

9 (F) at least 1 member shall be a mental  
10 health professional who has research or clinical  
11 mental health experience in working with mi-  
12 norities;

13 (G) at least 1 member shall be a mental  
14 health professional who has research or clinical  
15 mental health experience in working with medi-  
16 cally underserved populations;

17 (H) at least 1 member shall be a State cer-  
18 tified mental health peer support specialist;

19 (I) at least 1 member shall be a judge with  
20 experience in adjudicating cases related to  
21 criminal justice or serious mental illness;

22 (J) at least 1 member shall be a law en-  
23 forcement officer or corrections officer with ex-  
24 tensive experience in interfacing with adults  
25 with a serious mental illness, children with a se-

1           rious emotional disturbance, or individuals in a  
2           mental health crisis; and

3           (K) at least 1 member shall have experi-  
4           ence providing services for homeless individuals  
5           and working with adults with a serious mental  
6           illness, children with a serious emotional dis-  
7           turbance, or individuals in a mental health cri-  
8           sis.

9           (3) TERMS.—A member of the Committee ap-  
10          pointed under subsection (e)(2) shall serve for a  
11          term of 3 years, and may be reappointed for 1 or  
12          more additional 3-year terms. Any member ap-  
13          pointed to fill a vacancy for an unexpired term shall  
14          be appointed for the remainder of such term. A  
15          member may serve after the expiration of the mem-  
16          ber's term until a successor has been appointed.

17          (f) WORKING GROUPS.—In carrying out its func-  
18          tions, the Committee may establish working groups. Such  
19          working groups shall be composed of Committee members,  
20          or their designees, and may hold such meetings as are nec-  
21          essary.

22          (g) SUNSET.—The Committee shall terminate on the  
23          date that is 6 years after the date on which the Committee  
24          is established under subsection (a)(1).

1 **TITLE VII—ENSURING MENTAL**  
2 **AND SUBSTANCE USE DIS-**  
3 **ORDERS PREVENTION,**  
4 **TREATMENT, AND RECOVERY**  
5 **PROGRAMS KEEP PACE WITH**  
6 **SCIENCE AND TECHNOLOGY**

7 **SEC. 7001. ENCOURAGING INNOVATION AND EVIDENCE-**  
8 **BASED PROGRAMS.**

9 Title V of the Public Health Service Act (42 U.S.C.  
10 290aa et seq.) is amended by inserting after section 501  
11 (42 U.S.C. 290aa) the following:

12 **“SEC. 501A. NATIONAL MENTAL HEALTH AND SUBSTANCE**  
13 **USE POLICY LABORATORY.**

14 “(a) **IN GENERAL.**—There shall be established within  
15 the Administration a National Mental Health and Sub-  
16 stance Use Policy Laboratory (referred to in this section  
17 as the ‘Laboratory’).

18 “(b) **RESPONSIBILITIES.**—The Laboratory shall—

19 “(1) continue to carry out the authorities and  
20 activities that were in effect for the Office of Policy,  
21 Planning, and Innovation as such Office existed  
22 prior to the date of enactment of the Helping Fami-  
23 lies in Mental Health Crisis Reform Act of 2016;

24 “(2) identify, coordinate, and facilitate the im-  
25 plementation of policy changes likely to have a sig-

1       nificant effect on mental health, mental illness, re-  
2       covery supports, and the prevention and treatment  
3       of substance use disorder services;

4               “(3) work with the Center for Behavioral  
5       Health Statistics and Quality to collect, as appro-  
6       priate, information from grantees under programs  
7       operated by the Administration in order to evaluate  
8       and disseminate information on evidence-based prac-  
9       tices, including culturally and linguistically appro-  
10      priate services, as appropriate, and service delivery  
11      models;

12              “(4) provide leadership in identifying and co-  
13      ordinating policies and programs, including evidence-  
14      based programs, related to mental and substance use  
15      disorders;

16              “(5) periodically review programs and activities  
17      operated by the Administration relating to the diag-  
18      nosis or prevention of, treatment for, and recovery  
19      from, mental and substance use disorders to—

20                      “(A) identify any such programs or activi-  
21                      ties that are duplicative;

22                      “(B) identify any such programs or activi-  
23                      ties that are not evidence-based, effective, or ef-  
24                      ficient; and

1           “(C) formulate recommendations for co-  
2           ordinating, eliminating, or improving programs  
3           or activities identified under subparagraph (A)  
4           or (B) and merging such programs or activities  
5           into other successful programs or activities; and

6           “(6) carry out other activities as deemed nec-  
7           essary to continue to encourage innovation and dis-  
8           seminate evidence-based programs and practices.

9           “(c) EVIDENCE-BASED PRACTICES AND SERVICE  
10          DELIVERY MODELS.—

11           “(1) IN GENERAL.—In carrying out subsection  
12          (b)(3), the Laboratory—

13           “(A) may give preference to models that  
14          improve—

15           “(i) the coordination between mental  
16          health and physical health providers;

17           “(ii) the coordination among such pro-  
18          viders and the justice and corrections sys-  
19          tem; and

20           “(iii) the cost effectiveness, quality,  
21          effectiveness, and efficiency of health care  
22          services furnished to adults with a serious  
23          mental illness, children with a serious emo-  
24          tional disturbance, or individuals in a men-  
25          tal health crisis; and

1           “(B) may include clinical protocols and  
2           practices that address the needs of individuals  
3           with early serious mental illness.

4           “(2) CONSULTATION.—In carrying out this sec-  
5           tion, the Laboratory shall consult with—

6           “(A) the Chief Medical Officer appointed  
7           under section 501(g);

8           “(B) representatives of the National Insti-  
9           tute of Mental Health, the National Institute  
10          on Drug Abuse, and the National Institute on  
11          Alcohol Abuse and Alcoholism, on an ongoing  
12          basis;

13          “(C) other appropriate Federal agencies;

14          “(D) clinical and analytical experts with  
15          expertise in psychiatric medical care and clinical  
16          psychological care, health care management,  
17          education, corrections health care, and mental  
18          health court systems, as appropriate; and

19          “(E) other individuals and agencies as de-  
20          termined appropriate by the Assistant Sec-  
21          retary.

22          “(d) DEADLINE FOR BEGINNING IMPLEMENTA-  
23          TION.—The Laboratory shall begin implementation of this  
24          section not later than January 1, 2018.

25          “(e) PROMOTING INNOVATION.—



1           “(1) IN GENERAL.—The Assistant Secretary, in  
2           coordination with the Laboratory, may award grants  
3           to States, local governments, Indian tribes or tribal  
4           organizations (as such terms are defined in section  
5           4 of the Indian Self-Determination and Education  
6           Assistance Act), educational institutions, and non-  
7           profit organizations to develop evidence-based inter-  
8           ventions, including culturally and linguistically ap-  
9           propriate services, as appropriate, for—

10                   “(A) evaluating a model that has been sci-  
11                   entifically demonstrated to show promise, but  
12                   would benefit from further applied development,  
13                   for—

14                           “(i) enhancing the prevention, diag-  
15                           nosis, intervention, and treatment of, and  
16                           recovery from, mental illness, serious emo-  
17                           tional disturbances, substance use dis-  
18                           orders, and co-occurring illness or dis-  
19                           orders; or

20                           “(ii) integrating or coordinating phys-  
21                           ical health services and mental and sub-  
22                           stance use disorders services; and

23                   “(B) expanding, replicating, or scaling evi-  
24                   dence-based programs across a wider area to  
25                   enhance effective screening, early diagnosis,

1 intervention, and treatment with respect to  
2 mental illness, serious mental illness, serious  
3 emotional disturbances, and substance use dis-  
4 orders, primarily by—

5 “(i) applying such evidence-based pro-  
6 grams to the delivery of care, including by  
7 training staff in effective evidence-based  
8 treatments; or

9 “(ii) integrating such evidence-based  
10 programs into models of care across spe-  
11 cialties and jurisdictions.

12 “(2) CONSULTATION.—In awarding grants  
13 under this subsection, the Assistant Secretary shall,  
14 as appropriate, consult with the Chief Medical Offi-  
15 cer, appointed under section 501(g), the advisory  
16 councils described in section 502, the National Insti-  
17 tute of Mental Health, the National Institute on  
18 Drug Abuse, and the National Institute on Alcohol  
19 Abuse and Alcoholism, as appropriate.

20 “(3) AUTHORIZATION OF APPROPRIATIONS.—  
21 There are authorized to be appropriated—

22 “(A) to carry out paragraph (1)(A),  
23 \$7,000,000 for the period of fiscal years 2018  
24 through 2020; and

1           “(B) to carry out paragraph (1)(B),  
2           \$7,000,000 for the period of fiscal years 2018  
3           through 2020.”.

4 **SEC. 7002. PROMOTING ACCESS TO INFORMATION ON EVI-**  
5 **DENCE-BASED PROGRAMS AND PRACTICES.**

6           Part D of title V of the Public Health Service Act  
7 (42 U.S.C. 290dd et seq.) is amended by inserting after  
8 section 543 of such Act (42 U.S.C. 290dd–2) the fol-  
9 lowing:

10 **“SEC. 543A. PROMOTING ACCESS TO INFORMATION ON EVI-**  
11 **DENCE-BASED PROGRAMS AND PRACTICES.**

12           “(a) IN GENERAL.—The Assistant Secretary shall, as  
13 appropriate, improve access to reliable and valid informa-  
14 tion on evidence-based programs and practices, including  
15 information on the strength of evidence associated with  
16 such programs and practices, related to mental and sub-  
17 stance use disorders for States, local communities, non-  
18 profit entities, and other stakeholders, by posting on the  
19 Internet website of the Administration information on evi-  
20 dence-based programs and practices that have been re-  
21 viewed by the Assistant Secretary in accordance with the  
22 requirements of this section.

23           “(b) APPLICATIONS.—

24           “(1) APPLICATION PERIOD.—In carrying out  
25 subsection (a), the Assistant Secretary may establish

1 a period for the submission of applications for evi-  
2 dence-based programs and practices to be posted  
3 publicly in accordance with subsection (a).

4 “(2) NOTICE.—In establishing the application  
5 period under paragraph (1), the Assistant Secretary  
6 shall provide for the public notice of such application  
7 period in the Federal Register. Such notice may so-  
8 licit applications for evidence-based programs and  
9 practices to address gaps in information identified  
10 by the Assistant Secretary, the National Mental  
11 Health and Substance Use Policy Laboratory estab-  
12 lished under section 501A, or the Assistant Sec-  
13 retary for Planning and Evaluation, including pursu-  
14 ant to the evaluation and recommendations under  
15 section 6021 of the Helping Families in Mental  
16 Health Crisis Reform Act of 2016 or priorities iden-  
17 tified in the strategic plan under section 501(l).

18 “(c) REQUIREMENTS.—The Assistant Secretary may  
19 establish minimum requirements for the applications sub-  
20 mitted under subsection (b), including applications related  
21 to the submission of research and evaluation.

22 “(d) REVIEW AND RATING.—

23 “(1) IN GENERAL.—The Assistant Secretary  
24 shall review applications prior to public posting in  
25 accordance with subsection (a), and may prioritize

1 the review of applications for evidence-based pro-  
2 grams and practices that are related to topics in-  
3 cluded in the notice provided under subsection  
4 (b)(2).

5 “(2) SYSTEM.—In carrying out paragraph (1),  
6 the Assistant Secretary may utilize a rating and re-  
7 view system, which may include information on the  
8 strength of evidence associated with the evidence-  
9 based programs and practices and a rating of the  
10 methodological rigor of the research supporting the  
11 applications.

12 “(3) PUBLIC ACCESS TO METRICS AND RAT-  
13 ING.—The Assistant Secretary shall make the  
14 metrics used to evaluate applications under this sec-  
15 tion, and any resulting ratings of such applications,  
16 publicly available.”.

17 **SEC. 7003. PRIORITY MENTAL HEALTH NEEDS OF RE-**  
18 **GIONAL AND NATIONAL SIGNIFICANCE.**

19 Section 520A of the Public Health Service Act (42  
20 U.S.C. 290bb–32) is amended—

21 (1) in subsection (a)—

22 (A) in paragraph (4), by inserting before  
23 the period “, which may include technical as-  
24 sistance centers”; and

1 (B) in the flush sentence following para-  
2 graph (4)—

3 (i) by inserting “, contracts,” before  
4 “or cooperative agreements”; and

5 (ii) by striking “Indian tribes and  
6 tribal organizations” and inserting “Indian  
7 tribes or tribal organizations (as such  
8 terms are defined in section 4 of the In-  
9 dian Self-Determination and Education  
10 Assistance Act), health facilities, or pro-  
11 grams operated by or in accordance with a  
12 contract or grant with the Indian Health  
13 Service, or”; and

14 (2) by amending subsection (f) to read as fol-  
15 lows:

16 “(f) AUTHORIZATION OF APPROPRIATIONS.—There  
17 are authorized to be appropriated to carry out this section  
18 \$394,550,000 for each of fiscal years 2018 through  
19 2022.”.

20 **SEC. 7004. PRIORITY SUBSTANCE USE DISORDER TREAT-**  
21 **MENT NEEDS OF REGIONAL AND NATIONAL**  
22 **SIGNIFICANCE.**

23 Section 509 of the Public Health Service Act (42  
24 U.S.C. 290bb–2) is amended—

25 (1) in subsection (a)—

1 (A) in the matter preceding paragraph (1),  
2 by striking “abuse” and inserting “use dis-  
3 order”;

4 (B) in paragraph (3), by inserting before  
5 the period “that permit States, local govern-  
6 ments, communities, and Indian tribes and trib-  
7 al organizations (as the terms ‘Indian tribes’  
8 and ‘tribal organizations’ are defined in section  
9 4 of the Indian Self-Determination and Edu-  
10 cation Assistance Act) to focus on emerging  
11 trends in substance abuse and co-occurrence of  
12 substance use disorders with mental illness or  
13 other conditions”; and

14 (C) in the flush sentence following para-  
15 graph (3)—

16 (i) by inserting “, contracts,” before  
17 “or cooperative agreements”; and

18 (ii) by striking “Indian tribes and  
19 tribal organizations,” and inserting “In-  
20 dian tribes or tribal organizations (as such  
21 terms are defined in section 4 of the In-  
22 dian Self-Determination and Education  
23 Assistance Act), health facilities, or pro-  
24 grams operated by or in accordance with a

1 contract or grant with the Indian Health  
2 Service, or”;

3 (2) in subsection (b)—

4 (A) in paragraph (1), by striking “abuse”  
5 and inserting “use disorder”; and

6 (B) in paragraph (2), by striking “abuse”  
7 and inserting “use disorder”;

8 (3) in subsection (e), by striking “abuse” and  
9 inserting “use disorder”; and

10 (4) in subsection (f), by striking  
11 “\$300,000,000” and all that follows through the pe-  
12 riod and inserting “\$333,806,000 for each of fiscal  
13 years 2018 through 2022.”.

14 **SEC. 7005. PRIORITY SUBSTANCE USE DISORDER PREVEN-**  
15 **TION NEEDS OF REGIONAL AND NATIONAL**  
16 **SIGNIFICANCE.**

17 Section 516 of the Public Health Service Act (42  
18 U.S.C. 290bb–22) is amended—

19 (1) in the section heading, by striking  
20 “**ABUSE**” and inserting “**USE DISORDER**”;

21 (2) in subsection (a)—

22 (A) in the matter preceding paragraph (1),  
23 by striking “abuse” and inserting “use dis-  
24 order”;



1 (B) in paragraph (3), by inserting before  
2 the period “, including such programs that  
3 focus on emerging drug abuse issues”; and

4 (C) in the flush sentence following para-  
5 graph (3)—

6 (i) by inserting “, contracts,” before  
7 “or cooperative agreements”; and

8 (ii) by striking “Indian tribes and  
9 tribal organizations,” and inserting “In-  
10 dian tribes or tribal organizations (as such  
11 terms are defined in section 4 of the In-  
12 dian Self-Determination and Education  
13 Assistance Act), health facilities, or pro-  
14 grams operated by or in accordance with a  
15 contract or grant with the Indian Health  
16 Service,”;

17 (3) in subsection (b)—

18 (A) in paragraph (1), by striking “abuse”  
19 and inserting “use disorder”; and

20 (B) in paragraph (2)—

21 (i) in subparagraph (A), by striking “;  
22 and” at the end and inserting “;”;

23 (ii) in subparagraph (B)—

24 (I) by striking “abuse” and in-  
25 serting “use disorder”; and

1 (II) by striking the period and  
2 inserting “; and”; and

3 (iii) by adding at the end the fol-  
4 lowing:

5 “(C) substance use disorder prevention  
6 among high-risk groups.”;

7 (4) in subsection (e), by striking “abuse” and  
8 inserting “use disorder”; and

9 (5) in subsection (f), by striking  
10 “\$300,000,000” and all that follows through the pe-  
11 riod and inserting “\$211,148,000 for each of fiscal  
12 years 2018 through 2022.”.

13 **TITLE VIII—SUPPORTING STATE**  
14 **PREVENTION ACTIVITIES AND**  
15 **RESPONSES TO MENTAL**  
16 **HEALTH AND SUBSTANCE**  
17 **USE DISORDER NEEDS**

18 **SEC. 8001. COMMUNITY MENTAL HEALTH SERVICES BLOCK**  
19 **GRANT.**

20 (a) FORMULA GRANTS.—Section 1911(b) of the Pub-  
21 lic Health Service Act (42 U.S.C. 300x(b)) is amended—

22 (1) by redesignating paragraphs (1) through  
23 (3) as paragraphs (2) through (4), respectively; and

24 (2) by inserting before paragraph (2) (as so re-  
25 designated) the following:

1           “(1) providing community mental health serv-  
2           ices for adults with a serious mental illness and chil-  
3           dren with a serious emotional disturbance as defined  
4           in accordance with section 1912(c);”.

5           (b) STATE PLAN.—Section 1912(b) of the Public  
6 Health Service Act (42 U.S.C. 300x–1(b)) is amended—

7           (1) in paragraph (3), by redesignating subpara-  
8           graphs (A) through (C) as clauses (i) through (iii),  
9           respectively, and realigning the margins accordingly;

10          (2) by redesignating paragraphs (1) through  
11          (5) as subparagraphs (A) through (E), respectively,  
12          and realigning the margins accordingly;

13          (3) in the matter preceding subparagraph (A)  
14          (as so redesignated), by striking “With respect to”  
15          and all that follows through “are as follows:” and  
16          inserting “In accordance with subsection (a), a State  
17          shall submit to the Secretary a plan every two years  
18          that, at a minimum, includes each of the following:”;

19          (4) by inserting before subparagraph (A) (as so  
20          redesignated) the following:

21                 “(1) SYSTEM OF CARE.—A description of the  
22                 State’s system of care that contains the following:”;

23          (5) by striking subparagraph (A) (as so redesi-  
24          gnated) and inserting the following:

1                   “(A) COMPREHENSIVE COMMUNITY-BASED  
2 HEALTH SYSTEMS.—The plan shall—

3                   “(i) identify the single State agency to  
4 be responsible for the administration of the  
5 program under the grant, including any  
6 third party who administers mental health  
7 services and is responsible for complying  
8 with the requirements of this part with re-  
9 spect to the grant;

10                   “(ii) provide for an organized commu-  
11 nity-based system of care for individuals  
12 with mental illness, and describe available  
13 services and resources in a comprehensive  
14 system of care, including services for indi-  
15 viduals with co-occurring disorders;

16                   “(iii) include a description of the  
17 manner in which the State and local enti-  
18 ties will coordinate services to maximize  
19 the efficiency, effectiveness, quality, and  
20 cost-effectiveness of services and programs  
21 to produce the best possible outcomes (in-  
22 cluding health services, rehabilitation serv-  
23 ices, employment services, housing services,  
24 educational services, substance use dis-  
25 order services, legal services, law enforce-

1                   ment services, social services, child welfare  
2                   services, medical and dental care services,  
3                   and other support services to be provided  
4                   with Federal, State, and local public and  
5                   private resources) with other agencies to  
6                   enable individuals receiving services to  
7                   function outside of inpatient or residential  
8                   institutions, to the maximum extent of  
9                   their capabilities, including services to be  
10                  provided by local school systems under the  
11                  Individuals with Disabilities Education  
12                  Act;

13                  “(iv) include a description of how the  
14                  State promotes evidence-based practices,  
15                  including those evidence-based programs  
16                  that address the needs of individuals with  
17                  early serious mental illness regardless of  
18                  the age of the individual at onset, provide  
19                  comprehensive individualized treatment, or  
20                  integrate mental and physical health serv-  
21                  ices;

22                  “(v) include a description of case  
23                  management services;

24                  “(vi) include a description of activities  
25                  that seek to engage adults with a serious

1           mental illness or children with a serious  
2           emotional disturbance and their caregivers  
3           where appropriate in making health care  
4           decisions, including activities that enhance  
5           communication among individuals, fami-  
6           lies, caregivers, and treatment providers;  
7           and

8                   “(vii) as appropriate to, and reflective  
9           of, the uses the State proposes for the  
10          block grant funds, include—

11                   “(I) a description of the activities  
12           intended to reduce hospitalizations  
13           and hospital stays using the block  
14           grant funds;

15                   “(II) a description of the activi-  
16           ties intended to reduce incidents of  
17           suicide using the block grant funds;

18                   “(III) a description of how the  
19           State integrates mental health and  
20           primary care using the block grant  
21           funds, which may include providing,  
22           in the case of individuals with co-oc-  
23           curring mental and substance use dis-  
24           orders, both mental and substance use  
25           disorders services in primary care set-

1                   tings or arrangements to provide pri-  
2                   mary and specialty care services in  
3                   community-based mental and sub-  
4                   stance use disorders settings; and

5                               “(IV) a description of recovery  
6                   and recovery support services for  
7                   adults with a serious mental illness  
8                   and children with a serious emotional  
9                   disturbance.”;

10                   (6) in subparagraph (B) (as so redesignated)—

11                               (A) by striking “The plan contains” and  
12                   inserting “The plan shall contain”; and

13                               (B) by striking “presents quantitative tar-  
14                   gets to be achieved in the implementation of the  
15                   system described in paragraph (1)” and insert-  
16                   ing “present quantitative targets and outcome  
17                   measures for programs and services provided  
18                   under this subpart”;

19                   (7) in subparagraph (C) (as so redesignated)—

20                               (A) by striking “serious emotional disturb-  
21                   ance” in the matter preceding clause (i) (as so  
22                   redesignated) and all that follows through “sub-  
23                   stance abuse services” in clause (i) (as so red-  
24                   esignated) and inserting the following: “a serious  
25                   emotional disturbance (as defined pursuant to

1 subsection (c)), the plan shall provide for a sys-  
2 tem of integrated social services, educational  
3 services, child welfare services, juvenile justice  
4 services, law enforcement services, and sub-  
5 stance use disorder services”;

6 (B) by striking “Education Act);” and in-  
7 serting “Education Act).”; and

8 (C) by striking clauses (ii) and (iii) (as so  
9 redesignated);

10 (8) in subparagraph (D) (as so redesignated),  
11 by striking “plan describes” and inserting “plan  
12 shall describe”;

13 (9) in subparagraph (E) (as so redesignated)—

14 (A) in the subparagraph heading by strik-  
15 ing “SYSTEMS” and inserting “SERVICES”;

16 (B) in the first sentence, by striking “plan  
17 describes” and all that follows through “and  
18 provides for” and inserting “plan shall describe  
19 the financial resources available, the existing  
20 mental health workforce, and the workforce  
21 trained in treating individuals with co-occurring  
22 mental and substance use disorders, and shall  
23 provide for”; and

24 (C) in the second sentence—



1 (i) by striking “further describes” and  
2 inserting “shall further describe”; and

3 (ii) by striking “involved.” and insert-  
4 ing “involved, and the manner in which the  
5 State intends to comply with each of the  
6 funding agreements in this subpart and  
7 subpart III.”;

8 (10) by striking the flush matter at the end;  
9 and

10 (11) by adding at the end the following:

11 “(2) GOALS AND OBJECTIVES.—The establish-  
12 ment of goals and objectives for the period of the  
13 plan, including targets and milestones that are in-  
14 tended to be met, and the activities that will be un-  
15 dertaken to achieve those targets.”.

16 (c) EARLY SERIOUS MENTAL ILLNESS.—Section  
17 1920 of the Public Health Service Act (42 U.S.C. 300x-  
18 9) is amended by adding at the end the following:

19 “(c) EARLY SERIOUS MENTAL ILLNESS.—

20 “(1) IN GENERAL.—Except as provided in para-  
21 graph (2), a State shall expend not less than 10 per-  
22 cent of the amount the State receives for carrying  
23 out this section for each fiscal year to support evi-  
24 dence-based programs that address the needs of in-  
25 dividuals with early serious mental illness, including

1       psychotic disorders, regardless of the age of the indi-  
2       vidual at onset.

3               “(2) STATE FLEXIBILITY.—In lieu of expending  
4       10 percent of the amount the State receives under  
5       this section for a fiscal year as required under para-  
6       graph (1), a State may elect to expend not less than  
7       20 percent of such amount by the end of such suc-  
8       ceeding fiscal year.”.

9       (d) ADDITIONAL PROVISIONS.—Section 1915(b) of  
10      the Public Health Service Act (42 U.S.C. 300x-4(b)) is  
11      amended—

12               (1) in paragraph (3)—

13                       (A) by striking “The Secretary” and in-  
14                       serting the following:

15                               “(A) IN GENERAL.—The Secretary”;

16                               (B) by striking “paragraph (1) if” and in-  
17                               serting “paragraph (1) in whole or in part if”;

18                               (C) by striking “State justify the waiver.”  
19                               and inserting “State in the fiscal year involved  
20                               or in the previous fiscal year justify the wai-  
21                               ver”; and

22                               (D) by adding at the end the following:

23                               “(B) DATE CERTAIN FOR ACTION UPON  
24                               REQUEST.—The Secretary shall approve or  
25                               deny a request for a waiver under this para-

1 graph not later than 120 days after the date on  
2 which the request is made.

3 “(C) APPLICABILITY OF WAIVER.—A waiv-  
4 er provided by the Secretary under this para-  
5 graph shall be applicable only to the fiscal year  
6 involved.”; and

7 (2) in paragraph (4)—

8 (A) in subparagraph (A)—

9 (i) by inserting after the subpara-  
10 graph designation the following: “IN GEN-  
11 ERAL.—”;

12 (ii) by striking “In making a grant”  
13 and inserting the following:

14 “(i) DETERMINATION.—In making a  
15 grant”; and

16 (iii) by inserting at the end the fol-  
17 lowing:

18 “(ii) ALTERNATIVE.—A State that  
19 has failed to comply with paragraph (1)  
20 and would otherwise be subject to a reduc-  
21 tion in the State’s allotment under section  
22 1911 may, upon request by the State, in  
23 lieu of having the amount of the allotment  
24 under section 1911 for the State reduced  
25 for the fiscal year of the grant, agree to

1           comply with a negotiated agreement that is  
2           approved by the Secretary and carried out  
3           in accordance with guidelines issued by the  
4           Secretary. If a State fails to enter into or  
5           comply with a negotiated agreement, the  
6           Secretary may take action under this para-  
7           graph or the terms of the negotiated agree-  
8           ment.”; and

9           (B) in subparagraph (B)—

10           (i) by inserting after the subpara-  
11           graph designation the following: “SUBMIS-  
12           SION OF INFORMATION TO THE SEC-  
13           RETARY.—”; and

14           (ii) by striking “subparagraph (A)”  
15           and inserting “subparagraph (A)(i)”.

16           (e) APPLICATION FOR GRANT.—Section 1917(a) of  
17           the Public Health Service Act (42 U.S.C. 300x–6(a)) is  
18           amended—

19           (1) in paragraph (1), by striking “1941” and  
20           inserting “1942(a)”; and

21           (2) in paragraph (5), by striking  
22           “1915(b)(3)(B)” and inserting “1915(b)”.

23           (f) FUNDING.—Section 1920 of the Public Health  
24           Service Act (42 U.S.C. 300x–9) is amended—

25           (1) in subsection (a)—

1 (A) by striking “section 505” and insert-  
2 ing “section 505(c)”; and

3 (B) by striking “\$450,000,000” and all  
4 that follows through the period and inserting  
5 “\$532,571,000 for each of fiscal years 2018  
6 through 2022.”; and

7 (2) in subsection (b)(2) by striking “sections  
8 505 and” and inserting “sections 505(c) and”.

9 **SEC. 8002. SUBSTANCE ABUSE PREVENTION AND TREAT-**  
10 **MENT BLOCK GRANT.**

11 (a) **FORMULA GRANTS.**—Section 1921(b) of the Pub-  
12 lic Health Service Act (42 U.S.C. 300x–21(b)) is amend-  
13 ed—

14 (1) by inserting “carrying out the plan devel-  
15 oped in accordance with section 1932(b) and for”  
16 after “for the purpose of”; and

17 (2) by striking “abuse” and inserting “use dis-  
18 orders”.

19 (b) **OUTREACH TO PERSONS WHO INJECT DRUGS.**—  
20 Section 1923(b) of the Public Health Service Act (42  
21 U.S.C. 300x–23(b)) is amended—

22 (1) in the subsection heading, by striking “RE-  
23 GARDING INTRAVENOUS SUBSTANCE ABUSE” and  
24 inserting “TO PERSONS WHO INJECT DRUGS”; and

1           (2) by striking “for intravenous drug abuse”  
2           and inserting “for persons who inject drugs”.

3           (c) REQUIREMENTS REGARDING TUBERCULOSIS AND  
4 HUMAN IMMUNODEFICIENCY VIRUS.—Section 1924 of the  
5 Public Health Service Act (42 U.S.C. 300x–24) is amend-  
6 ed—

7           (1) in subsection (a)(1)—

8           (A) in the matter preceding subparagraph  
9           (A), by striking “substance abuse” and insert-  
10          ing “substance use disorders”; and

11          (B) in subparagraph (A), by striking “such  
12          abuse” and inserting “such disorders”;

13          (2) in subsection (b)—

14          (A) in paragraph (1)(A), by striking “sub-  
15          stance abuse” and inserting “substance use dis-  
16          orders”;

17          (B) in paragraph (2), by inserting “and  
18          Prevention” after “Disease Control”;

19          (C) in paragraph (3)—

20               (i) in the paragraph heading, by strik-  
21               ing “ABUSE” and inserting “USE DIS-  
22               ORDERS”; and

23               (ii) by striking “substance abuse” and  
24               inserting “substance use disorders”; and

1 (D) in paragraph (6)(B), by striking “sub-  
2 stance abuse” and inserting “substance use dis-  
3 orders”;

4 (3) by striking subsection (d); and

5 (4) by redesignating subsection (e) as sub-  
6 section (d).

7 (d) GROUP HOMES.—Section 1925 of the Public  
8 Health Service Act (42 U.S.C. 300x–25) is amended—

9 (1) in the section heading, by striking “**RE-**  
10 **COVERING SUBSTANCE ABUSERS**” and inserting  
11 “**PERSONS IN RECOVERY FROM SUBSTANCE**  
12 **USE DISORDERS**”; and

13 (2) in subsection (a), in the matter preceding  
14 paragraph (1), by striking “recovering substance  
15 abusers” and inserting “persons in recovery from  
16 substance use disorders”.

17 (e) ADDITIONAL AGREEMENTS.—Section 1928 of the  
18 Public Health Service Act (42 U.S.C. 300x–28) is amend-  
19 ed—

20 (1) in subsection (a), by striking “(relative to  
21 fiscal year 1992)”;

22 (2) by striking subsection (b) and inserting the  
23 following:

24 “(b) PROFESSIONAL DEVELOPMENT.—A funding  
25 agreement for a grant under section 1921 is that the State

1 involved will ensure that prevention, treatment, and recov-  
2 ery personnel operating in the State’s substance use dis-  
3 order prevention, treatment, and recovery systems have an  
4 opportunity to receive training, on an ongoing basis, con-  
5 cerning—

6           “(1) recent trends in substance use disorders in  
7 the State;

8           “(2) improved methods and evidence-based  
9 practices for providing substance use disorder pre-  
10 vention and treatment services;

11           “(3) performance-based accountability;

12           “(4) data collection and reporting requirements;

13 and

14           “(5) any other matters that would serve to fur-  
15 ther improve the delivery of substance use disorder  
16 prevention and treatment services within the State.”;

17 and

18           (3) in subsection (d)(1), by striking “substance  
19 abuse” and inserting “substance use disorders”.

20 (f) REPEAL.—Section 1929 of the Public Health  
21 Service Act (42 U.S.C. 300x–29) is repealed.

22 (g) MAINTENANCE OF EFFORT.—Section 1930 of the  
23 Public Health Service Act (42 U.S.C. 300x–30) is amend-  
24 ed—



1           (1) in subsection (c)(1), by striking “in the  
2           State justify the waiver” and inserting “exist in the  
3           State, or any part of the State, to justify the waiv-  
4           er”; and

5           (2) in subsection (d), by inserting at the end  
6           the following:

7           “(3) ALTERNATIVE.—A State that has failed to  
8           comply with this section and would otherwise be sub-  
9           ject to a reduction in the State’s allotment under  
10          section 1921, may, upon request by the State, in lieu  
11          of having the State’s allotment under section 1921  
12          reduced, agree to comply with a negotiated agree-  
13          ment that is approved by the Secretary and carried  
14          out in accordance with guidelines issued by the Sec-  
15          retary. If a State fails to enter into or comply with  
16          a negotiated agreement, the Secretary may take ac-  
17          tion under this paragraph or the terms of the nego-  
18          tiated agreement.”.

19          (h) RESTRICTIONS ON EXPENDITURES.—Section  
20          1931(b)(1) of the Public Health Service Act (42 U.S.C.  
21          300x–31(b)(1)) is amended by striking “substance abuse”  
22          and inserting “substance use disorders”.

23          (i) APPLICATION.—Section 1932 of the Public Health  
24          Service Act (42 U.S.C. 300x–32) is amended—

25                 (1) in subsection (a)—

1 (A) in the matter preceding paragraph (1),  
2 by striking “subsections (c) and (d)(2)” and in-  
3 serting “subsection (c)”; and

4 (B) in paragraph (5), by striking “the in-  
5 formation required in section 1929, the infor-  
6 mation required in section 1930(c)(2), and”;

7 (2) in subsection (b)—

8 (A) by striking paragraph (1) and insert-  
9 ing the following:

10 “(1) IN GENERAL.—In order for a State to be  
11 in compliance with subsection (a)(6), the State shall  
12 submit to the Secretary a plan that, at a minimum,  
13 includes the following:

14 “(A) A description of the State’s system of  
15 care that—

16 “(i) identifies the single State agency  
17 responsible for the administration of the  
18 program, including any third party who  
19 administers substance use disorder services  
20 and is responsible for complying with the  
21 requirements of the grant;

22 “(ii) provides information on the need  
23 for substance use disorder prevention and  
24 treatment services in the State, including  
25 estimates on the number of individuals

1           who need treatment, who are pregnant  
2           women, women with dependent children,  
3           individuals with a co-occurring mental  
4           health and substance use disorder, persons  
5           who inject drugs, and persons who are ex-  
6           periencing homelessness;

7           “(iii) provides aggregate information  
8           on the number of individuals in treatment  
9           within the State, including the number of  
10          such individuals who are pregnant women,  
11          women with dependent children, individ-  
12          uals with a co-occurring mental health and  
13          substance use disorder, persons who inject  
14          drugs, and persons who are experiencing  
15          homelessness;

16          “(iv) provides a description of the sys-  
17          tem that is available to provide services by  
18          modality, including the provision of recov-  
19          ery support services;

20          “(v) provides a description of the  
21          State’s comprehensive statewide prevention  
22          efforts, including the number of individuals  
23          being served in the system, target popu-  
24          lations, and priority needs, and provides a  
25          description of the amount of funds from

1 the prevention set-aside expended on pri-  
2 mary prevention;

3 “(vi) provides a description of the fi-  
4 nancial resources available;

5 “(vii) describes the existing substance  
6 use disorders workforce and workforce  
7 trained in treating co-occurring substance  
8 use and mental disorders;

9 “(viii) includes a description of how  
10 the State promotes evidence-based prac-  
11 tices; and

12 “(ix) describes how the State inte-  
13 grates substance use disorder services and  
14 primary health care, which in the case of  
15 those individuals with co-occurring mental  
16 health and substance use disorders may in-  
17 clude providing both mental health and  
18 substance use disorder services in primary  
19 care settings or providing primary and spe-  
20 cialty care services in community-based  
21 mental health and substance use disorder  
22 service settings.

23 “(B) The establishment of goals and objec-  
24 tives for the period of the plan, including tar-  
25 gets and milestones that are intended to be

1 met, and the activities that will be undertaken  
2 to achieve those targets.

3 “(C) A description of how the State will  
4 comply with each funding agreement for a  
5 grant under section 1921 that is applicable to  
6 the State, including a description of the manner  
7 in which the State intends to expend grant  
8 funds.”; and

9 (B) in paragraph (2)—

10 (i) in the paragraph heading, by strik-  
11 ing “AUTHORITY OF SECRETARY REGARD-  
12 ING MODIFICATIONS” and inserting “MODI-  
13 FICATIONS”;

14 (ii) by striking “As a condition” and  
15 inserting the following:

16 “(A) AUTHORITY OF SECRETARY.—As a  
17 condition;”; and

18 (iii) by adding at the end the fol-  
19 lowing:

20 “(B) STATE REQUEST FOR MODIFICA-  
21 TION.—If the State determines that a modifica-  
22 tion to such plan is necessary, the State may  
23 request the Secretary to approve the modifica-  
24 tion. Any such modification shall be in accord-

1           ance with paragraph (1) and section 1941.”;

2           and

3                   (C) in paragraph (3), by inserting, “, in-

4           cluding any modification under paragraph (2)”

5           after “subsection (a)(6)”;

6                   (3) in subsection (e)(2), by striking “section

7           1922(e)” and inserting “section 1922(b)”.

8           (j) DEFINITIONS.—Section 1934 of the Public Health

9           Service Act (42 U.S.C. 300x–34) is amended—

10                   (1) in paragraph (3), by striking “substance

11           abuse” and inserting “substance use disorders”; and

12                   (2) in paragraph (7), by striking “substance

13           abuse” and inserting “substance use disorders”.

14           (k) FUNDING.—Section 1935 of the Public Health

15           Service Act (42 U.S.C. 300x–35) is amended—

16                   (1) in subsection (a)—

17                           (A) by striking “section 505” and insert-

18           ing “section 505(d)”;

19                           (B) by striking “\$2,000,000,000 for fiscal

20           year 2001, and such sums as may be necessary

21           for each of the fiscal years 2002 and 2003” and

22           inserting “\$1,858,079,000 for each of fiscal

23           years 2018 through 2022.”;

24                   (2) in subsection (b)(1)(B) by striking “sections

25           505 and” and inserting “sections 505(d) and”.

1 **SEC. 8003. ADDITIONAL PROVISIONS RELATED TO THE**  
2 **BLOCK GRANTS.**

3 Subpart III of part B of title XIX of the Public  
4 Health Service Act (42 U.S.C. 300x–51 et seq.) is amend-  
5 ed—

6 (1) in section 1943(a)(3) (42 U.S.C. 300x–  
7 53(a)(3)), by striking “section 505” and inserting  
8 “subsections (c) and (d) of section 505”;

9 (2) in section 1953(b) (42 U.S.C. 300x–63(b)),  
10 by striking “substance abuse” and inserting “sub-  
11 stance use disorder”; and

12 (3) by adding at the end the following:

13 **“SEC. 1957. PUBLIC HEALTH EMERGENCIES.**

14 “In the case of a public health emergency (as deter-  
15 mined under section 319), the Secretary, on a State by  
16 State basis, may, as the circumstances of the emergency  
17 reasonably require and for the period of the emergency,  
18 grant an extension, or waive application deadlines or com-  
19 pliance with any other requirement, of a grant authorized  
20 under section 521, 1911, or 1921 or an allotment author-  
21 ized under Public Law 99–319 (42 U.S.C. 10801 et seq.).

22 **“SEC. 1958. JOINT APPLICATIONS.**

23 “The Secretary, acting through the Assistant Sec-  
24 retary for Mental Health and Substance Use, shall permit  
25 a joint application to be submitted for grants under sub-  
26 part I and subpart II upon the request of a State. Such

1 application may be jointly reviewed and approved by the  
2 Secretary with respect to such subparts, consistent with  
3 the purposes and authorized activities of each such grant  
4 program. A State submitting such a joint application shall  
5 otherwise meet the requirements with respect to each such  
6 subpart.”.

7 **SEC. 8004. STUDY OF DISTRIBUTION OF FUNDS UNDER THE**  
8 **SUBSTANCE ABUSE PREVENTION AND TREAT-**  
9 **MENT BLOCK GRANT AND THE COMMUNITY**  
10 **MENTAL HEALTH SERVICES BLOCK GRANT.**

11 (a) IN GENERAL.—The Secretary of Health and  
12 Human Services, acting through the Assistant Secretary  
13 for Mental Health and Substance Use, shall through a  
14 grant or contract, or through an agreement with a third  
15 party, conduct a study on the formulas for distribution  
16 of funds under the substance abuse prevention and treat-  
17 ment block grant, and the community mental health serv-  
18 ices block grant, under part B of title XIX of the Public  
19 Health Service Act (42 U.S.C. 300x et seq.) and rec-  
20 ommend changes if necessary. Such study shall include—

21 (1) an analysis of whether the distributions  
22 under such block grants accurately reflect the need  
23 for the services under the grants in the States;

24 (2) an examination of whether the indices used  
25 under the formulas for distribution of funds under



1 such block grants are appropriate, and if not, alter-  
2 natives recommended by the Secretary;

3 (3) where recommendations are included under  
4 paragraph (2) for the use of different indices, a de-  
5 scription of the variables and data sources that  
6 should be used to determine the indices;

7 (4) an evaluation of the variables and data  
8 sources that are being used for each of the indices  
9 involved, and whether such variables and data  
10 sources accurately represent the need for services,  
11 the cost of providing services, and the ability of the  
12 States to pay for such services;

13 (5) the effect that the minimum allotment re-  
14 quirements for each such block grant have on each  
15 State's final allotment and the effect of such re-  
16 quirements, if any, on each State's formula-based al-  
17 lotment;

18 (6) recommendations for modifications to the  
19 minimum allotment provisions to ensure an appro-  
20 priate distribution of funds; and

21 (7) any other information that the Secretary  
22 determines appropriate.

23 (b) REPORT.—Not later than 2 years after the date  
24 of enactment of this Act, the Secretary of Health and  
25 Human Services shall submit to the Committee on Health,

1 Education, Labor, and Pensions of the Senate and the  
2 Committee on Energy and Commerce of the House of  
3 Representatives, a report containing the findings and rec-  
4 ommendations of the study conducted under subsection  
5 (a) and the study conducted under section 9004(g).

6 **TITLE IX—PROMOTING ACCESS**  
7 **TO MENTAL HEALTH AND**  
8 **SUBSTANCE USE DISORDER**  
9 **CARE**

10 **Subtitle A—Helping Individuals**  
11 **and Families**

12 **SEC. 9001. GRANTS FOR TREATMENT AND RECOVERY FOR**  
13 **HOMELESS INDIVIDUALS.**

14 Section 506 of the Public Health Service Act (42  
15 U.S.C. 290aa-5) is amended—

16 (1) in subsection (a), by striking “substance  
17 abuse” and inserting “substance use disorder”;

18 (2) in subsection (b)—

19 (A) in paragraphs (1) and (3), by striking  
20 “substance abuse” each place the term appears  
21 and inserting “substance use disorder”; and

22 (B) in paragraph (4), by striking “sub-  
23 stance abuse” and inserting “a substance use  
24 disorder”;

25 (3) in subsection (c)—

1 (A) in paragraph (1), by striking “sub-  
2 stance abuse disorder” and inserting “sub-  
3 stance use disorder”; and

4 (B) in paragraph (2)—

5 (i) in subparagraph (A), by striking  
6 “substance abuse” and inserting “a sub-  
7 stance use disorder”; and

8 (ii) in subparagraph (B), by striking  
9 “substance abuse” and inserting “sub-  
10 stance use disorder”; and

11 (4) in subsection (e), by striking “,  
12 \$50,000,000 for fiscal year 2001, and such sums as  
13 may be necessary for each of the fiscal years 2002  
14 and 2003” and inserting “\$41,304,000 for each of  
15 fiscal years 2018 through 2022”.

16 **SEC. 9002. GRANTS FOR JAIL DIVERSION PROGRAMS.**

17 Section 520G of the Public Health Service Act (42  
18 U.S.C. 290bb–38) is amended—

19 (1) by striking “substance abuse” each place  
20 such term appears and inserting “substance use dis-  
21 order”;

22 (2) in subsection (a)—

23 (A) by striking “Indian tribes, and tribal  
24 organizations” and inserting “and Indian tribes  
25 and tribal organizations (as the terms ‘Indian

1 tribes' and 'tribal organizations' are defined in  
2 section 4 of the Indian Self-Determination and  
3 Education Assistance Act)"; and

4 (B) by inserting "or a health facility or  
5 program operated by or in accordance with a  
6 contract or grant with the Indian Health Serv-  
7 ice," after "entities,";

8 (3) in subsection (c)(2)(A)(i), by striking "the  
9 best known" and inserting "evidence-based";

10 (4) by redesignating subsections (d) through (i)  
11 as subsections (e) through (j), respectively;

12 (5) by inserting after subsection (c) the fol-  
13 lowing:

14 "(d) SPECIAL CONSIDERATION REGARDING VET-  
15 ERANS.—In awarding grants under subsection (a), the  
16 Secretary shall, as appropriate, give special consideration  
17 to entities proposing to use grant funding to support jail  
18 diversion services for veterans.";

19 (6) in subsection (e), as so redesignated—

20 (A) in paragraph (3), by striking "; and"  
21 and inserting a semicolon;

22 (B) in paragraph (4), by striking the pe-  
23 riod and inserting "; and"; and

24 (C) by adding at the end the following:

1           “(5) develop programs to divert individuals  
2 prior to booking or arrest.”; and

3           (7) in subsection (j), as so redesignated, by  
4 striking “\$10,000,000 for fiscal year 2001, and such  
5 sums as may be necessary for fiscal years 2002  
6 through 2003” and inserting “\$4,269,000 for each  
7 of fiscal years 2018 through 2022”.

8 **SEC. 9003. PROMOTING INTEGRATION OF PRIMARY AND BE-**  
9 **HAVIORAL HEALTH CARE.**

10       Section 520K of the Public Health Service Act (42  
11 U.S.C. 290bb–42) is amended to read as follows:

12 **“SEC. 520K. INTEGRATION INCENTIVE GRANTS AND COOP-**  
13 **ERATIVE AGREEMENTS.**

14       “(a) DEFINITIONS.—In this section:

15           “(1) ELIGIBLE ENTITY.—The term ‘eligible en-  
16 tity’ means a State, or other appropriate State agen-  
17 cy, in collaboration with 1 or more qualified commu-  
18 nity programs as described in section 1913(b)(1) or  
19 1 or more community health centers as described in  
20 section 330.

21           “(2) INTEGRATED CARE.—The term ‘integrated  
22 care’ means collaborative models or practices offer-  
23 ing mental and physical health services, which may  
24 include practices that share the same space in the  
25 same facility.

1           “(3) SPECIAL POPULATION.—The term ‘special  
2           population’ means—

3                   “(A) adults with a mental illness who have  
4                   co-occurring physical health conditions or  
5                   chronic diseases;

6                   “(B) adults with a serious mental illness  
7                   who have co-occurring physical health condi-  
8                   tions or chronic diseases;

9                   “(C) children and adolescents with a seri-  
10                  ous emotional disturbance with co-occurring  
11                  physical health conditions or chronic diseases;  
12                  or

13                  “(D) individuals with a substance use dis-  
14                  order.

15           “(b) GRANTS AND COOPERATIVE AGREEMENTS.—

16                   “(1) IN GENERAL.—The Secretary may award  
17                   grants and cooperative agreements to eligible entities  
18                   to support the improvement of integrated care for  
19                   primary care and behavioral health care in accord-  
20                   ance with paragraph (2).

21                   “(2) PURPOSES.—A grant or cooperative agree-  
22                   ment awarded under this section shall be designed  
23                   to—

1           “(A) promote full integration and collabo-  
2           ration in clinical practices between primary and  
3           behavioral health care;

4           “(B) support the improvement of inte-  
5           grated care models for primary care and behav-  
6           ioral health care to improve the overall wellness  
7           and physical health status of adults with a seri-  
8           ous mental illness or children with a serious  
9           emotional disturbance; and

10          “(C) promote integrated care services re-  
11          lated to screening, diagnosis, prevention, and  
12          treatment of mental and substance use dis-  
13          orders, and co-occurring physical health condi-  
14          tions and chronic diseases.

15          “(c) APPLICATIONS.—

16          “(1) IN GENERAL.—An eligible entity seeking a  
17          grant or cooperative agreement under this section  
18          shall submit an application to the Secretary at such  
19          time, in such manner, and accompanied by such in-  
20          formation as the Secretary may require, including  
21          the contents described in paragraph (2).

22          “(2) CONTENTS.—The contents described in  
23          this paragraph are—

1           “(A) a description of a plan to achieve  
2 fully collaborative agreements to provide serv-  
3 ices to special populations;

4           “(B) a document that summarizes the poli-  
5 cies, if any, that serve as barriers to the provi-  
6 sion of integrated care, and the specific steps,  
7 if applicable, that will be taken to address such  
8 barriers;

9           “(C) a description of partnerships or other  
10 arrangements with local health care providers  
11 to provide services to special populations;

12           “(D) an agreement and plan to report to  
13 the Secretary performance measures necessary  
14 to evaluate patient outcomes and facilitate eval-  
15 uations across participating projects; and

16           “(E) a plan for sustainability beyond the  
17 grant or cooperative agreement period under  
18 subsection (e).

19       “(d) GRANT AND COOPERATIVE AGREEMENT  
20 AMOUNTS.—

21           “(1) TARGET AMOUNT.—The target amount  
22 that an eligible entity may receive for a year through  
23 a grant or cooperative agreement under this section  
24 shall be \$2,000,000.



1           “(2) ADJUSTMENT PERMITTED.—The Sec-  
2           retary, taking into consideration the quality of the  
3           application and the number of eligible entities that  
4           received grants under this section prior to the date  
5           of enactment of the Helping Families in Mental  
6           Health Crisis Reform Act of 2016, may adjust the  
7           target amount that an eligible entity may receive for  
8           a year through a grant or cooperative agreement  
9           under this section.

10           “(3) LIMITATION.—An eligible entity receiving  
11           funding under this section may not allocate more  
12           than 10 percent of funds awarded under this section  
13           to administrative functions, and the remaining  
14           amounts shall be allocated to health facilities that  
15           provide integrated care.

16           “(e) DURATION.—A grant or cooperative agreement  
17           under this section shall be for a period not to exceed 5  
18           years.

19           “(f) REPORT ON PROGRAM OUTCOMES.—An eligible  
20           entity receiving a grant or cooperative agreement under  
21           this section shall submit an annual report to the Secretary  
22           that includes—

23           “(1) the progress made to reduce barriers to in-  
24           tegrated care as described in the entity’s application  
25           under subsection (c); and

1           “(2) a description of functional outcomes of  
2 special populations, including—

3           “(A) with respect to adults with a serious  
4 mental illness, participation in supportive hous-  
5 ing or independent living programs, attendance  
6 in social and rehabilitative programs, participa-  
7 tion in job training opportunities, satisfactory  
8 performance in work settings, attendance at  
9 scheduled medical and mental health appoint-  
10 ments, and compliance with prescribed medica-  
11 tion regimes;

12           “(B) with respect to individuals with co-oc-  
13 ccurring mental illness and physical health con-  
14 ditions and chronic diseases, attendance at  
15 scheduled medical and mental health appoint-  
16 ments, compliance with prescribed medication  
17 regimes, and participation in learning opportu-  
18 nities related to improved health and lifestyle  
19 practices; and

20           “(C) with respect to children and adoles-  
21 cents with a serious emotional disturbance who  
22 have co-occurring physical health conditions and  
23 chronic diseases, attendance at scheduled med-  
24 ical and mental health appointments, compli-  
25 ance with prescribed medication regimes, and

1 participation in learning opportunities at school  
2 and extracurricular activities.

3 “(g) TECHNICAL ASSISTANCE FOR PRIMARY-BEHAV-  
4 IORAL HEALTH CARE INTEGRATION.—

5 “(1) IN GENERAL.—The Secretary may provide  
6 appropriate information, training, and technical as-  
7 sistance to eligible entities that receive a grant or  
8 cooperative agreement under this section, in order to  
9 help such entities meet the requirements of this sec-  
10 tion, including assistance with—

11 “(A) development and selection of inte-  
12 grated care models;

13 “(B) dissemination of evidence-based inter-  
14 ventions in integrated care;

15 “(C) establishment of organizational prac-  
16 tices to support operational and administrative  
17 success; and

18 “(D) other activities, as the Secretary de-  
19 termines appropriate.

20 “(2) ADDITIONAL DISSEMINATION OF TECH-  
21 NICAL INFORMATION.—The information and re-  
22 sources provided by the Secretary under paragraph  
23 (1) shall, as appropriate, be made available to  
24 States, political subdivisions of States, Indian tribes  
25 or tribal organizations (as defined in section 4 of the

1 Indian Self-Determination and Education Assistance  
2 Act), outpatient mental health and addiction treat-  
3 ment centers, community mental health centers that  
4 meet the criteria under section 1913(e), certified  
5 community behavioral health clinics described in sec-  
6 tion 223 of the Protecting Access to Medicare Act  
7 of 2014, primary care organizations such as Feder-  
8 ally qualified health centers or rural health clinics as  
9 defined in section 1861(aa) of the Social Security  
10 Act, other community-based organizations, or other  
11 entities engaging in integrated care activities, as the  
12 Secretary determines appropriate.

13 “(h) AUTHORIZATION OF APPROPRIATIONS.—To  
14 carry out this section, there are authorized to be appro-  
15 priated \$51,878,000 for each of fiscal years 2018 through  
16 2022.”.

17 **SEC. 9004. PROJECTS FOR ASSISTANCE IN TRANSITION**  
18 **FROM HOMELESSNESS.**

19 (a) FORMULA GRANTS TO STATES.—Section 521 of  
20 the Public Health Service Act (42 U.S.C. 290cc–21) is  
21 amended by striking “1991 through 1994” and inserting  
22 “2018 through 2022”.

23 (b) PURPOSE OF GRANTS.—Section 522 of the Public  
24 Health Service Act (42 U.S.C. 290cc–22) is amended—

1           (1) in subsection (a)(1)(B), by striking “sub-  
2           stance abuse” and inserting “a substance use dis-  
3           order”;

4           (2) in subsection (b)(6), by striking “substance  
5           abuse” and inserting “substance use disorder”;

6           (3) in subsection (c), by striking “substance  
7           abuse” and inserting “a substance use disorder”;

8           (4) in subsection (e)—

9                 (A) in paragraph (1), by striking “sub-  
10           stance abuse” and inserting “a substance use  
11           disorder”; and

12                 (B) in paragraph (2), by striking “sub-  
13           stance abuse” and inserting “substance use dis-  
14           order”;

15           (5) by striking subsection (g) and redesignating  
16           subsections (h) and (i) as (g) and (h), accordingly;  
17           and

18           (6) in subsection (g), as redesignated by para-  
19           graph (5), by striking “substance abuse” each place  
20           such term appears and inserting “substance use dis-  
21           order”.

22           (c) DESCRIPTION OF INTENDED EXPENDITURES OF  
23           GRANT.—Section 527 of the Public Health Service Act  
24           (42 U.S.C. 290cc–27) is amended by striking “substance

1 abuse” each place such term appears and inserting “sub-  
2 stance use disorder”.

3 (d) TECHNICAL ASSISTANCE.—Section 530 of the  
4 Public Health Service Act (42 U.S.C. 290cc–30) is amend-  
5 ed by striking “through the National Institute of Mental  
6 Health, the National Institute of Alcohol Abuse and Alco-  
7 holism, and the National Institute on Drug Abuse” and  
8 inserting “acting through the Assistant Secretary”.

9 (e) DEFINITIONS.—Section 534(4) of the Public  
10 Health Service Act (42 U.S.C. 290cc–34(4)) is amended  
11 to read as follows:

12 “(4) SUBSTANCE USE DISORDER SERVICES.—  
13 The term ‘substance use disorder services’ has the  
14 meaning given the term ‘substance abuse services’ in  
15 section 330(h)(5)(C).”.

16 (f) FUNDING.—Section 535(a) of the Public Health  
17 Service Act (42 U.S.C. 290cc–35(a)) is amended by strik-  
18 ing “\$75,000,000 for each of the fiscal years 2001  
19 through 2003” and inserting “\$64,635,000 for each of fis-  
20 cal years 2018 through 2022”.

21 (g) STUDY CONCERNING FORMULA.—

22 (1) IN GENERAL.—Not later than 2 years after  
23 the date of enactment of this Act, the Assistant Sec-  
24 retary for Mental Health and Substance Use (re-  
25 ferred to in this section as the “Assistant Sec-



1 tion as the ‘program’), authorized under section 520A and  
2 in effect prior to the date of enactment of the Helping  
3 Families in Mental Health Crisis Reform Act of 2016.

4 “(b) ACTIVITIES.—In maintaining the program, the  
5 activities of the Secretary shall include—

6 “(1) coordinating a network of crisis centers  
7 across the United States for providing suicide pre-  
8 vention and crisis intervention services to individuals  
9 seeking help at any time, day or night;

10 “(2) maintaining a suicide prevention hotline to  
11 link callers to local emergency, mental health, and  
12 social services resources; and

13 “(3) consulting with the Secretary of Veterans  
14 Affairs to ensure that veterans calling the suicide  
15 prevention hotline have access to a specialized vet-  
16 erans’ suicide prevention hotline.

17 “(c) AUTHORIZATION OF APPROPRIATIONS.—To  
18 carry out this section, there are authorized to be appro-  
19 priated \$7,198,000 for each of fiscal years 2018 through  
20 2022.”.

21 **SEC. 9006. CONNECTING INDIVIDUALS AND FAMILIES WITH**  
22 **CARE.**

23 Subpart 3 of part B of title V of the Public Health  
24 Service Act (42 U.S.C. 290bb–31 et seq.), as amended by



1 section 9005, is further amended by inserting after section  
2 520E–3 the following:

3 **“SEC. 520E–4. TREATMENT REFERRAL ROUTING SERVICE.**

4 “(a) IN GENERAL.—The Secretary, acting through  
5 the Assistant Secretary, shall maintain the National  
6 Treatment Referral Routing Service (referred to in this  
7 section as the ‘Routing Service’) to assist individuals and  
8 families in locating mental and substance use disorders  
9 treatment providers.

10 “(b) ACTIVITIES OF THE SECRETARY.—To maintain  
11 the Routing Service, the activities of the Assistant Sec-  
12 retary shall include administering—

13 “(1) a nationwide, telephone number providing  
14 year-round access to information that is updated on  
15 a regular basis regarding local behavioral health pro-  
16 viders and community-based organizations in a man-  
17 ner that is confidential, without requiring individuals  
18 to identify themselves, is in languages that include  
19 at least English and Spanish, and is at no cost to  
20 the individual using the Routing Service; and

21 “(2) an Internet website to provide a search-  
22 able, online treatment services locator of behavioral  
23 health treatment providers and community-based or-  
24 ganizations, which shall include information on the

1 name, location, contact information, and basic serv-  
2 ices provided by such providers and organizations.

3 “(c) REMOVING PRACTITIONER CONTACT INFORMA-  
4 TION.—In the event that the Internet website described  
5 in subsection (b)(2) contains information on any qualified  
6 practitioner that is certified to prescribe medication for  
7 opioid dependency under section 303(g)(2)(B) of the Con-  
8 trolled Substances Act, the Assistant Secretary—

9 “(1) shall provide an opportunity to such prac-  
10 titioner to have the contact information of the prac-  
11 titioner removed from the website at the request of  
12 the practitioner; and

13 “(2) may evaluate other methods to periodically  
14 update the information displayed on such website.

15 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
16 tion shall be construed to prevent the Assistant Secretary  
17 from using any unobligated amounts otherwise made  
18 available to the Administration to maintain the Routing  
19 Service.”.

20 **SEC. 9007. STRENGTHENING COMMUNITY CRISIS RE-**  
21 **SPONSE SYSTEMS.**

22 Section 520F of the Public Health Service Act (42  
23 U.S.C. 290bb–37) is amended to read as follows:

1 **“SEC. 520F. STRENGTHENING COMMUNITY CRISIS RE-**  
2 **SPONSE SYSTEMS.**

3 “(a) IN GENERAL.—The Secretary shall award com-  
4 petitive grants to—

5 “(1) State and local governments and Indian  
6 tribes and tribal organizations, to enhance commu-  
7 nity-based crisis response systems; or

8 “(2) States to develop, maintain, or enhance a  
9 database of beds at inpatient psychiatric facilities,  
10 crisis stabilization units, and residential community  
11 mental health and residential substance use disorder  
12 treatment facilities, for adults with a serious mental  
13 illness, children with a serious emotional disturb-  
14 ance, or individuals with a substance use disorder.

15 “(b) APPLICATIONS.—

16 “(1) IN GENERAL.—To receive a grant under  
17 subsection (a), an entity shall submit to the Sec-  
18 retary an application, at such time, in such manner,  
19 and containing such information as the Secretary  
20 may require.

21 “(2) COMMUNITY-BASED CRISIS RESPONSE  
22 PLAN.—An application for a grant under subsection  
23 (a)(1) shall include a plan for—

24 “(A) promoting integration and coordina-  
25 tion between local public and private entities  
26 engaged in crisis response, including first re-

1           sponders, emergency health care providers, pri-  
2           mary care providers, law enforcement, court  
3           systems, health care payers, social service pro-  
4           viders, and behavioral health providers;

5           “(B) developing memoranda of under-  
6           standing with public and private entities to im-  
7           plement crisis response services;

8           “(C) addressing gaps in community re-  
9           sources for crisis intervention and prevention;  
10          and

11          “(D) developing models for minimizing  
12          hospital readmissions, including through appro-  
13          priate discharge planning.

14          “(3) BEDS DATABASE PLAN.—An application  
15          for a grant under subsection (a)(2) shall include a  
16          plan for developing, maintaining, or enhancing a  
17          real-time, Internet-based bed database to collect, ag-  
18          gregate, and display information about beds in inpa-  
19          tient psychiatric facilities and crisis stabilization  
20          units, and residential community mental health and  
21          residential substance use disorder treatment facili-  
22          ties to facilitate the identification and designation of  
23          facilities for the temporary treatment of individuals  
24          in mental or substance use disorder crisis.

1       “(c) DATABASE REQUIREMENTS.—A bed database  
2 described in this section is a database that—

3           “(1) includes information on inpatient psy-  
4 chiatric facilities, crisis stabilization units, and resi-  
5 dential community mental health and residential  
6 substance use disorder facilities in the State in-  
7 volved, including contact information for the facility  
8 or unit;

9           “(2) provides real-time information about the  
10 number of beds available at each facility or unit and,  
11 for each available bed, the type of patient that may  
12 be admitted, the level of security provided, and any  
13 other information that may be necessary to allow for  
14 the proper identification of appropriate facilities for  
15 treatment of individuals in mental or substance use  
16 disorder crisis; and

17           “(3) enables searches of the database to iden-  
18 tify available beds that are appropriate for the treat-  
19 ment of individuals in mental or substance use dis-  
20 order crisis.

21       “(d) EVALUATION.—An entity receiving a grant  
22 under subsection (a)(1) shall submit to the Secretary, at  
23 such time, in such manner, and containing such informa-  
24 tion as the Secretary may reasonably require, a report,  
25 including an evaluation of the effect of such grant on—



1 period at the end of paragraph (2) and inserting  
2 “acting through the Assistant Secretary, shall estab-  
3 lish a research, training, and technical assistance re-  
4 source center to provide appropriate information,  
5 training, and technical assistance to States, political  
6 subdivisions of States, federally recognized Indian  
7 tribes, tribal organizations, institutions of higher  
8 education, public organizations, or private nonprofit  
9 organizations regarding the prevention of suicide  
10 among all ages, particularly among groups that are  
11 at a high risk for suicide.”;

12 (3) by striking subsections (b) and (c);

13 (4) by redesignating subsection (d) as sub-  
14 section (b);

15 (5) in subsection (b), as so redesignated—

16 (A) in the subsection heading, by striking  
17 “ADDITIONAL CENTER” and inserting “RE-  
18 SPONSIBILITIES OF THE CENTER”;

19 (B) in the matter preceding paragraph (1),  
20 by striking “The additional research” and all  
21 that follows through “nonprofit organizations  
22 for” and inserting “The center established  
23 under subsection (a) shall conduct activities for  
24 the purpose of”;

1 (C) by striking “youth suicide” each place  
2 such term appears and inserting “suicide”;

3 (D) in paragraph (1)—

4 (i) by striking “the development or  
5 continuation of” and inserting “developing  
6 and continuing”; and

7 (ii) by inserting “for all ages, particu-  
8 larly among groups that are at a high risk  
9 for suicide” before the semicolon at the  
10 end;

11 (E) in paragraph (2), by inserting “for all  
12 ages, particularly among groups that are at a  
13 high risk for suicide” before the semicolon at  
14 the end;

15 (F) in paragraph (3), by inserting “and  
16 tribal” after “statewide”;

17 (G) in paragraph (5), by inserting “and  
18 prevention” after “intervention”;

19 (H) in paragraph (8), by striking “in  
20 youth”;

21 (I) in paragraph (9), by striking “and be-  
22 havioral health” and inserting “health and sub-  
23 stance use disorder”; and

24 (J) in paragraph (10), by inserting “con-  
25 ducting” before “other”; and



1           (6) by striking subsection (e) and inserting the  
2           following:

3           “(c) AUTHORIZATION OF APPROPRIATIONS.—For the  
4           purpose of carrying out this section, there are authorized  
5           to be appropriated \$5,988,000 for each of fiscal years  
6           2018 through 2022.

7           “(d) ANNUAL REPORT.—Not later than 2 years after  
8           the date of enactment of this subsection, the Secretary  
9           shall submit to Congress a report on the activities carried  
10          out by the center established under subsection (a) during  
11          the year involved, including the potential effects of such  
12          activities, and the States, organizations, and institutions  
13          that have worked with the center.”.

14          (b) YOUTH SUICIDE EARLY INTERVENTION AND  
15          PREVENTION STRATEGIES.—Section 520E of the Public  
16          Health Service Act (42 U.S.C. 290bb–36) is amended—

17                 (1) in paragraph (1) of subsection (a) and in  
18                 subsection (c), by striking “substance abuse” each  
19                 place such term appears and inserting “substance  
20                 use disorder”;

21                 (2) in subsection (b)—

22                         (A) in paragraph (2)—

23                                 (i) by striking “ensure that each State  
24                                 is awarded only 1 grant or cooperative  
25                                 agreement under this section” and insert-

1           ing “ensure that a State does not receive  
2           more than 1 grant or cooperative agree-  
3           ment under this section at any 1 time”;  
4           and

5                   (ii) by striking “been awarded” and  
6           inserting “received”; and

7           (B) by adding after paragraph (2) the fol-  
8           lowing:

9           “(3) CONSIDERATION.—In awarding grants  
10          under this section, the Secretary shall take into con-  
11          sideration the extent of the need of the applicant, in-  
12          cluding the incidence and prevalence of suicide in  
13          the State and among the populations of focus, in-  
14          cluding rates of suicide determined by the Centers  
15          for Disease Control and Prevention for the State or  
16          population of focus.”;

17           (3) in subsection (g)(2), by striking “2 years  
18          after the date of enactment of this section,” and in-  
19          sert “2 years after the date of enactment of Helping  
20          Families in Mental Health Crisis Reform Act of  
21          2016,”; and

22           (4) by striking subsection (m) and inserting the  
23          following:

24          “(m) AUTHORIZATION OF APPROPRIATIONS.—For  
25          the purpose of carrying out this section, there are author-

1 ized to be appropriated \$30,000,000 for each of fiscal  
2 years 2018 through 2022.”.

3 **SEC. 9009. ADULT SUICIDE PREVENTION.**

4 Subpart 3 of part B of title V of the Public Health  
5 Service Act (42 U.S.C. 290bb–31 et seq.) is amended by  
6 adding at the end the following:

7 **“SEC. 520L. ADULT SUICIDE PREVENTION.**

8 “(a) GRANTS.—

9 “(1) IN GENERAL.—The Assistant Secretary  
10 shall award grants to eligible entities described in  
11 paragraph (2) to implement suicide prevention and  
12 intervention programs, for individuals who are 25  
13 years of age or older, that are designed to raise  
14 awareness of suicide, establish referral processes,  
15 and improve care and outcomes for such individuals  
16 who are at risk of suicide.

17 “(2) ELIGIBLE ENTITIES.—To be eligible to re-  
18 ceive a grant under this section, an entity shall be  
19 a community-based primary care or behavioral  
20 health care setting, an emergency department, a  
21 State mental health agency (or State health agency  
22 with mental or behavioral health functions), public  
23 health agency, a territory of the United States, or  
24 an Indian tribe or tribal organization (as the terms  
25 ‘Indian tribe’ and ‘tribal organization’ are defined in

1 section 4 of the Indian Self-Determination and Edu-  
2 cation Assistance Act).

3 “(3) USE OF FUNDS.—The grants awarded  
4 under paragraph (1) shall be used to implement pro-  
5 grams, in accordance with such paragraph, that in-  
6 clude one or more of the following components:

7 “(A) Screening for suicide risk, suicide  
8 intervention services, and services for referral  
9 for treatment for individuals at risk for suicide.

10 “(B) Implementing evidence-based prac-  
11 tices to provide treatment for individuals at risk  
12 for suicide, including appropriate followup serv-  
13 ices.

14 “(C) Raising awareness and reducing stig-  
15 ma of suicide.

16 “(b) EVALUATIONS AND TECHNICAL ASSISTANCE.—  
17 The Assistant Secretary shall—

18 “(1) evaluate the activities supported by grants  
19 awarded under subsection (a), and disseminate, as  
20 appropriate, the findings from the evaluation; and

21 “(2) provide appropriate information, training,  
22 and technical assistance, as appropriate, to eligible  
23 entities that receive a grant under this section, in  
24 order to help such entities to meet the requirements  
25 of this section, including assistance with selection

1 and implementation of evidence-based interventions  
2 and frameworks to prevent suicide.

3 “(c) DURATION.—A grant under this section shall be  
4 for a period of not more than 5 years.

5 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
6 are authorized to be appropriated to carry out this section  
7 \$30,000,000 for the period of fiscal years 2018 through  
8 2022.”.

9 **SEC. 9010. MENTAL HEALTH AWARENESS TRAINING**  
10 **GRANTS.**

11 Section 520J of the Public Health Service Act (42  
12 U.S.C. 290bb–41) is amended—

13 (1) in the section heading, by inserting “**MEN-**  
14 **TAL HEALTH AWARENESS**” before “**TRAINING**”;  
15 and

16 (2) in subsection (b)—

17 (A) in the subsection heading, by striking  
18 “ILLNESS” and inserting “HEALTH”;

19 (B) in paragraph (1), by inserting “vet-  
20 erans, law enforcement, and other categories of  
21 individuals, as determined by the Secretary,”  
22 after “emergency services personnel”;

23 (C) in paragraph (5)—

24 (i) in the matter preceding subpara-  
25 graph (A), by striking “to” and inserting

1 “for evidence-based programs that provide  
2 training and education in accordance with  
3 paragraph (1) on matters including”; and

4 (ii) by striking subparagraphs (A)  
5 through (C) and inserting the following:

6 “(A) recognizing the signs and symptoms  
7 of mental illness; and

8 “(B)(i) resources available in the commu-  
9 nity for individuals with a mental illness and  
10 other relevant resources; or

11 “(ii) safely de-escalating crisis situations  
12 involving individuals with a mental illness.”;  
13 and

14 (D) in paragraph (7), by striking “,  
15 \$25,000,000” and all that follows through the  
16 period at the end and inserting “\$14,693,000  
17 for each of fiscal years 2018 through 2022.”.

18 **SEC. 9011. SENSE OF CONGRESS ON PRIORITIZING AMER-**  
19 **ICAN INDIANS AND ALASKA NATIVE YOUTH**  
20 **WITHIN SUICIDE PREVENTION PROGRAMS.**

21 (a) FINDINGS.—The Congress finds as follows:

22 (1) Suicide is the eighth leading cause of death  
23 among American Indians and Alaska Natives across  
24 all ages.



1 as well as disseminate information about such evi-  
2 dence-based practices to States and nongrantees  
3 throughout the United States.”.

4 **SEC. 9013. NATIONAL VIOLENT DEATH REPORTING SYSTEM.**

5 The Secretary of Health and Human Services, acting  
6 through the Director of the Centers for Disease Control  
7 and Prevention, is encouraged to improve, particularly  
8 through the inclusion of additional States, the National  
9 Violent Death Reporting System as authorized by title III  
10 of the Public Health Service Act (42 U.S.C. 241 et seq.).  
11 Participation in the system by the States shall be vol-  
12 untary.

13 **SEC. 9014. ASSISTED OUTPATIENT TREATMENT.**

14 Section 224 of the Protecting Access to Medicare Act  
15 of 2014 (42 U.S.C. 290aa note) is amended—

16 (1) in subsection (e), by striking “and 2018,”  
17 and inserting “2018, 2019, 2020, 2021, and 2022,”;  
18 and

19 (2) in subsection (g)—

20 (A) in paragraph (1), by striking “2018”  
21 and inserting “2022”; and

22 (B) in paragraph (2), by striking “is au-  
23 thorized to be appropriated to carry out this  
24 section \$15,000,000 for each of fiscal years  
25 2015 through 2018” and inserting “are author-



1            ized to be appropriated to carry out this section  
2            \$15,000,000 for each of fiscal years 2015  
3            through 2017, \$20,000,000 for fiscal year  
4            2018, \$19,000,000 for each of fiscal years 2019  
5            and 2020, and \$18,000,000 for each of fiscal  
6            years 2021 and 2022”.

7 **SEC. 9015. ASSERTIVE COMMUNITY TREATMENT GRANT**  
8            **PROGRAM.**

9            Part B of title V of the Public Health Service Act  
10          (42 U.S.C. 290bb et seq.), as amended by section 9009,  
11          is further amended by adding at the end the following:

12 **“SEC. 520M. ASSERTIVE COMMUNITY TREATMENT GRANT**  
13            **PROGRAM.**

14            “(a) IN GENERAL.—The Assistant Secretary shall  
15          award grants to eligible entities—

16            “(1) to establish assertive community treatment  
17          programs for adults with a serious mental illness; or

18            “(2) to maintain or expand such programs.

19            “(b) ELIGIBLE ENTITIES.—To be eligible to receive  
20          a grant under this section, an entity shall be a State, polit-  
21          ical subdivision of a State, Indian tribe or tribal organiza-  
22          tion (as such terms are defined in section 4 of the Indian  
23          Self-Determination and Education Assistance Act), men-  
24          tal health system, health care facility, or any other entity  
25          the Assistant Secretary deems appropriate.

1           “(c) SPECIAL CONSIDERATION.—In selecting among  
2 applicants for a grant under this section, the Assistant  
3 Secretary may give special consideration to the potential  
4 of the applicant’s program to reduce hospitalization,  
5 homelessness, and involvement with the criminal justice  
6 system while improving the health and social outcomes of  
7 the patient.

8           “(d) ADDITIONAL ACTIVITIES.—The Assistant Sec-  
9 retary shall—

10                   “(1) not later than the end of fiscal year 2021,  
11 submit a report to the appropriate congressional  
12 committees on the grant program under this section,  
13 including an evaluation of—

14                           “(A) any cost savings and public health  
15 outcomes such as mortality, suicide, substance  
16 use disorders, hospitalization, and use of serv-  
17 ices;

18                           “(B) rates of involvement with the criminal  
19 justice system of patients;

20                           “(C) rates of homelessness among patients;  
21 and

22                           “(D) patient and family satisfaction with  
23 program participation; and

24                   “(2) provide appropriate information, training,  
25 and technical assistance to grant recipients under

1 this section to help such recipients to establish,  
2 maintain, or expand their assertive community treat-  
3 ment programs.

4 “(e) AUTHORIZATION OF APPROPRIATIONS.—

5 “(1) IN GENERAL.—To carry out this section,  
6 there is authorized to be appropriated \$5,000,000  
7 for the period of fiscal years 2018 through 2022.

8 “(2) USE OF CERTAIN FUNDS.—Of the funds  
9 appropriated to carry out this section in any fiscal  
10 year, not more than 5 percent shall be available to  
11 the Assistant Secretary for carrying out subsection  
12 (d).”.

13 **SEC. 9016. SOBER TRUTH ON PREVENTING UNDERAGE**  
14 **DRINKING REAUTHORIZATION.**

15 Section 519B of the Public Health Service Act (42  
16 U.S.C. 290bb–25b) is amended—

17 (1) in subsection (e)(3), by striking “fiscal year  
18 2007” and all that follows through the period at the  
19 end and inserting “each of the fiscal years 2018  
20 through 2022.”;

21 (2) in subsection (d)(4), by striking “fiscal year  
22 2007” and all that follows through the period at the  
23 end and inserting “each of the fiscal years 2018  
24 through 2022.”;

1           (3) in subsection (e)(1)(I), by striking “fiscal  
2           year 2007” and all that follows through the period  
3           at the end and inserting “each of the fiscal years  
4           2018 through 2022.”;

5           (4) in subsection (f)(2), by striking  
6           “\$6,000,000 for fiscal year 2007” and all that fol-  
7           lows through the period at the end and inserting  
8           “\$3,000,000 for each of the fiscal years 2018  
9           through 2022”; and

10          (5) by adding at the end the following new sub-  
11          section:

12          “(g) REDUCING UNDERAGE DRINKING THROUGH  
13          SCREENING AND BRIEF INTERVENTION.—

14                 “(1) GRANTS TO PEDIATRIC HEALTH CARE  
15                 PROVIDERS TO REDUCE UNDERAGE DRINKING.—The  
16                 Assistant Secretary may make grants to eligible en-  
17                 tities to increase implementation of practices for re-  
18                 ducing the prevalence of alcohol use among individ-  
19                 uals under the age of 21, including college students.

20                 “(2) PURPOSES.—Grants under this subsection  
21                 shall be made to improve—

22                         “(A) screening children and adolescents for  
23                         alcohol use;

24                         “(B) offering brief interventions to chil-  
25                         dren and adolescents to discourage such use;

1           “(C) educating parents about the dangers  
2 of, and methods of discouraging, such use;

3           “(D) diagnosing and treating alcohol use  
4 disorders; and

5           “(E) referring patients, when necessary, to  
6 other appropriate care.

7           “(3) USE OF FUNDS.—An entity receiving a  
8 grant under this subsection may use such funding  
9 for the purposes identified in paragraph (2) by—

10           “(A) providing training to health care pro-  
11 viders;

12           “(B) disseminating best practices, includ-  
13 ing culturally and linguistically appropriate best  
14 practices, as appropriate, and developing and  
15 distributing materials; and

16           “(C) supporting other activities, as deter-  
17 mined appropriate by the Assistant Secretary.

18           “(4) APPLICATION.—To be eligible to receive a  
19 grant under this subsection, an entity shall submit  
20 an application to the Assistant Secretary at such  
21 time, and in such manner, and accompanied by such  
22 information as the Assistant Secretary may require.  
23 Each application shall include—

24           “(A) a description of the entity;

1           “(B) a description of activities to be com-  
2           pleted;

3           “(C) a description of how the services spec-  
4           ified in paragraphs (2) and (3) will be carried  
5           out and the qualifications for providing such  
6           services; and

7           “(D) a timeline for the completion of such  
8           activities.

9           “(5) DEFINITIONS.—For the purpose of this  
10          subsection:

11           “(A) BRIEF INTERVENTION.—The term  
12           ‘brief intervention’ means, after screening a pa-  
13           tient, providing the patient with brief advice  
14           and other brief motivational enhancement tech-  
15           niques designed to increase the insight of the  
16           patient regarding the patient’s alcohol use, and  
17           any realized or potential consequences of such  
18           use, to effect the desired related behavioral  
19           change.

20           “(B) CHILDREN AND ADOLESCENTS.—The  
21           term ‘children and adolescents’ means any per-  
22           son under 21 years of age.

23           “(C) ELIGIBLE ENTITY.—The term ‘eligi-  
24           ble entity’ means an entity consisting of pedi-  
25           atric health care providers and that is qualified

1 to support or provide the activities identified in  
2 paragraph (2).

3 “(D) PEDIATRIC HEALTH CARE PRO-  
4 VIDER.—The term ‘pediatric health care pro-  
5 vider’ means a provider of primary health care  
6 to individuals under the age of 21 years.

7 “(E) SCREENING.—The term ‘screening’  
8 means using validated patient interview tech-  
9 niques to identify and assess the existence and  
10 extent of alcohol use in a patient.”.

11 **SEC. 9017. CENTER AND PROGRAM REPEALS.**

12 Part B of title V of the Public Health Service Act  
13 (42 U.S.C. 290bb et seq.) is amended by striking section  
14 506B (42 U.S.C. 290aa–5b), the second section 514 (42  
15 U.S.C. 290bb–9) relating to methamphetamine and am-  
16 phetamine treatment initiatives, and each of sections  
17 514A, 517, 519A, 519C, 519E, 520B, 520D, and 520H  
18 (42 U.S.C. 290bb–8, 290bb–23, 290bb–25a, 290bb–25c,  
19 290bb–25e, 290bb–33, 290bb–35, and 290bb–39).

20 **Subtitle B—Strengthening the**  
21 **Health Care Workforce**

22 **SEC. 9021. MENTAL AND BEHAVIORAL HEALTH EDUCATION**  
23 **AND TRAINING GRANTS.**

24 Section 756 of the Public Health Service Act (42  
25 U.S.C. 294e–1) is amended—

1 (1) in subsection (a)—

2 (A) in the matter preceding paragraph (1),  
3 by striking “of higher education”; and

4 (B) by striking paragraphs (1) through (4)  
5 and inserting the following:

6 “(1) accredited institutions of higher education  
7 or accredited professional training programs that are  
8 establishing or expanding internships or other field  
9 placement programs in mental health in psychiatry,  
10 psychology, school psychology, behavioral pediatrics,  
11 psychiatric nursing (which may include master’s and  
12 doctoral level programs), social work, school social  
13 work, substance use disorder prevention and treat-  
14 ment, marriage and family therapy, occupational  
15 therapy, school counseling, or professional coun-  
16 seling, including such programs with a focus on  
17 child and adolescent mental health and transitional-  
18 age youth;

19 “(2) accredited doctoral, internship, and post-  
20 doctoral residency programs of health service psy-  
21 chology (including clinical psychology, counseling,  
22 and school psychology) for the development and im-  
23 plementation of interdisciplinary training of psy-  
24 chology graduate students for providing behavioral  
25 health services, including substance use disorder pre-



1       vention and treatment services, as well as the devel-  
2       opment of faculty in health service psychology;

3           “(3) accredited master’s and doctoral degree  
4       programs of social work for the development and im-  
5       plementation of interdisciplinary training of social  
6       work graduate students for providing behavioral  
7       health services, including substance use disorder pre-  
8       vention and treatment services, and the development  
9       of faculty in social work; and

10           “(4) State-licensed mental health nonprofit and  
11       for-profit organizations to enable such organizations  
12       to pay for programs for preservice or in-service  
13       training in a behavioral health-related paraprofes-  
14       sional field with preference for preservice or in-serv-  
15       ice training of paraprofessional child and adolescent  
16       mental health workers.”;

17           (2) in subsection (b)—

18           (A) by striking paragraph (5);

19           (B) by redesignating paragraphs (1)  
20       through (4) as paragraphs (2) through (5), re-  
21       spectively;

22           (C) by inserting before paragraph (2), as  
23       so redesignated, the following:

1           “(1) an ability to recruit and place the students  
2 described in subsection (a) in areas with a high need  
3 and high demand population;”;

4           (D) in paragraph (3), as so redesignated,  
5 by striking “subsection (a)” and inserting  
6 “paragraph (2), especially individuals with men-  
7 tal disorder symptoms or diagnoses, particularly  
8 children and adolescents, and transitional-age  
9 youth”;

10          (E) in paragraph (4), as so redesignated,  
11 by striking “;” and inserting “; and”; and

12          (F) in paragraph (5), as so redesignated,  
13 by striking “; and” and inserting a period;

14          (3) in subsection (c), by striking “authorized  
15 under subsection (a)(1)” and inserting “awarded  
16 under paragraphs (2) and (3) of subsection (a)”;

17          (4) by amending subsection (d) to read as fol-  
18 lows:

19          “(d) PRIORITY.—In selecting grant recipients under  
20 this section, the Secretary shall give priority to—

21           “(1) programs that have demonstrated the abil-  
22 ity to train psychology, psychiatry, and social work  
23 professionals to work in integrated care settings for  
24 purposes of recipients under paragraphs (1), (2),  
25 and (3) of subsection (a); and

1           “(2) programs for paraprofessionals that em-  
2           phasize the role of the family and the lived experi-  
3           ence of the consumer and family-paraprofessional  
4           partnerships for purposes of recipients under sub-  
5           section (a)(4).”; and

6           (5) by striking subsection (e) and inserting the  
7           following:

8           “(e) REPORT TO CONGRESS.—Not later than 4 years  
9           after the date of enactment of the Helping Families in  
10          Mental Health Crisis Reform Act of 2016, the Secretary  
11          shall include in the biennial report submitted to Congress  
12          under section 501(m) an assessment on the effectiveness  
13          of the grants under this section in—

14                 “(1) providing graduate students support for  
15                 experiential training (internship or field placement);

16                 “(2) recruiting students interested in behavioral  
17                 health practice;

18                 “(3) recruiting students in accordance with sub-  
19                 section (b)(1);

20                 “(4) developing and implementing interprofes-  
21                 sional training and integration within primary care;

22                 “(5) developing and implementing accredited  
23                 field placements and internships; and

1           “(6) collecting data on the number of students  
2           trained in behavioral health care and the number of  
3           available accredited internships and field placements.

4           “(f) AUTHORIZATION OF APPROPRIATIONS.—For  
5           each of fiscal years 2018 through 2022, there are author-  
6           ized to be appropriated to carry out this section  
7           \$50,000,000, to be allocated as follows:

8           “(1) For grants described in subsection (a)(1),  
9           \$15,000,000.

10           “(2) For grants described in subsection (a)(2),  
11           \$15,000,000.

12           “(3) For grants described in subsection (a)(3),  
13           \$10,000,000.

14           “(4) For grants described in subsection (a)(4),  
15           \$10,000,000.”.

16   **SEC. 9022. STRENGTHENING THE MENTAL AND SUBSTANCE**  
17                           **USE DISORDERS WORKFORCE.**

18           Part D of title VII of the Public Health Service Act  
19           (42 U.S.C. 294 et seq.) is amended by adding at the end  
20           the following:

21   **“SEC. 760. TRAINING DEMONSTRATION PROGRAM.**

22           “(a) IN GENERAL.—The Secretary shall establish a  
23           training demonstration program to award grants to eligi-  
24           ble entities to support—

1           “(1) training for medical residents and fellows  
2           to practice psychiatry and addiction medicine in un-  
3           derserved, community-based settings that integrate  
4           primary care with mental and substance use dis-  
5           orders prevention and treatment services;

6           “(2) training for nurse practitioners, physician  
7           assistants, health service psychologists, and social  
8           workers to provide mental and substance use dis-  
9           orders services in underserved community-based set-  
10          tings that integrate primary care and mental and  
11          substance use disorders services; and

12          “(3) establishing, maintaining, or improving  
13          academic units or programs that—

14                 “(A) provide training for students or fac-  
15                 ulty, including through clinical experiences and  
16                 research, to improve the ability to be able to  
17                 recognize, diagnose, and treat mental and sub-  
18                 stance use disorders, with a special focus on ad-  
19                 diction; or

20                 “(B) develop evidence-based practices or  
21                 recommendations for the design of the units or  
22                 programs described in subparagraph (A), in-  
23                 cluding curriculum content standards.

24          “(b) ACTIVITIES.—

1           “(1) TRAINING FOR RESIDENTS AND FEL-  
2           LWS.—A recipient of a grant under subsection  
3           (a)(1)—

4                   “(A) shall use the grant funds—

5                           “(i)(I) to plan, develop, and operate a  
6                           training program for medical psychiatry  
7                           residents and fellows in addiction medicine  
8                           practicing in eligible entities described in  
9                           subsection (c)(1); or

10                           “(II) to train new psychiatric resi-  
11                           dents and fellows in addiction medicine to  
12                           provide and expand access to integrated  
13                           mental and substance use disorders serv-  
14                           ices; and

15                           “(ii) to provide at least 1 training  
16                           track that is—

17                                   “(I) a virtual training track that  
18                                   includes an in-person rotation at a  
19                                   teaching health center or in a commu-  
20                                   nity-based setting, followed by a vir-  
21                                   tual rotation in which the resident or  
22                                   fellow continues to support the care of  
23                                   patients at the teaching health center  
24                                   or in the community-based setting  
25                                   through the use of health information

1 technology and, as appropriate, tele-  
2 health services;

3 “(II) an in-person training track  
4 that includes a rotation, during which  
5 the resident or fellow practices at a  
6 teaching health center or in a commu-  
7 nity-based setting; or

8 “(III) an in-person training track  
9 that includes a rotation during which  
10 the resident practices in a community-  
11 based setting that specializes in the  
12 treatment of infants, children, adoles-  
13 cents, or pregnant or postpartum  
14 women; and

15 “(B) may use the grant funds to provide  
16 additional support for the administration of the  
17 program or to meet the costs of projects to es-  
18 tablish, maintain, or improve faculty develop-  
19 ment, or departments, divisions, or other units  
20 necessary to implement such training.

21 “(2) TRAINING FOR OTHER PROVIDERS.—A re-  
22 cipient of a grant under subsection (a)(2)—

23 “(A) shall use the grant funds to plan, de-  
24 velop, or operate a training program to provide  
25 mental and substance use disorders services in

1 underserved, community-based settings, as ap-  
2 propriate, that integrate primary care and men-  
3 tal and substance use disorders prevention and  
4 treatment services; and

5 “(B) may use the grant funds to provide  
6 additional support for the administration of the  
7 program or to meet the costs of projects to es-  
8 tablish, maintain, or improve faculty develop-  
9 ment, or departments, divisions, or other units  
10 necessary to implement such program.

11 “(3) ACADEMIC UNITS OR PROGRAMS.—A re-  
12 cipient of a grant under subsection (a)(3) shall enter  
13 into a partnership with organizations such as an  
14 education accrediting organization (such as the Liai-  
15 son Committee on Medical Education, the Accredita-  
16 tion Council for Graduate Medical Education, the  
17 Commission on Osteopathic College Accreditation,  
18 the Accreditation Commission for Education in  
19 Nursing, the Commission on Collegiate Nursing  
20 Education, the Accreditation Council for Pharmacy  
21 Education, the Council on Social Work Education,  
22 American Psychological Association Commission on  
23 Accreditation, or the Accreditation Review Commis-  
24 sion on Education for the Physician Assistant) to  
25 carry out activities under subsection (a)(3).



1 “(c) ELIGIBLE ENTITIES.—

2 “(1) TRAINING FOR RESIDENTS AND FEL-  
3 LOWS.—To be eligible to receive a grant under sub-  
4 section (a)(1), an entity shall—

5 “(A) be a consortium consisting of—

6 “(i) at least one teaching health cen-  
7 ter; and

8 “(ii) the sponsoring institution (or  
9 parent institution of the sponsoring insti-  
10 tution) of—

11 “(I) a psychiatry residency pro-  
12 gram that is accredited by the Accred-  
13 itation Council of Graduate Medical  
14 Education (or the parent institution  
15 of such a program); or

16 “(II) a fellowship in addiction  
17 medicine, as determined appropriate  
18 by the Secretary; or

19 “(B) be an entity described in subpara-  
20 graph (A)(ii) that provides opportunities for  
21 residents or fellows to train in community-based  
22 settings that integrate primary care with men-  
23 tal and substance use disorders prevention and  
24 treatment services.

1           “(2) TRAINING FOR OTHER PROVIDERS.—To be  
2 eligible to receive a grant under subsection (a)(2),  
3 an entity shall be—

4           “(A) a teaching health center (as defined  
5 in section 749A(f));

6           “(B) a Federally qualified health center  
7 (as defined in section 1905(l)(2)(B) of the So-  
8 cial Security Act);

9           “(C) a community mental health center (as  
10 defined in section 1861(ff)(3)(B) of the Social  
11 Security Act);

12           “(D) a rural health clinic (as defined in  
13 section 1861(aa) of the Social Security Act);

14           “(E) a health center operated by the In-  
15 dian Health Service, an Indian tribe, a tribal  
16 organization, or an urban Indian organization  
17 (as defined in section 4 of the Indian Health  
18 Care Improvement Act); or

19           “(F) an entity with a demonstrated record  
20 of success in providing training for nurse prac-  
21 titioners, physician assistants, health service  
22 psychologists, and social workers.

23           “(3) ACADEMIC UNITS OR PROGRAMS.—To be  
24 eligible to receive a grant under subsection (a)(3),  
25 an entity shall be a school of medicine or osteopathic

1 medicine, a nursing school, a physician assistant  
2 training program, a school of pharmacy, a school of  
3 social work, an accredited public or nonprofit private  
4 hospital, an accredited medical residency program,  
5 or a public or private nonprofit entity which the Sec-  
6 retary has determined is capable of carrying out  
7 such grant.

8 “(d) PRIORITY.—

9 “(1) IN GENERAL.—In awarding grants under  
10 subsection (a)(1) or (a)(2), the Secretary shall give  
11 priority to eligible entities that—

12 “(A) demonstrate sufficient size, scope,  
13 and capacity to undertake the requisite training  
14 of an appropriate number of psychiatric resi-  
15 dents, fellows, nurse practitioners, physician as-  
16 sistants, or social workers in addiction medicine  
17 per year to meet the needs of the area served;

18 “(B) demonstrate experience in training  
19 providers to practice team-based care that inte-  
20 grates mental and substance use disorder pre-  
21 vention and treatment services with primary  
22 care in community-based settings;

23 “(C) demonstrate experience in using  
24 health information technology and, as appro-  
25 priate, telehealth to support—

1                   “(i) the delivery of mental and sub-  
2                   stance use disorders services at the eligible  
3                   entities described in subsections (c)(1) and  
4                   (c)(2); and

5                   “(ii) community health centers in in-  
6                   tegrating primary care and mental and  
7                   substance use disorders treatment; or

8                   “(D) have the capacity to expand access to  
9                   mental and substance use disorders services in  
10                  areas with demonstrated need, as determined by  
11                  the Secretary, such as tribal, rural, or other un-  
12                  derserved communities.

13                  “(2) ACADEMIC UNITS OR PROGRAMS.—In  
14                  awarding grants under subsection (a)(3), the Sec-  
15                  retary shall give priority to eligible entities that—

16                  “(A) have a record of training the greatest  
17                  percentage of mental and substance use dis-  
18                  orders providers who enter and remain in these  
19                  fields or who enter and remain in settings with  
20                  integrated primary care and mental and sub-  
21                  stance use disorder prevention and treatment  
22                  services;

23                  “(B) have a record of training individuals  
24                  who are from underrepresented minority

1 groups, including native populations, or from a  
2 rural or disadvantaged background;

3 “(C) provide training in the care of vulner-  
4 able populations such as infants, children, ado-  
5 lescents, pregnant and postpartum women,  
6 older adults, homeless individuals, victims of  
7 abuse or trauma, individuals with disabilities,  
8 and other groups as defined by the Secretary;

9 “(D) teach trainees the skills to provide  
10 interprofessional, integrated care through col-  
11 laboration among health professionals; or

12 “(E) provide training in cultural com-  
13 petency and health literacy.

14 “(e) DURATION.—Grants awarded under this section  
15 shall be for a minimum of 5 years.

16 “(f) STUDY AND REPORT.—

17 “(1) STUDY.—

18 “(A) IN GENERAL.—The Secretary, acting  
19 through the Administrator of the Health Re-  
20 sources and Services Administration, shall con-  
21 duct a study on the results of the demonstra-  
22 tion program under this section.

23 “(B) DATA SUBMISSION.—Not later than  
24 90 days after the completion of the first year  
25 of the training program and each subsequent

1 year that the program is in effect, each recipi-  
2 ent of a grant under subsection (a) shall submit  
3 to the Secretary such data as the Secretary  
4 may require for analysis for the report de-  
5 scribed in paragraph (2).

6 “(2) REPORT TO CONGRESS.—Not later than 1  
7 year after receipt of the data described in paragraph  
8 (1)(B), the Secretary shall submit to Congress a re-  
9 port that includes—

10 “(A) an analysis of the effect of the dem-  
11 onstration program under this section on the  
12 quality, quantity, and distribution of mental  
13 and substance use disorders services;

14 “(B) an analysis of the effect of the dem-  
15 onstration program on the prevalence of un-  
16 treated mental and substance use disorders in  
17 the surrounding communities of health centers  
18 participating in the demonstration; and

19 “(C) recommendations on whether the  
20 demonstration program should be expanded.

21 “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
22 are authorized to be appropriated to carry out this section  
23 \$10,000,000 for each of fiscal years 2018 through 2022.”.

1 **SEC. 9023. CLARIFICATION ON CURRENT ELIGIBILITY FOR**  
2 **LOAN REPAYMENT PROGRAMS.**

3 The Administrator of the Health Resources and Serv-  
4 ices Administration shall clarify the eligibility pursuant to  
5 section 338B(b)(1)(B) of the Public Health Service Act  
6 (42 U.S.C. 254l–1(b)(1)(B)) of child and adolescent psy-  
7 chiatrists for the National Health Service Corps Loan Re-  
8 payment Program under subpart III of part D of title III  
9 of such Act (42 U.S.C. 254l et seq.).

10 **SEC. 9024. MINORITY FELLOWSHIP PROGRAM.**

11 Title V of the Public Health Service Act (42 U.S.C.  
12 290aa et seq.) is amended by adding at the end the fol-  
13 lowing:

14 **“PART K—MINORITY FELLOWSHIP PROGRAM**  
15 **“SEC. 597. FELLOWSHIPS.**

16 “(a) IN GENERAL.—The Secretary shall maintain a  
17 program, to be known as the Minority Fellowship Pro-  
18 gram, under which the Secretary shall award fellowships,  
19 which may include stipends, for the purposes of—

20 “(1) increasing the knowledge of mental and  
21 substance use disorders practitioners on issues re-  
22 lated to prevention, treatment, and recovery support  
23 for individuals who are from racial and ethnic mi-  
24 nority populations and who have a mental or sub-  
25 stance use disorder;

1           “(2) improving the quality of mental and sub-  
2           stance use disorder prevention and treatment serv-  
3           ices delivered to racial and ethnic minority popu-  
4           lations; and

5           “(3) increasing the number of culturally com-  
6           petent mental and substance use disorders profes-  
7           sionals who teach, administer services, conduct re-  
8           search, and provide direct mental or substance use  
9           disorder services to racial and ethnic minority popu-  
10          lations.

11          “(b) TRAINING COVERED.—The fellowships awarded  
12          under subsection (a) shall be for postbaccalaureate train-  
13          ing (including for master’s and doctoral degrees) for men-  
14          tal and substance use disorder treatment professionals, in-  
15          cluding in the fields of psychiatry, nursing, social work,  
16          psychology, marriage and family therapy, mental health  
17          counseling, and substance use disorder and addiction  
18          counseling.

19          “(c) AUTHORIZATION OF APPROPRIATIONS.—To  
20          carry out this section, there are authorized to be appro-  
21          priated \$12,669,000 for each of fiscal years 2018 through  
22          2022.”.



1 **SEC. 9025. LIABILITY PROTECTIONS FOR HEALTH PROFES-**  
2 **SIONAL VOLUNTEERS AT COMMUNITY**  
3 **HEALTH CENTERS.**

4 Section 224 of the Public Health Service Act (42  
5 U.S.C. 233) is amended by adding at the end the fol-  
6 lowing:

7 “(q)(1) For purposes of this section, a health profes-  
8 sional volunteer at a deemed entity described in subsection  
9 (g)(4) shall, in providing a health professional service eli-  
10 gible for funding under section 330 to an individual, be  
11 deemed to be an employee of the Public Health Service  
12 for a calendar year that begins during a fiscal year for  
13 which a transfer was made under paragraph (4)(C). The  
14 preceding sentence is subject to the provisions of this sub-  
15 section.

16 “(2) In providing a health service to an individual,  
17 a health care practitioner shall for purposes of this sub-  
18 section be considered to be a health professional volunteer  
19 at an entity described in subsection (g)(4) if the following  
20 conditions are met:

21 “(A) The service is provided to the individual at  
22 the facilities of an entity described in subsection  
23 (g)(4), or through offsite programs or events carried  
24 out by the entity.

25 “(B) The entity is sponsoring the health care  
26 practitioner pursuant to paragraph (3)(B).

1           “(C) The health care practitioner does not re-  
2           ceive any compensation for the service from the indi-  
3           vidual, the entity described in subsection (g)(4), or  
4           any third-party payer (including reimbursement  
5           under any insurance policy or health plan, or under  
6           any Federal or State health benefits program), ex-  
7           cept that the health care practitioner may receive re-  
8           payment from the entity described in subsection  
9           (g)(4) for reasonable expenses incurred by the health  
10          care practitioner in the provision of the service to  
11          the individual, which may include travel expenses to  
12          or from the site of services.

13           “(D) Before the service is provided, the health  
14          care practitioner or the entity described in sub-  
15          section (g)(4) posts a clear and conspicuous notice  
16          at the site where the service is provided of the extent  
17          to which the legal liability of the health care practi-  
18          tioner is limited pursuant to this subsection.

19           “(E) At the time the service is provided, the  
20          health care practitioner is licensed or certified in ac-  
21          cordance with applicable Federal and State laws re-  
22          garding the provision of the service.

23           “(F) At the time the service is provided, the en-  
24          tity described in subsection (g)(4) maintains relevant

1 documentation certifying that the health care practi-  
2 tioner meets the requirements of this subsection.

3 “(3) Subsection (g) (other than paragraphs (3) and  
4 (5)) and subsections (h), (i), and (l) apply to a health care  
5 practitioner for purposes of this subsection to the same  
6 extent and in the same manner as such subsections apply  
7 to an officer, governing board member, employee, or con-  
8 tractor of an entity described in subsection (g)(4), subject  
9 to paragraph (4), and subject to the following:

10 “(A) The first sentence of paragraph (1) ap-  
11 plies in lieu of the first sentence of subsection  
12 (g)(1)(A).

13 “(B) With respect to an entity described in sub-  
14 section (g)(4), a health care practitioner is not a  
15 health professional volunteer at such entity unless  
16 the entity sponsors the health care practitioner. For  
17 purposes of this subsection, the entity shall be con-  
18 sidered to be sponsoring the health care practitioner  
19 if—

20 “(i) with respect to the health care practi-  
21 tioner, the entity submits to the Secretary an  
22 application meeting the requirements of sub-  
23 section (g)(1)(D); and

24 “(ii) the Secretary, pursuant to subsection  
25 (g)(1)(E), determines that the health care prac-

1           titioner is deemed to be an employee of the  
2           Public Health Service.

3           “(C) In the case of a health care practitioner  
4           who is determined by the Secretary pursuant to sub-  
5           section (g)(1)(E) to be a health professional volun-  
6           teer at such entity, this subsection applies to the  
7           health care practitioner (with respect to services per-  
8           formed on behalf of the entity sponsoring the health  
9           care practitioner pursuant to subparagraph (B)) for  
10          any cause of action arising from an act or omission  
11          of the health care practitioner occurring on or after  
12          the date on which the Secretary makes such deter-  
13          mination.

14          “(D) Subsection (g)(1)(F) applies to a health  
15          care practitioner for purposes of this subsection only  
16          to the extent that, in providing health services to an  
17          individual, each of the conditions specified in para-  
18          graph (2) is met.

19          “(4)(A) Amounts in the fund established under sub-  
20          section (k)(2) shall be available for transfer under sub-  
21          paragraph (C) for purposes of carrying out this sub-  
22          section.

23          “(B)(i) Not later than May 1 of each fiscal year, the  
24          Attorney General, in consultation with the Secretary, shall  
25          submit to the Congress a report providing an estimate of

1 the amount of claims (together with related fees and ex-  
2 penses of witnesses) that, by reason of the acts or omis-  
3 sions of health professional volunteers, will be paid pursu-  
4 ant to this section during the calendar year that begins  
5 in the following fiscal year.

6 “(ii) Subsection (k)(1)(B) applies to the estimate  
7 under clause (i) regarding health professional volunteers  
8 to the same extent and in the same manner as such sub-  
9 section applies to the estimate under such subsection re-  
10 garding officers, governing board members, employees,  
11 and contractors of entities described in subsection (g)(4).

12 “(iii) The report shall include a summary of the data  
13 relied upon for the estimate in clause (i), including the  
14 number of claims filed and paid from the previous cal-  
15 endar year.

16 “(C) Not later than December 31 of each fiscal year,  
17 the Secretary shall transfer from the fund under sub-  
18 section (k)(2) to the appropriate accounts in the Treasury  
19 an amount equal to the estimate made under subpara-  
20 graph (B) for the calendar year beginning in such fiscal  
21 year, subject to the extent of amounts in the fund.

22 “(5)(A) This subsection shall take effect on October  
23 1, 2017, except as provided in subparagraph (B) and  
24 paragraph (6).

1 “(B) Effective on the date of the enactment of this  
2 subsection—

3 “(i) the Secretary may issue regulations for car-  
4 rying out this subsection, and the Secretary may ac-  
5 cept and consider applications submitted pursuant to  
6 paragraph (3)(B); and

7 “(ii) reports under paragraph (4)(B) may be  
8 submitted to Congress.

9 “(6) Beginning on October 1, 2022, this subsection  
10 shall cease to have any force or effect.”.

11 **SEC. 9026. REPORTS.**

12 (a) WORKFORCE DEVELOPMENT REPORT.—

13 (1) IN GENERAL.—Not later than 2 years after  
14 the date of enactment of this Act, the Administrator  
15 of the Health Resources and Services Administra-  
16 tion, in consultation with the Assistant Secretary for  
17 Mental Health and Substance Use, shall conduct a  
18 study and publicly post on the appropriate Internet  
19 website of the Department of Health and Human  
20 Services a report on the adult and pediatric mental  
21 health and substance use disorder workforce in order  
22 to inform Federal, State, and local efforts related to  
23 workforce enhancement.

24 (2) CONTENTS.—The report under this sub-  
25 section shall contain—

1 (A) national and State-level projections of  
2 the supply and demand of the mental health  
3 and substance use disorder health workforce,  
4 disaggregated by profession;

5 (B) an assessment of the mental health  
6 and substance use disorder workforce capacity,  
7 strengths, and weaknesses as of the date of the  
8 report, including the extent to which primary  
9 care providers are preventing, screening, or re-  
10 ferring for mental and substance use disorder  
11 services;

12 (C) information on trends within the men-  
13 tal health and substance use disorder provider  
14 workforce, including the number of individuals  
15 expected to enter the mental health workforce  
16 over the next 5 years; and

17 (D) any additional information determined  
18 by the Administrator of the Health Resources  
19 and Services Administration, in consultation  
20 with the Assistant Secretary for Mental Health  
21 and Substance Use, to be relevant to the mental  
22 health and substance use disorder provider  
23 workforce.

24 (b) PEER-SUPPORT SPECIALIST PROGRAMS.—

1           (1) IN GENERAL.—The Comptroller General of  
2           the United States shall conduct a study on peer-sup-  
3           port specialist programs in up to 10 States that re-  
4           ceive funding from the Substance Abuse and Mental  
5           Health Services Administration.

6           (2) CONTENTS OF STUDY.—In conducting the  
7           study under paragraph (1), the Comptroller General  
8           of the United States shall examine and identify best  
9           practices, in the States selected pursuant to such  
10          paragraph, related to training and credential re-  
11          quirements for peer-support specialist programs,  
12          such as—

13                 (A) hours of formal work or volunteer ex-  
14                 perience related to mental and substance use  
15                 disorders conducted through such programs;

16                 (B) types of peer-support specialist exams  
17                 required for such programs in the selected  
18                 States;

19                 (C) codes of ethics used by such programs  
20                 in the selected States;

21                 (D) required or recommended skill sets for  
22                 such programs in the selected States; and

23                 (E) requirements for continuing education.

24          (3) REPORT.—Not later than 2 years after the  
25          date of enactment of this Act, the Comptroller Gen-



1           eral of the United States shall submit to the Com-  
2           mittee on Health, Education, Labor, and Pensions  
3           of the Senate and the Committee on Energy and  
4           Commerce of the House of Representatives a report  
5           on the study conducted under paragraph (1).

6           **Subtitle C—Mental Health on**  
7           **Campus Improvement**

8           **SEC. 9031. MENTAL HEALTH AND SUBSTANCE USE DIS-**  
9           **ORDER SERVICES ON CAMPUS.**

10          Section 520E–2 of the Public Health Service Act (42  
11          U.S.C. 290bb–36b) is amended—

12                   (1) in the section heading, by striking “**AND**  
13                   **BEHAVIORAL HEALTH**” and inserting “**HEALTH**  
14                   **AND SUBSTANCE USE DISORDER**”;

15                   (2) in subsection (a)—

16                           (A) by striking “Services,” and inserting  
17                           “Services and”;

18                           (B) by striking “and behavioral health  
19                           problems” and inserting “health or substance  
20                           use disorders”;

21                           (C) by striking “substance abuse” and in-  
22                           serting “substance use disorders”; and

23                           (D) by adding after, “suicide attempts,”  
24                           the following: “prevent mental and substance  
25                           use disorders, reduce stigma, and improve the

1 identification and treatment for students at  
2 risk,”;

3 (3) in subsection (b)—

4 (A) in the matter preceding paragraph (1),  
5 by striking “for—” and inserting “for one or  
6 more of the following:”; and

7 (B) by striking paragraphs (1) through (6)  
8 and inserting the following:

9 “(1) Educating students, families, faculty, and  
10 staff to increase awareness of mental and substance  
11 use disorders.

12 “(2) The operation of hotlines.

13 “(3) Preparing informational material.

14 “(4) Providing outreach services to notify stu-  
15 dents about available mental and substance use dis-  
16 order services.

17 “(5) Administering voluntary mental and sub-  
18 stance use disorder screenings and assessments.

19 “(6) Supporting the training of students, fac-  
20 ulty, and staff to respond effectively to students with  
21 mental and substance use disorders.

22 “(7) Creating a network infrastructure to link  
23 institutions of higher education with health care pro-  
24 viders who treat mental and substance use disorders.

1           “(8) Providing mental and substance use dis-  
2           orders prevention and treatment services to stu-  
3           dents, which may include early intervention, treat-  
4           ment, and management, including through the use  
5           of telehealth services.

6           “(9) Conducting research through a counseling  
7           or health center at the institution of higher edu-  
8           cation involved regarding improving the behavioral  
9           health of students through clinical services, out-  
10          reach, prevention, or academic success, in a manner  
11          that is in compliance with all applicable personal pri-  
12          vacy laws.

13          “(10) Supporting student groups on campus,  
14          including athletic teams, that engage in activities to  
15          educate students, including activities to reduce stig-  
16          ma surrounding mental and behavioral disorders,  
17          and promote mental health.

18          “(11) Employing appropriately trained staff.

19          “(12) Developing and supporting evidence-  
20          based and emerging best practices, including a focus  
21          on culturally and linguistically appropriate best  
22          practices.”;

23                 (4) in subsection (c)(5), by striking “substance  
24                 abuse” and inserting “substance use disorder”;

25                 (5) in subsection (d)—

1 (A) in the matter preceding paragraph (1),  
2 by striking “An institution of higher education  
3 desiring a grant under this section” and insert-  
4 ing “To be eligible to receive a grant under this  
5 section, an institution of higher education”;

6 (B) by striking paragraph (1) and insert-  
7 ing—

8 “(1) A description of the population to be tar-  
9 geted by the program carried out under the grant,  
10 including veterans whenever possible and appro-  
11 priate, and of identified mental and substance use  
12 disorder needs of students at the institution of high-  
13 er education.”;

14 (C) in paragraph (2), by inserting “, which  
15 may include, as appropriate and in accordance  
16 with subsection (b)(7), a plan to seek input  
17 from relevant stakeholders in the community,  
18 including appropriate public and private enti-  
19 ties, in order to carry out the program under  
20 the grant” before the period at the end; and

21 (D) by adding after paragraph (5) the fol-  
22 lowing new paragraphs:

23 “(6) An outline of the objectives of the program  
24 carried out under the grant.

1           “(7) For an institution of higher education pro-  
2           posing to use the grant for an activity described in  
3           paragraph (8) or (9) of subsection (b), a description  
4           of the policies and procedures of the institution of  
5           higher education that are related to applicable laws  
6           regarding access to, and sharing of, treatment  
7           records of students at any campus-based mental  
8           health center or partner organization, including the  
9           policies and State laws governing when such records  
10          can be accessed and shared for non-treatment pur-  
11          poses and a description of the process used by the  
12          institution of higher education to notify students of  
13          these policies and procedures, including the extent to  
14          which written consent is required.

15          “(8) An assurance that grant funds will be used  
16          to supplement and not supplant any other Federal,  
17          State, or local funds available to carry out activities  
18          of the type carried out under the grant.”;

19          (6) in subsection (e)(1), by striking “and behav-  
20          ioral health problems” and inserting “health and  
21          substance use disorders”;

22          (7) in subsection (f)(2)—

23                  (A) by striking “and behavioral health”  
24                  and inserting “health and substance use dis-  
25                  order”; and

1 (B) by striking “suicide and substance  
2 abuse” and inserting “suicide and substance  
3 use disorders”;

4 (8) by redesignating subsection (h) as sub-  
5 section (i);

6 (9) by inserting after subsection (g) the fol-  
7 lowing new subsection:

8 “(h) TECHNICAL ASSISTANCE.—The Secretary may  
9 provide technical assistance to grantees in carrying out  
10 this section.”; and

11 (10) in subsection (i), as redesignated by para-  
12 graph (8), by striking “\$5,000,000 for fiscal year  
13 2005” and all that follows through the period at the  
14 end and inserting “\$7,000,000 for each of fiscal  
15 years 2018 through 2022.”.

16 **SEC. 9032. INTERAGENCY WORKING GROUP ON COLLEGE**  
17 **MENTAL HEALTH.**

18 (a) PURPOSE.—It is the purpose of this section to  
19 provide for the establishment of a College Campus Task  
20 Force to discuss mental and behavioral health concerns  
21 on campuses of institutions of higher education.

22 (b) ESTABLISHMENT.—The Secretary of Health and  
23 Human Services (referred to in this section as the “Sec-  
24 retary”) shall establish a College Campus Task Force (re-  
25 ferred to in this section as the “Task Force”) to discuss

1 mental and behavioral health concerns on campuses of in-  
2 stitutions of higher education.

3 (c) MEMBERSHIP.—The Task Force shall be com-  
4 posed of a representative from each Federal agency (as  
5 appointed by the head of the agency) that has jurisdiction  
6 over, or is affected by, mental health and education poli-  
7 cies and projects, including—

8 (1) the Department of Education;

9 (2) the Department of Health and Human  
10 Services;

11 (3) the Department of Veterans Affairs; and

12 (4) such other Federal agencies as the Assist-  
13 ant Secretary for Mental Health and Substance Use,  
14 in consultation with the Secretary, determines to be  
15 appropriate.

16 (d) DUTIES.—The Task Force shall—

17 (1) serve as a centralized mechanism to coordi-  
18 nate a national effort to—

19 (A) discuss and evaluate evidence and  
20 knowledge on mental and behavioral health  
21 services available to, and the prevalence of men-  
22 tal illness among, the age population of stu-  
23 dents attending institutions of higher education  
24 in the United States;

1 (B) determine the range of effective, fea-  
2 sible, and comprehensive actions to improve  
3 mental and behavioral health on campuses of  
4 institutions of higher education;

5 (C) examine and better address the needs  
6 of the age population of students attending in-  
7 stitutions of higher education dealing with men-  
8 tal illness;

9 (D) survey Federal agencies to determine  
10 which policies are effective in encouraging, and  
11 how best to facilitate outreach without dupli-  
12 cating, efforts relating to mental and behavioral  
13 health promotion;

14 (E) establish specific goals within and  
15 across Federal agencies for mental health pro-  
16 motion, including determinations of account-  
17 ability for reaching those goals;

18 (F) develop a strategy for allocating re-  
19 sponsibilities and ensuring participation in men-  
20 tal and behavioral health promotion, particu-  
21 larly in the case of competing agency priorities;

22 (G) coordinate plans to communicate re-  
23 search results relating to mental and behavioral  
24 health amongst the age population of students  
25 attending institutions of higher education to en-



1           able reporting and outreach activities to  
2           produce more useful and timely information;

3           (H) provide a description of evidence-based  
4           practices, model programs, effective guidelines,  
5           and other strategies for promoting mental and  
6           behavioral health on campuses of institutions of  
7           higher education;

8           (I) make recommendations to improve  
9           Federal efforts relating to mental and behav-  
10          ioral health promotion on campuses of institu-  
11          tions of higher education and to ensure Federal  
12          efforts are consistent with available standards,  
13          evidence, and other programs in existence as of  
14          the date of enactment of this Act;

15          (J) monitor Federal progress in meeting  
16          specific mental and behavioral health promotion  
17          goals as they relate to settings of institutions of  
18          higher education; and

19          (K) examine and disseminate best prac-  
20          tices related to intracampus sharing of treat-  
21          ment records;

22          (2) consult with national organizations with ex-  
23          pertise in mental and behavioral health, especially  
24          those organizations working with the age population

1 of students attending institutions of higher edu-  
2 cation; and

3 (3) consult with and seek input from mental  
4 health professionals working on campuses of institu-  
5 tions of higher education as appropriate.

6 (e) MEETINGS.—

7 (1) IN GENERAL.—The Task Force shall meet  
8 not fewer than three times each year.

9 (2) ANNUAL CONFERENCE.—The Secretary  
10 shall sponsor an annual conference on mental and  
11 behavioral health in settings of institutions of higher  
12 education to enhance coordination, build partner-  
13 ships, and share best practices in mental and behav-  
14 ioral health promotion, data collection, analysis, and  
15 services.

16 (f) DEFINITION.—In this section, the term “institu-  
17 tion of higher education” has the meaning given such term  
18 in section 101 of the Higher Education Act of 1965 (20  
19 U.S.C. 1001).

20 (g) AUTHORIZATION OF APPROPRIATIONS.—To carry  
21 out this section, there are authorized to be appropriated  
22 \$1,000,000 for the period of fiscal years 2018 through  
23 2022.

1 **SEC. 9033. IMPROVING MENTAL HEALTH ON COLLEGE CAM-**  
2 **PUSES.**

3 Part D of title V of the Public Health Service Act  
4 (42 U.S.C. 290dd et seq.) is amended by adding at the  
5 end the following:

6 **“SEC. 549. MENTAL AND BEHAVIORAL HEALTH OUTREACH**  
7 **AND EDUCATION ON COLLEGE CAMPUSES.**

8 “(a) PURPOSE.—It is the purpose of this section to  
9 increase access to, and reduce the stigma associated with,  
10 mental health services to ensure that students at institu-  
11 tions of higher education have the support necessary to  
12 successfully complete their studies.

13 “(b) NATIONAL PUBLIC EDUCATION CAMPAIGN.—  
14 The Secretary, acting through the Assistant Secretary and  
15 in collaboration with the Director of the Centers for Dis-  
16 ease Control and Prevention, shall convene an interagency,  
17 public-private sector working group to plan, establish, and  
18 begin coordinating and evaluating a targeted public edu-  
19 cation campaign that is designed to focus on mental and  
20 behavioral health on the campuses of institutions of higher  
21 education. Such campaign shall be designed to—

22 “(1) improve the general understanding of men-  
23 tal health and mental disorders;

24 “(2) encourage help-seeking behaviors relating  
25 to the promotion of mental health, prevention of  
26 mental disorders, and treatment of such disorders;

1           “(3) make the connection between mental and  
2 behavioral health and academic success; and

3           “(4) assist the general public in identifying the  
4 early warning signs and reducing the stigma of men-  
5 tal illness.

6           “(c) COMPOSITION.—The working group convened  
7 under subsection (b) shall include—

8           “(1) mental health consumers, including stu-  
9 dents and family members;

10           “(2) representatives of institutions of higher  
11 education;

12           “(3) representatives of national mental and be-  
13 havioral health associations and associations of insti-  
14 tutions of higher education;

15           “(4) representatives of health promotion and  
16 prevention organizations at institutions of higher  
17 education;

18           “(5) representatives of mental health providers,  
19 including community mental health centers; and

20           “(6) representatives of private-sector and pub-  
21 lic-sector groups with experience in the development  
22 of effective public health education campaigns.

23           “(d) PLAN.—The working group under subsection (b)  
24 shall develop a plan that—

1           “(1) targets promotional and educational efforts  
2           to the age population of students at institutions of  
3           higher education and individuals who are employed  
4           in settings of institutions of higher education, in-  
5           cluding through the use of roundtables;

6           “(2) develops and proposes the implementation  
7           of research-based public health messages and activi-  
8           ties;

9           “(3) provides support for local efforts to reduce  
10          stigma by using the National Health Information  
11          Center as a primary point of contact for informa-  
12          tion, publications, and service program referrals; and

13          “(4) develops and proposes the implementation  
14          of a social marketing campaign that is targeted at  
15          the population of students attending institutions of  
16          higher education and individuals who are employed  
17          in settings of institutions of higher education.

18          “(e) DEFINITION.—In this section, the term ‘institu-  
19          tion of higher education’ has the meaning given such term  
20          in section 101 of the Higher Education Act of 1965 (20  
21          U.S.C. 1001).

22          “(f) AUTHORIZATION OF APPROPRIATIONS.—To  
23          carry out this section, there are authorized to be appro-  
24          priated \$1,000,000 for the period of fiscal years 2018  
25          through 2022.”.

1 **TITLE X—STRENGTHENING MEN-**  
2 **TAL AND SUBSTANCE USE**  
3 **DISORDER CARE FOR CHIL-**  
4 **DREN AND ADOLESCENTS**

5 **SEC. 10001. PROGRAMS FOR CHILDREN WITH A SERIOUS**  
6 **EMOTIONAL DISTURBANCE.**

7 (a) COMPREHENSIVE COMMUNITY MENTAL HEALTH  
8 SERVICES FOR CHILDREN WITH A SERIOUS EMOTIONAL  
9 DISTURBANCE.—Section 561(a)(1) of the Public Health  
10 Service Act (42 U.S.C. 290ff(a)(1)) is amended by insert-  
11 ing “, which may include efforts to identify and serve chil-  
12 dren at risk” before the period.

13 (b) REQUIREMENTS WITH RESPECT TO CARRYING  
14 OUT PURPOSE OF GRANTS.—Section 562(b) of the Public  
15 Health Service Act (42 U.S.C. 290ff–1(b)) is amended by  
16 striking “will not provide an individual with access to the  
17 system if the individual is more than 21 years of age”  
18 and inserting “will provide an individual with access to  
19 the system through the age of 21 years”.

20 (c) ADDITIONAL PROVISIONS.—Section 564(f) of the  
21 Public Health Service Act (42 U.S.C. 290ff–3(f)) is  
22 amended by inserting “(and provide a copy to the State  
23 involved)” after “to the Secretary”.

24 (d) GENERAL PROVISIONS.—Section 565 of the Pub-  
25 lic Health Service Act (42 U.S.C. 290ff–4) is amended—

1 (1) in subsection (b)(1)—

2 (A) in the matter preceding subparagraph  
3 (A), by striking “receiving a grant under sec-  
4 tion 561(a)” and inserting “, regardless of  
5 whether such public entity is receiving a grant  
6 under section 561(a)”; and

7 (B) in subparagraph (B), by striking “pur-  
8 suant to” and inserting “described in”;

9 (2) in subsection (d)(1), by striking “not more  
10 than 21 years of age” and inserting “through the  
11 age of 21 years”; and

12 (3) in subsection (f)(1), by striking  
13 “\$100,000,000 for fiscal year 2001, and such sums  
14 as may be necessary for each of the fiscal years  
15 2002 and 2003” and inserting “\$119,026,000 for  
16 each of fiscal years 2018 through 2022”.

17 **SEC. 10002. INCREASING ACCESS TO PEDIATRIC MENTAL**  
18 **HEALTH CARE.**

19 Title III of the Public Health Service Act is amended  
20 by inserting after section 330L of such Act (42 U.S.C.  
21 254c–18) the following new section:

22 **“SEC. 330M PEDIATRIC MENTAL HEALTH CARE ACCESS**  
23 **GRANTS.**

24 “(a) IN GENERAL.—The Secretary, acting through  
25 the Administrator of the Health Resources and Services

1 Administration and in coordination with other relevant  
2 Federal agencies, shall award grants to States, political  
3 subdivisions of States, and Indian tribes and tribal organi-  
4 zations (for purposes of this section, as such terms are  
5 defined in section 4 of the Indian Self-Determination and  
6 Education Assistance Act (25 U.S.C. 450b)) to promote  
7 behavioral health integration in pediatric primary care  
8 by—

9           “(1) supporting the development of statewide or  
10 regional pediatric mental health care telehealth ac-  
11 cess programs; and

12           “(2) supporting the improvement of existing  
13 statewide or regional pediatric mental health care  
14 telehealth access programs.

15           “(b) PROGRAM REQUIREMENTS.—

16           “(1) IN GENERAL.—A pediatric mental health  
17 care telehealth access program referred to in sub-  
18 section (a), with respect to which a grant under such  
19 subsection may be used, shall—

20           “(A) be a statewide or regional network of  
21 pediatric mental health teams that provide sup-  
22 port to pediatric primary care sites as an inte-  
23 grated team;

24           “(B) support and further develop orga-  
25 nized State or regional networks of pediatric



1           mental health teams to provide consultative  
2           support to pediatric primary care sites;

3           “(C) conduct an assessment of critical be-  
4           havioral consultation needs among pediatric  
5           providers and such providers’ preferred mecha-  
6           nisms for receiving consultation, training, and  
7           technical assistance;

8           “(D) develop an online database and com-  
9           munication mechanisms, including telehealth, to  
10          facilitate consultation support to pediatric prac-  
11          tices;

12          “(E) provide rapid statewide or regional  
13          clinical telephone or telehealth consultations  
14          when requested between the pediatric mental  
15          health teams and pediatric primary care pro-  
16          viders;

17          “(F) conduct training and provide tech-  
18          nical assistance to pediatric primary care pro-  
19          viders to support the early identification, diag-  
20          nosis, treatment, and referral of children with  
21          behavioral health conditions;

22          “(G) provide information to pediatric pro-  
23          viders about, and assist pediatric providers in  
24          accessing, pediatric mental health care pro-  
25          viders, including child and adolescent psychia-

1 trists, and licensed mental health professionals,  
2 such as psychologists, social workers, or mental  
3 health counselors and in scheduling and con-  
4 ducting technical assistance;

5 “(H) assist with referrals to specialty care  
6 and community or behavioral health resources;  
7 and

8 “(I) establish mechanisms for measuring  
9 and monitoring increased access to pediatric  
10 mental health care services by pediatric primary  
11 care providers and expanded capacity of pedi-  
12 atric primary care providers to identify, treat,  
13 and refer children with mental health problems.

14 “(2) PEDIATRIC MENTAL HEALTH TEAMS.—In  
15 this subsection, the term ‘pediatric mental health  
16 team’ means a team consisting of at least one case  
17 coordinator, at least one child and adolescent psy-  
18 chiatrist, and at least one licensed clinical mental  
19 health professional, such as a psychologist, social  
20 worker, or mental health counselor. Such a team  
21 may be regionally based.

22 “(c) APPLICATION.—A State, political subdivision of  
23 a State, Indian tribe, or tribal organization seeking a  
24 grant under this section shall submit an application to the  
25 Secretary at such time, in such manner, and containing

1 such information as the Secretary may require, including  
2 a plan for the comprehensive evaluation of activities that  
3 are carried out with funds received under such grant.

4       “(d) EVALUATION.—A State, political subdivision of  
5 a State, Indian tribe, or tribal organization that receives  
6 a grant under this section shall prepare and submit an  
7 evaluation of activities that are carried out with funds re-  
8 ceived under such grant to the Secretary at such time,  
9 in such manner, and containing such information as the  
10 Secretary may reasonably require, including a process and  
11 outcome evaluation.

12       “(e) ACCESS TO BROADBAND.—In administering  
13 grants under this section, the Secretary may coordinate  
14 with other agencies to ensure that funding opportunities  
15 are available to support access to reliable, high-speed  
16 Internet for providers.

17       “(f) MATCHING REQUIREMENT.—The Secretary may  
18 not award a grant under this section unless the State, po-  
19 litical subdivision of a State, Indian tribe, or tribal organi-  
20 zation involved agrees, with respect to the costs to be in-  
21 curred by the State, political subdivision of a State, Indian  
22 tribe, or tribal organization in carrying out the purpose  
23 described in this section, to make available non-Federal  
24 contributions (in cash or in kind) toward such costs in

1 an amount that is not less than 20 percent of Federal  
2 funds provided in the grant.

3 “(g) AUTHORIZATION OF APPROPRIATIONS.—To  
4 carry out this section, there are authorized to be appro-  
5 priated, \$9,000,000 for the period of fiscal years 2018  
6 through 2022.”.

7 **SEC. 10003. SUBSTANCE USE DISORDER TREATMENT AND**  
8 **EARLY INTERVENTION SERVICES FOR CHIL-**  
9 **DREN AND ADOLESCENTS.**

10 The first section 514 of the Public Health Service  
11 Act (42 U.S.C. 290bb-7), relating to substance abuse  
12 treatment services for children and adolescents, is amend-  
13 ed—

14 (1) in the section heading, by striking “**ABUSE**  
15 **TREATMENT**” and inserting “**USE DISORDER**  
16 **TREATMENT AND EARLY INTERVENTION**”;

17 (2) by striking subsection (a) and inserting the  
18 following:

19 “(a) IN GENERAL.—The Secretary shall award  
20 grants, contracts, or cooperative agreements to public and  
21 private nonprofit entities, including Indian tribes or tribal  
22 organizations (as such terms are defined in section 4 of  
23 the Indian Self-Determination and Education Assistance  
24 Act), or health facilities or programs operated by or in

1 accordance with a contract or grant with the Indian  
2 Health Service, for the purpose of—

3 “(1) providing early identification and services  
4 to meet the needs of children and adolescents who  
5 are at risk of substance use disorders;

6 “(2) providing substance use disorder treatment  
7 services for children, including children and adoles-  
8 cents with co-occurring mental illness and substance  
9 use disorders; and

10 “(3) providing assistance to pregnant women,  
11 and parenting women, with substance use disorders,  
12 in obtaining treatment services, linking mothers to  
13 community resources to support independent family  
14 lives, and staying in recovery so that children are in  
15 safe, stable home environments and receive appro-  
16 priate health care services.”;

17 (3) in subsection (b)—

18 (A) by striking paragraph (1) and insert-  
19 ing the following:

20 “(1) apply evidence-based and cost-effective  
21 methods;”;

22 (B) in paragraph (2)—

23 (i) by striking “treatment”; and

24 (ii) by inserting “substance abuse,”  
25 after “child welfare,”;

1 (C) in paragraph (3), by striking “sub-  
2 stance abuse disorders” and inserting “sub-  
3 stance use disorders, including children and  
4 adolescents with co-occurring mental illness and  
5 substance use disorders,”;

6 (D) in paragraph (5), by striking “treat-  
7 ment;” and inserting “services; and”;

8 (E) in paragraph (6), by striking “sub-  
9 stance abuse treatment; and” and inserting  
10 “treatment.”; and

11 (F) by striking paragraph (7); and

12 (4) in subsection (f), by striking “\$40,000,000”  
13 and all that follows through the period and inserting  
14 “\$29,605,000 for each of fiscal years 2018 through  
15 2022.”.

16 **SEC. 10004. CHILDREN’S RECOVERY FROM TRAUMA.**

17 The first section 582 of the Public Health Service  
18 Act (42 U.S.C. 290hh–1; relating to grants to address the  
19 problems of persons who experience violence related  
20 stress) is amended—

21 (1) in subsection (a), by striking “developing  
22 programs” and all that follows through the period at  
23 the end and inserting the following: “developing and  
24 maintaining programs that provide for—

1           “(1) the continued operation of the National  
2           Child Traumatic Stress Initiative (referred to in this  
3           section as the ‘NCTSI’), which includes a coopera-  
4           tive agreement with a coordinating center, that fo-  
5           cuses on the mental, behavioral, and biological as-  
6           pects of psychological trauma response, prevention  
7           of the long-term consequences of child trauma, and  
8           early intervention services and treatment to address  
9           the long-term consequences of child trauma; and

10           “(2) the development of knowledge with regard  
11           to evidence-based practices for identifying and treat-  
12           ing mental, behavioral, and biological disorders of  
13           children and youth resulting from witnessing or ex-  
14           periencing a traumatic event.”;

15           (2) in subsection (b)—

16           (A) by striking “subsection (a) related”  
17           and inserting “subsection (a)(2) (related”;

18           (B) by striking “treating disorders associ-  
19           ated with psychological trauma” and inserting  
20           “treating mental, behavioral, and biological dis-  
21           orders associated with psychological trauma)”;  
22           and

23           (C) by striking “mental health agencies  
24           and programs that have established clinical and  
25           basic research” and inserting “universities, hos-

1           pitals, mental health agencies, and other pro-  
2           grams that have established clinical expertise  
3           and research”;

4           (3) by redesignating subsections (c) through (g)  
5           as subsections (g) through (k), respectively;

6           (4) by inserting after subsection (b), the fol-  
7           lowing:

8           “(c) CHILD OUTCOME DATA.—The NCTSI coordi-  
9           nating center described in subsection (a)(1) shall collect,  
10          analyze, report, and make publicly available, as appro-  
11          priate, NCTSI-wide child treatment process and outcome  
12          data regarding the early identification and delivery of evi-  
13          dence-based treatment and services for children and fami-  
14          lies served by the NCTSI grantees.

15          “(d) TRAINING.—The NCTSI coordinating center  
16          shall facilitate the coordination of training initiatives in  
17          evidence-based and trauma-informed treatments, interven-  
18          tions, and practices offered to NCTSI grantees, providers,  
19          and partners.

20          “(e) DISSEMINATION AND COLLABORATION.—The  
21          NCTSI coordinating center shall, as appropriate, collabo-  
22          rate with—

23                  “(1) the Secretary, in the dissemination of evi-  
24          dence-based and trauma-informed interventions,



1 treatments, products, and other resources to appro-  
2 priate stakeholders; and

3 “(2) appropriate agencies that conduct or fund  
4 research within the Department of Health and  
5 Human Services, for purposes of sharing NCTSI ex-  
6 pertise, evaluation data, and other activities, as ap-  
7 propriate.

8 “(f) REVIEW.—The Secretary shall, consistent with  
9 the peer-review process, ensure that NCTSI applications  
10 are reviewed by appropriate experts in the field as part  
11 of a consensus-review process. The Secretary shall include  
12 review criteria related to expertise and experience in child  
13 trauma and evidence-based practices.”;

14 (5) in subsection (g) (as so redesignated), by  
15 striking “with respect to centers of excellence are  
16 distributed equitably among the regions of the coun-  
17 try” and inserting “are distributed equitably among  
18 the regions of the United States”;

19 (6) in subsection (i) (as so redesignated), by  
20 striking “recipient may not exceed 5 years” and in-  
21 sserting “recipient shall not be less than 4 years, but  
22 shall not exceed 5 years”; and

23 (7) in subsection (j) (as so redesignated), by  
24 striking “\$50,000,000” and all that follows through

1 “2006” and inserting “\$46,887,000 for each of fis-  
2 cal years 2018 through 2022”.

3 **SEC. 10005. SCREENING AND TREATMENT FOR MATERNAL**  
4 **DEPRESSION.**

5 Part B of title III of the Public Health Service Act  
6 (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
7 tion 317L (42 U.S.C. 247b–13) the following:

8 **“SEC. 317L–1. SCREENING AND TREATMENT FOR MATER-**  
9 **NAL DEPRESSION.**

10 “(a) GRANTS.—The Secretary shall make grants to  
11 States to establish, improve, or maintain programs for  
12 screening, assessment, and treatment services, including  
13 culturally and linguistically appropriate services, as appro-  
14 priate, for women who are pregnant, or who have given  
15 birth within the preceding 12 months, for maternal de-  
16 pression.

17 “(b) APPLICATION.—To seek a grant under this sec-  
18 tion, a State shall submit an application to the Secretary  
19 at such time, in such manner, and containing such infor-  
20 mation as the Secretary may require. At a minimum, any  
21 such application shall include explanations of—

22 “(1) how a program, or programs, will increase  
23 the percentage of women screened and treated, as  
24 appropriate, for maternal depression in 1 or more  
25 communities; and

1           “(2) how a program, or programs, if expanded,  
2           would increase access to screening and treatment  
3           services for maternal depression.

4           “(c) PRIORITY.—In awarding grants under this sec-  
5           tion, the Secretary may give priority to States proposing  
6           to improve or enhance access to screening services for ma-  
7           ternal depression in primary care settings.

8           “(d) USE OF FUNDS.—The activities eligible for  
9           funding through a grant under subsection (a)—

10           “(1) shall include—

11                   “(A) providing appropriate training to  
12                   health care providers; and

13                   “(B) providing information to health care  
14                   providers, including information on maternal  
15                   depression screening, treatment, and followup  
16                   support services, and linkages to community-  
17                   based resources; and

18           “(2) may include—

19                   “(A) enabling health care providers (in-  
20                   cluding obstetrician-gynecologists, pediatricians,  
21                   psychiatrists, mental health care providers, and  
22                   adult primary care clinicians) to provide or re-  
23                   ceive real-time psychiatric consultation (in-per-  
24                   son or remotely) to aid in the treatment of  
25                   pregnant and parenting women;

1           “(B) establishing linkages with and among  
2           community-based resources, including mental  
3           health resources, primary care resources, and  
4           support groups; and

5           “(C) utilizing telehealth services for rural  
6           areas and medically underserved areas (as de-  
7           fined in section 330I(a)).

8           “(e) AUTHORIZATION OF APPROPRIATIONS.—To  
9           carry out this section, there are authorized to be appro-  
10          priated \$5,000,000 for each of fiscal years 2018 through  
11          2022.”.

12 **SEC. 10006. INFANT AND EARLY CHILDHOOD MENTAL**  
13                   **HEALTH PROMOTION, INTERVENTION, AND**  
14                   **TREATMENT.**

15          Part Q of title III of the Public Health Service Act  
16          (42 U.S.C. 280h et seq.) is amended by adding at the end  
17          the following:

18 **“SEC. 399Z-2. INFANT AND EARLY CHILDHOOD MENTAL**  
19                   **HEALTH PROMOTION, INTERVENTION, AND**  
20                   **TREATMENT.**

21          “(a) GRANTS.—The Secretary shall—

22                   “(1) award grants to eligible entities to develop,  
23                   maintain, or enhance infant and early childhood  
24                   mental health promotion, intervention, and treat-  
25                   ment programs, including—

1           “(A) programs for infants and children at  
2           significant risk of developing, showing early  
3           signs of, or having been diagnosed with mental  
4           illness, including a serious emotional disturb-  
5           ance; and

6           “(B) multigenerational therapy and other  
7           services that support the caregiving relation-  
8           ship; and

9           “(2) ensure that programs funded through  
10          grants under this section are evidence-informed or  
11          evidence-based models, practices, and methods that  
12          are, as appropriate, culturally and linguistically ap-  
13          propriate, and can be replicated in other appropriate  
14          settings.

15          “(b) ELIGIBLE CHILDREN AND ENTITIES.—In this  
16          section:

17               “(1) ELIGIBLE CHILD.—The term ‘eligible  
18               child’ means a child from birth to not more than 12  
19               years of age who—

20                       “(A) is at risk for, shows early signs of, or  
21                       has been diagnosed with a mental illness, in-  
22                       cluding a serious emotional disturbance; and

23                       “(B) may benefit from infant and early  
24                       childhood intervention or treatment programs  
25                       or specialized preschool or elementary school

1 programs that are evidence-based or that have  
2 been scientifically demonstrated to show prom-  
3 ise but would benefit from further applied de-  
4 velopment.

5 “(2) ELIGIBLE ENTITY.—The term ‘eligible en-  
6 tity’ means a human services agency or nonprofit in-  
7 stitution that—

8 “(A) employs licensed mental health pro-  
9 fessionals who have specialized training and ex-  
10 perience in infant and early childhood mental  
11 health assessment, diagnosis, and treatment, or  
12 is accredited or approved by the appropriate  
13 State agency, as applicable, to provide for chil-  
14 dren from infancy to 12 years of age mental  
15 health promotion, intervention, or treatment  
16 services; and

17 “(B) provides services or programs de-  
18 scribed in subsection (a) that are evidence-  
19 based or that have been scientifically dem-  
20 onstrated to show promise but would benefit  
21 from further applied development.

22 “(c) APPLICATION.—An eligible entity seeking a  
23 grant under subsection (a) shall submit to the Secretary  
24 an application at such time, in such manner, and con-  
25 taining such information as the Secretary may require.

1           “(d) USE OF FUNDS FOR EARLY INTERVENTION AND  
2 TREATMENT PROGRAMS.—An eligible entity may use  
3 amounts awarded under a grant under subsection (a)(1)  
4 to carry out the following:

5           “(1) Provide age-appropriate mental health pro-  
6 motion and early intervention services or mental ill-  
7 ness treatment services, which may include special-  
8 ized programs, for eligible children at significant  
9 risk of developing, showing early signs of, or having  
10 been diagnosed with a mental illness, including a se-  
11 rious emotional disturbance. Such services may in-  
12 clude social and behavioral services as well as  
13 multigenerational therapy and other services that  
14 support the caregiving relationship.

15           “(2) Provide training for health care profes-  
16 sionals with expertise in infant and early childhood  
17 mental health care with respect to appropriate and  
18 relevant integration with other disciplines such as  
19 primary care clinicians, early intervention specialists,  
20 child welfare staff, home visitors, early care and edu-  
21 cation providers, and others who work with young  
22 children and families.

23           “(3) Provide mental health consultation to per-  
24 sonnel of early care and education programs (includ-  
25 ing licensed or regulated center-based and home-

1 based child care, home visiting, preschool special  
2 education, and early intervention programs) who  
3 work with children and families.

4 “(4) Provide training for mental health clini-  
5 cians in infant and early childhood in promising and  
6 evidence-based practices and models for infant and  
7 early childhood mental health treatment and early  
8 intervention, including with regard to practices for  
9 identifying and treating mental illness and behav-  
10 ioral disorders of infants and children resulting from  
11 exposure or repeated exposure to adverse childhood  
12 experiences or childhood trauma.

13 “(5) Provide age-appropriate assessment, diag-  
14 nostic, and intervention services for eligible children,  
15 including early mental health promotion, interven-  
16 tion, and treatment services.

17 “(e) MATCHING FUNDS.—The Secretary may not  
18 award a grant under this section to an eligible entity un-  
19 less the eligible entity agrees, with respect to the costs to  
20 be incurred by the eligible entity in carrying out the activi-  
21 ties described in subsection (d), to make available non-  
22 Federal contributions (in cash or in kind) toward such  
23 costs in an amount that is not less than 10 percent of  
24 the total amount of Federal funds provided in the grant.



1       “(f) AUTHORIZATION OF APPROPRIATIONS.—To  
2 carry out this section, there are authorized to be appro-  
3 priated \$20,000,000 for the period of fiscal years 2018  
4 through 2022.”.

5       **TITLE XI—COMPASSIONATE**  
6       **COMMUNICATION ON HIPAA**

7       **SEC. 11001. SENSE OF CONGRESS.**

8       (a) FINDINGS.—Congress finds the following:

9           (1) According to the National Survey on Drug  
10       Use and Health, in 2015, there were approximately  
11       9,800,000 adults in the United States with serious  
12       mental illness.

13          (2) The Substance Abuse and Mental Health  
14       Services Administration defines the term “serious  
15       mental illness” as an illness affecting individuals 18  
16       years of age or older as having, at any time in the  
17       past year, a diagnosable mental, behavioral, or emo-  
18       tional disorder that results in serious functional im-  
19       pairment and substantially interferes with or limits  
20       one or more major life activities.

21          (3) In reporting on the incidence of serious  
22       mental illness, the Substance Abuse and Mental  
23       Health Services Administration includes major de-  
24       pression, schizophrenia, bipolar disorder, and other  
25       mental disorders that cause serious impairment.

1           (4) Adults with a serious mental illness are at  
2 a higher risk for chronic physical illnesses and pre-  
3 mature death.

4           (5) According to the World Health Organiza-  
5 tion, adults with a serious mental illness have life-  
6 spans that are 10 to 25 years shorter than those  
7 without serious mental illness. The vast majority of  
8 these deaths are due to chronic physical medical con-  
9 ditions, such as cardiovascular, respiratory, and in-  
10 fectionous diseases, as well as diabetes and hyper-  
11 tension.

12           (6) According to the World Health Organiza-  
13 tion, the majority of deaths of adults with a serious  
14 mental illness that are due to physical medical con-  
15 ditions are preventable.

16           (7) Supported decision making can facilitate  
17 care decisions in areas where serious mental illness  
18 may impact the capacity of an individual to deter-  
19 mine a course of treatment while still allowing the  
20 individual to make decisions independently.

21           (8) Help should be provided to adults with a se-  
22 rious mental illness to address their acute or chronic  
23 physical illnesses, make informed choices about  
24 treatment, and understand and follow through with  
25 appropriate treatment.

1           (9) There is confusion in the health care com-  
2           munity regarding permissible practices under the  
3           regulations promulgated under the Health Insurance  
4           Portability and Accountability Act of 1996 (com-  
5           monly known as “HIPAA”). This confusion may  
6           hinder appropriate communication of health care in-  
7           formation or treatment preferences with appropriate  
8           caregivers.

9           (b) SENSE OF CONGRESS.—It is the sense of Con-  
10          gress that clarification is needed regarding the privacy  
11          rule promulgated under section 264(c) of the Health In-  
12          surance Portability and Accountability Act of 1996 (42  
13          U.S.C. 1320d–2 note) regarding existing permitted uses  
14          and disclosures of health information by health care pro-  
15          fessionals to communicate with caregivers of adults with  
16          a serious mental illness to facilitate treatment.

17          **SEC. 11002. CONFIDENTIALITY OF RECORDS.**

18          Not later than 1 year after the date on which the  
19          Secretary of Health and Human Services (in this title re-  
20          ferred to as the “Secretary”) first finalizes regulations up-  
21          dating part 2 of title 42, Code of Federal Regulations,  
22          relating to confidentiality of alcohol and drug abuse pa-  
23          tient records, after the date of enactment of this Act, the  
24          Secretary shall convene relevant stakeholders to determine

1 the effect of such regulations on patient care, health out-  
2 comes, and patient privacy.

3 **SEC. 11003. CLARIFICATION ON PERMITTED USES AND DIS-**  
4 **CLOSURES OF PROTECTED HEALTH INFOR-**  
5 **MATION.**

6 (a) IN GENERAL.—The Secretary, acting through the  
7 Director of the Office for Civil Rights, shall ensure that  
8 health care providers, professionals, patients and their  
9 families, and others involved in mental or substance use  
10 disorder treatment have adequate, accessible, and easily  
11 comprehensible resources relating to appropriate uses and  
12 disclosures of protected health information under the reg-  
13 ulations promulgated under section 264(c) of the Health  
14 Insurance Portability and Accountability Act of 1996 (42  
15 U.S.C. 1320d–2 note).

16 (b) GUIDANCE.—

17 (1) ISSUANCE.—In carrying out subsection (a),  
18 not later than 1 year after the date of enactment of  
19 this section, the Secretary shall issue guidance clari-  
20 fying the circumstances under which, consistent with  
21 regulations promulgated under section 264(c) of the  
22 Health Insurance Portability and Accountability Act  
23 of 1996, a health care provider or covered entity  
24 may use or disclose protected health information.

1           (2) CIRCUMSTANCES ADDRESSED.—The guid-  
2           ance issued under this section shall address cir-  
3           cumstances including those that—

4                   (A) require the consent of the patient;

5                   (B) require providing the patient with an  
6           opportunity to object;

7                   (C) are based on the exercise of profes-  
8           sional judgment regarding whether the patient  
9           would object when the opportunity to object  
10          cannot practicably be provided because of the  
11          incapacity of the patient or an emergency treat-  
12          ment circumstance; and

13                  (D) are determined, based on the exercise  
14          of professional judgment, to be in the best in-  
15          terest of the patient when the patient is not  
16          present or otherwise incapacitated.

17          (3) COMMUNICATION WITH FAMILY MEMBERS  
18          AND CAREGIVERS.—In addressing the circumstances  
19          described in paragraph (2), the guidance issued  
20          under this section shall clarify permitted uses or dis-  
21          closures of protected health information for purposes  
22          of—

23                   (A) communicating with a family member  
24          of the patient, caregiver of the patient, or other  
25          individual, to the extent that such family mem-

1 ber, caregiver, or individual is involved in the  
2 care of the patient;

3 (B) in the case that the patient is an  
4 adult, communicating with a family member of  
5 the patient, caregiver of the patient, or other  
6 individual involved in the care of the patient;

7 (C) in the case that the patient is a minor,  
8 communicating with the parent or caregiver of  
9 the patient;

10 (D) involving the family members or care-  
11 givers of the patient, or others involved in the  
12 patient's care or care plan, including facilitating  
13 treatment and medication adherence;

14 (E) listening to the patient, or receiving in-  
15 formation with respect to the patient from the  
16 family or caregiver of the patient;

17 (F) communicating with family members  
18 of the patient, caregivers of the patient, law en-  
19 forcement, or others when the patient presents  
20 a serious and imminent threat of harm to self  
21 or others; and

22 (G) communicating to law enforcement and  
23 family members or caregivers of the patient  
24 about the admission of the patient to receive  
25 care at, or the release of a patient from, a facil-

1           ity for an emergency psychiatric hold or invol-  
2           untary treatment.

3 **SEC. 11004. DEVELOPMENT AND DISSEMINATION OF**  
4 **MODEL TRAINING PROGRAMS.**

5           (a) INITIAL PROGRAMS AND MATERIALS.—Not later  
6 than 1 year after the date of the enactment of this Act,  
7 the Secretary, in consultation with appropriate experts,  
8 shall identify the following model programs and materials,  
9 or (in the case that no such programs or materials exist)  
10 recognize private or public entities to develop and dissemi-  
11 nate each of the following:

12           (1) Model programs and materials for training  
13 health care providers (including physicians, emer-  
14 gency medical personnel, psychiatrists, including  
15 child and adolescent psychiatrists, psychologists,  
16 counselors, therapists, nurse practitioners, physician  
17 assistants, behavioral health facilities and clinics,  
18 care managers, and hospitals, including individuals  
19 such as general counsels or regulatory compliance  
20 staff who are responsible for establishing provider  
21 privacy policies) regarding the permitted uses and  
22 disclosures, consistent with the standards governing  
23 the privacy and security of individually identifiable  
24 health information promulgated by the Secretary  
25 under part C of title XI of the Social Security Act

1 (42 U.S.C. 1320d et seq.) and regulations promul-  
2 gated under section 264(c) of the Health Insurance  
3 Portability and Accountability Act of 1996 (42  
4 U.S.C. 1320d–2 note) and such part C, of the pro-  
5 tected health information of patients seeking or un-  
6 dergoing mental or substance use disorder treat-  
7 ment.

8 (2) A model program and materials for training  
9 patients and their families regarding their rights to  
10 protect and obtain information under the standards  
11 and regulations specified in paragraph (1).

12 (b) PERIODIC UPDATES.—The Secretary shall—

13 (1) periodically review and update the model  
14 programs and materials identified or developed  
15 under subsection (a); and

16 (2) disseminate the updated model programs  
17 and materials to the individuals described in sub-  
18 section (a).

19 (c) COORDINATION.—The Secretary shall carry out  
20 this section in coordination with the Director of the Office  
21 for Civil Rights within the Department of Health and  
22 Human Services, the Assistant Secretary for Mental  
23 Health and Substance Use, the Administrator of the  
24 Health Resources and Services Administration, and the



1 heads of other relevant agencies within the Department  
2 of Health and Human Services.

3 (d) INPUT OF CERTAIN ENTITIES.—In identifying,  
4 reviewing, or updating the model programs and materials  
5 under subsections (a) and (b), the Secretary shall solicit  
6 the input of relevant national, State, and local associa-  
7 tions; medical societies; licensing boards; providers of men-  
8 tal and substance use disorder treatment; organizations  
9 with expertise on domestic violence, sexual assault, elder  
10 abuse, and child abuse; and organizations representing pa-  
11 tients and consumers and the families of patients and con-  
12 sumers.

13 (e) FUNDING.—There are authorized to be appro-  
14 priated to carry out this section—

15 (1) \$4,000,000 for fiscal year 2018;

16 (2) \$2,000,000 for each of fiscal years 2019  
17 and 2020; and

18 (3) \$1,000,000 for each of fiscal years 2021  
19 and 2022.

1     **TITLE XII—MEDICAID MENTAL**  
2                   **HEALTH COVERAGE**

3     **SEC. 12001. RULE OF CONSTRUCTION RELATED TO MED-**  
4                   **ICAID COVERAGE OF MENTAL HEALTH SERV-**  
5                   **ICES AND PRIMARY CARE SERVICES FUR-**  
6                   **NISHED ON THE SAME DAY.**

7           Nothing in title XIX of the Social Security Act (42  
8 U.S.C. 1396 et seq.) shall be construed as prohibiting sep-  
9 arate payment under the State plan under such title (or  
10 under a waiver of the plan) for the provision of a mental  
11 health service or primary care service under such plan,  
12 with respect to an individual, because such service is—

13                   (1) a primary care service furnished to the indi-  
14           vidual by a provider at a facility on the same day  
15           a mental health service is furnished to such indi-  
16           vidual by such provider (or another provider) at the  
17           facility; or

18                   (2) a mental health service furnished to the in-  
19           dividual by a provider at a facility on the same day  
20           a primary care service is furnished to such individual  
21           by such provider (or another provider) at the facil-  
22           ity.

1 **SEC. 12002. STUDY AND REPORT RELATED TO MEDICAID**  
2 **MANAGED CARE REGULATION.**

3 (a) STUDY.—The Secretary of Health and Human  
4 Services, acting through the Administrator of the Centers  
5 for Medicare & Medicaid Services, shall conduct a study  
6 on coverage under the Medicaid program under title XIX  
7 of the Social Security Act (42 U.S.C. 1396 et seq.) of serv-  
8 ices provided through a medicaid managed care organiza-  
9 tion (as defined in section 1903(m) of such Act (42 U.S.C.  
10 1396b(m)) or a prepaid inpatient health plan (as defined  
11 in section 438.2 of title 42, Code of Federal Regulations  
12 (or any successor regulation)) with respect to individuals  
13 over the age of 21 and under the age of 65 for the treat-  
14 ment of a mental health disorder in institutions for mental  
15 diseases (as defined in section 1905(i) of such Act (42  
16 U.S.C. 1396d(i))). Such study shall include information  
17 on the following:

18 (1) The extent to which States, including the  
19 District of Columbia and each territory or possession  
20 of the United States, are providing capitated pay-  
21 ments to such organizations or plans for enrollees  
22 who are receiving services in institutions for mental  
23 diseases.

24 (2) The number of individuals receiving medical  
25 assistance under a State plan under such title XIX,  
26 or a waiver of such plan, who receive services in in-



1 & Medicaid Services shall issue a State Medicaid Director  
2 letter regarding opportunities to design innovative service  
3 delivery systems, including systems for providing commu-  
4 nity-based services, for adults with a serious mental illness  
5 or children with a serious emotional disturbance who are  
6 receiving medical assistance under title XIX of the Social  
7 Security Act (42 U.S.C. 1396 et seq.). The letter shall  
8 include opportunities for demonstration projects under  
9 section 1115 of such Act (42 U.S.C. 1315) to improve care  
10 for such adults and children.

11 **SEC. 12004. STUDY AND REPORT ON MEDICAID EMERGENCY**  
12 **PSYCHIATRIC DEMONSTRATION PROJECT.**

13 (a) COLLECTION OF INFORMATION.—The Secretary  
14 of Health and Human Services, acting through the Ad-  
15 ministrator of the Centers for Medicare & Medicaid Serv-  
16 ices, shall, to the extent practical and data is available,  
17 with respect to each State that has participated in the  
18 demonstration project established under section 2707 of  
19 the Patient Protection and Affordable Care Act (42  
20 U.S.C. 1396a note), collect from each such State informa-  
21 tion on the following:

22 (1) The number of institutions for mental dis-  
23 eases (as defined in section 1905(i) of the Social Se-  
24 curity Act (42 U.S.C. 1396d(i))) and beds in such  
25 institutions that received payment for the provision

1 of services to individuals who receive medical assist-  
2 ance under a State plan under the Medicaid pro-  
3 gram under title XIX of the Social Security Act (42  
4 U.S.C. 1396 et seq.) (or under a waiver of such  
5 plan) through the demonstration project in each  
6 such State as compared to the total number of insti-  
7 tutions for mental diseases and beds in the State.

8 (2) The extent to which there is a reduction in  
9 expenditures under the Medicaid program under title  
10 XIX of the Social Security Act (42 U.S.C. 1396 et  
11 seq.) or other spending on the full continuum of  
12 physical or mental health care for individuals who  
13 receive treatment in an institution for mental dis-  
14 eases under the demonstration project, including  
15 outpatient, inpatient, emergency, and ambulatory  
16 care, that is attributable to such individuals receiv-  
17 ing treatment in institutions for mental diseases  
18 under the demonstration project.

19 (3) The number of forensic psychiatric hos-  
20 pitals, the number of beds in such hospitals, and the  
21 number of forensic psychiatric beds in other hos-  
22 pitals in such State, based on the most recent data  
23 available, to the extent practical, as determined by  
24 such Administrator.

1           (4) The amount of any disproportionate share  
2           hospital payments under section 1923 of the Social  
3           Security Act (42 U.S.C. 1396r-4) that institutions  
4           for mental diseases in the State received during the  
5           period beginning on July 1, 2012, and ending on  
6           June 30, 2015, and the extent to which the dem-  
7           onstration project reduced the amount of such pay-  
8           ments.

9           (5) The most recent data regarding all facilities  
10          or sites in the State in which any adults with a seri-  
11          ous mental illness who are receiving medical assist-  
12          ance under a State plan under the Medicaid pro-  
13          gram under title XIX of the Social Security Act (42  
14          U.S.C. 1396 et seq.) (or under a waiver of such  
15          plan) are treated during the period referred to in  
16          paragraph (4), to the extent practical, as determined  
17          by the Administrator, including—

18                 (A) the types of such facilities or sites  
19                 (such as an institution for mental diseases, a  
20                 hospital emergency department, or other inpa-  
21                 tient hospital);

22                 (B) the average length of stay in such a  
23                 facility or site by such an individual,  
24                 disaggregated by facility type; and

1           (C) the payment rate under the State plan  
2           (or a waivers of such plan) for services fur-  
3           nished to such an individual for that treatment,  
4           disaggregated by facility type, during the period  
5           in which the demonstration project is in oper-  
6           ation.

7           (6) The extent to which the utilization of hos-  
8           pital emergency departments during the period in  
9           which the demonstration project was is in operation  
10          differed, with respect to individuals who are receiv-  
11          ing medical assistance under a State plan under the  
12          Medicaid program under title XIX of the Social Se-  
13          curity Act (42 U.S.C. 1396 et seq.) (or under a  
14          waiver of such plan), between—

15                (A) those individuals who received treat-  
16                ment in an institution for mental diseases  
17                under the demonstration project;

18                (B) those individuals who met the eligi-  
19                bility requirements for the demonstration  
20                project but who did not receive treatment in an  
21                institution for mental diseases under the dem-  
22                onstration project; and

23                (C) those adults with a serious mental ill-  
24                ness who did not meet such eligibility require-



1           ments and did not receive treatment for such  
2           illness in an institution for mental diseases.

3           (b) REPORT.—Not later than 2 years after the date  
4 of the enactment of this Act, the Secretary of Health and  
5 Human Services shall submit to Congress a report that  
6 summarizes and analyzes the information collected under  
7 subsection (a). Such report may be submitted as part of  
8 the report required under section 2707(f) of the Patient  
9 Protection and Affordable Care Act (42 U.S.C. 1396a  
10 note) or separately.

11 **SEC. 12005. PROVIDING EPSDT SERVICES TO CHILDREN IN**  
12 **IMDS.**

13           (a) IN GENERAL.—Section 1905(a)(16) of the Social  
14 Security Act (42 U.S.C. 1396d(a)(16)) is amended—

15           (1) by striking “effective January 1, 1973” and  
16           inserting “(A) effective January 1, 1973”; and

17           (2) by inserting before the semicolon at the end  
18           the following: “, and, (B) for individuals receiving  
19           services described in subparagraph (A), early and  
20           periodic screening, diagnostic, and treatment serv-  
21           ices (as defined in subsection (r)), whether or not  
22           such screening, diagnostic, and treatment services  
23           are furnished by the provider of the services de-  
24           scribed in such subparagraph”.

1 (b) EFFECTIVE DATE.—The amendments made by  
2 subsection (a) shall apply with respect to items and serv-  
3 ices furnished in calendar quarters beginning on or after  
4 January 1, 2019.

5 **SEC. 12006. ELECTRONIC VISIT VERIFICATION SYSTEM RE-**  
6 **QUIRED FOR PERSONAL CARE SERVICES AND**  
7 **HOME HEALTH CARE SERVICES UNDER MED-**  
8 **ICAID.**

9 (a) IN GENERAL.—Section 1903 of the Social Secu-  
10 rity Act (42 U.S.C. 1396b) is amended by inserting after  
11 subsection (k) the following new subsection:

12 “(l)(1) Subject to paragraphs (3) and (4), with re-  
13 spect to any amount expended for personal care services  
14 or home health care services requiring an in-home visit  
15 by a provider that are provided under a State plan under  
16 this title (or under a waiver of the plan) and furnished  
17 in a calendar quarter beginning on or after January 1,  
18 2019 (or, in the case of home health care services, on or  
19 after January 1, 2023), unless a State requires the use  
20 of an electronic visit verification system for such services  
21 furnished in such quarter under the plan or such waiver,  
22 the Federal medical assistance percentage shall be re-  
23 duced—

24 “(A) in the case of personal care services—

1           “(i) for calendar quarters in 2019 and  
2           2020, by .25 percentage points;

3           “(ii) for calendar quarters in 2021, by .5  
4           percentage points;

5           “(iii) for calendar quarters in 2022, by .75  
6           percentage points; and

7           “(iv) for calendar quarters in 2023 and  
8           each year thereafter, by 1 percentage point; and

9           “(B) in the case of home health care services—

10           “(i) for calendar quarters in 2023 and  
11           2024, by .25 percentage points;

12           “(ii) for calendar quarters in 2025, by .5  
13           percentage points;

14           “(iii) for calendar quarters in 2026, by .75  
15           percentage points; and

16           “(iv) for calendar quarters in 2027 and  
17           each year thereafter, by 1 percentage point.

18           “(2) Subject to paragraphs (3) and (4), in imple-  
19           menting the requirement for the use of an electronic visit  
20           verification system under paragraph (1), a State shall—

21           “(A) consult with agencies and entities that  
22           provide personal care services, home health care  
23           services, or both under the State plan (or under a  
24           waiver of the plan) to ensure that such system—

25           “(i) is minimally burdensome;

1           “(ii) takes into account existing best prac-  
2           tices and electronic visit verification systems in  
3           use in the State; and

4           “(iii) is conducted in accordance with the  
5           requirements of HIPAA privacy and security  
6           law (as defined in section 3009 of the Public  
7           Health Service Act);

8           “(B) take into account a stakeholder process  
9           that includes input from beneficiaries, family care-  
10          givers, individuals who furnish personal care services  
11          or home health care services, and other stakeholders,  
12          as determined by the State in accordance with guid-  
13          ance from the Secretary; and

14          “(C) ensure that individuals who furnish per-  
15          sonal care services, home health care services, or  
16          both under the State plan (or under a waiver of the  
17          plan) are provided the opportunity for training on  
18          the use of such system.

19          “(3) Paragraphs (1) and (2) shall not apply in the  
20          case of a State that, as of the date of the enactment of  
21          this subsection, requires the use of any system for the elec-  
22          tronic verification of visits conducted as part of both per-  
23          sonal care services and home health care services, so long  
24          as the State continues to require the use of such system  
25          with respect to the electronic verification of such visits.

1           “(4)(A) In the case of a State described in subpara-  
2 graph (B), the reduction under paragraph (1) shall not  
3 apply—

4           “(i) in the case of personal care services, for  
5 calendar quarters in 2019; and

6           “(ii) in the case of home health care services,  
7 for calendar quarters in 2023.

8           “(B) For purposes of subparagraph (A), a State de-  
9 scribed in this subparagraph is a State that demonstrates  
10 to the Secretary that the State—

11           “(i) has made a good faith effort to comply  
12 with the requirements of paragraphs (1) and (2) (in-  
13 cluding by taking steps to adopt the technology used  
14 for an electronic visit verification system); and

15           “(ii) in implementing such a system, has en-  
16 countered unavoidable system delays.

17           “(5) In this subsection:

18           “(A) The term ‘electronic visit verification sys-  
19 tem’ means, with respect to personal care services or  
20 home health care services, a system under which vis-  
21 its conducted as part of such services are electroni-  
22 cally verified with respect to—

23           “(i) the type of service performed;

24           “(ii) the individual receiving the service;

25           “(iii) the date of the service;

1                   “(iv) the location of service delivery;

2                   “(v) the individual providing the service;

3                   and

4                   “(vi) the time the service begins and ends.

5                   “(B) The term ‘home health care services’  
6                   means services described in section 1905(a)(7) pro-  
7                   vided under a State plan under this title (or under  
8                   a waiver of the plan).

9                   “(C) The term ‘personal care services’ means  
10                   personal care services provided under a State plan  
11                   under this title (or under a waiver of the plan), in-  
12                   cluding services provided under section 1905(a)(24),  
13                   1915(e), 1915(i), 1915(j), or 1915(k) or under a  
14                   wavier under section 1115.

15                   “(6)(A) In the case in which a State requires personal  
16                   care service and home health care service providers to uti-  
17                   lize an electronic visit verification system operated by the  
18                   State or a contractor on behalf of the State, the Secretary  
19                   shall pay to the State, for each quarter, an amount equal  
20                   to 90 per centum of so much of the sums expended during  
21                   such quarter as are attributable to the design, develop-  
22                   ment, or installation of such system, and 75 per centum  
23                   of so much of the sums for the operation and maintenance  
24                   of such system.

1           “(B) Subparagraph (A) shall not apply in the case  
2 in which a State requires personal care service and home  
3 health care service providers to utilize an electronic visit  
4 verification system that is not operated by the State or  
5 a contractor on behalf of the State.”.

6           (b) COLLECTION AND DISSEMINATION OF BEST  
7 PRACTICES.—Not later than January 1, 2018, the Sec-  
8 retary of Health and Human Services shall, with respect  
9 to electronic visit verification systems (as defined in sub-  
10 section (l)(5) of section 1903 of the Social Security Act  
11 (42 U.S.C. 1396b), as inserted by subsection (a)), collect  
12 and disseminate best practices to State Medicaid Directors  
13 with respect to—

14           (1) training individuals who furnish personal  
15 care services, home health care services, or both  
16 under the State plan under title XIX of such Act (or  
17 under a waiver of the plan) on such systems and the  
18 operation of such systems and the prevention of  
19 fraud with respect to the provision of personal care  
20 services or home health care services (as defined in  
21 such subsection (l)(5)); and

22           (2) the provision of notice and educational ma-  
23 terials to family caregivers and beneficiaries with re-  
24 spect to the use of such electronic visit verification  
25 systems and other means to prevent such fraud.

1 (c) RULES OF CONSTRUCTION.—

2 (1) NO EMPLOYER-EMPLOYEE RELATIONSHIP  
3 ESTABLISHED.—Nothing in the amendment made by  
4 this section may be construed as establishing an em-  
5 ployer-employee relationship between the agency or  
6 entity that provides for personal care services or  
7 home health care services and the individuals who,  
8 under a contract with such an agency or entity, fur-  
9 nish such services for purposes of part 552 of title  
10 29, Code of Federal Regulations (or any successor  
11 regulations).

12 (2) NO PARTICULAR OR UNIFORM ELECTRONIC  
13 VISIT VERIFICATION SYSTEM REQUIRED.—Nothing  
14 in the amendment made by this section shall be con-  
15 strued to require the use of a particular or uniform  
16 electronic visit verification system (as defined in sub-  
17 section (l)(5) of section 1903 of the Social Security  
18 Act (42 U.S.C. 1396b), as inserted by subsection  
19 (a)) by all agencies or entities that provide personal  
20 care services or home health care under a State plan  
21 under title XIX of the Social Security Act (or under  
22 a waiver of the plan) (42 U.S.C. 1396 et seq.).

23 (3) NO LIMITS ON PROVISION OF CARE.—Noth-  
24 ing in the amendment made by this section may be  
25 construed to limit, with respect to personal care



1 services or home health care services provided under  
2 a State plan under title XIX of the Social Security  
3 Act (or under a waiver of the plan) (42 U.S.C. 1396  
4 et seq.), provider selection, constrain beneficiaries'  
5 selection of a caregiver, or impede the manner in  
6 which care is delivered.

7 (4) NO PROHIBITION ON STATE QUALITY MEAS-  
8 URES REQUIREMENTS.—Nothing in the amendment  
9 made by this section shall be construed as prohib-  
10 iting a State, in implementing an electronic visit  
11 verification system (as defined in subsection (l)(5) of  
12 section 1903 of the Social Security Act (42 U.S.C.  
13 1396b), as inserted by subsection (a)), from estab-  
14 lishing requirements related to quality measures for  
15 such system.

16 **TITLE XIII—MENTAL HEALTH**  
17 **PARITY**

18 **SEC. 13001. ENHANCED COMPLIANCE WITH MENTAL**  
19 **HEALTH AND SUBSTANCE USE DISORDER**  
20 **COVERAGE REQUIREMENTS.**

21 (a) COMPLIANCE PROGRAM GUIDANCE DOCU-  
22 MENT.—Section 2726(a) of the Public Health Service Act  
23 (42 U.S.C. 300gg–26(a)) is amended by adding at the end  
24 the following:

1           “(6) COMPLIANCE PROGRAM GUIDANCE DOCU-  
2           MENT.—

3           “(A) IN GENERAL.—Not later than 12  
4           months after the date of enactment of the  
5           Helping Families in Mental Health Crisis Re-  
6           form Act of 2016, the Secretary, the Secretary  
7           of Labor, and the Secretary of the Treasury, in  
8           consultation with the Inspector General of the  
9           Department of Health and Human Services, the  
10          Inspector General of the Department of Labor,  
11          and the Inspector General of the Department of  
12          the Treasury, shall issue a compliance program  
13          guidance document to help improve compliance  
14          with this section, section 712 of the Employee  
15          Retirement Income Security Act of 1974, and  
16          section 9812 of the Internal Revenue Code of  
17          1986, as applicable. In carrying out this para-  
18          graph, the Secretaries may take into consider-  
19          ation the 2016 publication of the Department  
20          of Health and Human Services and the Depart-  
21          ment of Labor, entitled ‘Warning Signs - Plan  
22          or Policy Non-Quantitative Treatment Limita-  
23          tions (NQTLs) that Require Additional Anal-  
24          ysis to Determine Mental Health Parity Com-  
25          pliance’.

1                   “(B) EXAMPLES ILLUSTRATING COMPLI-  
2 ANCE AND NONCOMPLIANCE.—

3                   “(i) IN GENERAL.—The compliance  
4 program guidance document required  
5 under this paragraph shall provide illus-  
6 trative, de-identified examples (that do not  
7 disclose any protected health information  
8 or individually identifiable information) of  
9 previous findings of compliance and non-  
10 compliance with this section, section 712 of  
11 the Employee Retirement Income Security  
12 Act of 1974, or section 9812 of the Inter-  
13 nal Revenue Code of 1986, as applicable,  
14 based on investigations of violations of  
15 such sections, including—

16                   “(I) examples illustrating re-  
17 quirements for information disclosures  
18 and nonquantitative treatment limita-  
19 tions; and

20                   “(II) descriptions of the viola-  
21 tions uncovered during the course of  
22 such investigations.

23                   “(ii) NONQUANTITATIVE TREATMENT  
24 LIMITATIONS.—To the extent that any ex-  
25 ample described in clause (i) involves a

1 finding of compliance or noncompliance  
2 with regard to any requirement for non-  
3 quantitative treatment limitations, the ex-  
4 ample shall provide sufficient detail to fully  
5 explain such finding, including a full de-  
6 scription of the criteria involved for ap-  
7 proving medical and surgical benefits and  
8 the criteria involved for approving mental  
9 health and substance use disorder benefits.

10 “(iii) ACCESS TO ADDITIONAL INFOR-  
11 MATION REGARDING COMPLIANCE.—In de-  
12 veloping and issuing the compliance pro-  
13 gram guidance document required under  
14 this paragraph, the Secretaries specified in  
15 subparagraph (A)—

16 “(I) shall enter into interagency  
17 agreements with the Inspector Gen-  
18 eral of the Department of Health and  
19 Human Services, the Inspector Gen-  
20 eral of the Department of Labor, and  
21 the Inspector General of the Depart-  
22 ment of the Treasury to share find-  
23 ings of compliance and noncompliance  
24 with this section, section 712 of the  
25 Employee Retirement Income Security

1 Act of 1974, or section 9812 of the  
2 Internal Revenue Code of 1986, as  
3 applicable; and

4 “(II) shall seek to enter into an  
5 agreement with a State to share infor-  
6 mation on findings of compliance and  
7 noncompliance with this section, sec-  
8 tion 712 of the Employee Retirement  
9 Income Security Act of 1974, or sec-  
10 tion 9812 of the Internal Revenue  
11 Code of 1986, as applicable.

12 “(C) RECOMMENDATIONS.—The compli-  
13 ance program guidance document shall include  
14 recommendations to advance compliance with  
15 this section, section 712 of the Employee Re-  
16 tirement Income Security Act of 1974, or sec-  
17 tion 9812 of the Internal Revenue Code of  
18 1986, as applicable, and encourage the develop-  
19 ment and use of internal controls to monitor  
20 adherence to applicable statutes, regulations,  
21 and program requirements. Such internal con-  
22 trols may include illustrative examples of non-  
23 quantitative treatment limitations on mental  
24 health and substance use disorder benefits,  
25 which may fail to comply with this section, sec-

1           tion 712 of the Employee Retirement Income  
2           Security Act of 1974, or section 9812 of the In-  
3           ternal Revenue Code of 1986, as applicable, in  
4           relation to nonquantitative treatment limita-  
5           tions on medical and surgical benefits.

6           “(D) UPDATING THE COMPLIANCE PRO-  
7           GRAM GUIDANCE DOCUMENT.—The Secretary,  
8           the Secretary of Labor, and the Secretary of  
9           the Treasury, in consultation with the Inspector  
10          General of the Department of Health and  
11          Human Services, the Inspector General of the  
12          Department of Labor, and the Inspector Gen-  
13          eral of the Department of the Treasury, shall  
14          update the compliance program guidance docu-  
15          ment every 2 years to include illustrative, de-  
16          identified examples (that do not disclose any  
17          protected health information or individually  
18          identifiable information) of previous findings of  
19          compliance and noncompliance with this sec-  
20          tion, section 712 of the Employee Retirement  
21          Income Security Act of 1974, or section 9812  
22          of the Internal Revenue Code of 1986, as appli-  
23          cable.”.

24          (b) ADDITIONAL GUIDANCE.—Section 2726(a) of the  
25          Public Health Service Act (42 U.S.C. 300gg–26(a)), as

1 amended by subsection (a), is further amended by adding  
2 at the end the following:

3 “(7) ADDITIONAL GUIDANCE.—

4 “(A) IN GENERAL.—Not later than 12  
5 months after the date of enactment of the  
6 Helping Families in Mental Health Crisis Re-  
7 form Act of 2016, the Secretary, the Secretary  
8 of Labor, and the Secretary of the Treasury  
9 shall issue guidance to group health plans and  
10 health insurance issuers offering group or indi-  
11 vidual health insurance coverage to assist such  
12 plans and issuers in satisfying the requirements  
13 of this section, section 712 of the Employee Re-  
14 tirement Income Security Act of 1974, or sec-  
15 tion 9812 of the Internal Revenue Code of  
16 1986, as applicable.

17 “(B) DISCLOSURE.—

18 “(i) GUIDANCE FOR PLANS AND  
19 ISSUERS.—The guidance issued under this  
20 paragraph shall include clarifying informa-  
21 tion and illustrative examples of methods  
22 that group health plans and health insur-  
23 ance issuers offering group or individual  
24 health insurance coverage may use for dis-  
25 closing information to ensure compliance

1 with the requirements under this section,  
2 section 712 of the Employee Retirement  
3 Income Security Act of 1974, or section  
4 9812 of the Internal Revenue Code of  
5 1986, as applicable, (and any regulations  
6 promulgated pursuant to such sections, as  
7 applicable).

8 “(ii) DOCUMENTS FOR PARTICIPANTS,  
9 BENEFICIARIES, CONTRACTING PROVIDERS,  
10 OR AUTHORIZED REPRESENTATIVES.—The  
11 guidance issued under this paragraph shall  
12 include clarifying information and illus-  
13 trative examples of methods that group  
14 health plans and health insurance issuers  
15 offering group or individual health insur-  
16 ance coverage may use to provide any par-  
17 ticipant, beneficiary, contracting provider,  
18 or authorized representative, as applicable,  
19 with documents containing information  
20 that the health plans or issuers are re-  
21 quired to disclose to participants, bene-  
22 ficiaries, contracting providers, or author-  
23 ized representatives to ensure compliance  
24 with this section, section 712 of the Em-  
25 ployee Retirement Income Security Act of



1                   1974, or section 9812 of the Internal Rev-  
2                   enue Code of 1986, as applicable, compli-  
3                   ance with any regulation issued pursuant  
4                   to such respective section, or compliance  
5                   with any other applicable law or regula-  
6                   tion. Such guidance shall include informa-  
7                   tion that is comparative in nature with re-  
8                   spect to—

9                               “(I) nonquantitative treatment  
10                              limitations for both medical and sur-  
11                              gical benefits and mental health and  
12                              substance use disorder benefits;

13                             “(II) the processes, strategies,  
14                             evidentiary standards, and other fac-  
15                             tors used to apply the limitations de-  
16                             scribed in subclause (I); and

17                             “(III) the application of the limi-  
18                             tations described in subclause (I) to  
19                             ensure that such limitations are ap-  
20                             plied in parity with respect to both  
21                             medical and surgical benefits and  
22                             mental health and substance use dis-  
23                             order benefits.

24                             “(C) NONQUANTITATIVE TREATMENT LIM-  
25                             ITATIONS.—The guidance issued under this

1 paragraph shall include clarifying information  
2 and illustrative examples of methods, processes,  
3 strategies, evidentiary standards, and other fac-  
4 tors that group health plans and health insur-  
5 ance issuers offering group or individual health  
6 insurance coverage may use regarding the de-  
7 velopment and application of nonquantitative  
8 treatment limitations to ensure compliance with  
9 this section, section 712 of the Employee Re-  
10 tirement Income Security Act of 1974, or sec-  
11 tion 9812 of the Internal Revenue Code of  
12 1986, as applicable, (and any regulations pro-  
13 mulgated pursuant to such respective section),  
14 including—

15 “(i) examples of methods of deter-  
16 mining appropriate types of nonquantita-  
17 tive treatment limitations with respect to  
18 both medical and surgical benefits and  
19 mental health and substance use disorder  
20 benefits, including nonquantitative treat-  
21 ment limitations pertaining to—

22 “(I) medical management stand-  
23 ards based on medical necessity or ap-  
24 propriateness, or whether a treatment  
25 is experimental or investigative;

1                   “(II) limitations with respect to  
2                   prescription drug formulary design;  
3                   and

4                   “(III) use of fail-first or step  
5                   therapy protocols;

6                   “(ii) examples of methods of deter-  
7                   mining—

8                   “(I) network admission standards  
9                   (such as credentialing); and

10                  “(II) factors used in provider re-  
11                  imbursement methodologies (such as  
12                  service type, geographic market, de-  
13                  mand for services, and provider sup-  
14                  ply, practice size, training, experience,  
15                  and licensure) as such factors apply to  
16                  network adequacy;

17                  “(iii) examples of sources of informa-  
18                  tion that may serve as evidentiary stand-  
19                  ards for the purposes of making deter-  
20                  minations regarding the development and  
21                  application of nonquantitative treatment  
22                  limitations;

23                  “(iv) examples of specific factors, and  
24                  the evidentiary standards used to evaluate  
25                  such factors, used by such plans or issuers

1 in performing a nonquantitative treatment  
2 limitation analysis;

3 “(v) examples of how specific evi-  
4 dentiary standards may be used to deter-  
5 mine whether treatments are considered  
6 experimental or investigative;

7 “(vi) examples of how specific evi-  
8 dentiary standards may be applied to each  
9 service category or classification of bene-  
10 fits;

11 “(vii) examples of methods of reach-  
12 ing appropriate coverage determinations  
13 for new mental health or substance use  
14 disorder treatments, such as evidence-  
15 based early intervention programs for indi-  
16 viduals with a serious mental illness and  
17 types of medical management techniques;

18 “(viii) examples of methods of reach-  
19 ing appropriate coverage determinations  
20 for which there is an indirect relationship  
21 between the covered mental health or sub-  
22 stance use disorder benefit and a tradi-  
23 tional covered medical and surgical benefit,  
24 such as residential treatment or hos-

1           pitalizations involving voluntary or involun-  
2           tary commitment; and

3           “(ix) additional illustrative examples  
4           of methods, processes, strategies, evi-  
5           dentiary standards, and other factors for  
6           which the Secretary determines that addi-  
7           tional guidance is necessary to improve  
8           compliance with this section, section 712 of  
9           the Employee Retirement Income Security  
10          Act of 1974, or section 9812 of the Inter-  
11          nal Revenue Code of 1986, as applicable.

12          “(D) PUBLIC COMMENT.—Prior to issuing  
13          any final guidance under this paragraph, the  
14          Secretary shall provide a public comment period  
15          of not less than 60 days during which any  
16          member of the public may provide comments on  
17          a draft of the guidance.”.

18          (c) AVAILABILITY OF PLAN INFORMATION.—

19           (1) SOLICITATION OF PUBLIC FEEDBACK.—Not  
20          later than 6 months after the date of enactment of  
21          this Act, the Secretary of Health and Human Serv-  
22          ices, the Secretary of Labor, and the Secretary of  
23          the Treasury shall solicit feedback from the public  
24          on how the disclosure request process for documents  
25          containing information that health plans or health

1 insurance issuers are required under Federal or  
2 State law to disclose to participants, beneficiaries,  
3 contracting providers, or authorized representatives  
4 to ensure compliance with existing mental health  
5 parity and addiction equity requirements can be im-  
6 proved while continuing to ensure consumers' rights  
7 to access all information required by Federal or  
8 State law to be disclosed.

9 (2) PUBLIC AVAILABILITY.—Not later than 12  
10 months after the date of the enactment of this Act,  
11 the Secretary of Health and Human Services, the  
12 Secretary of Labor, and the Secretary of the Treas-  
13 ury shall make such feedback publicly available.

14 (3) NAIC.—The Secretary of Health and  
15 Human Services, the Secretary of Labor, and the  
16 Secretary of the Treasury shall share feedback ob-  
17 tained pursuant to paragraph (1) directly with the  
18 National Association of Insurance Commissioners to  
19 the extent such feedback includes recommendations  
20 for the development of simplified information disclo-  
21 sure tools to provide consistent information for con-  
22 sumers. Such feedback may be taken into consider-  
23 ation by the National Association of Insurance Com-  
24 missioners and other appropriate entities for the vol-  
25 untary development and voluntary use of common

1 templates and other sample standardized forms to  
2 improve consumer access to plan information.

3 (d) IMPROVING COMPLIANCE.—

4 (1) IN GENERAL.—In the case that the Sec-  
5 retary of Health and Human Services, the Secretary  
6 of Labor, or the Secretary of the Treasury deter-  
7 mines that a group health plan or health insurance  
8 issuer offering group or individual health insurance  
9 coverage has violated, at least 5 times, section 2726  
10 of the Public Health Service Act (42 U.S.C. 300gg-  
11 26), section 712 of the Employee Retirement Income  
12 Security Act of 1974 (29 U.S.C. 1185a), or section  
13 9812 of the Internal Revenue Code of 1986, respec-  
14 tively, the appropriate Secretary shall audit plan  
15 documents for such health plan or issuer in the plan  
16 year following the Secretary's determination in order  
17 to help improve compliance with such section.

18 (2) RULE OF CONSTRUCTION.—Nothing in this  
19 subsection shall be construed to limit the authority,  
20 as in effect on the day before the date of enactment  
21 of this Act, of the Secretary of Health and Human  
22 Services, the Secretary of Labor, or the Secretary of  
23 the Treasury to audit documents of health plans or  
24 health insurance issuers.

1 **SEC. 13002. ACTION PLAN FOR ENHANCED ENFORCEMENT**  
2 **OF MENTAL HEALTH AND SUBSTANCE USE**  
3 **DISORDER COVERAGE.**

4 (a) PUBLIC MEETING.—

5 (1) IN GENERAL.—Not later than 6 months  
6 after the date of enactment of this Act, the Sec-  
7 retary of Health and Human Services shall convene  
8 a public meeting of stakeholders described in para-  
9 graph (2) to produce an action plan for improved  
10 Federal and State coordination related to the en-  
11 forcement of section 2726 of the Public Health Serv-  
12 ice Act (42 U.S.C. 300gg–26), section 712 of the  
13 Employee Retirement Income Security Act of 1974  
14 (29 U.S.C. 1185a), and section 9812 of the Internal  
15 Revenue Code of 1986, and any comparable provi-  
16 sions of State law (in this section such sections and  
17 provisions are collectively referred to as “mental  
18 health parity and addiction equity requirements”).

19 (2) STAKEHOLDERS.—The stakeholders de-  
20 scribed in this paragraph shall include each of the  
21 following:

22 (A) The Federal Government, including  
23 representatives from—

24 (i) the Department of Health and  
25 Human Services;

26 (ii) the Department of the Treasury;



1 (iii) the Department of Labor; and

2 (iv) the Department of Justice.

3 (B) State governments, including—

4 (i) State health insurance commis-  
5 sioners;

6 (ii) appropriate State agencies, includ-  
7 ing agencies on public health or mental  
8 health; and

9 (iii) State attorneys general or other  
10 representatives of State entities involved in  
11 the enforcement of mental health parity  
12 and addiction equity requirements.

13 (C) Representatives from key stakeholder  
14 groups, including—

15 (i) the National Association of Insur-  
16 ance Commissioners;

17 (ii) health insurance issuers;

18 (iii) providers of mental health and  
19 substance use disorder treatment;

20 (iv) employers; and

21 (v) patients or their advocates.

22 (b) ACTION PLAN.—Not later than 6 months after  
23 the conclusion of the public meeting under subsection (a),  
24 the Secretary of Health and Human Services shall finalize  
25 the action plan described in such subsection and make it

1 plainly available on the Internet website of the Depart-  
2 ment of Health and Human Services.

3 (c) CONTENT.—The action plan under this section  
4 shall—

5 (1) take into consideration the recommenda-  
6 tions of the Mental Health and Substance Use Dis-  
7 order Parity Task Force in its final report issued in  
8 October of 2016, and any subsequent Federal and  
9 State actions in relation to such recommendations;

10 (2) reflect the input of the stakeholders partici-  
11 pating in the public meeting under subsection (a);

12 (3) identify specific strategic objectives regard-  
13 ing how the various Federal and State agencies  
14 charged with enforcement of mental health parity  
15 and addiction equity requirements will collaborate to  
16 improve enforcement of such requirements;

17 (4) provide a timeline for implementing the ac-  
18 tion plan; and

19 (5) provide specific examples of how such objec-  
20 tives may be met, which may include—

21 (A) providing common educational infor-  
22 mation and documents, such as the Consumer  
23 Guide to Disclosure Rights, to patients about  
24 their rights under mental health parity and ad-  
25 diction equity requirements;

1 (B) facilitating the centralized collection  
2 of, monitoring of, and response to patient com-  
3 plaints or inquiries relating to mental health  
4 parity and addiction equity requirements, which  
5 may be through the development and adminis-  
6 tration of—

7 (i) a single, toll-free telephone num-  
8 ber; and

9 (ii) a new parity website—

10 (I) to help consumers find the  
11 appropriate Federal or State agency  
12 to assist with their parity complaints,  
13 appeals, and other actions; and

14 (II) that takes into consideration,  
15 but is not duplicative of, the parity  
16 beta site being tested, and released for  
17 public comment, by the Department  
18 of Health and Human Services as of  
19 the date of the enactment of this Act;

20 (C) Federal and State law enforcement  
21 agencies entering into memoranda of under-  
22 standing to better coordinate enforcement re-  
23 sponsibilities and information sharing—

24 (i) including whether such agencies  
25 should make the results of enforcement ac-

1                   tions related to mental health parity and  
2                   addiction equity requirements publicly  
3                   available; and

4                   (ii) which may include State Policy  
5                   Academies on Parity Implementation for  
6                   State Officials and other forums to bring  
7                   together national experts to provide tech-  
8                   nical assistance to teams of State officials  
9                   on strategies to advance compliance with  
10                  mental health parity and addiction equity  
11                  requirements in both the commercial mar-  
12                  ket, and in the Medicaid program under  
13                  title XIX of the Social Security Act and  
14                  the State Children's Health Insurance Pro-  
15                  gram under title XXI of such Act; and

16                  (D) recommendations to the Congress re-  
17                  garding the need for additional legal authority  
18                  to improve enforcement of mental health parity  
19                  and addiction equity requirements, including  
20                  the need for additional legal authority to ensure  
21                  that nonquantitative treatment limitations are  
22                  applied, and the extent and frequency of the ap-  
23                  plications of such limitations, both to medical  
24                  and surgical benefits and to mental health and

1 substance use disorder benefits in a comparable  
2 manner.

3 **SEC. 13003. REPORT ON INVESTIGATIONS REGARDING PAR-**  
4 **ITY IN MENTAL HEALTH AND SUBSTANCE**  
5 **USE DISORDER BENEFITS.**

6 (a) IN GENERAL.—Not later than 1 year after the  
7 date of enactment of this Act, and annually thereafter for  
8 the subsequent 5 years, the Assistant Secretary of Labor  
9 of the Employee Benefits Security Administration, in col-  
10 laboration with the Administrator of the Centers for Medi-  
11 care & Medicaid Services and the Secretary of the Treas-  
12 ury, shall submit to the Committee on Energy and Com-  
13 merce of the House of Representatives and the Committee  
14 on Health, Education, Labor, and Pensions of the Senate  
15 a report summarizing the results of all closed Federal in-  
16 vestigations completed during the preceding 12-month pe-  
17 riod with findings of any serious violation regarding com-  
18 pliance with mental health and substance use disorder cov-  
19 erage requirements under section 2726 of the Public  
20 Health Service Act (42 U.S.C. 300gg–26), section 712 of  
21 the Employee Retirement Income Security Act of 1974  
22 (29 U.S.C. 1185a), and section 9812 of the Internal Rev-  
23 enue Code of 1986.

1 (b) CONTENTS.—Subject to subsection (c), a report  
2 under subsection (a) shall, with respect to investigations  
3 described in such subsection, include each of the following:

4 (1) The number of closed Federal investigations  
5 conducted during the covered reporting period.

6 (2) Each benefit classification examined by any  
7 such investigation conducted during the covered re-  
8 porting period.

9 (3) Each subject matter, including compliance  
10 with requirements for quantitative and nonquantita-  
11 tive treatment limitations, of any such investigation  
12 conducted during the covered reporting period.

13 (4) A summary of the basis of the final decision  
14 rendered for each closed investigation conducted  
15 during the covered reporting period that resulted in  
16 a finding of a serious violation.

17 (c) LIMITATION.—Any individually identifiable infor-  
18 mation shall be excluded from reports under subsection  
19 (a) consistent with protections under the health privacy  
20 and security rules promulgated under section 264(c) of the  
21 Health Insurance Portability and Accountability Act of  
22 1996 (42 U.S.C. 1320d–2 note).

1 **SEC. 13004. GAO STUDY ON PARITY IN MENTAL HEALTH**  
2 **AND SUBSTANCE USE DISORDER BENEFITS.**

3 Not later than 3 years after the date of enactment  
4 of this Act, the Comptroller General of the United States,  
5 in consultation with the Secretary of Health and Human  
6 Services, the Secretary of Labor, and the Secretary of the  
7 Treasury, shall submit to the Committee on Energy and  
8 Commerce of the House of Representatives and the Com-  
9 mittee on Health, Education, Labor, and Pensions of the  
10 Senate a report detailing the extent to which group health  
11 plans or health insurance issuers offering group or indi-  
12 vidual health insurance coverage that provides both med-  
13 ical and surgical benefits and mental health or substance  
14 use disorder benefits, medicaid managed care organiza-  
15 tions with a contract under section 1903(m) of the Social  
16 Security Act (42 U.S.C. 1396b(m)), and health plans pro-  
17 vided under the State Children's Health Insurance Pro-  
18 gram under title XXI of the Social Security Act (42  
19 U.S.C. 1397aa et seq.) comply with section 2726 of the  
20 Public Health Service Act (42 U.S.C. 300gg-26), section  
21 712 of the Employee Retirement Income Security Act of  
22 1974 (29 U.S.C. 1185a), and section 9812 of the Internal  
23 Revenue Code of 1986, including—

24 (1) how nonquantitative treatment limitations,  
25 including medical necessity criteria, of such plans or  
26 issuers comply with such sections;

1           (2) how the responsible Federal departments  
2           and agencies ensure that such plans or issuers com-  
3           ply with such sections, including an assessment of  
4           how the Secretary of Health and Human Services  
5           has used its authority to conduct audits of such  
6           plans to ensure compliance;

7           (3) a review of how the various Federal and  
8           State agencies responsible for enforcing mental  
9           health parity requirements have improved enforce-  
10          ment of such requirements in accordance with the  
11          objectives and timeline described in the action plan  
12          under section 13002; and

13          (4) recommendations for how additional en-  
14          forcement, education, and coordination activities by  
15          responsible Federal and State departments and  
16          agencies could better ensure compliance with such  
17          sections, including recommendations regarding the  
18          need for additional legal authority.

19 **SEC. 13005. INFORMATION AND AWARENESS ON EATING**  
20 **DISORDERS.**

21          (a) INFORMATION.—The Secretary of Health and  
22          Human Services, acting through the Director of the Office  
23          on Women’s Health, may—

24                 (1) update information, related fact sheets, and  
25                 resource lists related to eating disorders that are



1 available on the public Internet website of the Na-  
2 tional Women's Health Information Center spon-  
3 sored by the Office on Women's Health, to include—

4 (A) updated findings and current research  
5 related to eating disorders, as appropriate; and

6 (B) information about eating disorders, in-  
7 cluding information related to males and fe-  
8 males;

9 (2) incorporate, as appropriate, and in coordi-  
10 nation with the Secretary of Education, information  
11 from publicly available resources into appropriate  
12 obesity prevention programs developed by the Office  
13 on Women's Health; and

14 (3) make publicly available (through a public  
15 Internet website or other method) information, re-  
16 lated fact sheets, and resource lists, as updated  
17 under paragraph (1), and the information incor-  
18 porated into appropriate obesity prevention pro-  
19 grams under paragraph (2).

20 (b) AWARENESS.—The Secretary of Health and  
21 Human Services may advance public awareness on—

22 (1) the types of eating disorders;

23 (2) the seriousness of eating disorders, includ-  
24 ing prevalence, comorbidities, and physical and men-  
25 tal health consequences;

1           (3) methods to identify, intervene, refer for  
2           treatment, and prevent behaviors that may lead to  
3           the development of eating disorders;

4           (4) discrimination and bullying based on body  
5           size;

6           (5) the effects of media on self-esteem and body  
7           image; and

8           (6) the signs and symptoms of eating disorders.

9   **SEC. 13006. EDUCATION AND TRAINING ON EATING DIS-**  
10                                   **ORDERS.**

11        The Secretary of Health and Human Services may  
12        facilitate the identification of model programs and mate-  
13        rials for educating and training health professionals in ef-  
14        fective strategies to—

15           (1) identify individuals with eating disorders;

16           (2) provide early intervention services for indi-  
17        viduals with eating disorders;

18           (3) refer patients with eating disorders for ap-  
19        propriate treatment;

20           (4) prevent the development of eating disorders;  
21        and

22           (5) provide appropriate treatment services for  
23        individuals with eating disorders.

1 **SEC. 13007. CLARIFICATION OF EXISTING PARITY RULES.**

2 If a group health plan or a health insurance issuer  
3 offering group or individual health insurance coverage pro-  
4 vides coverage for eating disorder benefits, including resi-  
5 dential treatment, such group health plan or health insur-  
6 ance issuer shall provide such benefits consistent with the  
7 requirements of section 2726 of the Public Health Service  
8 Act (42 U.S.C. 300gg-26), section 712 of the Employee  
9 Retirement Income Security Act of 1974 (29 U.S.C.  
10 1185a), and section 9812 of the Internal Revenue Code  
11 of 1986.

12 **TITLE XIV—MENTAL HEALTH**  
13 **AND SAFE COMMUNITIES**  
14 **Subtitle A—Mental Health and Safe**  
15 **Communities**

16 **SEC. 14001. LAW ENFORCEMENT GRANTS FOR CRISIS**  
17 **INTERVENTION TEAMS, MENTAL HEALTH**  
18 **PURPOSES.**

19 (a) EDWARD BYRNE MEMORIAL JUSTICE ASSIST-  
20 ANCE GRANT PROGRAM.—Section 501(a)(1) of title I of  
21 the Omnibus Crime Control and Safe Streets Act of 1968  
22 (42 U.S.C. 3751(a)(1)) is amended by adding at the end  
23 the following:

24 “(H) Mental health programs and related  
25 law enforcement and corrections programs, in-

1 including behavioral programs and crisis interven-  
2 tion teams.”.

3 (b) COMMUNITY ORIENTED POLICING SERVICES  
4 PROGRAM.—Section 1701(b) of title I of the Omnibus  
5 Crime Control and Safe Streets Act of 1968 (42 U.S.C.  
6 3796dd(b)) is amended—

7 (1) in paragraph (17), by striking “and” at the  
8 end;

9 (2) by redesignating paragraph (18) as para-  
10 graph (22);

11 (3) by inserting after paragraph (17) the fol-  
12 lowing:

13 “(18) to provide specialized training to law en-  
14 forcement officers to—

15 “(A) recognize individuals who have a  
16 mental illness; and

17 “(B) properly interact with individuals who  
18 have a mental illness, including strategies for  
19 verbal de-escalation of crises;

20 “(19) to establish collaborative programs that  
21 enhance the ability of law enforcement agencies to  
22 address the mental health, behavioral, and substance  
23 abuse problems of individuals encountered by law  
24 enforcement officers in the line of duty;



1 U.S.C. 3796ii) is amended in paragraph (2)(B), by insert-  
2 ing before the semicolon the following: “, or court-ordered  
3 assisted outpatient treatment when the court has deter-  
4 mined such treatment to be necessary”.

5 (b) DEFINITIONS.—Section 2202 of title I of the Om-  
6 nibus Crime Control and Safe Streets Act of 1968 (42  
7 U.S.C. 3796ii—1) is amended—

8 (1) in paragraph (1), by striking “and” at the  
9 end;

10 (2) in paragraph (2), by striking the period at  
11 the end and inserting a semicolon; and

12 (3) by adding at the end the following:

13 “(3) the term ‘court-ordered assisted outpatient  
14 treatment’ means a program through which a court  
15 may order a treatment plan for an eligible patient  
16 that—

17 “(A) requires such patient to obtain out-  
18 patient mental health treatment while the pa-  
19 tient is not currently residing in a correctional  
20 facility or inpatient treatment facility; and

21 “(B) is designed to improve access and ad-  
22 herence by such patient to intensive behavioral  
23 health services in order to—

24 “(i) avert relapse, repeated hos-  
25 pitalizations, arrest, incarceration, suicide,

1 property destruction, and violent behavior;  
2 and

3 “(ii) provide such patient with the op-  
4 portunity to live in a less restrictive alter-  
5 native to incarceration or involuntary hos-  
6 pitalization; and

7 “(4) the term ‘eligible patient’ means an adult,  
8 mentally ill person who, as determined by a court—

9 “(A) has a history of violence, incarcer-  
10 ation, or medically unnecessary hospitalizations;

11 “(B) without supervision and treatment,  
12 may be a danger to self or others in the com-  
13 munity;

14 “(C) is substantially unlikely to voluntarily  
15 participate in treatment;

16 “(D) may be unable, for reasons other  
17 than indigence, to provide for any of his or her  
18 basic needs, such as food, clothing, shelter,  
19 health, or safety;

20 “(E) has a history of mental illness or a  
21 condition that is likely to substantially deterio-  
22 rate if the person is not provided with timely  
23 treatment; or

24 “(F) due to mental illness, lacks capacity  
25 to fully understand or lacks judgment to make

1 informed decisions regarding his or her need for  
2 treatment, care, or supervision.”.

3 **SEC. 14003. FEDERAL DRUG AND MENTAL HEALTH COURTS.**

4 (a) DEFINITIONS.—In this section—

5 (1) the term “eligible offender” means a person  
6 who—

7 (A)(i) previously or currently has been di-  
8 agnosed by a qualified mental health profes-  
9 sional as having a mental illness, mental retar-  
10 dation, or co-occurring mental illness and sub-  
11 stance abuse disorders; or

12 (ii) manifests obvious signs of mental ill-  
13 ness, mental retardation, or co-occurring mental  
14 illness and substance abuse disorders during ar-  
15 rest or confinement or before any court;

16 (B) comes into contact with the criminal  
17 justice system or is arrested or charged with an  
18 offense that is not—

19 (i) a crime of violence, as defined  
20 under applicable State law or in section  
21 3156 of title 18, United States Code; or

22 (ii) a serious drug offense, as defined  
23 in section 924(e)(2)(A) of title 18, United  
24 States Code; and



1 (C) is determined by a judge to be eligible;

2 and

3 (2) the term “mental illness” means a  
4 diagnosable mental, behavioral, or emotional dis-  
5 order—

6 (A) of sufficient duration to meet diag-  
7 nostic criteria within the most recent edition of  
8 the Diagnostic and Statistical Manual of Men-  
9 tal Disorders published by the American Psy-  
10 chiatric Association; and

11 (B) that has resulted in functional impair-  
12 ment that substantially interferes with or limits  
13 1 or more major life activities.

14 (b) ESTABLISHMENT OF PROGRAM.—Not later than  
15 1 year after the date of enactment of this Act, the Attor-  
16 ney General shall establish a pilot program to determine  
17 the effectiveness of diverting eligible offenders from Fed-  
18 eral prosecution, Federal probation, or a Bureau of Pris-  
19 ons facility, and placing such eligible offenders in drug or  
20 mental health courts.

21 (c) PROGRAM SPECIFICATIONS.—The pilot program  
22 established under subsection (b) shall involve—

23 (1) continuing judicial supervision, including  
24 periodic review, of program participants who have a  
25 substance abuse problem or mental illness; and

1           (2) the integrated administration of services  
2           and sanctions, which shall include—

3                   (A) mandatory periodic testing, as appro-  
4                   priate, for the use of controlled substances or  
5                   other addictive substances during any period of  
6                   supervised release or probation for each pro-  
7                   gram participant;

8                   (B) substance abuse treatment for each  
9                   program participant who requires such services;

10                   (C) diversion, probation, or other super-  
11                   vised release with the possibility of prosecution,  
12                   confinement, or incarceration based on non-  
13                   compliance with program requirements or fail-  
14                   ure to show satisfactory progress toward com-  
15                   pleting program requirements;

16                   (D) programmatic offender management,  
17                   including case management, and aftercare serv-  
18                   ices, such as relapse prevention, health care,  
19                   education, vocational training, job placement,  
20                   housing placement, and child care or other fam-  
21                   ily support services for each program partici-  
22                   pant who requires such services;

23                   (E) outpatient or inpatient mental health  
24                   treatment, as ordered by the court, that carries  
25                   with it the possibility of dismissal of charges or

1 reduced sentencing upon successful completion  
2 of such treatment;

3 (F) centralized case management, includ-  
4 ing—

5 (i) the consolidation of all cases, in-  
6 cluding violations of probations, of the pro-  
7 gram participant; and

8 (ii) coordination of all mental health  
9 treatment plans and social services, includ-  
10 ing life skills and vocational training, hous-  
11 ing and job placement, education, health  
12 care, and relapse prevention for each pro-  
13 gram participant who requires such serv-  
14 ices; and

15 (G) continuing supervision of treatment  
16 plan compliance by the program participant for  
17 a term not to exceed the maximum allowable  
18 sentence or probation period for the charged or  
19 relevant offense and, to the extent practicable,  
20 continuity of psychiatric care at the end of the  
21 supervised period.

22 (d) IMPLEMENTATION; DURATION.—The pilot pro-  
23 gram established under subsection (b) shall be con-  
24 ducted—

1           (1) in not less than 1 United States judicial  
2           district, designated by the Attorney General in con-  
3           sultation with the Director of the Administrative Of-  
4           fice of the United States Courts, as appropriate for  
5           the pilot program; and

6           (2) during fiscal year 2017 through fiscal year  
7           2021.

8           (e) CRITERIA FOR DESIGNATION.—Before making a  
9           designation under subsection (d)(1), the Attorney General  
10          shall—

11          (1) obtain the approval, in writing, of the  
12          United States Attorney for the United States judi-  
13          cial district being designated;

14          (2) obtain the approval, in writing, of the chief  
15          judge for the United States judicial district being  
16          designated; and

17          (3) determine that the United States judicial  
18          district being designated has adequate behavioral  
19          health systems for treatment, including substance  
20          abuse and mental health treatment.

21          (f) ASSISTANCE FROM OTHER FEDERAL ENTI-  
22          TIES.—The Administrative Office of the United States  
23          Courts and the United States Probation Offices shall pro-  
24          vide such assistance and carry out such functions as the  
25          Attorney General may request in monitoring, supervising,

1 providing services to, and evaluating eligible offenders  
2 placed in a drug or mental health court under this section.

3 (g) REPORTS.—The Attorney General, in consulta-  
4 tion with the Director of the Administrative Office of the  
5 United States Courts, shall monitor the drug and mental  
6 health courts under this section, and shall submit a report  
7 to Congress on the outcomes of the program at the end  
8 of the period described in subsection (d)(2).

9 **SEC. 14004. MENTAL HEALTH IN THE JUDICIAL SYSTEM.**

10 Part V of title I of the Omnibus Crime Control and  
11 Safe Streets Act of 1968 (42 U.S.C. 3796ii et seq.) is  
12 amended by inserting at the end the following:

13 **“SEC. 2209. MENTAL HEALTH RESPONSES IN THE JUDICIAL**  
14 **SYSTEM.**

15 “(a) PRETRIAL SCREENING AND SUPERVISION.—

16 “(1) IN GENERAL.—The Attorney General may  
17 award grants to States, units of local government,  
18 territories, Indian Tribes, nonprofit agencies, or any  
19 combination thereof, to develop, implement, or ex-  
20 pand pretrial services programs to improve the iden-  
21 tification and outcomes of individuals with mental  
22 illness.

23 “(2) ALLOWABLE USES.—Grants awarded  
24 under this subsection may be may be used for—

1           “(A) behavioral health needs and risk  
2 screening of defendants, including verification  
3 of interview information, mental health evalua-  
4 tion, and criminal history screening;

5           “(B) assessment of risk of pretrial mis-  
6 conduct through objective, statistically validated  
7 means, and presentation to the court of rec-  
8 ommendations based on such assessment, in-  
9 cluding services that will reduce the risk of pre-  
10 trial misconduct;

11           “(C) followup review of defendants unable  
12 to meet the conditions of pretrial release;

13           “(D) evaluation of process and results of  
14 pre-trial service programs;

15           “(E) supervision of defendants who are on  
16 pretrial release, including reminders to defend-  
17 ants of scheduled court dates;

18           “(F) reporting on process and results of  
19 pretrial services programs to relevant public  
20 and private mental health stakeholders; and

21           “(G) data collection and analysis necessary  
22 to make available information required for as-  
23 sessment of risk.

24           “(b) BEHAVIORAL HEALTH ASSESSMENTS AND  
25 INTERVENTION.—

1           “(1) IN GENERAL.—The Attorney General may  
2           award grants to States, units of local government,  
3           territories, Indian Tribes, nonprofit agencies, or any  
4           combination thereof, to develop, implement, or ex-  
5           pand a behavioral health screening and assessment  
6           program framework for State or local criminal jus-  
7           tice systems.

8           “(2) ALLOWABLE USES.—Grants awarded  
9           under this subsection may be used for—

10                   “(A) promotion of the use of validated as-  
11                   sessment tools to gauge the criminogenic risk,  
12                   substance abuse needs, and mental health needs  
13                   of individuals;

14                   “(B) initiatives to match the risk factors  
15                   and needs of individuals to programs and prac-  
16                   tices associated with research-based, positive  
17                   outcomes;

18                   “(C) implementing methods for identifying  
19                   and treating individuals who are most likely to  
20                   benefit from coordinated supervision and treat-  
21                   ment strategies, and identifying individuals who  
22                   can do well with fewer interventions; and

23                   “(D) collaborative decision-making among  
24                   the heads of criminal justice agencies, mental  
25                   health systems, judicial systems, substance

1 abuse systems, and other relevant systems or  
2 agencies for determining how treatment and in-  
3 tensive supervision services should be allocated  
4 in order to maximize benefits, and developing  
5 and utilizing capacity accordingly.

6 “(c) USE OF GRANT FUNDS.—A State, unit of local  
7 government, territory, Indian Tribe, or nonprofit agency  
8 that receives a grant under this section shall, in accord-  
9 ance with subsection (b)(2), use grant funds for the ex-  
10 penses of a treatment program, including—

11 “(1) salaries, personnel costs, equipment costs,  
12 and other costs directly related to the operation of  
13 the program, including costs relating to enforcement;

14 “(2) payments for treatment providers that are  
15 approved by the State or Indian Tribe and licensed,  
16 if necessary, to provide needed treatment to program  
17 participants, including aftercare supervision, voca-  
18 tional training, education, and job placement; and

19 “(3) payments to public and nonprofit private  
20 entities that are approved by the State or Indian  
21 Tribe and licensed, if necessary, to provide alcohol  
22 and drug addiction treatment to offenders partici-  
23 pating in the program.

24 “(d) SUPPLEMENT OF NON-FEDERAL FUNDS.—



1           “(1) IN GENERAL.—Grants awarded under this  
2           section shall be used to supplement, and not sup-  
3           plant, non-Federal funds that would otherwise be  
4           available for programs described in this section.

5           “(2) FEDERAL SHARE.—The Federal share of a  
6           grant made under this section may not exceed 50  
7           percent of the total costs of the program described  
8           in an application under subsection (e).

9           “(e) APPLICATIONS.—To request a grant under this  
10          section, a State, unit of local government, territory, Indian  
11          Tribe, or nonprofit agency shall submit an application to  
12          the Attorney General in such form and containing such  
13          information as the Attorney General may reasonably re-  
14          quire.

15          “(f) GEOGRAPHIC DISTRIBUTION.—The Attorney  
16          General shall ensure that, to the extent practicable, the  
17          distribution of grants under this section is equitable and  
18          includes—

19                 “(1) each State; and

20                 “(2) a unit of local government, territory, In-  
21          dian Tribe, or nonprofit agency—

22                         “(A) in each State; and

23                         “(B) in rural, suburban, Tribal, and urban  
24          jurisdictions.

1           “(g) REPORTS AND EVALUATIONS.—For each fiscal  
2 year, each grantee under this section during that fiscal  
3 year shall submit to the Attorney General a report on the  
4 effectiveness of activities carried out using such grant.  
5 Each report shall include an evaluation in such form and  
6 containing such information as the Attorney General may  
7 reasonably require. The Attorney General shall specify the  
8 dates on which such reports shall be submitted.

9           “(h) ACCOUNTABILITY.—Grants awarded under this  
10 section shall be subject to the following accountability pro-  
11 visions:

12                   “(1) AUDIT REQUIREMENT.—

13                           “(A) DEFINITION.—In this paragraph, the  
14 term ‘unresolved audit finding’ means a finding  
15 in the final audit report of the Inspector Gen-  
16 eral of the Department of Justice under sub-  
17 paragraph (C) that the audited grantee has  
18 used grant funds for an unauthorized expendi-  
19 ture or otherwise unallowable cost that is not  
20 closed or resolved within 1 year after the date  
21 on which final audit report is issued.

22                           “(B) AUDITS.—Beginning in the first fis-  
23 cal year beginning after the date of enactment  
24 of this section, and in each fiscal year there-  
25 after, the Inspector General of the Department

1 of Justice shall conduct audits of grantees  
2 under this section to prevent waste, fraud, and  
3 abuse of funds by grantees. The Inspector Gen-  
4 eral shall determine the appropriate number of  
5 grantees to be audited each year.

6 “(C) FINAL AUDIT REPORT.—The Inspec-  
7 tor General of the Department of Justice shall  
8 submit to the Attorney General a final report  
9 on each audit conducted under subparagraph  
10 (B).

11 “(D) MANDATORY EXCLUSION.—Grantees  
12 under this section about which there is an unre-  
13 solved audit finding shall not be eligible to re-  
14 ceive a grant under this section during the 2  
15 fiscal years beginning after the end of the 1-  
16 year period described in subparagraph (A).

17 “(E) PRIORITY.—In making grants under  
18 this section, the Attorney General shall give pri-  
19 ority to applicants that did not have an unre-  
20 solved audit finding during the 3 fiscal years  
21 before submitting an application for a grant  
22 under this section.

23 “(F) REIMBURSEMENT.—If an entity re-  
24 ceives a grant under this section during the 2-  
25 fiscal-year period during which the entity is

1 prohibited from receiving grants under subpara-  
2 graph (D), the Attorney General shall—

3 “(i) deposit an amount equal to the  
4 amount of the grant that was improperly  
5 awarded to the grantee into the General  
6 Fund of the Treasury; and

7 “(ii) seek to recoup the costs of the  
8 repayment under clause (i) from the grant-  
9 ee that was erroneously awarded grant  
10 funds.

11 “(2) NONPROFIT AGENCY REQUIREMENTS.—

12 “(A) DEFINITION.—For purposes of this  
13 paragraph and the grant program under this  
14 section, the term ‘nonprofit agency’ means an  
15 organization that is described in section  
16 501(c)(3) of the Internal Revenue Code of 1986  
17 (26 U.S.C. 501(c)(3)) and is exempt from tax-  
18 ation under section 501(a) of the Internal Rev-  
19 enue Code of 1986 (26 U.S.C. 501(a)).

20 “(B) PROHIBITION.—The Attorney Gen-  
21 eral may not award a grant under this section  
22 to a nonprofit agency that holds money in an  
23 offshore account for the purpose of avoiding  
24 paying the tax described in section 511(a) of

1 the Internal Revenue Code of 1986 (26 U.S.C.  
2 511(a)).

3 “(C) DISCLOSURE.—Each nonprofit agen-  
4 cy that is awarded a grant under this section  
5 and uses the procedures prescribed in regula-  
6 tions to create a rebuttable presumption of rea-  
7 sonableness for the compensation of its officers,  
8 directors, trustees, and key employees, shall dis-  
9 close to the Attorney General, in the application  
10 for the grant, the process for determining such  
11 compensation, including the independent per-  
12 sons involved in reviewing and approving such  
13 compensation, the comparability data used, and  
14 contemporaneous substantiation of the delibera-  
15 tion and decision. Upon request, the Attorney  
16 General shall make the information disclosed  
17 under this subparagraph available for public in-  
18 spection.

19 “(3) CONFERENCE EXPENDITURES.—

20 “(A) LIMITATION.—Not more than  
21 \$20,000 of the amounts made available to the  
22 Department of Justice to carry out this section  
23 may be used by the Attorney General, or by any  
24 individual or entity awarded a grant under this  
25 section to host, or make any expenditures relat-

1           ing to, a conference unless the Deputy Attorney  
2           General provides prior written authorization  
3           that the funds may be expended to host the  
4           conference or make such expenditure.

5                   “(B) WRITTEN APPROVAL.—Written ap-  
6           proval under subparagraph (A) shall include a  
7           written estimate of all costs associated with the  
8           conference, including the cost of all food, bev-  
9           erages, audio-visual equipment, honoraria for  
10          speakers, and entertainment.

11                   “(C) REPORT.—The Deputy Attorney Gen-  
12          eral shall submit an annual report to the Com-  
13          mittee on the Judiciary of the Senate and the  
14          Committee on the Judiciary of the House of  
15          Representatives on all conference expenditures  
16          approved under this paragraph.

17                   “(4) ANNUAL CERTIFICATION.—Beginning in  
18          the first fiscal year beginning after the date of en-  
19          actment of this subsection, the Attorney General  
20          shall submit to the Committee on the Judiciary and  
21          the Committee on Appropriations of the Senate and  
22          the Committee on the Judiciary and the Committee  
23          on Appropriations of the House of Representatives  
24          an annual certification—

25                   “(A) indicating whether—

1                   “(i) all final audit reports issued by  
2                   the Office of the Inspector General under  
3                   paragraph (1) have been completed and re-  
4                   viewed by the appropriate Assistant Attor-  
5                   ney General or Director;

6                   “(ii) all mandatory exclusions required  
7                   under paragraph (1)(D) have been issued;  
8                   and

9                   “(iii) any reimbursements required  
10                  under paragraph (1)(F) have been made;  
11                  and

12                  “(B) that includes a list of any grantees  
13                  excluded under paragraph (1)(D) from the pre-  
14                  vious year.

15                  “(i) PREVENTING DUPLICATIVE GRANTS.—

16                  “(1) IN GENERAL.—Before the Attorney Gen-  
17                  eral awards a grant to an applicant under this sec-  
18                  tion, the Attorney General shall compare the pos-  
19                  sible grant with any other grants awarded to the ap-  
20                  plicant under this Act to determine whether the  
21                  grants are for the same purpose.

22                  “(2) REPORT.—If the Attorney General awards  
23                  multiple grants to the same applicant for the same  
24                  purpose, the Attorney General shall submit to the  
25                  Committee on the Judiciary of the Senate and the

1 Committee on the Judiciary of the House of Rep-  
2 resentatives a report that includes—

3 “(A) a list of all duplicate grants awarded,  
4 including the total dollar amount of any such  
5 grants awarded; and

6 “(B) the reason the Attorney General  
7 awarded the duplicate grants.”.

8 **SEC. 14005. FORENSIC ASSERTIVE COMMUNITY TREAT-**  
9 **MENT INITIATIVES.**

10 Section 2991 of the Omnibus Crime Control and Safe  
11 Streets Act of 1968 (42 U.S.C. 3797aa) is amended by—

12 (1) redesignating subsection (j) as subsection  
13 (o); and

14 (2) inserting after subsection (i) the following:

15 “(j) FORENSIC ASSERTIVE COMMUNITY TREATMENT  
16 (FACT) INITIATIVE PROGRAM.—

17 “(1) IN GENERAL.—The Attorney General may  
18 make grants to States, units of local government,  
19 territories, Indian Tribes, nonprofit agencies, or any  
20 combination thereof, to develop, implement, or ex-  
21 pand Assertive Community Treatment initiatives to  
22 develop forensic assertive community treatment (re-  
23 ferred to in this subsection as ‘FACT’) programs  
24 that provide high intensity services in the commu-  
25 nity for individuals with mental illness with involve-



1           ment in the criminal justice system to prevent future  
2           incarcerations.

3           “(2) ALLOWABLE USES.—Grant funds awarded  
4           under this subsection may be used for—

5                   “(A) multidisciplinary team initiatives for  
6                   individuals with mental illnesses with criminal  
7                   justice involvement that address criminal justice  
8                   involvement as part of treatment protocols;

9                   “(B) FACT programs that involve mental  
10                   health professionals, criminal justice agencies,  
11                   chemical dependency specialists, nurses, psychi-  
12                   atrists, vocational specialists, forensic peer spe-  
13                   cialists, forensic specialists, and dedicated ad-  
14                   ministrative support staff who work together to  
15                   provide recovery oriented, 24/7 wraparound  
16                   services;

17                   “(C) services such as integrated evidence-  
18                   based practices for the treatment of co-occur-  
19                   ring mental health and substance-related dis-  
20                   orders, assertive outreach and engagement,  
21                   community-based service provision at partici-  
22                   pants’ residence or in the community, psy-  
23                   chiatric rehabilitation, recovery oriented serv-  
24                   ices, services to address criminogenic risk fac-  
25                   tors, and community tenure;

1           “(D) payments for treatment providers  
2           that are approved by the State or Indian Tribe  
3           and licensed, if necessary, to provide needed  
4           treatment to eligible offenders participating in  
5           the program, including behavioral health serv-  
6           ices and aftercare supervision; and

7           “(E) training for all FACT teams to pro-  
8           mote high-fidelity practice principles and tech-  
9           nical assistance to support effective and con-  
10          tinuing integration with criminal justice agency  
11          partners.

12          “(3) SUPPLEMENT AND NOT SUPPLANT.—  
13          Grants made under this subsection shall be used to  
14          supplement, and not supplant, non-Federal funds  
15          that would otherwise be available for programs de-  
16          scribed in this subsection.

17          “(4) APPLICATIONS.—To request a grant under  
18          this subsection, a State, unit of local government,  
19          territory, Indian Tribe, or nonprofit agency shall  
20          submit an application to the Attorney General in  
21          such form and containing such information as the  
22          Attorney General may reasonably require.”.

1 **SEC. 14006. ASSISTANCE FOR INDIVIDUALS TRANSITIONING**  
2 **OUT OF SYSTEMS.**

3 Section 2976(f) of title I of the Omnibus Crime Con-  
4 trol and Safe Streets Act of 1968 (42 U.S.C. 3797w(f))  
5 is amended—

6 (1) in paragraph (5), by striking “and” at the  
7 end;

8 (2) in paragraph (6), by striking the period at  
9 the end and inserting a semicolon; and

10 (3) by adding at the end the following:

11 “(7) provide mental health treatment and tran-  
12 sitional services for those with mental illnesses or  
13 with co-occurring disorders, including housing place-  
14 ment or assistance; and”.

15 **SEC. 14007. CO-OCCURRING SUBSTANCE ABUSE AND MEN-**  
16 **TAL HEALTH CHALLENGES IN DRUG COURTS.**

17 Part EE of title I of the Omnibus Crime Control and  
18 Safe Streets Act of 1968 (42 U.S.C. 3797u et seq.) is  
19 amended—

20 (1) in section 2951(a)(1) (42 U.S.C.  
21 3797u(a)(1)), by inserting “, including co-occurring  
22 substance abuse and mental health problems,” after  
23 “problems”; and

24 (2) in section 2959(a) (42 U.S.C. 3797u–8(a)),  
25 by inserting “, including training for drug court per-  
26 sonnel and officials on identifying and addressing co-

1 occurring substance abuse and mental health prob-  
2 lems” after “part”.

3 **SEC. 14008. MENTAL HEALTH TRAINING FOR FEDERAL UNI-**  
4 **FORMED SERVICES.**

5 (a) IN GENERAL.—Not later than 180 days after the  
6 date of enactment of this Act, the Secretary of Defense,  
7 the Secretary of Homeland Security, the Secretary of  
8 Health and Human Services, and the Secretary of Com-  
9 merce shall provide the following to each of the uniformed  
10 services (as that term is defined in section 101 of title  
11 10, United States Code) under their direction:

12 (1) TRAINING PROGRAMS.—Programs that offer  
13 specialized and comprehensive training in procedures  
14 to identify and respond appropriately to incidents in  
15 which the unique needs of individuals with mental  
16 illnesses are involved.

17 (2) IMPROVED TECHNOLOGY.—Computerized  
18 information systems or technological improvements  
19 to provide timely information to Federal law enforce-  
20 ment personnel, other branches of the uniformed  
21 services, and criminal justice system personnel to  
22 improve the Federal response to mentally ill individ-  
23 uals.

24 (3) COOPERATIVE PROGRAMS.—The establish-  
25 ment and expansion of cooperative efforts to pro-

1       mote public safety through the use of effective inter-  
2       vention with respect to mentally ill individuals en-  
3       countered by members of the uniformed services.

4       **SEC. 14009. ADVANCING MENTAL HEALTH AS PART OF OF-**  
5                                   **FENDER REENTRY.**

6       (a) REENTRY DEMONSTRATION PROJECTS.—Section  
7       2976(f) of title I of the Omnibus Crime Control and Safe  
8       Streets Act of 1968 (42 U.S.C. 3797w(f)), as amended  
9       by section 14006, is amended—

10               (1) in paragraph (3)(C), by inserting “mental  
11       health services,” before “drug treatment”; and

12               (2) by adding at the end the following:

13                       “(8) target offenders with histories of homeless-  
14       ness, substance abuse, or mental illness, including a  
15       prerelease assessment of the housing status of the  
16       offender and behavioral health needs of the offender  
17       with clear coordination with mental health, sub-  
18       stance abuse, and homelessness services systems to  
19       achieve stable and permanent housing outcomes with  
20       appropriate support service.”.

21       (b) MENTORING GRANTS.—Section 211(b)(2) of the  
22       Second Chance Act of 2007 (42 U.S.C. 17531(b)(2)) is  
23       amended by inserting “, including mental health care”  
24       after “community”.

1 **SEC. 14010. SCHOOL MENTAL HEALTH CRISIS INTERVEN-**  
2 **TION TEAMS.**

3 Section 2701(b) of title I of the Omnibus Crime Con-  
4 trol and Safe Streets Act of 1968 (42 U.S.C. 3797a(b))  
5 is amended—

6 (1) by redesignating paragraphs (4) and (5) as  
7 paragraphs (5) and (6), respectively; and

8 (2) by inserting after paragraph (3) the fol-  
9 lowing:

10 “(4) The development and operation of crisis  
11 intervention teams that may include coordination  
12 with law enforcement agencies and specialized train-  
13 ing for school officials in responding to mental  
14 health crises.”.

15 **SEC. 14011. ACTIVE-SHOOTER TRAINING FOR LAW EN-**  
16 **FORCEMENT.**

17 The Attorney General, as part of the Preventing Vio-  
18 lence Against Law Enforcement and Ensuring Officer Re-  
19 silience and Survivability Initiative (VALOR) of the De-  
20 partment of Justice, may provide safety training and tech-  
21 nical assistance to local law enforcement agencies, includ-  
22 ing active-shooter response training.

1 **SEC. 14012. CO-OCCURRING SUBSTANCE ABUSE AND MEN-**  
2 **TAL HEALTH CHALLENGES IN RESIDENTIAL**  
3 **SUBSTANCE ABUSE TREATMENT PROGRAMS.**

4 Section 1901(a) of title I of the Omnibus Crime Con-  
5 trol and Safe Streets Act of 1968 (42 U.S.C. 3796ff(a))  
6 is amended—

7 (1) in paragraph (1), by striking “and” at the  
8 end;

9 (2) in paragraph (2), by striking the period at  
10 the end and inserting “; and”; and

11 (3) by adding at the end the following:

12 “(3) developing and implementing specialized  
13 residential substance abuse treatment programs that  
14 identify and provide appropriate treatment to in-  
15 mates with co-occurring mental health and sub-  
16 stance abuse disorders or challenges.”.

17 **SEC. 14013. MENTAL HEALTH AND DRUG TREATMENT AL-**  
18 **TERNATIVES TO INCARCERATION PRO-**  
19 **GRAMS.**

20 Title I of the Omnibus Crime Control and Safe  
21 Streets Act of 1968 (42 U.S.C. 3711 et seq.) is amended  
22 by striking part CC and inserting the following:

1 **“PART CC—MENTAL HEALTH AND DRUG TREAT-**  
2 **MENT ALTERNATIVES TO INCARCERATION**  
3 **PROGRAMS**

4 **“SEC. 2901. MENTAL HEALTH AND DRUG TREATMENT AL-**  
5 **TERNATIVES TO INCARCERATION PRO-**  
6 **GRAMS.**

7 “(a) DEFINITIONS.—In this section—

8 “(1) the term ‘eligible entity’ means a State,  
9 unit of local government, Indian tribe, or nonprofit  
10 organization; and

11 “(2) the term ‘eligible participant’ means an in-  
12 dividual who—

13 “(A) comes into contact with the criminal  
14 justice system or is arrested or charged with an  
15 offense that is not—

16 “(i) a crime of violence, as defined  
17 under applicable State law or in section  
18 3156 of title 18, United States Code; or

19 “(ii) a serious drug offense, as defined  
20 in section 924(e)(2)(A) of title 18, United  
21 States Code;

22 “(B) has a history of, or a current—

23 “(i) substance use disorder;

24 “(ii) mental illness; or

25 “(iii) co-occurring mental illness and  
26 substance use disorder; and



1           “(C) has been approved for participation in  
2           a program funded under this section by the rel-  
3           evant law enforcement agency, prosecuting at-  
4           torney, defense attorney, probation official, cor-  
5           rections official, judge, representative of a men-  
6           tal health agency, or representative of a sub-  
7           stance abuse agency, as required by law.

8           “(b) PROGRAM AUTHORIZED.—The Attorney General  
9           may make grants to eligible entities to develop, implement,  
10          or expand a treatment alternative to incarceration pro-  
11          gram for eligible participants, including—

12           “(1) pre-booking treatment alternative to incar-  
13          ceration programs, including—

14           “(A) law enforcement training on sub-  
15          stance use disorders, mental illness, and co-oc-  
16          curring mental illness and substance use dis-  
17          orders;

18           “(B) receiving centers as alternatives to in-  
19          carceration of eligible participants;

20           “(C) specialized response units for calls re-  
21          lated to substance use disorders, mental illness,  
22          or co-occurring mental illness and substance  
23          use disorders; and

24           “(D) other arrest and pre-booking treat-  
25          ment alternatives to incarceration models; or

1           “(2) post-booking treatment alternative to in-  
2           carceration programs, including—

3                   “(A) specialized clinical case management;

4                   “(B) pre-trial services related to sub-  
5           stances use disorders, mental illness, and co-oc-  
6           curring mental illness and substance use dis-  
7           orders;

8                   “(C) prosecutor and defender based pro-  
9           grams;

10                  “(D) specialized probation;

11                  “(E) treatment and rehabilitation pro-  
12           grams; and

13                  “(F) problem-solving courts, including  
14           mental health courts, drug courts, co-occurring  
15           mental health and substance abuse courts, DWI  
16           courts, and veterans treatment courts.

17           “(c) APPLICATION.—

18                   “(1) IN GENERAL.—An eligible entity desiring a  
19           grant under this section shall submit an application  
20           to the Attorney General—

21                   “(A) that meets the criteria under para-  
22           graph (2); and

23                   “(B) at such time, in such manner, and  
24           accompanied by such information as the Attor-  
25           ney General may require.

1           “(2) CRITERIA.—An eligible entity, in submit-  
2           ting an application under paragraph (1), shall—

3                   “(A) provide extensive evidence of collabo-  
4                   ration with State and local government agencies  
5                   overseeing health, community corrections,  
6                   courts, prosecution, substance abuse, mental  
7                   health, victims services, and employment serv-  
8                   ices, and with local law enforcement agencies;

9                   “(B) demonstrate consultation with the  
10                  Single State Authority for Substance Abuse of  
11                  the State (as that term is defined in section  
12                  201(e) of the Second Chance Act of 2007);

13                  “(C) demonstrate that evidence-based  
14                  treatment practices will be utilized; and

15                  “(D) demonstrate that evidence-based  
16                  screening and assessment tools will be used to  
17                  place participants in the treatment alternative  
18                  to incarceration program.

19           “(d) REQUIREMENTS.—Each eligible entity awarded  
20 a grant for a treatment alternative to incarceration pro-  
21 gram under this section shall—

22                   “(1) determine the terms and conditions of par-  
23                   ticipation in the program by eligible participants,  
24                   taking into consideration the collateral consequences  
25                   of an arrest, prosecution or criminal conviction;

1           “(2) ensure that each substance abuse and  
2           mental health treatment component is licensed and  
3           qualified by the relevant jurisdiction;

4           “(3) for programs described in subsection  
5           (b)(2), organize an enforcement unit comprised of  
6           appropriately trained law enforcement professionals  
7           under the supervision of the State, Tribal, or local  
8           criminal justice agency involved, the duties of which  
9           shall include—

10           “(A) the verification of addresses and  
11           other contact information of each eligible par-  
12           ticipant who participates or desires to partici-  
13           pate in the program; and

14           “(B) if necessary, the location, apprehen-  
15           sion, arrest, and return to custody of an eligible  
16           participant in the program who has absconded  
17           from the facility of a treatment provider or has  
18           otherwise significantly violated the terms and  
19           conditions of the program, consistent with Fed-  
20           eral and State confidentiality requirements;

21           “(4) notify the relevant criminal justice entity if  
22           any eligible participant in the program absconds  
23           from the facility of the treatment provider or other-  
24           wise violates the terms and conditions of the pro-

1           gram, consistent with Federal and State confiden-  
2           tiality requirements;

3           “(5) submit periodic reports on the progress of  
4           treatment or other measured outcomes from partici-  
5           pation in the program of each eligible participant in  
6           the program to the relevant State, Tribal, or local  
7           criminal justice agency, including mental health  
8           courts, drug courts, co-occurring mental health and  
9           substance abuse courts, DWI courts, and veterans  
10          treatment courts;

11          “(6) describe the evidence-based methodology  
12          and outcome measurements that will be used to  
13          evaluate the program, and specifically explain how  
14          such measurements will provide valid measures of  
15          the impact of the program; and

16          “(7) describe how the program could be broadly  
17          replicated if demonstrated to be effective.

18          “(e) USE OF FUNDS.—An eligible entity shall use a  
19          grant received under this section for expenses of a treat-  
20          ment alternative to incarceration program, including—

21                 “(1) salaries, personnel costs, equipment costs,  
22                 and other costs directly related to the operation of  
23                 the program, including the enforcement unit;

24                 “(2) payments for treatment providers that are  
25                 approved by the relevant State or Tribal jurisdiction

1 and licensed, if necessary, to provide needed treat-  
2 ment to eligible offenders participating in the pro-  
3 gram, including aftercare supervision, vocational  
4 training, education, and job placement; and

5 “(3) payments to public and nonprofit private  
6 entities that are approved by the State or Tribal ju-  
7 risdiction and licensed, if necessary, to provide alco-  
8 hol and drug addiction treatment to eligible offend-  
9 ers participating in the program.

10 “(f) SUPPLEMENT NOT SUPPLANT.—An eligible enti-  
11 ty shall use Federal funds received under this section only  
12 to supplement the funds that would, in the absence of  
13 those Federal funds, be made available from other Federal  
14 and non-Federal sources for the activities described in this  
15 section, and not to supplant those funds. The Federal  
16 share of a grant made under this section may not exceed  
17 50 percent of the total costs of the program described in  
18 an application under subsection (d).

19 “(g) GEOGRAPHIC DISTRIBUTION.—The Attorney  
20 General shall ensure that, to the extent practicable, the  
21 geographical distribution of grants under this section is  
22 equitable and includes a grant to an eligible entity in—

23 “(1) each State;

24 “(2) rural, suburban, and urban areas; and

25 “(3) Tribal jurisdictions.

1       “(h) REPORTS AND EVALUATIONS.—Each fiscal  
2 year, each recipient of a grant under this section during  
3 that fiscal year shall submit to the Attorney General a  
4 report on the outcomes of activities carried out using that  
5 grant in such form, containing such information, and on  
6 such dates as the Attorney General shall specify.

7       “(i) ACCOUNTABILITY.—All grants awarded by the  
8 Attorney General under this section shall be subject to the  
9 following accountability provisions:

10           “(1) AUDIT REQUIREMENT.—

11                   “(A) DEFINITION.—In this paragraph, the  
12 term ‘unresolved audit finding’ means a finding  
13 in the final audit report of the Inspector Gen-  
14 eral of the Department of Justice that the au-  
15 dited grantee has utilized grant funds for an  
16 unauthorized expenditure or otherwise unallow-  
17 able cost that is not closed or resolved within  
18 12 months from the date on which the final  
19 audit report is issued.

20                   “(B) AUDITS.—Beginning in the first fis-  
21 cal year beginning after the date of enactment  
22 of this subsection, and in each fiscal year there-  
23 after, the Inspector General of the Department  
24 of Justice shall conduct audits of recipients of  
25 grants under this section to prevent waste,

1 fraud, and abuse of funds by grantees. The In-  
2 spector General shall determine the appropriate  
3 number of grantees to be audited each year.

4 “(C) MANDATORY EXCLUSION.—A recipi-  
5 ent of grant funds under this section that is  
6 found to have an unresolved audit finding shall  
7 not be eligible to receive grant funds under this  
8 section during the first 2 fiscal years beginning  
9 after the end of the 12-month period described  
10 in subparagraph (A).

11 “(D) PRIORITY.—In awarding grants  
12 under this section, the Attorney General shall  
13 give priority to eligible applicants that did not  
14 have an unresolved audit finding during the 3  
15 fiscal years before submitting an application for  
16 a grant under this section.

17 “(E) REIMBURSEMENT.—If an entity is  
18 awarded grant funds under this section during  
19 the 2-fiscal-year period during which the entity  
20 is barred from receiving grants under subpara-  
21 graph (C), the Attorney General shall—

22 “(i) deposit an amount equal to the  
23 amount of the grant funds that were im-  
24 properly awarded to the grantee into the  
25 General Fund of the Treasury; and



1                   “(ii) seek to recoup the costs of the  
2                   repayment to the fund from the grant re-  
3                   cipient that was erroneously awarded grant  
4                   funds.

5                   “(2) NONPROFIT ORGANIZATION REQUIRE-  
6                   MENTS.—

7                   “(A) DEFINITION.—For purposes of this  
8                   paragraph and the grant programs under this  
9                   part, the term ‘nonprofit organization’ means  
10                  an organization that is described in section  
11                  501(c)(3) of the Internal Revenue Code of 1986  
12                  and is exempt from taxation under section  
13                  501(a) of such Code.

14                  “(B) PROHIBITION.—The Attorney Gen-  
15                  eral may not award a grant under this part to  
16                  a nonprofit organization that holds money in  
17                  offshore accounts for the purpose of avoiding  
18                  paying the tax described in section 511(a) of  
19                  the Internal Revenue Code of 1986.

20                  “(C) DISCLOSURE.—Each nonprofit orga-  
21                  nization that is awarded a grant under this sec-  
22                  tion and uses the procedures prescribed in regu-  
23                  lations to create a rebuttable presumption of  
24                  reasonableness for the compensation of its offi-  
25                  cers, directors, trustees, and key employees,

1 shall disclose to the Attorney General, in the  
2 application for the grant, the process for deter-  
3 mining such compensation, including the inde-  
4 pendent persons involved in reviewing and ap-  
5 proving such compensation, the comparability  
6 data used, and contemporaneous substantiation  
7 of the deliberation and decision. Upon request,  
8 the Attorney General shall make the informa-  
9 tion disclosed under this subparagraph available  
10 for public inspection.

11 “(3) CONFERENCE EXPENDITURES.—

12 “(A) LIMITATION.—No amounts made  
13 available to the Department of Justice under  
14 this section may be used by the Attorney Gen-  
15 eral, or by any individual or entity awarded dis-  
16 cretionary funds through a cooperative agree-  
17 ment under this section, to host or support any  
18 expenditure for conferences that uses more than  
19 \$20,000 in funds made available by the Depart-  
20 ment of Justice, unless the head of the relevant  
21 agency or department, provides prior written  
22 authorization that the funds may be expended  
23 to host the conference.

24 “(B) WRITTEN APPROVAL.—Written ap-  
25 proval under subparagraph (A) shall include a

1 written estimate of all costs associated with the  
2 conference, including the cost of all food, bev-  
3 erages, audio-visual equipment, honoraria for  
4 speakers, and entertainment.

5 “(C) REPORT.—The Deputy Attorney Gen-  
6 eral shall submit an annual report to the Com-  
7 mittee on the Judiciary of the Senate and the  
8 Committee on the Judiciary of the House of  
9 Representatives on all conference expenditures  
10 approved under this paragraph.

11 “(4) ANNUAL CERTIFICATION.—Beginning in  
12 the first fiscal year beginning after the date of en-  
13 actment of this subsection, the Attorney General  
14 shall submit, to the Committee on the Judiciary and  
15 the Committee on Appropriations of the Senate and  
16 the Committee on the Judiciary and the Committee  
17 on Appropriations of the House of Representatives,  
18 an annual certification—

19 “(A) indicating whether—

20 “(i) all audits issued by the Office of  
21 the Inspector General under paragraph (1)  
22 have been completed and reviewed by the  
23 appropriate Assistant Attorney General or  
24 Director;

1                   “(ii) all mandatory exclusions required  
2                   under paragraph (1)(C) have been issued;  
3                   and

4                   “(iii) all reimbursements required  
5                   under paragraph (1)(E) have been made;  
6                   and

7                   “(B) that includes a list of any grant re-  
8                   cipients excluded under paragraph (1) from the  
9                   previous year.

10                  “(5) PREVENTING DUPLICATIVE GRANTS.—

11                   “(A) IN GENERAL.—Before the Attorney  
12                   General awards a grant to an applicant under  
13                   this section, the Attorney General shall compare  
14                   potential grant awards with other grants  
15                   awarded under this Act to determine if dupli-  
16                   cate grant awards are awarded for the same  
17                   purpose.

18                   “(B) REPORT.—If the Attorney General  
19                   awards duplicate grants to the same applicant  
20                   for the same purpose the Attorney General shall  
21                   submit to the Committee on the Judiciary of  
22                   the Senate and the Committee on the Judiciary  
23                   of the House of Representatives a report that  
24                   includes—

1                   “(i) a list of all duplicate grants  
2                   awarded, including the total dollar amount  
3                   of any duplicate grants awarded; and

4                   “(ii) the reason the Attorney General  
5                   awarded the duplicate grants.”.

6 **SEC. 14014. NATIONAL CRIMINAL JUSTICE AND MENTAL**  
7                   **HEALTH TRAINING AND TECHNICAL ASSIST-**  
8                   **ANCE.**

9                   Part HH of title I of the Omnibus Crime Control and  
10 Safe Streets Act of 1968 (42 U.S.C. 3797aa et seq.) is  
11 amended by adding at the end the following:

12 **“SEC. 2992. NATIONAL CRIMINAL JUSTICE AND MENTAL**  
13                   **HEALTH TRAINING AND TECHNICAL ASSIST-**  
14                   **ANCE.**

15                   “(a) **AUTHORITY.**—The Attorney General may make  
16 grants to eligible organizations to provide for the estab-  
17 lishment of a National Criminal Justice and Mental  
18 Health Training and Technical Assistance Center.

19                   “(b) **ELIGIBLE ORGANIZATION.**—For purposes of  
20 subsection (a), the term ‘eligible organization’ means a na-  
21 tional nonprofit organization that provides technical as-  
22 sistance and training to, and has special expertise and  
23 broad, national-level experience in, mental health, crisis  
24 intervention, criminal justice systems, law enforcement,  
25 translating evidence into practice, training, and research,

1 and education and support of people with mental illness  
2 and the families of such individuals.

3 “(c) USE OF FUNDS.—Any organization that receives  
4 a grant under subsection (a) shall collaborate with other  
5 grant recipients to establish and operate a National Crimi-  
6 nal Justice and Mental Health Training and Technical As-  
7 sistance Center to—

8 “(1) provide law enforcement officer training  
9 regarding mental health and working with individ-  
10 uals with mental illnesses, with an emphasis on de-  
11 escalation of encounters between law enforcement of-  
12 ficers and those with mental disorders or in crisis,  
13 which shall include support the development of in-  
14 person and technical information exchanges between  
15 systems and the individuals working in those sys-  
16 tems in support of the concepts identified in the  
17 training;

18 “(2) provide education, training, and technical  
19 assistance for States, Indian tribes, territories, units  
20 of local government, service providers, nonprofit or-  
21 ganizations, probation or parole officers, prosecu-  
22 tors, defense attorneys, emergency response pro-  
23 viders, and corrections institutions to advance prac-  
24 tice and knowledge relating to mental health crisis

1 and approaches to mental health and criminal jus-  
2 tice across systems;

3 “(3) provide training and best practices to men-  
4 tal health providers and criminal justice agencies re-  
5 lating to diversion initiatives, jail and prison strate-  
6 gies, reentry of individuals with mental illnesses into  
7 the community, and dispatch protocols and triage  
8 capabilities, including the establishment of learning  
9 sites;

10 “(4) develop suicide prevention and crisis inter-  
11 vention training and technical assistance for criminal  
12 justice agencies;

13 “(5) develop a receiving center system and pilot  
14 strategy that provides, for a jurisdiction, a single  
15 point of entry into the mental health and substance  
16 abuse system for assessments and appropriate place-  
17 ment of individuals experiencing a crisis;

18 “(6) collect data and best practices in mental  
19 health and criminal health and criminal justice ini-  
20 tiatives and policies from grantees under this part,  
21 other recipients of grants under this section, Fed-  
22 eral, State, and local agencies involved in the provi-  
23 sion of mental health services, and nongovernmental  
24 organizations involved in the provision of mental  
25 health services;

1           “(7) develop and disseminate to mental health  
2 providers and criminal justice agencies evaluation  
3 tools, mechanisms, and measures to better assess  
4 and document performance measures and outcomes  
5 relating to the provision of mental health services;

6           “(8) disseminate information to States, units of  
7 local government, criminal justice agencies, law en-  
8 forcement agencies, and other relevant entities about  
9 best practices, policy standards, and research find-  
10 ings relating to the provision of mental health serv-  
11 ices; and

12           “(9) provide education and support to individ-  
13 uals with mental illness involved with, or at risk of  
14 involvement with, the criminal justice system, includ-  
15 ing the families of such individuals.

16           “(d) ACCOUNTABILITY.—Grants awarded under this  
17 section shall be subject to the following accountability pro-  
18 visions:

19           “(1) AUDIT REQUIREMENT.—

20           “(A) DEFINITION.—In this paragraph, the  
21 term ‘unresolved audit finding’ means a finding  
22 in the final audit report of the Inspector Gen-  
23 eral of the Department of Justice under sub-  
24 paragraph (C) that the audited grantee has  
25 used grant funds for an unauthorized expendi-



1           ture or otherwise unallowable cost that is not  
2           closed or resolved within 1 year after the date  
3           on which the final audit report is issued.

4           “(B) AUDITS.—Beginning in the first fis-  
5           cal year beginning after the date of enactment  
6           of this section, and in each fiscal year there-  
7           after, the Inspector General of the Department  
8           of Justice shall conduct audits of grantees  
9           under this section to prevent waste, fraud, and  
10          abuse of funds by grantees. The Inspector Gen-  
11          eral shall determine the appropriate number of  
12          grantees to be audited each year.

13          “(C) FINAL AUDIT REPORT.—The Inspec-  
14          tor General of the Department of Justice shall  
15          submit to the Attorney General a final report  
16          on each audit conducted under subparagraph  
17          (B).

18          “(D) MANDATORY EXCLUSION.—Grantees  
19          under this section about which there is an unre-  
20          solved audit finding shall not be eligible to re-  
21          ceive a grant under this section during the 2  
22          fiscal years beginning after the end of the 1-  
23          year period described in subparagraph (A).

24          “(E) PRIORITY.—In making grants under  
25          this section, the Attorney General shall give pri-

1 ority to applicants that did not have an unre-  
2 solved audit finding during the 3 fiscal years  
3 before submitting an application for a grant  
4 under this section.

5 “(F) REIMBURSEMENT.—If an entity re-  
6 ceives a grant under this section during the 2-  
7 fiscal-year period during which the entity is  
8 prohibited from receiving grants under subpara-  
9 graph (D), the Attorney General shall—

10 “(i) deposit an amount equal to the  
11 amount of the grant that was improperly  
12 awarded to the grantee into the General  
13 Fund of the Treasury; and

14 “(ii) seek to recoup the costs of the  
15 repayment under clause (i) from the grant-  
16 ee that was erroneously awarded grant  
17 funds.

18 “(2) NONPROFIT AGENCY REQUIREMENTS.—

19 “(A) DEFINITION.—For purposes of this  
20 paragraph and the grant program under this  
21 section, the term ‘nonprofit agency’ means an  
22 organization that is described in section  
23 501(c)(3) of the Internal Revenue Code of 1986  
24 (26 U.S.C. 501(c)(3)) and is exempt from tax-

1           ation under section 501(a) of the Internal Rev-  
2           enue Code of 1986 (26 U.S.C. 501(a)).

3           “(B) PROHIBITION.—The Attorney Gen-  
4           eral may not award a grant under this section  
5           to a nonprofit agency that holds money in an  
6           offshore account for the purpose of avoiding  
7           paying the tax described in section 511(a) of  
8           the Internal Revenue Code of 1986 (26 U.S.C.  
9           511(a)).

10          “(C) DISCLOSURE.—Each nonprofit agen-  
11          cy that is awarded a grant under this section  
12          and uses the procedures prescribed in regula-  
13          tions to create a rebuttable presumption of rea-  
14          sonableness for the compensation of its officers,  
15          directors, trustees, and key employees, shall dis-  
16          close to the Attorney General, in the application  
17          for the grant, the process for determining such  
18          compensation, including the independent per-  
19          sons involved in reviewing and approving such  
20          compensation, the comparability data used, and  
21          contemporaneous substantiation of the delibera-  
22          tion and decision. Upon request, the Attorney  
23          General shall make the information disclosed  
24          under this subparagraph available for public in-  
25          spection.

1           “(3) CONFERENCE EXPENDITURES.—

2           “(A) LIMITATION.—No amounts made  
3 available to the Department of Justice under  
4 this section may be used by the Attorney Gen-  
5 eral, or by any individual or entity awarded dis-  
6 cretionary funds through a cooperative agree-  
7 ment under this section, to host or support any  
8 expenditure for conferences that uses more than  
9 \$20,000 in funds made available by the Depart-  
10 ment of Justice, unless the head of the relevant  
11 agency or department, provides prior written  
12 authorization that the funds may be expended  
13 to host the conference.

14           “(B) WRITTEN APPROVAL.—Written ap-  
15 proval under subparagraph (A) shall include a  
16 written estimate of all costs associated with the  
17 conference, including the cost of all food, bev-  
18 erages, audio-visual equipment, honoraria for  
19 speakers, and entertainment.

20           “(C) REPORT.—The Deputy Attorney Gen-  
21 eral shall submit an annual report to the Com-  
22 mittee on the Judiciary of the Senate and the  
23 Committee on the Judiciary of the House of  
24 Representatives on all conference expenditures  
25 approved under this paragraph.

1           “(4) ANNUAL CERTIFICATION.—Beginning in  
2           the first fiscal year beginning after the date of en-  
3           actment of this subsection, the Attorney General  
4           shall submit to the Committee on the Judiciary and  
5           the Committee on Appropriations of the Senate and  
6           the Committee on the Judiciary and the Committee  
7           on Appropriations of the House of Representatives  
8           an annual certification—

9                   “(A) indicating whether—

10                           “(i) all final audit reports issued by  
11                           the Office of the Inspector General under  
12                           paragraph (1) have been completed and re-  
13                           viewed by the appropriate Assistant Attor-  
14                           ney General or Director;

15                           “(ii) all mandatory exclusions required  
16                           under paragraph (1)(D) have been issued;  
17                           and

18                           “(iii) any reimbursements required  
19                           under paragraph (1)(F) have been made;  
20                           and

21                           “(B) that includes a list of any grantees  
22                           excluded under paragraph (1)(D) from the pre-  
23                           vious year.

24                           “(5) PREVENTING DUPLICATIVE GRANTS.—

1           “(A) IN GENERAL.—Before the Attorney  
2           General awards a grant to an applicant under  
3           this section, the Attorney General shall compare  
4           potential grant awards with other grants  
5           awarded under this Act to determine if dupli-  
6           cate grant awards are awarded for the same  
7           purpose.

8           “(B) REPORT.—If the Attorney General  
9           awards duplicate grants to the same applicant  
10          for the same purpose the Attorney General shall  
11          submit to the Committee on the Judiciary of  
12          the Senate and the Committee on the Judiciary  
13          of the House of Representatives a report that  
14          includes—

15                 “(i) a list of all duplicate grants  
16                 awarded, including the total dollar amount  
17                 of any duplicate grants awarded; and

18                 “(ii) the reason the Attorney General  
19                 awarded the duplicate grants.”.

20 **SEC. 14015. IMPROVING DEPARTMENT OF JUSTICE DATA**  
21 **COLLECTION ON MENTAL ILLNESS INVOLVED**  
22 **IN CRIME.**

23          (a) IN GENERAL.—Notwithstanding any other provi-  
24          sion of law, on or after the date that is 90 days after the  
25          date on which the Attorney General promulgates regula-

1 tions under subsection (b), any data prepared by, or sub-  
2 mitted to, the Attorney General or the Director of the  
3 Federal Bureau of Investigation with respect to the  
4 incidences of homicides, law enforcement officers killed,  
5 seriously injured, and assaulted, or individuals killed or  
6 seriously injured by law enforcement officers shall include  
7 data with respect to the involvement of mental illness in  
8 such incidences, if any.

9 (b) REGULATIONS.—Not later than 90 days after the  
10 date of the enactment of this Act, the Attorney General  
11 shall promulgate or revise regulations as necessary to  
12 carry out subsection (a).

13 **SEC. 14016. REPORTS ON THE NUMBER OF MENTALLY ILL**  
14 **OFFENDERS IN PRISON.**

15 (a) REPORT ON THE COST OF TREATING THE MEN-  
16 TALLY ILL IN THE CRIMINAL JUSTICE SYSTEM.—Not  
17 later than 12 months after the date of enactment of this  
18 Act, the Comptroller General of the United States shall  
19 submit to Congress a report detailing the cost of imprison-  
20 ment for individuals who have serious mental illness by  
21 the Federal Government or a State or unit of local govern-  
22 ment, which shall include—

23 (1) the number and type of crimes committed  
24 by individuals with serious mental illness each year;  
25 and

1           (2) detail strategies or ideas for preventing  
2 crimes by those individuals with serious mental ill-  
3 ness from occurring.

4           (b) DEFINITION.—For purposes of this section, the  
5 Attorney General, in consultation with the Assistant Sec-  
6 retary of Mental Health and Substance Use Disorders,  
7 shall define “serious mental illness” based on the “Health  
8 Care Reform for Americans with Severe Mental Illnesses:  
9 Report” of the National Advisory Mental Health Council,  
10 American Journal of Psychiatry 1993; 150:1447–1465.

11 **SEC. 14017. DEPARTMENT OF VETERANS AFFAIRS PA-**  
12 **TIENTS’ RIGHTS.**

13           (a) IN GENERAL.—Chapter 55 of title 38, United  
14 States Code, is amended by adding at the end the fol-  
15 lowing new section:

16 **“§ 5511. Limitation on determinations regarding men-**  
17 **tal competence of individuals**

18           “(a) IN GENERAL.—The Secretary may not make an  
19 adjudicative determination concerning the mental capacity  
20 of an individual unless such individual has been provided  
21 all of the following:

22                   “(1) Notice of the proposed determination.

23                   “(2) An opportunity to request a hearing.



1           “(3) An opportunity to request the opinion or  
2           presence of a medical professional at any such hear-  
3           ing.

4           “(4) An opportunity to be represented (includ-  
5           ing by counsel) at any such hearing.

6           “(b) APPEAL.—A determination of incompetency by  
7           the Secretary under subsection (a) may be appealed in ac-  
8           cordance with the provisions of chapters 71 and 72 of this  
9           title.”.

10          (b) CLERICAL AMENDMENT.—The table of sections  
11          at the beginning of chapter 55 of such title is amended  
12          by adding at the end the following new item:

          “5511. Limitation on determinations regarding mental competence of individ-  
          uals.”.

13          **SEC. 14018. REAUTHORIZATION OF APPROPRIATIONS.**

14          Subsection (o) of section 2991 of the Omnibus Crime  
15          Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa),  
16          as redesignated by section 14006, is amended—

17                 (1) in paragraph (1)(C), by striking “2009  
18                 through 2014” and inserting “2017 through 2021”;  
19                 and

20                 (2) by adding at the end the following:

21                 “(3) LIMITATION.—Not more than 20 percent of the  
22                 funds authorized to be appropriated under this section  
23                 may be used for purposes described in subsection (i) (re-  
24                 lating to veterans).”.

1 **Subtitle B—Comprehensive Justice**  
2 **and Mental Health**

3 **SEC. 14021. SEQUENTIAL INTERCEPT MODEL.**

4 Section 2991 of title I of the Omnibus Crime Control  
5 and Safe Streets Act of 1968 (42 U.S.C. 3797aa), as  
6 amended by section 14005, is amended by inserting after  
7 subsection (j), the following:

8 “(k) SEQUENTIAL INTERCEPT GRANTS.—

9 “(1) DEFINITION.—In this subsection, the term  
10 ‘eligible entity’ means a State, unit of local govern-  
11 ment, Indian tribe, or tribal organization.

12 “(2) AUTHORIZATION.—The Attorney General  
13 may make grants under this subsection to an eligible  
14 entity for sequential intercept mapping and imple-  
15 mentation in accordance with paragraph (3).

16 “(3) SEQUENTIAL INTERCEPT MAPPING; IMPLE-  
17 MENTATION.—An eligible entity that receives a  
18 grant under this subsection may use funds for—

19 “(A) sequential intercept mapping,  
20 which—

21 “(i) shall consist of—

22 “(I) convening mental health and  
23 criminal justice stakeholders to—

24 “(aa) develop a shared un-  
25 derstanding of the flow of justice-

1 involved individuals with mental  
2 illnesses through the criminal  
3 justice system; and

4 “(bb) identify opportunities  
5 for improved collaborative re-  
6 sponses to the risks and needs of  
7 individuals described in item  
8 (aa); and

9 “(II) developing strategies to ad-  
10 dress gaps in services and bring inno-  
11 vative and effective programs to scale  
12 along multiple intercepts, including—

13 “(aa) emergency and crisis  
14 services;

15 “(bb) specialized police-  
16 based responses;

17 “(cc) court hearings and dis-  
18 position alternatives;

19 “(dd) reentry from jails and  
20 prisons; and

21 “(ee) community super-  
22 vision, treatment and support  
23 services; and

24 “(ii) may serve as a starting point for  
25 the development of strategic plans to

1 achieve positive public health and safety  
2 outcomes; and

3 “(B) implementation, which shall—

4 “(i) be derived from the strategic  
5 plans described in subparagraph (A)(ii);  
6 and

7 “(ii) consist of—

8 “(I) hiring and training per-  
9 sonnel;

10 “(II) identifying the eligible enti-  
11 ty’s target population;

12 “(III) providing services and sup-  
13 ports to reduce unnecessary penetra-  
14 tion into the criminal justice system;

15 “(IV) reducing recidivism;

16 “(V) evaluating the impact of the  
17 eligible entity’s approach; and

18 “(VI) planning for the sustain-  
19 ability of effective interventions.”.

20 **SEC. 14022. PRISON AND JAILS.**

21 Section 2991 of title I of the Omnibus Crime Control  
22 and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is  
23 amended by inserting after subsection (k), as added by  
24 section 14021, the following:

25 “(l) CORRECTIONAL FACILITIES.—

1 “(1) DEFINITIONS.—

2 “(A) CORRECTIONAL FACILITY.—The term  
3 ‘correctional facility’ means a jail, prison, or  
4 other detention facility used to house people  
5 who have been arrested, detained, held, or con-  
6 victed by a criminal justice agency or a court.

7 “(B) ELIGIBLE INMATE.—The term ‘eligi-  
8 ble inmate’ means an individual who—

9 “(i) is being held, detained, or incar-  
10 cerated in a correctional facility; and

11 “(ii) manifests obvious signs of a  
12 mental illness or has been diagnosed by a  
13 qualified mental health professional as hav-  
14 ing a mental illness.

15 “(2) CORRECTIONAL FACILITY GRANTS.—The  
16 Attorney General may award grants to applicants to  
17 enhance the capabilities of a correctional facility—

18 “(A) to identify and screen for eligible in-  
19 mates;

20 “(B) to plan and provide—

21 “(i) initial and periodic assessments of  
22 the clinical, medical, and social needs of in-  
23 mates; and

1                   “(ii) appropriate treatment and serv-  
2                   ices that address the mental health and  
3                   substance abuse needs of inmates;

4                   “(C) to develop, implement, and enhance—

5                   “(i) post-release transition plans for  
6                   eligible inmates that, in a comprehensive  
7                   manner, coordinate health, housing, med-  
8                   ical, employment, and other appropriate  
9                   services and public benefits;

10                   “(ii) the availability of mental health  
11                   care services and substance abuse treat-  
12                   ment services; and

13                   “(iii) alternatives to solitary confine-  
14                   ment and segregated housing and mental  
15                   health screening and treatment for inmates  
16                   placed in solitary confinement or seg-  
17                   regated housing; and

18                   “(D) to train each employee of the correc-  
19                   tional facility to identify and appropriately re-  
20                   spond to incidents involving inmates with men-  
21                   tal health or co-occurring mental health and  
22                   substance abuse disorders.”.

23 **SEC. 14023. ALLOWABLE USES.**

24                   Section 2991(b)(5)(I) of title I of the Omnibus Crime  
25                   Control and Safe Streets Act of 1968 (42 U.S.C.

1 3797aa(b)(5)(I) is amended by adding at the end the fol-  
2 lowing:

3 “(v) TEAMS ADDRESSING FREQUENT  
4 USERS OF CRISIS SERVICES.—Multidisci-  
5 plinary teams that—

6 “(I) coordinate, implement, and  
7 administer community-based crisis re-  
8 sponses and long-term plans for fre-  
9 quent users of crisis services;

10 “(II) provide training on how to  
11 respond appropriately to the unique  
12 issues involving frequent users of cri-  
13 sis services for public service per-  
14 sonnel, including criminal justice,  
15 mental health, substance abuse, emer-  
16 gency room, healthcare, law enforce-  
17 ment, corrections, and housing per-  
18 sonnel;

19 “(III) develop or support alter-  
20 natives to hospital and jail admissions  
21 for frequent users of crisis services  
22 that provide treatment, stabilization,  
23 and other appropriate supports in the  
24 least restrictive, yet appropriate, envi-  
25 ronment; and

1                   “(IV) develop protocols and sys-  
2                   tems among law enforcement, mental  
3                   health, substance abuse, housing, cor-  
4                   rections, and emergency medical serv-  
5                   ice operations to provide coordinated  
6                   assistance to frequent users of crisis  
7                   services.”.

8   **SEC. 14024. LAW ENFORCEMENT TRAINING.**

9           Section 2991(h) of title I of the Omnibus Crime Con-  
10   trol and Safe Streets Act of 1968 (42 U.S.C. 3797aa(h))  
11   is amended—

12                   (1) in paragraph (1), by adding at the end the  
13   following:

14                   “(F) **ACADEMY TRAINING.**—To provide  
15                   support for academy curricula, law enforcement  
16                   officer orientation programs, continuing edu-  
17                   cation training, and other programs that teach  
18                   law enforcement personnel how to identify and  
19                   respond to incidents involving persons with  
20                   mental health disorders or co-occurring mental  
21                   health and substance abuse disorders.”; and

22                   (2) by adding at the end the following:

23                   “(4) **PRIORITY CONSIDERATION.**—The Attorney  
24   General, in awarding grants under this subsection,  
25   shall give priority to programs that law enforcement



1 personnel and members of the mental health and  
2 substance abuse professions develop and administer  
3 cooperatively.”.

4 **SEC. 14025. FEDERAL LAW ENFORCEMENT TRAINING.**

5 Not later than 1 year after the date of enactment  
6 of this Act, the Attorney General shall provide direction  
7 and guidance for the following:

8 (1) TRAINING PROGRAMS.—Programs that offer  
9 specialized and comprehensive training, in proce-  
10 dures to identify and appropriately respond to inci-  
11 dents in which the unique needs of individuals who  
12 have a mental illness are involved, to first respond-  
13 ers and tactical units of—

14 (A) Federal law enforcement agencies; and

15 (B) other Federal criminal justice agencies  
16 such as the Bureau of Prisons, the Administra-  
17 tive Office of the United States Courts, and  
18 other agencies that the Attorney General deter-  
19 mines appropriate.

20 (2) IMPROVED TECHNOLOGY.—The establish-  
21 ment of, or improvement of existing, computerized  
22 information systems to provide timely information to  
23 employees of Federal law enforcement agencies, and  
24 Federal criminal justice agencies to improve the re-

1        sponse of such employees to situations involving in-  
2        dividuals who have a mental illness.

3        **SEC. 14026. GAO REPORT.**

4        No later than 1 year after the date of enactment of  
5        this Act, the Comptroller General of the United States,  
6        in coordination with the Attorney General, shall submit  
7        to Congress a report on—

8                (1) the practices that Federal first responders,  
9                tactical units, and corrections officers are trained to  
10              use in responding to individuals with mental illness;

11              (2) procedures to identify and appropriately re-  
12              spond to incidents in which the unique needs of indi-  
13              viduals who have a mental illness are involved, to  
14              Federal first responders and tactical units;

15              (3) the application of evidence-based practices  
16              in criminal justice settings to better address individ-  
17              uals with mental illnesses; and

18              (4) recommendations on how the Department of  
19              Justice can expand and improve information sharing  
20              and dissemination of best practices.

21        **SEC. 14027. EVIDENCE BASED PRACTICES.**

22        Section 2991(c) of title I of the Omnibus Crime Con-  
23        trol and Safe Streets Act of 1968 (42 U.S.C. 3797aa(e))  
24        is amended—

1 (1) in paragraph (3), by striking “or” at the  
2 end;

3 (2) by redesignating paragraph (4) as para-  
4 graph (6); and

5 (3) by inserting after paragraph (3), the fol-  
6 lowing:

7 “(4) propose interventions that have been  
8 shown by empirical evidence to reduce recidivism;

9 “(5) when appropriate, use validated assess-  
10 ment tools to target preliminarily qualified offenders  
11 with a moderate or high risk of recidivism and a  
12 need for treatment and services; or”.

13 **SEC. 14028. TRANSPARENCY, PROGRAM ACCOUNTABILITY,**  
14 **AND ENHANCEMENT OF LOCAL AUTHORITY.**

15 (a) IN GENERAL.—Section 2991(a) of title I of the  
16 Omnibus Crime Control and Safe Streets Act of 1968 (42  
17 U.S.C. 3797aa(a)) is amended—

18 (1) in paragraph (7)—

19 (A) in the heading, by striking “MENTAL  
20 ILLNESS” and inserting “MENTAL ILLNESS;  
21 MENTAL HEALTH DISORDER”; and

22 (B) by striking “term ‘mental illness’  
23 means” and inserting “terms ‘mental illness’  
24 and ‘mental health disorder’ mean”; and

1           (2) by striking paragraph (9) and inserting the  
2 following:

3           “(9) PRELIMINARILY QUALIFIED OFFENDER.—

4           “(A) IN GENERAL.—The term ‘prelimi-  
5 narily qualified offender’ means an adult or ju-  
6 venile accused of an offense who—

7           “(i)(I) previously or currently has  
8 been diagnosed by a qualified mental  
9 health professional as having a mental ill-  
10 ness or co-occurring mental illness and  
11 substance abuse disorders;

12           “(II) manifests obvious signs of men-  
13 tal illness or co-occurring mental illness  
14 and substance abuse disorders during ar-  
15 rest or confinement or before any court; or

16           “(III) in the case of a veterans treat-  
17 ment court provided under subsection (i),  
18 has been diagnosed with, or manifests ob-  
19 vious signs of, mental illness or a sub-  
20 stance abuse disorder or co-occurring men-  
21 tal illness and substance abuse disorder;

22           “(ii) has been unanimously approved  
23 for participation in a program funded  
24 under this section by, when appropriate—

25           “(I) the relevant—

1                   “(aa) prosecuting attorney;  
2                   “(bb) defense attorney;  
3                   “(cc) probation or correc-  
4                   tions official; and  
5                   “(dd) judge; and  
6                   “(II) a representative from the  
7                   relevant mental health agency de-  
8                   scribed in subsection (b)(5)(B)(i);  
9                   “(iii) has been determined, by each  
10                  person described in clause (ii) who is in-  
11                  volved in approving the adult or juvenile  
12                  for participation in a program funded  
13                  under this section, to not pose a risk of vi-  
14                  olence to any person in the program, or  
15                  the public, if selected to participate in the  
16                  program; and  
17                  “(iv) has not been charged with or  
18                  convicted of—  
19                  “(I) any sex offense (as defined  
20                  in section 111 of the Sex Offender  
21                  Registration and Notification Act (42  
22                  U.S.C. 16911)) or any offense relat-  
23                  ing to the sexual exploitation of chil-  
24                  dren; or

1                   “(II) murder or assault with in-  
2                   tent to commit murder.

3                   “(B) DETERMINATION.—In determining  
4                   whether to designate a defendant as a prelimi-  
5                   narily qualified offender, the relevant pros-  
6                   ecuting attorney, defense attorney, probation or  
7                   corrections official, judge, and mental health or  
8                   substance abuse agency representative shall  
9                   take into account—

10                   “(i) whether the participation of the  
11                   defendant in the program would pose a  
12                   substantial risk of violence to the commu-  
13                   nity;

14                   “(ii) the criminal history of the de-  
15                   fendant and the nature and severity of the  
16                   offense for which the defendant is charged;

17                   “(iii) the views of any relevant victims  
18                   to the offense;

19                   “(iv) the extent to which the defend-  
20                   ant would benefit from participation in the  
21                   program;

22                   “(v) the extent to which the commu-  
23                   nity would realize cost savings because of  
24                   the defendant’s participation in the pro-  
25                   gram; and

1           “(vi) whether the defendant satisfies  
2           the eligibility criteria for program partici-  
3           pation unanimously established by the rel-  
4           evant prosecuting attorney, defense attor-  
5           ney, probation or corrections official, judge  
6           and mental health or substance abuse  
7           agency representative.”.

8           (b) TECHNICAL AND CONFORMING AMENDMENT.—  
9           Section 2927(2) of title I of the Omnibus Crime Control  
10          and Safe Streets Act of 1968 (42 U.S.C. 3797s–6(2)) is  
11          amended by striking “has the meaning given that term  
12          in section 2991(a).” and inserting “means an offense  
13          that—

14                       “(A) does not have as an element the use,  
15                       attempted use, or threatened use of physical  
16                       force against the person or property of another;  
17                       or

18                       “(B) is not a felony that by its nature in-  
19                       volves a substantial risk that physical force  
20                       against the person or property of another may  
21                       be used in the course of committing the of-  
22                       fense.”.

23          **SEC. 14029. GRANT ACCOUNTABILITY.**

24          Section 2991 of title I of the Omnibus Crime Control  
25          and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is

1 amended by inserting after subsection (l), as added by sec-  
2 tion 14022, the following:

3 “(m) ACCOUNTABILITY.—All grants awarded by the  
4 Attorney General under this section shall be subject to the  
5 following accountability provisions:

6 “(1) AUDIT REQUIREMENT.—

7 “(A) DEFINITION.—In this paragraph, the  
8 term ‘unresolved audit finding’ means a finding  
9 in the final audit report of the Inspector Gen-  
10 eral of the Department of Justice that the au-  
11 dited grantee has utilized grant funds for an  
12 unauthorized expenditure or otherwise unallow-  
13 able cost that is not closed or resolved within  
14 12 months from the date when the final audit  
15 report is issued.

16 “(B) AUDITS.—Beginning in the first fis-  
17 cal year beginning after the date of enactment  
18 of this subsection, and in each fiscal year there-  
19 after, the Inspector General of the Department  
20 of Justice shall conduct audits of recipients of  
21 grants under this section to prevent waste,  
22 fraud, and abuse of funds by grantees. The In-  
23 spector General shall determine the appropriate  
24 number of grantees to be audited each year.



1           “(C) MANDATORY EXCLUSION.—A recipi-  
2           ent of grant funds under this section that is  
3           found to have an unresolved audit finding shall  
4           not be eligible to receive grant funds under this  
5           section during the first 2 fiscal years beginning  
6           after the end of the 12-month period described  
7           in subparagraph (A).

8           “(D) PRIORITY.—In awarding grants  
9           under this section, the Attorney General shall  
10          give priority to eligible applicants that did not  
11          have an unresolved audit finding during the 3  
12          fiscal years before submitting an application for  
13          a grant under this section.

14          “(E) REIMBURSEMENT.—If an entity is  
15          awarded grant funds under this section during  
16          the 2-fiscal-year period during which the entity  
17          is barred from receiving grants under subpara-  
18          graph (C), the Attorney General shall—

19                 “(i) deposit an amount equal to the  
20                 amount of the grant funds that were im-  
21                 properly awarded to the grantee into the  
22                 General Fund of the Treasury; and

23                 “(ii) seek to recoup the costs of the  
24                 repayment to the fund from the grant re-

1                   cipient that was erroneously awarded grant  
2                   funds.

3                   “(2) NONPROFIT ORGANIZATION REQUIRE-  
4                   MENTS.—

5                   “(A) DEFINITION.—For purposes of this  
6                   paragraph and the grant programs under this  
7                   part, the term ‘nonprofit organization’ means  
8                   an organization that is described in section  
9                   501(c)(3) of the Internal Revenue Code of 1986  
10                  and is exempt from taxation under section  
11                  501(a) of such Code.

12                  “(B) PROHIBITION.—The Attorney Gen-  
13                  eral may not award a grant under this part to  
14                  a nonprofit organization that holds money in  
15                  offshore accounts for the purpose of avoiding  
16                  paying the tax described in section 511(a) of  
17                  the Internal Revenue Code of 1986.

18                  “(C) DISCLOSURE.—Each nonprofit orga-  
19                  nization that is awarded a grant under this sec-  
20                  tion and uses the procedures prescribed in regu-  
21                  lations to create a rebuttable presumption of  
22                  reasonableness for the compensation of its offi-  
23                  cers, directors, trustees, and key employees,  
24                  shall disclose to the Attorney General, in the  
25                  application for the grant, the process for deter-

1           mining such compensation, including the inde-  
2           pendent persons involved in reviewing and ap-  
3           proving such compensation, the comparability  
4           data used, and contemporaneous substantiation  
5           of the deliberation and decision. Upon request,  
6           the Attorney General shall make the informa-  
7           tion disclosed under this subparagraph available  
8           for public inspection.

9           “(3) CONFERENCE EXPENDITURES.—

10           “(A) LIMITATION.—No amounts made  
11           available to the Department of Justice under  
12           this section may be used by the Attorney Gen-  
13           eral, or by any individual or entity awarded dis-  
14           cretionary funds through a cooperative agree-  
15           ment under this section, to host or support any  
16           expenditure for conferences that uses more than  
17           \$20,000 in funds made available by the Depart-  
18           ment of Justice, unless the head of the relevant  
19           agency or department, provides prior written  
20           authorization that the funds may be expended  
21           to host the conference.

22           “(B) WRITTEN APPROVAL.—Written ap-  
23           proval under subparagraph (A) shall include a  
24           written estimate of all costs associated with the  
25           conference, including the cost of all food, bev-

1 erages, audio-visual equipment, honoraria for  
2 speakers, and entertainment.

3 “(C) REPORT.—The Deputy Attorney Gen-  
4 eral shall submit an annual report to the Com-  
5 mittee on the Judiciary of the Senate and the  
6 Committee on the Judiciary of the House of  
7 Representatives on all conference expenditures  
8 approved under this paragraph.

9 “(4) ANNUAL CERTIFICATION.—Beginning in  
10 the first fiscal year beginning after the date of en-  
11 actment of this subsection, the Attorney General  
12 shall submit, to the Committee on the Judiciary and  
13 the Committee on Appropriations of the Senate and  
14 the Committee on the Judiciary and the Committee  
15 on Appropriations of the House of Representatives,  
16 an annual certification—

17 “(A) indicating whether—

18 “(i) all audits issued by the Office of  
19 the Inspector General under paragraph (1)  
20 have been completed and reviewed by the  
21 appropriate Assistant Attorney General or  
22 Director;

23 “(ii) all mandatory exclusions required  
24 under paragraph (1)(C) have been issued;  
25 and

1                   “(iii) all reimbursements required  
2                   under paragraph (1)(E) have been made;  
3                   and

4                   “(B) that includes a list of any grant re-  
5                   cipients excluded under paragraph (1) from the  
6                   previous year.

7                   “(n) PREVENTING DUPLICATIVE GRANTS.—

8                   “(1) IN GENERAL.—Before the Attorney Gen-  
9                   eral awards a grant to an applicant under this sec-  
10                  tion, the Attorney General shall compare potential  
11                  grant awards with other grants awarded under this  
12                  Act to determine if duplicate grant awards are  
13                  awarded for the same purpose.

14                  “(2) REPORT.—If the Attorney General awards  
15                  duplicate grants to the same applicant for the same  
16                  purpose the Attorney General shall submit to the  
17                  Committee on the Judiciary of the Senate and the  
18                  Committee on the Judiciary of the House of Rep-  
19                  resentatives a report that includes—

20                         “(A) a list of all duplicate grants awarded,  
21                         including the total dollar amount of any dupli-  
22                         cate grants awarded; and

23                         “(B) the reason the Attorney General  
24                         awarded the duplicate grants.”.

1 **DIVISION C—INCREASING**  
2 **CHOICE, ACCESS, AND QUAL-**  
3 **ITY IN HEALTH CARE FOR**  
4 **AMERICANS**

5 **SEC. 15000. SHORT TITLE.**

6 This division may be cited as the “Increasing Choice,  
7 Access, and Quality in Health Care for Americans Act”.

8 **TITLE XV—PROVISIONS RELAT-**  
9 **ING TO MEDICARE PART A**

10 **SEC. 15001. DEVELOPMENT OF MEDICARE HCPCS VERSION**  
11 **OF MS-DRG CODES FOR SIMILAR HOSPITAL**  
12 **SERVICES.**

13 Section 1886 of the Social Security Act (42 U.S.C.  
14 1395ww) is amended by adding at the end the following  
15 new subsection:

16 “(t) RELATING SIMILAR INPATIENT AND OUT-  
17 PATIENT HOSPITAL SERVICES.—

18 “(1) DEVELOPMENT OF HCPCS VERSION OF  
19 MS-DRG CODES.—Not later than January 1, 2018,  
20 the Secretary shall develop HCPCS versions for  
21 MS-DRGs that are similar to the ICD-10-PCS for  
22 such MS-DRGs such that, to the extent possible,  
23 the MS-DRG assignment shall be similar for a  
24 claim coded with the HCPCS version as an identical  
25 claim coded with a ICD-10-PCS code.

1           “(2) COVERAGE OF SURGICAL MS-DRGS.—In  
2 carrying out paragraph (1), the Secretary shall de-  
3 velop HCPCS versions of MS-DRG codes for not  
4 fewer than 10 surgical MS-DRGs.

5           “(3) PUBLICATION AND DISSEMINATION OF  
6 THE HCPCS VERSIONS OF MS-DRGS.—

7           “(A) IN GENERAL.—The Secretary shall  
8 develop a HCPCS MS-DRG definitions manual  
9 and software that is similar to the definitions  
10 manual and software for ICD-10-PCS codes  
11 for such MS-DRGs. The Secretary shall post  
12 the HCPCS MS-DRG definitions manual and  
13 software on the Internet website of the Centers  
14 for Medicare & Medicaid Services. The HCPCS  
15 MS-DRG definitions manual and software shall  
16 be in the public domain and available for use  
17 and redistribution without charge.

18           “(B) USE OF PREVIOUS ANALYSIS DONE  
19 BY MEDPAC.—In developing the HCPCS MS-  
20 DRG definitions manual and software under  
21 subparagraph (A), the Secretary shall consult  
22 with the Medicare Payment Advisory Commis-  
23 sion and shall consider the analysis done by  
24 such Commission in translating outpatient sur-  
25 gical claims into inpatient surgical MS-DRGs

1 in preparing chapter 7 (relating to hospital  
2 short-stay policy issues) of its ‘Medicare and  
3 the Health Care Delivery System’ report sub-  
4 mitted to Congress in June 2015.

5 “(4) DEFINITION AND REFERENCE.—In this  
6 subsection:

7 “(A) HCPCS.—The term ‘HCPCS’ means,  
8 with respect to hospital items and services, the  
9 code under the Healthcare Common Procedure  
10 Coding System (HCPCS) (or a successor code)  
11 for such items and services.

12 “(B) ICD–10–PCS.—The term ‘ICD–10–  
13 PCS’ means the International Classification of  
14 Diseases, 10th Revision, Procedure Coding Sys-  
15 tem, and includes any subsequent revision of  
16 such International Classification of Diseases,  
17 Procedure Coding System.”.

18 **SEC. 15002. ESTABLISHING BENEFICIARY EQUITY IN THE**  
19 **MEDICARE HOSPITAL READMISSION PRO-**  
20 **GRAM.**

21 (a) TRANSITIONAL ADJUSTMENT FOR DUAL ELIGI-  
22 BLE POPULATION.—Section 1886(q)(3) of the Social Se-  
23 curity Act (42 U.S.C. 1395ww(q)(3)) is amended—



1           (1) in subparagraph (A), by inserting “subject  
2           to subparagraph (D),” after “purposes of paragraph  
3           (1),”; and

4           (2) by adding at the end the following new sub-  
5           paragraph:

6                   “(D) TRANSITIONAL ADJUSTMENT FOR  
7                   DUAL ELIGIBLES.—

8                           “(i) IN GENERAL.—In determining a  
9                           hospital’s adjustment factor under this  
10                           paragraph for purposes of making pay-  
11                           ments for discharges occurring during and  
12                           after fiscal year 2019, and before the ap-  
13                           plication of clause (i) of subparagraph (E),  
14                           the Secretary shall assign hospitals to  
15                           groups (as defined by the Secretary under  
16                           clause (ii)) and apply the applicable provi-  
17                           sions of this subsection using a method-  
18                           ology in a manner that allows for separate  
19                           comparison of hospitals within each such  
20                           group, as determined by the Secretary.

21                           “(ii) DEFINING GROUPS.—For pur-  
22                           poses of this subparagraph, the Secretary  
23                           shall define groups of hospitals, based on  
24                           their overall proportion, of the inpatients  
25                           who are entitled to, or enrolled for, bene-

1 fits under part A, and who are full-benefit  
2 dual eligible individuals (as defined in sec-  
3 tion 1935(c)(6)). In defining groups, the  
4 Secretary shall consult the Medicare Pay-  
5 ment Advisory Commission and may con-  
6 sider the analysis done by such Commis-  
7 sion in preparing the portion of its report  
8 submitted to Congress in June 2013 relat-  
9 ing to readmissions.

10 “(iii) MINIMIZING REPORTING BUR-  
11 DEN ON HOSPITALS.—In carrying out this  
12 subparagraph, the Secretary shall not im-  
13 pose any additional reporting requirements  
14 on hospitals.

15 “(iv) BUDGET NEUTRAL DESIGN  
16 METHODOLOGY.—The Secretary shall de-  
17 sign the methodology to implement this  
18 subparagraph so that the estimated total  
19 amount of reductions in payments under  
20 this subsection equals the estimated total  
21 amount of reductions in payments that  
22 would otherwise occur under this sub-  
23 section if this subparagraph did not  
24 apply.”.

1 (b) CHANGES IN RISK ADJUSTMENT.—Section  
2 1886(q)(3) of the Social Security Act (42 U.S.C.  
3 1395ww(q)(3)), as amended by subsection (a), is further  
4 amended by adding at the end the following new subpara-  
5 graph:

6 “(E) CHANGES IN RISK ADJUSTMENT.—

7 “(i) CONSIDERATION OF REC-  
8 OMMENDATIONS IN IMPACT REPORTS.—  
9 The Secretary may take into account the  
10 studies conducted and the recommenda-  
11 tions made by the Secretary under section  
12 2(d)(1) of the IMPACT Act of 2014 (Pub-  
13 lic Law 113–185; 42 U.S.C. 1395lll note)  
14 with respect to the application under this  
15 subsection of risk adjustment methodolo-  
16 gies. Nothing in this clause shall be con-  
17 strued as precluding consideration of the  
18 use of groupings of hospitals.

19 “(ii) CONSIDERATION OF EXCLUSION  
20 OF PATIENT CASES BASED ON V OR OTHER  
21 APPROPRIATE CODES.—In promulgating  
22 regulations to carry out this subsection  
23 with respect to discharges occurring after  
24 fiscal year 2018, the Secretary may con-  
25 sider the use of V or other ICD-related

1 codes for removal of a readmission. The  
2 Secretary may consider modifying meas-  
3 ures under this subsection to incorporate V  
4 or other ICD-related codes at the same  
5 time as other changes are being made  
6 under this subparagraph.

7 “(iii) REMOVAL OF CERTAIN RE-  
8 ADMISSIONS.—In promulgating regulations  
9 to carry out this subsection, with respect  
10 to discharges occurring after fiscal year  
11 2018, the Secretary may consider removal  
12 as a readmission of an admission that is  
13 classified within one or more of the fol-  
14 lowing: transplants, end-stage renal dis-  
15 ease, burns, trauma, psychosis, or sub-  
16 stance abuse. The Secretary may consider  
17 modifying measures under this subsection  
18 to remove readmissions at the same time  
19 as other changes are being made under  
20 this subparagraph.”.

21 (c) MEDPAC STUDY ON READMISSIONS PROGRAM.—  
22 The Medicare Payment Advisory Commission shall con-  
23 duct a study to review overall hospital readmissions de-  
24 scribed in section 1886(q)(5)(E) of the Social Security Act  
25 (42 U.S.C. 1395ww(q)(5)(E)) and whether such readmis-

1 sions are related to any changes in outpatient and emer-  
2 gency services furnished. The Commission shall submit to  
3 Congress a report on such study in its report to Congress  
4 in June 2018.

5 **SEC. 15003. FIVE-YEAR EXTENSION OF THE RURAL COMMU-**  
6 **NITY HOSPITAL DEMONSTRATION PROGRAM.**

7 (a) EXTENSION.—Section 410A of the Medicare Pre-  
8 scription Drug, Improvement, and Modernization Act of  
9 2003 (Public Law 108–173; 42 U.S.C. 1395ww note) is  
10 amended—

11 (1) in subsection (a)(5), by striking “5-year ex-  
12 tension period” and inserting “10-year extension pe-  
13 riod”; and

14 (2) in subsection (g)—

15 (A) in the subsection heading, by striking  
16 “FIVE-YEAR” and inserting “TEN-YEAR”;

17 (B) in paragraph (1), by striking “addi-  
18 tional 5-year” and inserting “additional 10-  
19 year”;

20 (C) by striking “5-year extension period”  
21 and inserting “10-year extension period” each  
22 place it appears;

23 (D) in paragraph (4)(B)—

1 (i) in the matter preceding clause (i),  
2 by inserting “each 5-year period in” after  
3 “hospital during”; and

4 (ii) in clause (i), by inserting “each  
5 applicable 5-year period in” after “the first  
6 day of”; and

7 (E) by adding at the end the following new  
8 paragraphs:

9 “(5) OTHER HOSPITALS IN DEMONSTRATION  
10 PROGRAM.—During the second 5 years of the 10-  
11 year extension period, the Secretary shall apply the  
12 provisions of paragraph (4) to rural community hos-  
13 pitals that are not described in paragraph (4) but  
14 are participating in the demonstration program  
15 under this section as of December 30, 2014, in a  
16 similar manner as such provisions apply to rural  
17 community hospitals described in paragraph (4).

18 “(6) EXPANSION OF DEMONSTRATION PROGRAM  
19 TO RURAL AREAS IN ANY STATE.—

20 “(A) IN GENERAL.—The Secretary shall,  
21 notwithstanding subsection (a)(2) or paragraph  
22 (2) of this subsection, not later than 120 days  
23 after the date of the enactment of this para-  
24 graph, issue a solicitation for applications to se-  
25 lect up to the maximum number of additional

1 rural community hospitals located in any State  
2 to participate in the demonstration program  
3 under this section for the second 5 years of the  
4 10-year extension period without exceeding the  
5 limitation under paragraph (3) of this sub-  
6 section.

7 “(B) PRIORITY.—In determining which  
8 rural community hospitals that submitted an  
9 application pursuant to the solicitation under  
10 subparagraph (A) to select for participation in  
11 the demonstration program, the Secretary—

12 “(i) shall give priority to rural com-  
13 munity hospitals located in one of the 20  
14 States with the lowest population densities  
15 (as determined by the Secretary using the  
16 2015 Statistical Abstract of the United  
17 States); and

18 “(ii) may consider—

19 “(I) closures of hospitals located  
20 in rural areas in the State in which  
21 the rural community hospital is lo-  
22 cated during the 5-year period imme-  
23 diately preceding the date of the en-  
24 actment of this paragraph; and

1                   “(II) the population density of  
2                   the State in which the rural commu-  
3                   nity hospital is located.”.

4           (b) CHANGE IN TIMING FOR REPORT.—Subsection  
5 (e) of such section 410A is amended—

6                   (1) by striking “Not later than 6 months after  
7                   the completion of the demonstration program under  
8                   this section” and inserting “Not later than August  
9                   1, 2018”; and

10                   (2) by striking “such program” and inserting  
11                   “the demonstration program under this section”.

12 **SEC. 15004. REGULATORY RELIEF FOR LTCHS.**

13           (a) TECHNICAL CHANGE TO THE MEDICARE LONG-  
14 TERM CARE HOSPITAL MORATORIUM EXCEPTION.—

15                   (1) IN GENERAL.—Section 114(d)(7) of the  
16 Medicare, Medicaid, and SCHIP Extension Act of  
17 2007 (42 U.S.C. 1395ww note), as amended by sec-  
18 tions 3106(b) and 10312(b) of Public Law 111–148,  
19 section 1206(b)(2) of the Pathway for SGR Reform  
20 Act of 2013 (division B of Public Law 113–67), and  
21 section 112 of the Protecting Access to Medicare Act  
22 of 2014 (Public Law 113–93), is amended by strik-  
23 ing “The moratorium under paragraph (1)(A)” and  
24 inserting “Any moratorium under paragraph (1)”.



1           (2) EFFECTIVE DATE.—The amendment made  
2           by paragraph (1) shall take effect as if included in  
3           the enactment of section 112 of the Protecting Ac-  
4           cess to Medicare Act of 2014.

5           (b) MODIFICATION TO MEDICARE LONG-TERM CARE  
6 HOSPITAL HIGH COST OUTLIER PAYMENTS.—Section  
7 1886(m) of the Social Security Act (42 U.S.C.  
8 1395ww(m)) is amended by adding at the end the fol-  
9           lowing new paragraph:

10           “(7) TREATMENT OF HIGH COST OUTLIER PAY-  
11           MENTS.—

12           “(A) ADJUSTMENT TO THE STANDARD  
13           FEDERAL PAYMENT RATE FOR ESTIMATED  
14           HIGH COST OUTLIER PAYMENTS.—Under the  
15           system described in paragraph (1), for fiscal  
16           years beginning on or after October 1, 2017,  
17           the Secretary shall reduce the standard Federal  
18           payment rate as if the estimated aggregate  
19           amount of high cost outlier payments for stand-  
20           ard Federal payment rate discharges for each  
21           such fiscal year would be equal to 8 percent of  
22           estimated aggregate payments for standard  
23           Federal payment rate discharges for each such  
24           fiscal year.

1           “(B) LIMITATION ON HIGH COST OUTLIER  
2           PAYMENT AMOUNTS.—Notwithstanding sub-  
3           paragraph (A), the Secretary shall set the fixed  
4           loss amount for high cost outlier payments such  
5           that the estimated aggregate amount of high  
6           cost outlier payments made for standard Fed-  
7           eral payment rate discharges for fiscal years be-  
8           ginning on or after October 1, 2017, shall be  
9           equal to 99.6875 percent of 8 percent of esti-  
10          mated aggregate payments for standard Fed-  
11          eral payment rate discharges for each such fis-  
12          cal year.

13          “(C) WAIVER OF BUDGET NEUTRALITY.—  
14          Any reduction in payments resulting from the  
15          application of subparagraph (B) shall not be  
16          taken into account in applying any budget neu-  
17          trality provision under such system.

18          “(D) NO EFFECT ON SITE NEUTRAL HIGH  
19          COST OUTLIER PAYMENT RATE.—This para-  
20          graph shall not apply with respect to the com-  
21          putation of the applicable site neutral payment  
22          rate under paragraph (6).”.

1 **SEC. 15005. SAVINGS FROM IPPS MACRA PAY-FOR**  
2 **THROUGH NOT APPLYING DOCUMENTATION**  
3 **AND CODING ADJUSTMENTS.**

4 Section 7(b)(1)(B)(iii) of the TMA, Abstinence Edu-  
5 cation, and QI Programs Extension Act of 2007 (Public  
6 Law 110–90), as amended by section 631(b) of the Amer-  
7 ican Taxpayer Relief Act of 2012 (Public Law 122–240)  
8 and section 414(1)(B)(iii) of the Medicare Access and  
9 CHIP Reauthorization Act of 2015 (Public Law 114–10),  
10 is amended by striking “an increase of 0.5 percentage  
11 points for discharges occurring during each of fiscal years  
12 2018 through 2023” and inserting “an increase of 0.4588  
13 percentage points for discharges occurring during fiscal  
14 year 2018 and 0.5 percentage points for discharges occur-  
15 ring during each of fiscal years 2019 through 2023”.

16 **SEC. 15006. EXTENSION OF CERTAIN LTCH MEDICARE PAY-**  
17 **MENT RULES.**

18 (a) 25–PERCENT PATIENT THRESHOLD PAYMENT  
19 ADJUSTMENT.—Section 114(c)(1)(A) of the Medicare,  
20 Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C.  
21 1395ww note), as amended by section 4302(a) of division  
22 B of the American Recovery and Reinvestment Act (Public  
23 Law 111–5), sections 3106(a) and 10312(a) of Public  
24 Law 111–148, and section 1206(b)(1)(B) of the Pathway  
25 for SGR Reform Act of 2013 (division B of Public Law  
26 113–67), is amended by striking “for a 9-year period” and

1 inserting “through June 30, 2016, and for discharges oc-  
2 ccurring on or after October 1, 2016, and before October  
3 1, 2017”.

4 (b) PAYMENT FOR HOSPITALS-WITHIN-HOS-  
5 PITALS.—Section 114(c)(2) of the Medicare, Medicaid,  
6 and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww  
7 note), as amended by section 4302(a) of division B of the  
8 American Recovery and Reinvestment Act (Public Law  
9 111–5), sections 3106(a) and 10312(a) of Public Law  
10 111–148, and section 1206(b)(1)(A) of the Pathway for  
11 SGR Reform Act of 2013 (division B of Public Law 113–  
12 67), is amended—

13 (1) in subparagraph (A), by inserting “or any  
14 similar provision,” after “Regulations,”;

15 (2) in subparagraph (B)—

16 (A) in clause (i), by inserting “or any simi-  
17 lar provision,” after “Regulations,”; and

18 (B) in clause (ii), by inserting “, or any  
19 similar provision,” after “Regulations”; and

20 (3) in subparagraph (C), by striking “for a 9-  
21 year period” and inserting “through June 30, 2016,  
22 and for discharges occurring on or after October 1,  
23 2016, and before October 1, 2017”.

1 **SEC. 15007. APPLICATION OF RULES ON THE CALCULATION**  
2 **OF HOSPITAL LENGTH OF STAY TO ALL**  
3 **LTCHS.**

4 (a) **IN GENERAL.**—Section 1206(a)(3) of the Path-  
5 way for SGR Reform Act of 2013 (division B of Public  
6 Law 113–67; 42 U.S.C. 1395ww note) is amended—

7 (1) by striking subparagraph (B);

8 (2) by striking “SITE NEUTRAL BASIS.—” and  
9 all that follows through “For discharges occurring”  
10 and inserting “SITE NEUTRAL BASIS.—For dis-  
11 charges occurring”;

12 (3) by striking “subject to subparagraph (B),”;

13 and

14 (4) by redesignating clauses (i) and (ii) as sub-  
15 paragraphs (A) and (B), respectively, and moving  
16 each of such subparagraphs (as so redesignated) 2  
17 ems to the left.

18 (b) **EFFECTIVE DATE.**—The amendments made by  
19 subsection (a) shall be effective as if included in the enact-  
20 ment of section 1206(a)(3) of the Pathway for SGR Re-  
21 form Act of 2013 (division B of Public Law 113–67; 42  
22 U.S.C. 1395ww note).

1 **SEC. 15008. CHANGE IN MEDICARE CLASSIFICATION FOR**  
2 **CERTAIN HOSPITALS.**

3 (a) IN GENERAL.—Subsection (d)(1)(B)(iv) of sec-  
4 tion 1886 of the Social Security Act (42 U.S.C. 1395ww)  
5 is amended—

6 (1) in subclause (I), by striking “or” at the  
7 end;

8 (2) in subclause (II)—

9 (A) by striking “, or” at the end and in-  
10 serting a semicolon;

11 (B) by redesignating such subclause as  
12 clause (vi) and by moving it to immediately fol-  
13 low clause (v); and

14 (C) in clause (v), by striking the semicolon  
15 at the end and inserting “, or”; and

16 (3) by striking “(iv)(I) a hospital” and insert-  
17 ing “(iv) a hospital”.

18 (b) CONFORMING PAYMENT REFERENCES.—The sec-  
19 ond sentence of subsection (d)(1)(B) of such section is  
20 amended—

21 (1) by inserting “(as in effect as of such date)”  
22 after “clause (iv)”;

23 (2) by inserting “(or, in the case of a hospital  
24 described in clause (iv)(II), as so in effect, shall be  
25 classified under clause (vi) on and after the effective  
26 date of such clause (vi) and for cost reporting peri-

1       ods beginning on or after January 1, 2015, shall not  
2       be subject to subsection (m) as of the date of such  
3       classification)” after “so classified”.

4       (c) APPLICATION.—

5           (1) IN GENERAL.—For cost reporting periods  
6       beginning on or after January 1, 2015, in the case  
7       of an applicable hospital (as defined in paragraph  
8       (3)), the following shall apply:

9           (A) Payment for inpatient operating costs  
10       shall be made on a reasonable cost basis in the  
11       manner provided in section 412.526(c)(3) of  
12       title 42, Code of Federal Regulations (as in ef-  
13       fect on January 1, 2015) and in any subse-  
14       quent modifications.

15           (B) Payment for capital costs shall be  
16       made in the manner provided by section  
17       412.526(c)(4) of title 42, Code of Federal Reg-  
18       ulations (as in effect on such date).

19           (C) Claims for payment for Medicare bene-  
20       ficiaries who are discharged on or after January  
21       1, 2017, shall be processed as claims which are  
22       paid on a reasonable cost basis as described in  
23       section 412.526(c) of title 42, Code of Federal  
24       Regulations (as in effect on such date).

1           (2) APPLICABLE HOSPITAL DEFINED.—In this  
2 subsection, the term “applicable hospital” means a  
3 hospital that is classified under clause (iv)(II) of sec-  
4 tion 1886(d)(1)(B) of the Social Security Act (42  
5 U.S.C. 1395ww(d)(1)(B)) on the day before the date  
6 of the enactment of this Act and which is classified  
7 under clause (vi) of such section, as redesignated  
8 and moved by subsection (a), on or after such date  
9 of enactment.

10       (d) CONFORMING TECHNICAL AMENDMENTS.—

11           (1) Section 1899B(a)(2)(A)(iv) of the Social  
12 Security Act (42 U.S.C. 1395lll(a)(2)(A)(iv)) is  
13 amended by striking “1886(d)(1)(B)(iv)(II)” and in-  
14 serting “1886(d)(1)(B)(vi)”.

15           (2) Section 1886(m)(5)(F) of such Act (42  
16 U.S.C. 1395ww(m)(5)(F)) is amended in each of  
17 clauses (i) and (ii) by striking “(d)(1)(B)(iv)(II)”  
18 and inserting “(d)(1)(B)(vi)”.

19       **SEC. 15009. TEMPORARY EXCEPTION TO THE APPLICATION**  
20                               **OF THE MEDICARE LTCH SITE NEUTRAL PRO-**  
21                               **VISIONS FOR CERTAIN SPINAL CORD SPE-**  
22                               **CIALTY HOSPITALS.**

23           (a) EXCEPTION.—Section 1886(m)(6) of the Social  
24 Security Act (42 U.S.C. 1395ww(m)(6)) is amended—



1           (1) in subparagraph (A)(i), by striking “and  
2           (E)” and inserting “, (E), and (F)”; and

3           (2) by adding at the end the following new sub-  
4           paragraph:

5                   “(F) TEMPORARY EXCEPTION FOR CER-  
6           TAIN SPINAL CORD SPECIALTY HOSPITALS.—  
7           For discharges in cost reporting periods begin-  
8           ning during fiscal years 2018 and 2019, sub-  
9           paragraph (A)(i) shall not apply (and payment  
10          shall be made to a long-term care hospital with-  
11          out regard to this paragraph) if such discharge  
12          is from a long-term care hospital that meets  
13          each of the following requirements:

14                   “(i) NOT-FOR-PROFIT.—The long-  
15          term care hospital was a not-for-profit  
16          long-term care hospital on June 1, 2014,  
17          as determined by cost report data.

18                   “(ii) PRIMARILY PROVIDING TREAT-  
19          MENT FOR CATASTROPHIC SPINAL CORD  
20          OR ACQUIRED BRAIN INJURIES OR OTHER  
21          PARALYZING NEUROMUSCULAR CONDI-  
22          TIONS.—Of the discharges in calendar year  
23          2013 from the long-term care hospital for  
24          which payment was made under this sec-  
25          tion, at least 50 percent were classified

1 under MS-LTCH-DRGs 28, 29, 52, 57,  
2 551, 573, and 963.

3 “(iii) SIGNIFICANT OUT-OF-STATE AD-  
4 MISSIONS.—

5 “(I) IN GENERAL.—The long-  
6 term care hospital discharged inpa-  
7 tients (including both individuals enti-  
8 tled to, or enrolled for, benefits under  
9 this title and individuals not so enti-  
10 tled or enrolled) during fiscal year  
11 2014 who had been admitted from at  
12 least 20 of the 50 States, determined  
13 by the States of residency of such in-  
14 patients and based on such data sub-  
15 mitted by the hospital to the Sec-  
16 retary as the Secretary may require.

17 “(II) IMPLEMENTATION.—Not-  
18 withstanding any other provision of  
19 law, the Secretary may implement  
20 subclause (I) by program instruction  
21 or otherwise.

22 “(III) NON-APPLICATION OF PA-  
23 PERWORK REDUCTION ACT.—Chapter  
24 35 of title 44, United States Code,

1 shall not apply to data collected under  
2 this clause.”.

3 (b) STUDY AND REPORT ON THE STATUS AND VIA-  
4 BILITY OF CERTAIN SPINAL CORD SPECIALTY LONG-  
5 TERM CARE HOSPITALS.—

6 (1) STUDY.—The Comptroller General of the  
7 United States shall conduct a study on long-term  
8 care hospitals described in section 1886(m)(6)(F) of  
9 the Social Security Act, as added by subsection (a).  
10 Such report shall include an analysis of the fol-  
11 lowing:

12 (A) The impact on such hospitals of the  
13 classification and facility licensure by State  
14 agencies of such hospitals.

15 (B) The Medicare payment rates for such  
16 hospitals.

17 (C) Data on the number and health care  
18 needs of Medicare beneficiaries who have been  
19 diagnosed with catastrophic spinal cord or ac-  
20 quired brain injuries or other paralyzing neuro-  
21 muscular conditions (as described within the  
22 discharge classifications specified in clause (ii)  
23 of such section) who are receiving services from  
24 such hospitals.

1           (2) REPORT.—Not later than October 1, 2018,  
2           the Comptroller General shall submit to Congress a  
3           report on the study conducted under paragraph (1),  
4           including recommendations for such legislation and  
5           administrative action as the Comptroller General de-  
6           termines appropriate.

7   **SEC. 15010. TEMPORARY EXTENSION TO THE APPLICATION**  
8                           **OF THE MEDICARE LTCH SITE NEUTRAL PRO-**  
9                           **VISIONS FOR CERTAIN DISCHARGES WITH SE-**  
10                          **VERE WOUNDS.**

11          (a) IN GENERAL.—Section 1886(m)(6) of the Social  
12          Security Act (42 U.S.C. 1395ww(m)(6)), as amended by  
13          section 15009, is further amended—

14                 (1) in subparagraph (A)(i) by striking “and  
15                 (F)” and inserting “(F), and (G)”;

16                 (2) in subparagraph (E)(i)(I)(aa), by striking  
17                 “the amendment made” and all that follows before  
18                 the semicolon and inserting “the last sentence of  
19                 subsection (d)(1)(B)”;

20                 (3) by adding at the end the following new sub-  
21                 paragraph:

22                         “(G) ADDITIONAL TEMPORARY EXCEPTION  
23                         FOR CERTAIN SEVERE WOUND DISCHARGES  
24                         FROM CERTAIN LONG-TERM CARE HOSPITALS.—

1           “(i) IN GENERAL.—For a discharge  
2           occurring in a cost reporting period begin-  
3           ning during fiscal year 2018, subpara-  
4           graph (A)(i) shall not apply (and payment  
5           shall be made to a long-term care hospital  
6           without regard to this paragraph) if such  
7           discharge—

8                   “(I) is from a long-term care  
9                   hospital identified by the last sentence  
10                  of subsection (d)(1)(B);

11                  “(II) is classified under MS-  
12                  LTCH-DRG 602, 603, 539, or 540;  
13                  and

14                  “(III) is with respect to an indi-  
15                  vidual treated by a long-term care  
16                  hospital for a severe wound.

17                  “(ii) SEVERE WOUND DEFINED.—In  
18                  this subparagraph, the term ‘severe wound’  
19                  means a wound which is a stage 3 wound,  
20                  stage 4 wound, unstageable wound, non-  
21                  healing surgical wound, or fistula as identi-  
22                  fied in the claim from the long-term care  
23                  hospital.

24                  “(iii) WOUND DEFINED.—In this sub-  
25                  paragraph, the term ‘wound’ means an in-

1                   jury involving division of tissue or rupture  
2                   of the integument or mucous membrane  
3                   with exposure to the external environ-  
4                   ment.”.

5           (c) STUDY AND REPORT TO CONGRESS.—

6                   (1) STUDY.—The Comptroller General of the  
7                   United States shall, in consultation with relevant  
8                   stakeholders, conduct a study on the treatment  
9                   needs of individuals entitled to benefits under part  
10                  A of title XVIII of the Social Security Act or en-  
11                  rolled under part B of such title who require special-  
12                  ized wound care, and the cost, for such individuals  
13                  and the Medicare program under such title, of treat-  
14                  ing severe wounds in rural and urban areas. Such  
15                  study shall include an assessment of—

16                           (A) access of such individuals to appro-  
17                           priate levels of care for such cases;

18                           (B) the potential impact that section  
19                           1886(m)(6)(A)(i) of such Act (42 U.S.C.  
20                           1395ww(m)(6)(A)(i)) will have on the access,  
21                           quality, and cost of care for such individuals;  
22                           and

23                           (C) how to appropriately pay for such care  
24                           under the Medicare program under such title.

1           (2) REPORT.—Not later than October 1, 2020,  
2           the Comptroller General shall submit to Congress a  
3           report on the study conducted under paragraph (1),  
4           including recommendations for such legislation and  
5           administrative action as the Comptroller General de-  
6           termines appropriate.

7           **TITLE XVI—PROVISIONS RELAT-**  
8           **ING TO MEDICARE PART B**

9           **SEC. 16001. CONTINUING MEDICARE PAYMENT UNDER**  
10           **HOPD PROSPECTIVE PAYMENT SYSTEM FOR**  
11           **SERVICES FURNISHED BY MID-BUILD OFF-**  
12           **CAMPUS OUTPATIENT DEPARTMENTS OF**  
13           **PROVIDERS.**

14           (a) IN GENERAL.—Section 1833(t)(21) of the Social  
15           Security Act (42 U.S.C. 1395l(t)(21)) is amended—

16           (1) in subparagraph (B)—

17           (A) in clause (i), by striking “clause (ii)”  
18           and inserting “the subsequent provisions of this  
19           subparagraph”; and

20           (B) by adding at the end the following new  
21           clauses:

22           “(iii) DEEMED TREATMENT FOR  
23           2017.—For purposes of applying clause (ii)  
24           with respect to applicable items and serv-  
25           ices furnished during 2017, a department

1 of a provider (as so defined) not described  
2 in such clause is deemed to be billing  
3 under this subsection with respect to cov-  
4 ered OPD services furnished prior to No-  
5 vember 2, 2015, if the Secretary received  
6 from the provider prior to December 2,  
7 2015, an attestation (pursuant to section  
8 413.65(b)(3) of title 42 of the Code of  
9 Federal Regulations) that such department  
10 was a department of a provider (as so de-  
11 fined).

12 “(iv) ALTERNATIVE EXCEPTION BE-  
13 GINNING WITH 2018.—For purposes of  
14 paragraph (1)(B)(v) and this paragraph  
15 with respect to applicable items and serv-  
16 ices furnished during 2018 or a subsequent  
17 year, the term ‘off-campus outpatient de-  
18 partment of a provider’ also shall not in-  
19 clude a department of a provider (as so de-  
20 fined) that is not described in clause (ii)  
21 if—

22 “(I) the Secretary receives from  
23 the provider an attestation (pursuant  
24 to such section 413.65(b)(3)) not later  
25 than December 31, 2016 (or, if later,



1                   60 days after the date of the enact-  
2                   ment of this clause), that such depart-  
3                   ment met the requirements of a de-  
4                   partment of a provider specified in  
5                   section 413.65 of title 42 of the Code  
6                   of Federal Regulations;

7                   “(II) the provider includes such  
8                   department as part of the provider on  
9                   its enrollment form in accordance with  
10                  the enrollment process under section  
11                  1866(j); and

12                  “(III) the department met the  
13                  mid-build requirement of clause (v)  
14                  and the Secretary receives, not later  
15                  than 60 days after the date of the en-  
16                  actment of this clause, from the chief  
17                  executive officer or chief operating of-  
18                  ficer of the provider a written certifi-  
19                  cation that the department met such  
20                  requirement.

21                  “(v) MID-BUILD REQUIREMENT DE-  
22                  SCRIBED.—The mid-build requirement of  
23                  this clause is, with respect to a department  
24                  of a provider, that before November 2,  
25                  2015, the provider had a binding written

1 agreement with an outside unrelated party  
2 for the actual construction of such depart-  
3 ment.

4 “(vii) AUDIT.—Not later than Decem-  
5 ber 31, 2018, the Secretary shall audit the  
6 compliance with requirements of clause (iv)  
7 with respect to each department of a pro-  
8 vider to which such clause applies. If the  
9 Secretary finds as a result of an audit  
10 under this clause that the applicable re-  
11 quirements were not met with respect to  
12 such department, the department shall not  
13 be excluded from the term ‘off-campus out-  
14 patient department of a provider’ under  
15 such clause.

16 “(viii) IMPLEMENTATION.—For pur-  
17 poses of implementing clauses (iii) through  
18 (vii):

19 “(I) Notwithstanding any other  
20 provision of law, the Secretary may  
21 implement such clauses by program  
22 instruction or otherwise.

23 “(II) Subchapter I of chapter 35  
24 of title 44, United States Code, shall  
25 not apply.

1                   “(III) For purposes of carrying  
2                   out this subparagraph with respect to  
3                   clauses (iii) and (iv) (and clause (vii)  
4                   insofar as it relates to clause (iv)),  
5                   \$10,000,000 shall be available from  
6                   the Federal Supplementary Medical  
7                   Insurance Trust Fund under section  
8                   1841, to remain available until De-  
9                   cember 31, 2018.”; and

10                   (2) in subparagraph (E), by adding at the end  
11                   the following new clause:

12                   “(iv) The determination of an audit  
13                   under subparagraph (B)(vii).”.

14                   (b) **EFFECTIVE DATE.**—The amendments made by  
15                   this section shall be effective as if included in the enact-  
16                   ment of section 603 of the Bipartisan Budget Act of 2015  
17                   (Public Law 114–74).

18                   **SEC. 16002. TREATMENT OF CANCER HOSPITALS IN OFF-**  
19                   **CAMPUS OUTPATIENT DEPARTMENT OF A**  
20                   **PROVIDER POLICY.**

21                   (a) **IN GENERAL.**—Section 1833(t)(21)(B) of the So-  
22                   cial Security Act (42 U.S.C. 1395l(t)(21)(B)), as amended  
23                   by section 16001(a), is amended—

24                   (1) by inserting after clause (v) the following  
25                   new clause:

1                   “(vi) EXCLUSION FOR CERTAIN CAN-  
2                   CER HOSPITALS.—For purposes of para-  
3                   graph (1)(B)(v) and this paragraph with  
4                   respect to applicable items and services  
5                   furnished during 2017 or a subsequent  
6                   year, the term ‘off-campus outpatient de-  
7                   partment of a provider’ also shall not in-  
8                   clude a department of a provider (as so de-  
9                   fined) that is not described in clause (ii) if  
10                  the provider is a hospital described in sec-  
11                  tion 1886(d)(1)(B)(v) and—

12                   “(I) in the case of a department  
13                   that met the requirements of section  
14                   413.65 of title 42 of the Code of Fed-  
15                   eral Regulations after November 1,  
16                   2015, and before the date of the en-  
17                   actment of this clause, the Secretary  
18                   receives from the provider an attesta-  
19                   tion that such department met such  
20                   requirements not later than 60 days  
21                   after such date of enactment; or

22                   “(II) in the case of a department  
23                   that meets such requirements after  
24                   such date of enactment, the Secretary  
25                   receives from the provider an attesta-

1                   tion that such department meets such  
2                   requirements not later than 60 days  
3                   after the date such requirements are  
4                   first met with respect to such depart-  
5                   ment.”;

6                   (2) in clause (vii), by inserting after the first  
7                   sentence the following: “Not later than 2 years after  
8                   the date the Secretary receives an attestation under  
9                   clause (vi) relating to compliance of a department of  
10                  a provider with requirements referred to in such  
11                  clause, the Secretary shall audit the compliance with  
12                  such requirements with respect to the department.”;  
13                  and

14                  (3) in clause (viii)(III), by adding at the end  
15                  the following: “For purposes of carrying out this  
16                  subparagraph with respect to clause (vi) (and clause  
17                  (vii) insofar as it relates to such clause), \$2,000,000  
18                  shall be available from the Federal Supplementary  
19                  Medical Insurance Trust Fund under section 1841,  
20                  to remain available until expended.”.

21                  (b) OFFSETTING SAVINGS.—Section 1833(t)(18) of  
22                  the Social Security Act (42 U.S.C. 1395l(t)(18)) is  
23                  amended—

24                  (1) in subparagraph (B), by inserting “, subject  
25                  to subparagraph (C),” after “shall”; and

1           (2) by adding at the end the following new sub-  
2 paragraph:

3                   “(C) TARGET PCR ADJUSTMENT.—In ap-  
4 plying section 419.43(i) of title 42 of the Code  
5 of Federal Regulations to implement the appro-  
6 priate adjustment under this paragraph for  
7 services furnished on or after January 1, 2018,  
8 the Secretary shall use a target PCR that is 1.0  
9 percentage points less than the target PCR that  
10 would otherwise apply. In addition to the per-  
11 centage point reduction under the previous sen-  
12 tence, the Secretary may consider making an  
13 additional percentage point reduction to such  
14 target PCR that takes into account payment  
15 rates for applicable items and services described  
16 in paragraph (21)(C) other than for services  
17 furnished by hospitals described in section  
18 1886(d)(1)(B)(v). In making any budget neu-  
19 trality adjustments under this subsection for  
20 2018 or a subsequent year, the Secretary shall  
21 not take into account the reduced expenditures  
22 that result from the application of this subpara-  
23 graph.”.

24           (c) EFFECTIVE DATE.—The amendments made by  
25 this section shall be effective as if included in the enact-

1 ment of section 603 of the Bipartisan Budget Act of 2015  
2 (Public Law 114–74).

3 **SEC. 16003. TREATMENT OF ELIGIBLE PROFESSIONALS IN**  
4 **AMBULATORY SURGICAL CENTERS FOR**  
5 **MEANINGFUL USE AND MIPS.**

6 Section 1848(a)(7)(D) of the Social Security Act (42  
7 U.S.C. 1395w–4(a)(7)(D)) is amended—

8 (1) by striking “HOSPITAL-BASED ELIGIBLE  
9 PROFESSIONALS” and all that follows through “No  
10 payment” and inserting the following: “HOSPITAL-  
11 BASED AND AMBULATORY SURGICAL CENTER-BASED  
12 ELIGIBLE PROFESSIONALS.—

13 “(i) HOSPITAL-BASED.—No pay-  
14 ment”; and

15 (2) by adding at the end the following new  
16 clauses:

17 “(ii) AMBULATORY SURGICAL CEN-  
18 TER-BASED.—Subject to clause (iv), no  
19 payment adjustment may be made under  
20 subparagraph (A) for 2017 and 2018 in  
21 the case of an eligible professional with re-  
22 spect to whom substantially all of the cov-  
23 ered professional services furnished by  
24 such professional are furnished in an am-  
25 bulatory surgical center.

1           “(iii) DETERMINATION.—The deter-  
2           mination of whether an eligible profes-  
3           sional is an eligible professional described  
4           in clause (ii) may be made on the basis  
5           of—

6                     “(I) the site of service (as de-  
7                     fined by the Secretary); or

8                     “(II) an attestation submitted by  
9                     the eligible professional.

10           Determinations made under subclauses (I)  
11           and (II) shall be made without regard to  
12           any employment or billing arrangement be-  
13           tween the eligible professional and any  
14           other supplier or provider of services.

15                     “(iv) SUNSET.—Clause (ii) shall no  
16                     longer apply as of the first year that be-  
17                     gins more than 3 years after the date on  
18                     which the Secretary determines, through  
19                     notice and comment rulemaking, that cer-  
20                     tified EHR technology applicable to the  
21                     ambulatory surgical center setting is avail-  
22                     able.”.



1 **SEC. 16004. CONTINUING ACCESS TO HOSPITALS ACT OF**  
2 **2016.**

3 (a) EXTENSION OF ENFORCEMENT INSTRUCTION ON  
4 SUPERVISION REQUIREMENTS FOR OUTPATIENT THERA-  
5 PEUTIC SERVICES IN CRITICAL ACCESS AND SMALL  
6 RURAL HOSPITALS THROUGH 2016.—Section 1 of Public  
7 Law 113–198, as amended by section 1 of Public Law  
8 114–112, is amended—

9 (1) in the heading, by striking “**2014 AND**  
10 **2015**” and inserting “**2016**”; and

11 (2) by striking “and 2015” and inserting “,  
12 2015, and 2016”.

13 (b) REPORT.—Not later than 1 year after the date  
14 of the enactment of this Act, the Medicare Payment Advi-  
15 sory Commission (established under section 1805 of the  
16 Social Security Act (42 U.S.C. 1395b–6)) shall submit to  
17 Congress a report analyzing the effect of the extension of  
18 the enforcement instruction under section 1 of Public Law  
19 113–198, as amended by section 1 of Public Law 114–  
20 112 and subsection (a) of this section, on the access to  
21 health care by Medicare beneficiaries, on the economic im-  
22 pact and the impact upon hospital staffing needs, and on  
23 the quality of health care furnished to such beneficiaries.

1 **SEC. 16005. DELAY OF IMPLEMENTATION OF MEDICARE**  
2 **FEE SCHEDULE ADJUSTMENTS FOR WHEEL-**  
3 **CHAIR ACCESSORIES AND SEATING SYSTEMS**  
4 **WHEN USED IN CONJUNCTION WITH COM-**  
5 **PLEX REHABILITATION TECHNOLOGY (CRT)**  
6 **WHEELCHAIRS.**

7 Section 2(a) of the Patient Access and Medicare Pro-  
8 tection Act (42 U.S.C. 1305 note) is amended by striking  
9 “January 1, 2017” and inserting “July 1, 2017”.

10 **SEC. 16006. ALLOWING PHYSICAL THERAPISTS TO UTILIZE**  
11 **LOCUM TENENS ARRANGEMENTS UNDER**  
12 **MEDICARE.**

13 (a) IN GENERAL.—The first sentence of section  
14 1842(b)(6) of the Social Security Act (42 U.S.C.  
15 1395u(b)(6)), as amended by section 5012, is further  
16 amended—

17 (1) by striking “and” before “(I)”; and

18 (2) by inserting before the period at the end the  
19 following: “, and (J) in the case of outpatient phys-  
20 ical therapy services furnished by physical therapists  
21 in a health professional shortage area (as defined in  
22 section 332(a)(1)(A) of the Public Health Service  
23 Act), a medically underserved area (as designated  
24 pursuant to section 330(b)(3)(A) of such Act), or a  
25 rural area (as defined in section 1886(d)(2)(D)),  
26 subparagraph (D) of this sentence shall apply to

1 such services and therapists in the same manner as  
2 such subparagraph applies to physicians' services  
3 furnished by physicians”.

4 (b) EFFECTIVE DATE; IMPLEMENTATION.—

5 (1) EFFECTIVE DATE.—The amendments made  
6 by subsection (a) shall apply to services furnished  
7 beginning not later than six months after the date  
8 of the enactment of this Act.

9 (2) IMPLEMENTATION.—The Secretary of  
10 Health and Human Services may implement sub-  
11 paragraph (J) of section 1842(b)(6) of the Social  
12 Security Act (42 U.S.C. 1395u(b)(6)), as added by  
13 subsection (a)(2), by program instruction or other-  
14 wise.

15 **SEC. 16007. EXTENSION OF THE TRANSITION TO NEW PAY-**  
16 **MENT RATES FOR DURABLE MEDICAL EQUIP-**  
17 **MENT UNDER THE MEDICARE PROGRAM.**

18 (a) IN GENERAL.—The Secretary of Health and  
19 Human Services shall extend the transition period de-  
20 scribed in clause (i) of section 414.210(g)(9) of title 42,  
21 Code of Federal Regulations, from June 30, 2016, to De-  
22 cember 31, 2016 (with the full implementation described  
23 in clause (ii) of such section applying to items and services  
24 furnished with dates of service on or after January 1,  
25 2017).

1 (b) STUDY AND REPORT.—

2 (1) STUDY.—

3 (A) IN GENERAL.—The Secretary of  
4 Health and Human Services shall conduct a  
5 study that examines the impact of applicable  
6 payment adjustments upon—

7 (i) the number of suppliers of durable  
8 medical equipment that, on a date that is  
9 not before January 1, 2016, and not later  
10 than December 31, 2016, ceased to con-  
11 duct business as such suppliers; and

12 (ii) the availability of durable medical  
13 equipment, during the period beginning on  
14 January 1, 2016, and ending on December  
15 31, 2016, to individuals entitled to benefits  
16 under part A of title XVIII of the Social  
17 Security Act (42 U.S.C. 1395 et seq.) or  
18 enrolled under part B of such title.

19 (B) DEFINITIONS.—For purposes of this  
20 subsection, the following definitions apply:

21 (i) SUPPLIER; DURABLE MEDICAL  
22 EQUIPMENT.—The terms “supplier” and  
23 “durable medical equipment” have the  
24 meanings given such terms by section 1861

1 of the Social Security Act (42 U.S.C.  
2 1395x).

3 (ii) APPLICABLE PAYMENT ADJUST-  
4 MENT.—The term “applicable payment ad-  
5 justment” means a payment adjustment  
6 described in section 414.210(g) of title 42,  
7 Code of Federal Regulations, that is  
8 phased in by paragraph (9)(i) of such sec-  
9 tion. For purposes of the preceding sen-  
10 tence, a payment adjustment that is  
11 phased in pursuant to the extension under  
12 subsection (a) shall be considered a pay-  
13 ment adjustment that is phased in by such  
14 paragraph (9)(i).

15 (2) REPORT.—The Secretary of Health and  
16 Human Services shall, not later than January 12,  
17 2017, submit to the Committees on Ways and  
18 Means and on Energy and Commerce of the House  
19 of Representatives, and to the Committee on Fi-  
20 nance of the Senate, a report on the findings of the  
21 study conducted under paragraph (1).

1 **SEC. 16008. REQUIREMENTS IN DETERMINING ADJUST-**  
2 **MENTS USING INFORMATION FROM COM-**  
3 **PETITIVE BIDDING PROGRAMS.**

4 (a) IN GENERAL.—Section 1834(a)(1)(G) of the So-  
5 cial Security Act (42 U.S.C. 1395m(a)(1)(G)) is amended  
6 by adding at the end the following new sentence: “In the  
7 case of items and services furnished on or after January  
8 1, 2019, in making any adjustments under clause (ii) or  
9 (iii) of subparagraph (F), under subsection (h)(1)(H)(ii),  
10 or under section 1842(s)(3)(B), the Secretary shall—

11 “(i) solicit and take into account  
12 stakeholder input; and

13 “(ii) take into account the highest  
14 amount bid by a winning supplier in a  
15 competitive acquisition area and a com-  
16 parison of each of the following with re-  
17 spect to non-competitive acquisition areas  
18 and competitive acquisition areas:

19 “(I) The average travel distance  
20 and cost associated with furnishing  
21 items and services in the area.

22 “(II) The average volume of  
23 items and services furnished by sup-  
24 pliers in the area.

25 “(III) The number of suppliers in  
26 the area.”.

1 (b) CONFORMING AMENDMENTS.—(1) Section  
2 1834(h)(1)(H)(ii) of the Social Security Act (42 U.S.C.  
3 1395m(h)(1)(H)(ii)) is amended by striking “the Sec-  
4 retary” and inserting “subject to subsection (a)(1)(G), the  
5 Secretary”.

6 (2) Section 1842(s)(3)(B) of the Social Security Act  
7 (42 U.S.C. 1395m(s)(3)(B)) is amended by striking “the  
8 Secretary” and inserting “subject to section  
9 1834(a)(1)(G), the Secretary”.

10 **TITLE XVII—OTHER MEDICARE**  
11 **PROVISIONS**

12 **SEC. 17001. DELAY IN AUTHORITY TO TERMINATE CON-**  
13 **TRACTS FOR MEDICARE ADVANTAGE PLANS**  
14 **FAILING TO ACHIEVE MINIMUM QUALITY**  
15 **RATINGS.**

16 (a) FINDINGS.—Consistent with the studies provided  
17 under the IMPACT Act of 2014 (Public Law 113–185),  
18 it is the intent of Congress—

19 (1) to continue to study and request input on  
20 the effects of socioeconomic status and dual-eligible  
21 populations on the Medicare Advantage STARS rat-  
22 ing system before reforming such system with the  
23 input of stakeholders; and

24 (2) pending the results of such studies and  
25 input, to provide for a temporary delay in authority

1 of the Centers for Medicare & Medicaid Services  
2 (CMS) to terminate Medicare Advantage plan con-  
3 tracts solely on the basis of performance of plans  
4 under the STARS rating system.

5 (b) DELAY IN MA CONTRACT TERMINATION AU-  
6 THORITY FOR PLANS FAILING TO ACHIEVE MINIMUM  
7 QUALITY RATINGS.—Section 1857(h) of the Social Secu-  
8 rity Act (42 U.S.C. 1395w–27(h)) is amended by adding  
9 at the end the following new paragraph:

10 “(3) DELAY IN CONTRACT TERMINATION AU-  
11 THORITY FOR PLANS FAILING TO ACHIEVE MINIMUM  
12 QUALITY RATING.—During the period beginning on  
13 the date of the enactment of this paragraph and  
14 through the end of plan year 2018, the Secretary  
15 may not terminate a contract under this section with  
16 respect to the offering of an MA plan by a Medicare  
17 Advantage organization solely because the MA plan  
18 has failed to achieve a minimum quality rating  
19 under the 5-star rating system under section  
20 1853(o)(4).”.

21 **SEC. 17002. REQUIREMENT FOR ENROLLMENT DATA RE-**  
22 **PORTING FOR MEDICARE.**

23 Section 1874 of the Social Security Act (42 U.S.C.  
24 1395kk) is amended by adding at the end the following  
25 new subsection:



1           “(g) REQUIREMENT FOR ENROLLMENT DATA RE-  
2 PORTING.—

3           “(1) IN GENERAL.—Each year (beginning with  
4 2016), the Secretary shall submit to the Committees  
5 on Ways and Means and Energy and Commerce of  
6 the House of Representatives and the Committee on  
7 Finance of the Senate a report on Medicare enroll-  
8 ment data (and, in the case of part A, on data on  
9 individuals receiving benefits under such part) as of  
10 a date in such year specified by the Secretary. Such  
11 data shall be presented—

12                   “(A) by Congressional district and State;  
13 and

14                   “(B) in a manner that provides for such  
15 data based on—

16                           “(i) fee-for-service enrollment (as de-  
17 fined in paragraph (2));

18                           “(ii) enrollment under part C (includ-  
19 ing separate for aggregate enrollment in  
20 MA–PD plans and aggregate enrollment in  
21 MA plans that are not MA–PD plans); and

22                           “(iii) enrollment under part D.

23           “(2) FEE-FOR-SERVICE ENROLLMENT DE-  
24 FINED.—For purpose of paragraph (1)(B)(i), the  
25 term ‘fee-for-service enrollment’ means aggregate en-

1 rollment (including receipt of benefits other than  
2 through enrollment) under—

3 “(A) part A only;

4 “(B) part B only; and

5 “(C) both part A and part B.”.

6 **SEC. 17003. UPDATING THE WELCOME TO MEDICARE PACK-**  
7 **AGE.**

8 (a) IN GENERAL.—Not later than 12 months after  
9 the last day of the period for the request of information  
10 described in subsection (b), the Secretary of Health and  
11 Human Services shall, taking into consideration informa-  
12 tion collected pursuant to subsection (b), update the infor-  
13 mation included in the Welcome to Medicare package to  
14 include information, presented in a clear and simple man-  
15 ner, about options for receiving benefits under the Medi-  
16 care program under title XVIII of the Social Security Act  
17 (42 U.S.C. 1395 et seq.), including through the original  
18 medicare fee-for-service program under parts A and B of  
19 such title (42 U.S.C. 1395c et seq., 42 U.S.C. 1395j et  
20 seq.), Medicare Advantage plans under part C of such title  
21 (42 U.S.C. 1395w–21 et seq.), and prescription drug plans  
22 under part D of such title (42 U.S.C. 1395w–101 et  
23 seq.)). The Secretary shall make subsequent updates to  
24 the information included in the Welcome to Medicare  
25 package as appropriate.

1 (b) REQUEST FOR INFORMATION.—Not later than 6  
2 months after the date of the enactment of this Act, the  
3 Secretary of Health and Human Services shall request in-  
4 formation, including recommendations, from stakeholders  
5 (including patient advocates, issuers, and employers) on  
6 information included in the Welcome to Medicare package,  
7 including pertinent data and information regarding enroll-  
8 ment and coverage for Medicare eligible individuals.

9 **SEC. 17004. NO PAYMENT FOR ITEMS AND SERVICES FUR-**  
10 **NISHED BY NEWLY ENROLLED PROVIDERS**  
11 **OR SUPPLIERS WITHIN A TEMPORARY MORA-**  
12 **TORIUM AREA.**

13 (a) MEDICARE.—Section 1866(j)(7) of the Social Se-  
14 curity Act (42 U.S.C. 1395cc(j)(7)) is amended—

15 (1) in the paragraph heading, by inserting “;  
16 NONPAYMENT” before the period; and

17 (2) by adding at the end the following new sub-  
18 paragraph:

19 “(C) NONPAYMENT.—

20 “(i) IN GENERAL.—No payment may  
21 be made under this title or under a pro-  
22 gram described in subparagraph (A) with  
23 respect to an item or service described in  
24 clause (ii) furnished on or after October 1,  
25 2017.

1 “(ii) ITEM OR SERVICE DESCRIBED.—

2 An item or service described in this clause  
3 is an item or service furnished—

4 “(I) within a geographic area  
5 with respect to which a temporary  
6 moratorium imposed under subpara-  
7 graph (A) is in effect; and

8 “(II) by a provider of services or  
9 supplier that meets the requirements  
10 of clause (iii).

11 “(iii) REQUIREMENTS.—For purposes  
12 of clause (ii), the requirements of this  
13 clause are that a provider of services or  
14 supplier—

15 “(I) enrolls under this title on or  
16 after the effective date of such tem-  
17 porary moratorium; and

18 “(II) is within a category of pro-  
19 viders of services and suppliers (as de-  
20 scribed in subparagraph (A)) subject  
21 to such temporary moratorium.

22 “(iv) PROHIBITION ON CHARGES FOR  
23 SPECIFIED ITEMS OR SERVICES.—In no  
24 case shall a provider of services or supplier  
25 described in clause (ii)(II) charge an indi-

1           vidual or other person for an item or serv-  
2           ice described in clause (ii) furnished on or  
3           after October 1, 2017, to an individual en-  
4           titled to benefits under part A or enrolled  
5           under part B or an individual under a pro-  
6           gram specified in subparagraph (A).”.

7           (b) CONFORMING AMENDMENTS.—

8           (1) MEDICAID.—

9           (A) IN GENERAL.—Section 1903(i)(2) of  
10          the Social Security Act (42 U.S.C.  
11          1396b(i)(2)), as amended by section  
12          5005(a)(4), is further amended—

13           (i) in subparagraph (C), by striking  
14           “or” at the end; and

15           (ii) by adding at the end the following  
16           new subparagraph:

17           “(E) with respect to any amount expended  
18          for such an item or service furnished during  
19          calendar quarters beginning on or after October  
20          1, 2017, subject to section  
21          1902(kk)(4)(A)(ii)(II), within a geographic area  
22          that is subject to a moratorium imposed under  
23          section 1866(j)(7) by a provider or supplier  
24          that meets the requirements specified in sub-

1 paragraph (C)(iii) of such section, during the  
2 period of such moratorium; or”.

3 (B) EXCEPTION WITH RESPECT TO AC-  
4 CESS.—Section 1902(kk)(4)(A)(ii) of the Social  
5 Security Act (42 U.S.C. 1396a(kk)(4)(A)(ii)) is  
6 amended to read as follows:

7 “(ii) EXCEPTIONS.—

8 “(I) COMPLIANCE WITH MORATO-  
9 RIUM.—A State shall not be required  
10 to comply with a temporary morato-  
11 rium described in clause (i) if the  
12 State determines that the imposition  
13 of such temporary moratorium would  
14 adversely impact beneficiaries’ access  
15 to medical assistance.

16 “(II) FFP AVAILABLE.—Not-  
17 withstanding section 1903(i)(2)(D),  
18 payment may be made to a State  
19 under this title with respect to  
20 amounts expended for items and serv-  
21 ices described in such section if the  
22 Secretary, in consultation with the  
23 State agency administering the State  
24 plan under this title (or a waiver of  
25 the plan), determines that denying

1 payment to the State pursuant to  
2 such section would adversely impact  
3 beneficiaries' access to medical assist-  
4 ance. ”.

5 (C) STATE PLAN REQUIREMENT WITH RE-  
6 SPECT TO LIMITATION ON CHARGES TO BENE-  
7 FICIARIES.—Section 1902(kk)(4)(A) of the So-  
8 cial Security Act (42 U.S.C. 1396a(kk)(4)(A))  
9 is amended by adding at the end the following  
10 new clause:

11 “(iii) LIMITATION ON CHARGES TO  
12 BENEFCIARIES.—With respect to any  
13 amount expended for items or services fur-  
14 nished during calendar quarters beginning  
15 on or after October 1, 2017, the State pro-  
16 hibits, during the period of a temporary  
17 moratorium described in clause (i), a pro-  
18 vider meeting the requirements specified in  
19 subparagraph (C)(iii) of section 1866(j)(7)  
20 from charging an individual or other per-  
21 son eligible to receive medical assistance  
22 under the State plan under this title (or a  
23 waiver of the plan) for an item or service  
24 described in section 1903(i)(2)(D) fur-  
25 nished to such an individual.”.

1           (2) CORRECTING AMENDMENTS TO RELATED  
2 PROVISIONS.—

3           (A) SECTION 1866(J).—Section 1866(j) of  
4 the Social Security Act (42 U.S.C. 1395cc(j)) is  
5 amended—

6           (i) in paragraph (1)(A)—

7                 (I) by striking “paragraph (4)”  
8 and inserting “paragraph (5)”;

9                 (II) by striking “moratoria in ac-  
10 cordance with paragraph (5)” and in-  
11 sserting “moratoria in accordance with  
12 paragraph (7)”;

13                 (III) by striking “paragraph (6)”  
14 and inserting “paragraph (9)”;

15           (ii) by redesignating the second para-  
16 graph (8) (redesignated by section 1304(1)  
17 of Public Law 111–152) as paragraph (9).

18           (B) SECTION 1902(KK).—Section 1902(kk)  
19 of such Act (42 U.S.C. 1396a(kk)) is amend-  
20 ed—

21           (i) in paragraph (1), by striking “sec-  
22 tion 1886(j)(2)” and inserting “section  
23 1866(j)(2)”;



1 (ii) in paragraph (2), by striking “sec-  
2 tion 1886(j)(3)” and inserting “section  
3 1866(j)(3)”;

4 (iii) in paragraph (3), by striking  
5 “section 1886(j)(4)” and inserting “section  
6 1866(j)(5)”;

7 (iv) in paragraph (4)(A), by striking  
8 “section 1886(j)(6)” and inserting “section  
9 1866(j)(7)”.

10 **SEC. 17005. PRESERVATION OF MEDICARE BENEFICIARY**  
11 **CHOICE UNDER MEDICARE ADVANTAGE.**

12 Section 1851(e)(2) of the Social Security Act (42  
13 U.S.C. 1395w-21(e)(2)) is amended—

14 (1) in subparagraph (C)—

15 (A) in the heading, by inserting “FROM  
16 2011 THROUGH 2018” after “45-DAY PERIOD”;  
17 and

18 (B) by inserting “and ending with 2018”  
19 after “beginning with 2011”; and

20 (2) by adding at the end the following new sub-  
21 paragraph:

22 “(G) CONTINUOUS OPEN ENROLLMENT  
23 AND DISENROLLMENT FOR FIRST 3 MONTHS IN  
24 2016 AND SUBSEQUENT YEARS.—

1                   “(i) IN GENERAL.—Subject to clause  
2                   (ii) and subparagraph (D)—

3                   “(I) in the case of an MA eligible  
4                   individual who is enrolled in an MA  
5                   plan, at any time during the first 3  
6                   months of a year (beginning with  
7                   2019); or

8                   “(II) in the case of an individual  
9                   who first becomes an MA eligible indi-  
10                  vidual during a year (beginning with  
11                  2019) and enrolls in an MA plan, dur-  
12                  ing the first 3 months during such  
13                  year in which the individual is an MA  
14                  eligible individual;

15                  such MA eligible individual may change the  
16                  election under subsection (a)(1).

17                  “(ii) LIMITATION OF ONE CHANGE  
18                  DURING OPEN ENROLLMENT PERIOD EACH  
19                  YEAR.—An individual may change the elec-  
20                  tion pursuant to clause (i) only once dur-  
21                  ing the applicable 3-month period de-  
22                  scribed in such clause in each year. The  
23                  limitation under this clause shall not apply  
24                  to changes in elections effected during an  
25                  annual, coordinated election period under

1 paragraph (3) or during a special enroll-  
2 ment period under paragraph (4).

3 “(iii) LIMITED APPLICATION TO PART  
4 D.—Clauses (i) and (ii) of this subpara-  
5 graph shall only apply with respect to  
6 changes in enrollment in a prescription  
7 drug plan under part D in the case of an  
8 individual who, previous to such change in  
9 enrollment, is enrolled in a Medicare Ad-  
10 vantage plan.

11 “(iv) LIMITATIONS ON MARKETING.—  
12 Pursuant to subsection (j), no unsolicited  
13 marketing or marketing materials may be  
14 sent to an individual described in clause (i)  
15 during the continuous open enrollment and  
16 disenrollment period established for the in-  
17 dividual under such clause, notwith-  
18 standing marketing guidelines established  
19 by the Centers for Medicare & Medicaid  
20 Services.”.

21 **SEC. 17006. ALLOWING END-STAGE RENAL DISEASE BENE-**  
22 **FICIARIES TO CHOOSE A MEDICARE ADVAN-**  
23 **TAGE PLAN.**

24 (a) REMOVING PROHIBITION.—

1           (1) IN GENERAL.—Section 1851(a)(3) of the  
2           Social Security Act (42 U.S.C. 1395w–21(a)(3)) is  
3           amended—

4                   (A) by striking subparagraph (B); and  
5                   (B) by striking “ELIGIBLE INDIVIDUAL”  
6           and all that follows through “In this title, sub-  
7           ject to subparagraph (B),” and inserting “ELI-  
8           GIBLE INDIVIDUAL.—In this title,”.

9           (2) CONFORMING AMENDMENTS.—

10                   (A) Section 1852(b)(1) of the Social Secu-  
11           rity Act (42 U.S.C. 1395w–22(b)(1)) is amend-  
12           ed—

13                           (i) by striking subparagraph (B); and  
14                           (ii) by striking “BENEFICIARIES” and  
15           all that follows through “A  
16           Medicare+Choice organization” and in-  
17           serting “BENEFICIARIES.—A Medicare Ad-  
18           vantage organization”.

19                   (B) Section 1859(b)(6) of the Social Secu-  
20           rity Act (42 U.S.C. 1395w–28(b)(6)) is amend-  
21           ed, in the last sentence, by striking “may  
22           waive” and all that follows through “subpara-  
23           graph and”.

1           (3) EFFECTIVE DATE.—The amendments made  
2           by this subsection shall apply with respect to plan  
3           years beginning on or after January 1, 2021.

4           (b) EXCLUDING COSTS FOR KIDNEY ACQUISITIONS  
5 FROM MA BENCHMARK.—Section 1853 of the Social Se-  
6           curity Act (42 U.S.C. 1395w-23) is amended—

7           (1) in subsection (k)—

8           (A) in paragraph (1)—

9           (i) in the matter preceding subpara-  
10           graph (A), by striking “paragraphs (2)  
11           and (4)” and inserting “paragraphs (2),  
12           (4), and (5)”; and

13           (ii) in subparagraph (B)(i), by strik-  
14           ing “paragraphs (2) and (4)” and insert-  
15           ing “paragraphs (2), (4), and (5)”; and

16           (B) by adding at the end the following new  
17           paragraph:

18           “(5) EXCLUSION OF COSTS FOR KIDNEY ACQUI-  
19           SITIONS FROM CAPITATION RATES.—After deter-  
20           mining the applicable amount for an area for a year  
21           under paragraph (1) (beginning with 2021), the Sec-  
22           retary shall adjust such applicable amount to ex-  
23           clude from such applicable amount the Secretary’s  
24           estimate of the standardized costs for payments for  
25           organ acquisitions for kidney transplants covered

1 under this title (including expenses covered under  
2 section 1881(d)) in the area for the year.”; and

3 (2) in subsection (n)(2)—

4 (A) in subparagraph (A)(i), by inserting  
5 “and, for 2021 and subsequent years, the exclu-  
6 sion of payments for organ acquisitions for kid-  
7 ney transplants from the capitation rate as de-  
8 scribed in subsection (k)(5)” before the semi-  
9 colon at the end;

10 (B) in subparagraph (E), in the matter  
11 preceding clause (i), by striking “subparagraph  
12 (F)” and inserting “subparagraphs (F) and  
13 (G)”; and

14 (C) by adding at the end the following new  
15 subparagraph:

16 “(G) APPLICATION OF KIDNEY ACQUISSI-  
17 TIONS ADJUSTMENT.—The base payment  
18 amount specified in subparagraph (E) for a  
19 year (beginning with 2021) shall be adjusted in  
20 the same manner under paragraph (5) of sub-  
21 section (k) as the applicable amount is adjusted  
22 under such subsection.”.

23 (c) FFS COVERAGE OF KIDNEY ACQUISITIONS.—

24 (1) IN GENERAL.—Section 1852(a)(1)(B)(i) of  
25 the Social Security Act (42 U.S.C. 1395w-

1       22(a)(1)(B)(i) is amended by inserting “or coverage  
2       for organ acquisitions for kidney transplants, includ-  
3       ing as covered under section 1881(d)” after “hospice  
4       care”.

5           (2) CONFORMING AMENDMENT.—Section  
6       1851(i) of the Social Security Act (42 U.S.C.  
7       1395w–21(i)) is amended by adding at the end the  
8       following new paragraph:

9           “(3) FFS PAYMENT FOR EXPENSES FOR KID-  
10       NEY ACQUISITIONS.—Paragraphs (1) and (2) shall  
11       not apply with respect to expenses for organ acqui-  
12       sitions for kidney transplants described in section  
13       1852(a)(1)(B)(i).”.

14           (3) EFFECTIVE DATE.—The amendments made  
15       by this subsection shall apply with respect to plan  
16       years beginning on or after January 1, 2021.

17       (d) EVALUATION OF QUALITY.—

18           (1) IN GENERAL.—The Secretary of Health and  
19       Human Services (in this subsection referred to as  
20       the “Secretary”) shall conduct an evaluation of  
21       whether the 5-star rating system based on the data  
22       collected under section 1852(e) of the Social Secu-  
23       rity Act (42 U.S.C. 1395w–22(e)) should include a  
24       quality measure specifically related to care for en-  
25       rollees in Medicare Advantage plans under part C of

1 title XVIII of such Act determined to have end-stage  
2 renal disease.

3 (2) PUBLIC AVAILABILITY.—Not later than  
4 April 1, 2020, the Secretary shall post on the Inter-  
5 net website of the Centers for Medicare & Medicaid  
6 Services the results of the evaluation under para-  
7 graph (1).

8 (e) REPORT.—Not later than December 31, 2023, the  
9 Secretary of Health and Human Services (in this sub-  
10 section referred to as the “Secretary”) shall submit to  
11 Congress a report on the impact of the provisions of, and  
12 amendments made by, this section with respect to the fol-  
13 lowing:

14 (1) Spending under—

15 (A) the original Medicare fee-for-service  
16 program under parts A and B of title XVIII of  
17 the Social Security Act; and

18 (B) the Medicare Advantage program  
19 under part C of such title.

20 (2) The number of enrollees determined to have  
21 end-stage renal disease—

22 (A) in the original Medicare fee-for-service  
23 program; and

24 (B) in the Medicare Advantage program.



1           (3) The sufficiency of the amount of data under  
2           the original Medicare fee-for-service program for in-  
3           dividuals determined to have end-stage renal disease  
4           for purposes of determining payment rates for end-  
5           stage renal disease under the Medicare Advantage  
6           program.

7           (f) IMPROVEMENTS TO RISK ADJUSTMENT UNDER  
8           MEDICARE ADVANTAGE.—

9           (1) IN GENERAL.—Section 1853(a)(1) of the  
10          Social Security Act (42 U.S.C. 1395w–23(a)(1)) is  
11          amended—

12                   (A) in subparagraph (C)(i), by striking  
13                   “The Secretary” and inserting “Subject to sub-  
14                   paragraph (I), the Secretary”; and

15                   (B) by adding at the end the following new  
16                   subparagraph:

17                           “(I) IMPROVEMENTS TO RISK ADJUSTMENT  
18                           FOR 2019 AND SUBSEQUENT YEARS.—

19                                   “(i) IN GENERAL.—In order to deter-  
20                                   mine the appropriate adjustment for health  
21                                   status under subparagraph (C)(i), the fol-  
22                                   lowing shall apply:

23   “(I) TAKING INTO ACCOUNT  
24   TOTAL NUMBER OF DISEASES OR CON-  
25   DITIONS.—The Secretary shall take

1 into account the total number of dis-  
2 eases or conditions of an individual  
3 enrolled in an MA plan. The Secretary  
4 shall make an additional adjustment  
5 under such subparagraph as the num-  
6 ber of diseases or conditions of an in-  
7 dividual increases.

8 “(II) USING AT LEAST 2 YEARS  
9 OF DIAGNOSTIC DATA.—The Secretary  
10 may use at least 2 years of diagnosis  
11 data.

12 “(III) PROVIDING SEPARATE AD-  
13 JUSTMENTS FOR DUAL ELIGIBLE IN-  
14 DIVIDUALS.—With respect to individ-  
15 uals who are dually eligible for bene-  
16 fits under this title and title XIX, the  
17 Secretary shall make separate adjust-  
18 ments for each of the following:

19 “(aa) Full-benefit dual eligi-  
20 ble individuals (as defined in sec-  
21 tion 1935(c)(6)).

22 “(bb) Such individuals not  
23 described in item (aa).

24 “(IV) EVALUATION OF MENTAL  
25 HEALTH AND SUBSTANCE USE DIS-

1                   ORDERS.—The Secretary shall evalu-  
2                   ate the impact of including additional  
3                   diagnosis codes related to mental  
4                   health and substance use disorders in  
5                   the risk adjustment model.

6                   “(V) EVALUATION OF CHRONIC  
7                   KIDNEY DISEASE.—The Secretary  
8                   shall evaluate the impact of including  
9                   the severity of chronic kidney disease  
10                  in the risk adjustment model.

11                  “(VI) EVALUATION OF PAYMENT  
12                  RATES FOR END-STAGE RENAL DIS-  
13                  EASE.—The Secretary shall evaluate  
14                  whether other factors (in addition to  
15                  those described in subparagraph (H))  
16                  should be taken into consideration  
17                  when computing payment rates under  
18                  such subparagraph.

19                  “(ii) PHASED-IN IMPLEMENTATION.—  
20                  The Secretary shall phase-in any changes  
21                  to risk adjustment payment amounts under  
22                  subparagraph (C)(i) under this subpara-  
23                  graph over a 3-year period, beginning with  
24                  2019, with such changes being fully imple-  
25                  mented for 2022 and subsequent years.

1                   “(iii) OPPORTUNITY FOR REVIEW AND  
2                   PUBLIC COMMENT.—The Secretary shall  
3                   provide an opportunity for review of the  
4                   proposed changes to such risk adjustment  
5                   payment amounts under this subparagraph  
6                   and a public comment period of not less  
7                   than 60 days before implementing such  
8                   changes.”.

9                   (2) STUDIES AND REPORTS.—

10                   (A) REPORTS ON THE RISK ADJUSTMENT  
11                   SYSTEM.—

12                   (i) MEDPAC EVALUATION AND RE-  
13                   PORT.—

14                   (I) EVALUATION.—The Medicare  
15                   Payment Advisory Commission shall  
16                   conduct an evaluation of the impact of  
17                   the provisions of, and amendments  
18                   made by, this section on risk scores  
19                   for enrollees in Medicare Advantage  
20                   plans under part C of title XVIII of  
21                   the Social Security Act and payments  
22                   to Medicare Advantage plans under  
23                   such part, including the impact of  
24                   such provisions and amendments on  
25                   the overall accuracy of risk scores

1 under the Medicare Advantage pro-  
2 gram.

3 (II) REPORT.—Not later than  
4 July 1, 2020, the Medicare Payment  
5 Advisory Commission shall submit to  
6 Congress a report on the evaluation  
7 under subclause (I), together with rec-  
8 ommendations for such legislation and  
9 administrative action as the Commis-  
10 sion determines appropriate.

11 (ii) REPORTS BY SECRETARY OF  
12 HEALTH AND HUMAN SERVICES.—Not  
13 later than December 31, 2018, and every  
14 3 years thereafter, the Secretary of Health  
15 and Human Services shall submit to Con-  
16 gress a report on the risk adjustment  
17 model and the ESRD risk adjustment  
18 model under the Medicare Advantage pro-  
19 gram under part C of title XVIII of the  
20 Social Security Act, including any revisions  
21 to either such model since the previous re-  
22 port. Such report shall include information  
23 on how such revisions impact the predictive  
24 ratios under either such model for groups  
25 of enrollees in Medicare Advantage plans,

1 including very high and very low cost en-  
2 rollees, and groups defined by the number  
3 of chronic conditions of enrollees.

4 (B) STUDY AND REPORT ON FUNCTIONAL  
5 STATUS.—

6 (i) STUDY.—The Comptroller General  
7 of the United States (in this subparagraph  
8 referred to as the “Comptroller General”)  
9 shall conduct a study on how to most accu-  
10 rately measure the functional status of en-  
11 rollees in Medicare Advantage plans and  
12 whether the use of such functional status  
13 would improve the accuracy of risk adjust-  
14 ment payments under the Medicare Advan-  
15 tage program under part C of title XVIII  
16 of the Social Security Act. Such study  
17 shall include an analysis of the challenges  
18 in collecting and reporting functional sta-  
19 tus information for Medicare Advantage  
20 plans under such part, providers of serv-  
21 ices and suppliers under the Medicare pro-  
22 gram, and the Centers for Medicare &  
23 Medicaid Services.

24 (ii) REPORT.—Not later than June  
25 30, 2018, the Comptroller General shall

1 submit to Congress a report containing the  
2 results of the study under clause (i), to-  
3 gether with recommendations for such leg-  
4 islation and administrative action as the  
5 Comptroller General determines appro-  
6 priate.

7 **SEC. 17007. IMPROVEMENTS TO THE ASSIGNMENT OF**  
8 **BENEFICIARIES UNDER THE MEDICARE**  
9 **SHARED SAVINGS PROGRAM.**

10 Section 1899(c) of the Social Security Act (42 U.S.C.  
11 1395jjj(c)) is amended—

12 (1) by striking “utilization of primary” and in-  
13 serting “utilization of—

14 “(1) in the case of performance years beginning  
15 on or after April 1, 2012, primary”;

16 (2) in paragraph (1), as added by paragraph  
17 (1) of this section, by striking the period at the end  
18 and inserting “; and”;

19 (3) by adding at the end the following new  
20 paragraph:

21 “(2) in the case of performance years beginning  
22 on or after January 1, 2019, services provided under  
23 this title by a Federally qualified health center or  
24 rural health clinic (as those terms are defined in sec-

1 tion 1861(aa)), as may be determined by the Sec-  
2 retary.”.

3 **TITLE XVIII—OTHER**  
4 **PROVISIONS**

5 **SEC. 18001. EXCEPTION FROM GROUP HEALTH PLAN RE-**  
6 **QUIREMENTS FOR QUALIFIED SMALL EM-**  
7 **PLOYER HEALTH REIMBURSEMENT AR-**  
8 **RANGEMENTS.**

9 (a) AMENDMENTS TO THE INTERNAL REVENUE  
10 CODE OF 1986 AND THE PATIENT PROTECTION AND AF-  
11 FORDABLE CARE ACT.—

12 (1) IN GENERAL.—Section 9831 of the Internal  
13 Revenue Code of 1986 is amended by adding at the  
14 end the following new subsection:

15 “(d) EXCEPTION FOR QUALIFIED SMALL EMPLOYER  
16 HEALTH REIMBURSEMENT ARRANGEMENTS.—

17 “(1) IN GENERAL.—For purposes of this title  
18 (except as provided in section 4980I(f)(4) and not-  
19 withstanding any other provision of this title), the  
20 term ‘group health plan’ shall not include any quali-  
21 fied small employer health reimbursement arrange-  
22 ment.

23 “(2) QUALIFIED SMALL EMPLOYER HEALTH  
24 REIMBURSEMENT ARRANGEMENT.—For purposes of  
25 this subsection—



1           “(A) IN GENERAL.—The term ‘qualified  
2           small employer health reimbursement arrange-  
3           ment’ means an arrangement which—

4                   “(i) is described in subparagraph (B),  
5           and

6                   “(ii) is provided on the same terms to  
7           all eligible employees of the eligible em-  
8           ployer.

9           “(B) ARRANGEMENT DESCRIBED.—An ar-  
10          rangement is described in this subparagraph  
11          if—

12                   “(i) such arrangement is funded solely  
13          by an eligible employer and no salary re-  
14          duction contributions may be made under  
15          such arrangement,

16                   “(ii) such arrangement provides, after  
17          the employee provides proof of coverage,  
18          for the payment of, or reimbursement of,  
19          an eligible employee for expenses for med-  
20          ical care (as defined in section 213(d)) in-  
21          curred by the eligible employee or the eligi-  
22          ble employee’s family members (as deter-  
23          mined under the terms of the arrange-  
24          ment), and

1                   “(iii) the amount of payments and re-  
2                   imbursements described in clause (ii) for  
3                   any year do not exceed \$4,950 (\$10,000 in  
4                   the case of an arrangement that also pro-  
5                   vides for payments or reimbursements for  
6                   family members of the employee).

7                   “(C) CERTAIN VARIATION PERMITTED.—  
8                   For purposes of subparagraph (A)(ii), an ar-  
9                   rangement shall not fail to be treated as pro-  
10                  vided on the same terms to each eligible em-  
11                  ployee merely because the employee’s permitted  
12                  benefit under such arrangement varies in ac-  
13                  cordance with the variation in the price of an  
14                  insurance policy in the relevant individual  
15                  health insurance market based on—

16                  “(i) the age of the eligible employee  
17                  (and, in the case of an arrangement which  
18                  covers medical expenses of the eligible em-  
19                  ployee’s family members, the age of such  
20                  family members), or

21                  “(ii) the number of family members of  
22                  the eligible employee the medical expenses  
23                  of which are covered under such arrange-  
24                  ment.

1           The variation permitted under the preceding  
2           sentence shall be determined by reference to the  
3           same insurance policy with respect to all eligible  
4           employees.

5                   “(D) RULES RELATING TO MAXIMUM DOL-  
6           LAR LIMITATION.—

7                           “(i) AMOUNT PRORATED IN CERTAIN  
8           CASES.—In the case of an individual who  
9           is not covered by an arrangement for the  
10          entire year, the limitation under subpara-  
11          graph (B)(iii) for such year shall be an  
12          amount which bears the same ratio to the  
13          amount which would (but for this clause)  
14          be in effect for such individual for such  
15          year under subparagraph (B)(iii) as the  
16          number of months for which such indi-  
17          vidual is covered by the arrangement for  
18          such year bears to 12.

19                          “(ii) INFLATION ADJUSTMENT.—In  
20          the case of any year beginning after 2016,  
21          each of the dollar amounts in subpara-  
22          graph (B)(iii) shall be increased by an  
23          amount equal to—

24                                   “(I) such dollar amount, multi-  
25                                   plied by

1                   “(II) the cost-of-living adjust-  
2                   ment determined under section 1(f)(3)  
3                   for the calendar year in which the tax-  
4                   able year begins, determined by sub-  
5                   stituting ‘calendar year 2015’ for ‘cal-  
6                   endar year 1992’ in subparagraph (B)  
7                   thereof.

8                   If any dollar amount increased under the  
9                   preceding sentence is not a multiple of  
10                  \$50, such dollar amount shall be rounded  
11                  to the next lowest multiple of \$50.

12                  “(3) OTHER DEFINITIONS.—For purposes of  
13                  this subsection—

14                         “(A) ELIGIBLE EMPLOYEE.—The term ‘eli-  
15                         gible employee’ means any employee of an eligi-  
16                         ble employer, except that the terms of the ar-  
17                         rangement may exclude from consideration em-  
18                         ployees described in any clause of section  
19                         105(h)(3)(B) (applied by substituting ‘90 days’  
20                         for ‘3 years’ in clause (i) thereof).

21                         “(B) ELIGIBLE EMPLOYER.—The term ‘el-  
22                         igible employer’ means an employer that—

23                                 “(i) is not an applicable large em-  
24                                 ployer as defined in section 4980H(c)(2),  
25                                 and

1                   “(ii) does not offer a group health  
2                   plan to any of its employees.

3                   “(C) PERMITTED BENEFIT.—The term  
4                   ‘permitted benefit’ means, with respect to any  
5                   eligible employee, the maximum dollar amount  
6                   of payments and reimbursements which may be  
7                   made under the terms of the qualified small  
8                   employer health reimbursement arrangement  
9                   for the year with respect to such employee.

10                  “(4) NOTICE.—

11                  “(A) IN GENERAL.—An employer funding  
12                  a qualified small employer health reimburse-  
13                  ment arrangement for any year shall, not later  
14                  than 90 days before the beginning of such year  
15                  (or, in the case of an employee who is not eligi-  
16                  ble to participate in the arrangement as of the  
17                  beginning of such year, the date on which such  
18                  employee is first so eligible), provide a written  
19                  notice to each eligible employee which includes  
20                  the information described in subparagraph (B).

21                  “(B) CONTENTS OF NOTICE.—The notice  
22                  required under subparagraph (A) shall include  
23                  each of the following:

24                         “(i) A statement of the amount which  
25                         would be such eligible employee’s permitted

1 benefit under the arrangement for the  
2 year.

3 “(ii) A statement that the eligible em-  
4 ployee should provide the information de-  
5 scribed in clause (i) to any health insur-  
6 ance exchange to which the employee ap-  
7 plies for advance payment of the premium  
8 assistance tax credit.

9 “(iii) A statement that if the employee  
10 is not covered under minimum essential  
11 coverage for any month the employee may  
12 be subject to tax under section 5000A for  
13 such month and reimbursements under the  
14 arrangement may be includible in gross in-  
15 come.”.

16 (2) LIMITATION ON EXCLUSION FROM GROSS  
17 INCOME.—Section 106 of such Code is amended by  
18 adding at the end the following:

19 “(g) QUALIFIED SMALL EMPLOYER HEALTH REIM-  
20 BURSEMENT ARRANGEMENT.—For purposes of this sec-  
21 tion and section 105, payments or reimbursements from  
22 a qualified small employer health reimbursement arrange-  
23 ment (as defined in section 9831(d)) of an individual for  
24 medical care (as defined in section 213(d)) shall not be  
25 treated as paid or reimbursed under employer-provided

1 coverage for medical expenses under an accident or health  
2 plan if for the month in which such medical care is pro-  
3 vided the individual does not have minimum essential cov-  
4 erage (within the meaning of section 5000A(f)).”.

5 (3) COORDINATION WITH HEALTH INSURANCE  
6 PREMIUM CREDIT.—Section 36B(c) of such Code is  
7 amended by adding at the end the following new  
8 paragraph:

9 “(4) SPECIAL RULES FOR QUALIFIED SMALL  
10 EMPLOYER HEALTH REIMBURSEMENT ARRANGE-  
11 MENTS.—

12 “(A) IN GENERAL.—The term ‘coverage  
13 month’ shall not include any month with re-  
14 spect to an employee (or any spouse or depend-  
15 ent of such employee) if for such month the em-  
16 ployee is provided a qualified small employer  
17 health reimbursement arrangement which con-  
18 stitutes affordable coverage.

19 “(B) DENIAL OF DOUBLE BENEFIT.—In  
20 the case of any employee who is provided a  
21 qualified small employer health reimbursement  
22 arrangement for any coverage month (deter-  
23 mined without regard to subparagraph (A)), the  
24 credit otherwise allowable under subsection (a)  
25 to the taxpayer for such month shall be reduced

1 (but not below zero) by the amount described in  
2 subparagraph (C)(i)(II) for such month.

3 “(C) AFFORDABLE COVERAGE.—For pur-  
4 poses of subparagraph (A), a qualified small  
5 employer health reimbursement arrangement  
6 shall be treated as constituting affordable cov-  
7 erage for a month if—

8 “(i) the excess of—

9 “(I) the amount that would be  
10 paid by the employee as the premium  
11 for such month for self-only coverage  
12 under the second lowest cost silver  
13 plan offered in the relevant individual  
14 health insurance market, over

15 “(II)  $\frac{1}{12}$  of the employee’s per-  
16 mitted benefit (as defined in section  
17 9831(d)(3)(C)) under such arrange-  
18 ment, does not exceed—

19 “(ii)  $\frac{1}{12}$  of 9.5 percent of the employ-  
20 ee’s household income.

21 “(D) QUALIFIED SMALL EMPLOYER  
22 HEALTH REIMBURSEMENT ARRANGEMENT.—  
23 For purposes of this paragraph, the term  
24 ‘qualified small employer health reimbursement



1 arrangement' has the meaning given such term  
2 by section 9831(d)(2).

3 “(E) COVERAGE FOR LESS THAN ENTIRE  
4 YEAR.—In the case of an employee who is pro-  
5 vided a qualified small employer health reim-  
6 bursement arrangement for less than an entire  
7 year, subparagraph (C)(i)(II) shall be applied  
8 by substituting ‘the number of months during  
9 the year for which such arrangement was pro-  
10 vided’ for ‘12’.

11 “(F) INDEXING.—In the case of plan years  
12 beginning in any calendar year after 2014, the  
13 Secretary shall adjust the 9.5 percent amount  
14 under subparagraph (C)(ii) in the same manner  
15 as the percentages are adjusted under sub-  
16 section (b)(3)(A)(ii).”.

17 (4) APPLICATION OF EXCISE TAX ON HIGH  
18 COST EMPLOYER-SPONSORED HEALTH COVERAGE.—

19 (A) IN GENERAL.—Section 4980I(f)(4) of  
20 such Code is amended by adding at the end the  
21 following: “Section 9831(d)(1) shall not apply  
22 for purposes of this section.”.

23 (B) DETERMINATION OF COST OF COV-  
24 ERAGE.—Section 4980I(d)(2) of such Code is  
25 amended by redesignating subparagraph (D) as

1           subparagraph (E) and by inserting after sub-  
2           paragraph (C) the following new subparagraph:

3                   “(D)   QUALIFIED   SMALL   EMPLOYER  
4           HEALTH REIMBURSEMENT ARRANGEMENTS.—

5           In the case of applicable employer-sponsored  
6           coverage consisting of coverage under any quali-  
7           fied small employer health reimbursement ar-  
8           rangement (as defined in section 9831(d)(2)),  
9           the cost of coverage shall be equal to the  
10          amount described in section 6051(a)(15).”.

11          (5) ENFORCEMENT OF NOTICE REQUIRE-  
12          MENT.—Section 6652 of such Code is amended by  
13          adding at the end the following new subsection:

14          “(o) FAILURE TO PROVIDE NOTICES WITH RESPECT  
15          TO QUALIFIED SMALL EMPLOYER HEALTH REIMBURSE-  
16          MENT ARRANGEMENTS.—In the case of each failure to  
17          provide a written notice as required by section 9831(d)(4),  
18          unless it is shown that such failure is due to reasonable  
19          cause and not willful neglect, there shall be paid, on notice  
20          and demand of the Secretary and in the same manner as  
21          tax, by the person failing to provide such written notice,  
22          an amount equal to \$50 per employee per incident of fail-  
23          ure to provide such notice, but the total amount imposed  
24          on such person for all such failures during any calendar  
25          year shall not exceed \$2,500.”.

1 (6) REPORTING.—

2 (A) W-2 REPORTING.—Section 6051(a) of  
3 such Code is amended by striking “and” at the  
4 end of paragraph (13), by striking the period at  
5 the end of paragraph (14) and inserting “,  
6 and”, and by inserting after paragraph (14) the  
7 following new paragraph:

8 “(15) the total amount of permitted benefit (as  
9 defined in section 9831(d)(3)(C)) for the year under  
10 a qualified small employer health reimbursement ar-  
11 rangement (as defined in section 9831(d)(2)) with  
12 respect to the employee.”.

13 (B) INFORMATION REQUIRED TO BE PRO-  
14 VIDED BY EXCHANGE SUBSIDY APPLICANTS.—  
15 Section 1411(b)(3) of the Patient Protection  
16 and Affordable Care Act is amended by redesignig-  
17 nating subparagraph (B) as subparagraph (C)  
18 and by inserting after subparagraph (A) the fol-  
19 lowing new subparagraph:

20 “(B) CERTAIN INDIVIDUAL HEALTH IN-  
21 SURANCE POLICIES OBTAINED THROUGH SMALL  
22 EMPLOYERS.—The amount of the enrollee’s  
23 permitted benefit (as defined in section  
24 9831(d)(3)(C) of the Internal Revenue Code of  
25 1986) under a qualified small employer health

1 reimbursement arrangement (as defined in sec-  
2 tion 9831(d)(2) of such Code).”.

3 (7) EFFECTIVE DATES.—

4 (A) IN GENERAL.—Except as otherwise  
5 provided in this paragraph, the amendments  
6 made by this subsection shall apply to years be-  
7 ginning after December 31, 2016.

8 (B) TRANSITION RELIEF.—The relief  
9 under Treasury Notice 2015–17 shall be treat-  
10 ed as applying to any plan year beginning on or  
11 before December 31, 2016.

12 (C) COORDINATION WITH HEALTH INSUR-  
13 ANCE PREMIUM CREDIT.—The amendments  
14 made by paragraph (3) shall apply to taxable  
15 years beginning after December 31, 2016.

16 (D) EMPLOYEE NOTICE.—

17 (i) IN GENERAL.—The amendments  
18 made by paragraph (5) shall apply to no-  
19 tices with respect to years beginning after  
20 December 31, 2016.

21 (ii) TRANSITION RELIEF.—For pur-  
22 poses of section 6652(o) of the Internal  
23 Revenue Code of 1986 (as added by this  
24 Act), a person shall not be treated as fail-  
25 ing to provide a written notice as required

1 by section 9831(d)(4) of such Code if such  
2 notice is so provided not later than 90  
3 days after the date of the enactment of  
4 this Act.

5 (E) W-2 REPORTING.—The amendments  
6 made by paragraph (6)(A) shall apply to cal-  
7 endar years beginning after December 31,  
8 2016.

9 (F) INFORMATION PROVIDED BY EX-  
10 CHANGE SUBSIDY APPLICANTS.—

11 (i) IN GENERAL.—The amendments  
12 made by paragraph (6)(B) shall apply to  
13 applications for enrollment made after De-  
14 cember 31, 2016.

15 (ii) VERIFICATION.—Verification  
16 under section 1411 of the Patient Protec-  
17 tion and Affordable Care Act of informa-  
18 tion provided under section 1411(b)(3)(B)  
19 of such Act shall apply with respect to  
20 months beginning after October 2016.

21 (iii) TRANSITIONAL RELIEF.—In the  
22 case of an application for enrollment under  
23 section 1411(b) of the Patient Protection  
24 and Affordable Care Act made before April  
25 1, 2017, the requirement of section

1                   1411(b)(3)(B) of such Act shall be treated  
2                   as met if the information described therein  
3                   is provided not later than 30 days after the  
4                   date on which the applicant receives the  
5                   notice described in section 9831(d)(4) of  
6                   the Internal Revenue Code of 1986.

7                   (8) SUBSTANTIATION REQUIREMENTS.—The  
8                   Secretary of the Treasury (or his designee) may  
9                   issue substantiation requirements as necessary to  
10                  carry out this subsection.

11                  (b) AMENDMENTS TO THE EMPLOYEE RETIREMENT  
12 INCOME SECURITY ACT OF 1974.—

13                  (1) IN GENERAL.—Section 733(a)(1) of the  
14                  Employee Retirement Income Security Act of 1974  
15                  (29 U.S.C. 1191b(a)(1)) is amended by adding at  
16                  the end the following: “Such term shall not include  
17                  any qualified small employer health reimbursement  
18                  arrangement (as defined in section 9831(d)(2) of the  
19                  Internal Revenue Code of 1986).”.

20                  (2) EXCEPTION FROM CONTINUATION COV-  
21                  ERAGE REQUIREMENTS, ETC.—Section 607(1) of  
22                  such Act (29 U.S.C. 1167(1)) is amended by adding  
23                  at the end the following: “Such term shall not in-  
24                  clude any qualified small employer health reimburse-

1       ment arrangement (as defined in section 9831(d)(2)  
2       of the Internal Revenue Code of 1986).”.

3           (3) EFFECTIVE DATE.—The amendments made  
4       by this subsection shall apply to plan years begin-  
5       ning after December 31, 2016.

6       (c) AMENDMENTS TO THE PUBLIC HEALTH SERVICE  
7       ACT.—

8           (1) IN GENERAL.—Section 2791(a)(1) of the  
9       Public Health Service Act (42 U.S.C. 300gg-  
10      91(a)(1)) is amended by adding at the end the fol-  
11     lowing: “Except for purposes of part C of title XI  
12     of the Social Security Act (42 U.S.C. 1320d et seq.),  
13     such term shall not include any qualified small em-  
14     ployer health reimbursement arrangement (as de-  
15     fined in section 9831(d)(2) of the Internal Revenue  
16     Code of 1986).”.

17          (2) EXCEPTION FROM CONTINUATION COV-  
18      ERAGE REQUIREMENTS.—Section 2208(1) of the  
19      Public Health Service Act (42 U.S.C. 300bb-8(1)) is  
20      amended by adding at the end the following: “Such  
21      term shall not include any qualified small employer  
22      health reimbursement arrangement (as defined in  
23      section 9831(d)(2) of the Internal Revenue Code of  
24      1986).”.

1           (3) EFFECTIVE DATE.—The amendments made  
2           by this subsection shall apply to plan years begin-  
3           ning after December 31, 2016.

4           **DIVISION D—CHILD AND FAMILY**  
5           **SERVICES AND SUPPORT**

6           **SEC. 19000. SHORT TITLE.**

7           This division may be cited as the “Family First Pre-  
8           vention Services Act of 2016”.

9           **TITLE XIX—INVESTING IN PRE-**  
10           **VENTION AND FAMILY SERV-**  
11           **ICES**

12           **SEC. 19001. PURPOSE.**

13           The purpose of this title is to enable States to use  
14           Federal funds available under parts B and E of title IV  
15           of the Social Security Act to provide enhanced support to  
16           children and families and prevent foster care placements  
17           through the provision of mental health and substance  
18           abuse prevention and treatment services, in-home parent  
19           skill-based programs, and kinship navigator services.

20           **Subtitle A—Prevention Activities**  
21           **Under Title IV–E**

22           **SEC. 19011. FOSTER CARE PREVENTION SERVICES AND**  
23           **PROGRAMS.**

24           (a) STATE OPTION.—Section 471 of the Social Secu-  
25           rity Act (42 U.S.C. 671) is amended—



1           (1) in subsection (a)(1), by striking “and” and  
2           all that follows through the semicolon and inserting  
3           “, adoption assistance in accordance with section  
4           473, and, at the option of the State, services or pro-  
5           grams specified in subsection (e)(1) of this section  
6           for children who are candidates for foster care or  
7           who are pregnant or parenting foster youth and the  
8           parents or kin caregivers of the children, in accord-  
9           ance with the requirements of that subsection;”; and  
10          (2) by adding at the end the following:

11          “(e) PREVENTION AND FAMILY SERVICES AND PRO-  
12          GRAMS.—

13           “(1) IN GENERAL.—Subject to the succeeding  
14           provisions of this subsection, the Secretary may  
15           make a payment to a State for providing the fol-  
16           lowing services or programs for a child described in  
17           paragraph (2) and the parents or kin caregivers of  
18           the child when the need of the child, such a parent,  
19           or such a caregiver for the services or programs are  
20           directly related to the safety, permanence, or well-  
21           being of the child or to preventing the child from en-  
22           tering foster care:

23           “(A) MENTAL HEALTH AND SUBSTANCE  
24           ABUSE PREVENTION AND TREATMENT SERV-  
25           ICES.—Mental health and substance abuse pre-

1           vention and treatment services provided by a  
2           qualified clinician for not more than a 12-  
3           month period that begins on any date described  
4           in paragraph (3) with respect to the child.

5           “(B) IN-HOME PARENT SKILL-BASED PRO-  
6           GRAMS.—In-home parent skill-based programs  
7           for not more than a 12-month period that be-  
8           gins on any date described in paragraph (3)  
9           with respect to the child and that include par-  
10          enting skills training, parent education, and in-  
11          dividual and family counseling.

12          “(2) CHILD DESCRIBED.—For purposes of  
13          paragraph (1), a child described in this paragraph is  
14          the following:

15                 “(A) A child who is a candidate for foster  
16                 care (as defined in section 475(13)) but can re-  
17                 main safely at home or in a kinship placement  
18                 with receipt of services or programs specified in  
19                 paragraph (1).

20                 “(B) A child in foster care who is a preg-  
21                 nant or parenting foster youth.

22          “(3) DATE DESCRIBED.—For purposes of para-  
23          graph (1), the dates described in this paragraph are  
24          the following:

1           “(A) The date on which a child is identi-  
2           fied in a prevention plan maintained under  
3           paragraph (4) as a child who is a candidate for  
4           foster care (as defined in section 475(13)).

5           “(B) The date on which a child is identi-  
6           fied in a prevention plan maintained under  
7           paragraph (4) as a pregnant or parenting foster  
8           youth in need of services or programs specified  
9           in paragraph (1).

10          “(4) REQUIREMENTS RELATED TO PROVIDING  
11          SERVICES AND PROGRAMS.—Services and programs  
12          specified in paragraph (1) may be provided under  
13          this subsection only if specified in advance in the  
14          child’s prevention plan described in subparagraph  
15          (A) and the requirements in subparagraphs (B)  
16          through (E) are met:

17                 “(A) PREVENTION PLAN.—The State  
18                 maintains a written prevention plan for the  
19                 child that meets the following requirements (as  
20                 applicable):

21                         “(i) CANDIDATES.—In the case of a  
22                         child who is a candidate for foster care de-  
23                         scribed in paragraph (2)(A), the prevention  
24                         plan shall—

1                   “(I) identify the foster care pre-  
2                   vention strategy for the child so that  
3                   the child may remain safely at home,  
4                   live temporarily with a kin caregiver  
5                   until reunification can be safely  
6                   achieved, or live permanently with a  
7                   kin caregiver;

8                   “(II) list the services or pro-  
9                   grams to be provided to or on behalf  
10                  of the child to ensure the success of  
11                  that prevention strategy; and

12                  “(III) comply with such other re-  
13                  quirements as the Secretary shall es-  
14                  tablish.

15                  “(ii) PREGNANT OR PARENTING FOS-  
16                  TER YOUTH.—In the case of a child who is  
17                  a pregnant or parenting foster youth de-  
18                  scribed in paragraph (2)(B), the preven-  
19                  tion plan shall—

20                  “(I) be included in the child’s  
21                  case plan required under section  
22                  475(1);

23                  “(II) list the services or pro-  
24                  grams to be provided to or on behalf  
25                  of the youth to ensure that the youth

1 is prepared (in the case of a pregnant  
2 foster youth) or able (in the case of a  
3 parenting foster youth) to be a par-  
4 ent;

5 “(III) describe the foster care  
6 prevention strategy for any child born  
7 to the youth; and

8 “(IV) comply with such other re-  
9 quirements as the Secretary shall es-  
10 tablish.

11 “(B) TRAUMA-INFORMED.—The services or  
12 programs to be provided to or on behalf of a  
13 child are provided under an organizational  
14 structure and treatment framework that in-  
15 volves understanding, recognizing, and respond-  
16 ing to the effects of all types of trauma and in  
17 accordance with recognized principles of a trau-  
18 ma-informed approach and trauma-specific  
19 interventions to address trauma’s consequences  
20 and facilitate healing.

21 “(C) ONLY SERVICES AND PROGRAMS PRO-  
22 VIDED IN ACCORDANCE WITH PROMISING, SUP-  
23 PORTED, OR WELL-SUPPORTED PRACTICES PER-  
24 MITTED.—

1           “(i) IN GENERAL.—Only State ex-  
2           penditures for services or programs speci-  
3           fied in subparagraph (A) or (B) of para-  
4           graph (1) that are provided in accordance  
5           with practices that meet the requirements  
6           specified in clause (ii) of this subparagraph  
7           and that meet the requirements specified  
8           in clause (iii), (iv), or (v), respectively, for  
9           being a promising, supported, or well-sup-  
10          ported practice, shall be eligible for a Fed-  
11          eral matching payment under section  
12          474(a)(6)(A).

13           “(ii) GENERAL PRACTICE REQUIRE-  
14          MENTS.—The general practice require-  
15          ments specified in this clause are the fol-  
16          lowing:

17                   “(I) The practice has a book,  
18                   manual, or other available writings  
19                   that specify the components of the  
20                   practice protocol and describe how to  
21                   administer the practice.

22                   “(II) There is no empirical basis  
23                   suggesting that, compared to its likely  
24                   benefits, the practice constitutes a  
25                   risk of harm to those receiving it.

1                   “(III) If multiple outcome studies  
2                   have been conducted, the overall  
3                   weight of evidence supports the bene-  
4                   fits of the practice.

5                   “(IV) Outcome measures are reli-  
6                   able and valid, and are administrated  
7                   consistently and accurately across all  
8                   those receiving the practice.

9                   “(V) There is no case data sug-  
10                  gesting a risk of harm that was prob-  
11                  ably caused by the treatment and that  
12                  was severe or frequent.

13                  “(iii) PROMISING PRACTICE.—A prac-  
14                  tice shall be considered to be a ‘promising  
15                  practice’ if the practice is superior to an  
16                  appropriate comparison practice using con-  
17                  ventional standards of statistical signifi-  
18                  cance (in terms of demonstrated meaning-  
19                  ful improvements in validated measures of  
20                  important child and parent outcomes, such  
21                  as mental health, substance abuse, and  
22                  child safety and well-being), as established  
23                  by the results or outcomes of at least one  
24                  study that—

1                   “(I) was rated by an independent  
2                   systematic review for the quality of  
3                   the study design and execution and  
4                   determined to be well-designed and  
5                   well-executed; and

6                   “(II) utilized some form of con-  
7                   trol (such as an untreated group, a  
8                   placebo group, or a wait list study).

9                   “(iv) SUPPORTED PRACTICE.—A prac-  
10                  tice shall be considered to be a ‘supported  
11                  practice’ if—

12                   “(I) the practice is superior to an  
13                   appropriate comparison practice using  
14                   conventional standards of statistical  
15                   significance (in terms of demonstrated  
16                   meaningful improvements in validated  
17                   measures of important child and par-  
18                   ent outcomes, such as mental health,  
19                   substance abuse, and child safety and  
20                   well-being), as established by the re-  
21                   sults or outcomes of at least one study  
22                   that—

23                   “(aa) was rated by an inde-  
24                   pendent systematic review for the  
25                   quality of the study design and



1 execution and determined to be  
2 well-designed and well-executed;

3 “(bb) was a rigorous ran-  
4 dom-controlled trial (or, if not  
5 available, a study using a rig-  
6 orous quasi-experimental re-  
7 search design); and

8 “(cc) was carried out in a  
9 usual care or practice setting;  
10 and

11 “(II) the study described in sub-  
12 clause (I) established that the practice  
13 has a sustained effect (when com-  
14 pared to a control group) for at least  
15 6 months beyond the end of the treat-  
16 ment.

17 “(v) WELL-SUPPORTED PRACTICE.—A  
18 practice shall be considered to be a ‘well-  
19 supported practice’ if—

20 “(I) the practice is superior to an  
21 appropriate comparison practice using  
22 conventional standards of statistical  
23 significance (in terms of demonstrated  
24 meaningful improvements in validated  
25 measures of important child and par-

1 ent outcomes, such as mental health,  
2 substance abuse, and child safety and  
3 well-being), as established by the re-  
4 sults or outcomes of at least two stud-  
5 ies that—

6 “(aa) were rated by an inde-  
7 pendent systematic review for the  
8 quality of the study design and  
9 execution and determined to be  
10 well-designed and well-executed;

11 “(bb) were rigorous random-  
12 controlled trials (or, if not avail-  
13 able, studies using a rigorous  
14 quasi-experimental research de-  
15 sign); and

16 “(cc) were carried out in a  
17 usual care or practice setting;  
18 and

19 “(II) at least one of the studies  
20 described in subclause (I) established  
21 that the practice has a sustained ef-  
22 fect (when compared to a control  
23 group) for at least 1 year beyond the  
24 end of treatment.

1           “(D) GUIDANCE ON PRACTICES CRITERIA  
2           AND PRE-APPROVED SERVICES AND PRO-  
3           GRAMS.—

4           “(i) IN GENERAL.—Not later than Oc-  
5           tober 1, 2018, the Secretary shall issue  
6           guidance to States regarding the practices  
7           criteria required for services or programs  
8           to satisfy the requirements of subpara-  
9           graph (C). The guidance shall include a  
10          pre-approved list of services and programs  
11          that satisfy the requirements.

12          “(ii) UPDATES.—The Secretary shall  
13          issue updates to the guidance required by  
14          clause (i) as often as the Secretary deter-  
15          mines necessary.

16          “(E) OUTCOME ASSESSMENT AND REPORT-  
17          ING.—The State shall collect and report to the  
18          Secretary the following information with respect  
19          to each child for whom, or on whose behalf  
20          mental health and substance abuse prevention  
21          and treatment services or in-home parent skill-  
22          based programs are provided during a 12-  
23          month period beginning on the date the child is  
24          determined by the State to be a child described  
25          in paragraph (2):

1           “(i) The specific services or programs  
2           provided and the total expenditures for  
3           each of the services or programs.

4           “(ii) The duration of the services or  
5           programs provided.

6           “(iii) In the case of a child described  
7           in paragraph (2)(A), the child’s placement  
8           status at the beginning, and at the end, of  
9           the 1-year period, respectively, and wheth-  
10          er the child entered foster care within 2  
11          years after being determined a candidate  
12          for foster care.

13          “(5) STATE PLAN COMPONENT.—

14               “(A) IN GENERAL.—A State electing to  
15               provide services or programs specified in para-  
16               graph (1) shall submit as part of the State plan  
17               required by subsection (a) a prevention services  
18               and programs plan component that meets the  
19               requirements of subparagraph (B).

20               “(B) PREVENTION SERVICES AND PRO-  
21               GRAMS PLAN COMPONENT.—In order to meet  
22               the requirements of this subparagraph, a pre-  
23               vention services and programs plan component,  
24               with respect to each 5-year period for which the

1 plan component is in operation in the State,  
2 shall include the following:

3 “(i) How providing services and pro-  
4 grams specified in paragraph (1) is ex-  
5 pected to improve specific outcomes for  
6 children and families.

7 “(ii) How the State will monitor and  
8 oversee the safety of children who receive  
9 services and programs specified in para-  
10 graph (1), including through periodic risk  
11 assessments throughout the period in  
12 which the services and programs are pro-  
13 vided on behalf of a child and reexamina-  
14 tion of the prevention plan maintained for  
15 the child under paragraph (4) for the pro-  
16 vision of the services or programs if the  
17 State determines the risk of the child en-  
18 tering foster care remains high despite the  
19 provision of the services or programs.

20 “(iii) With respect to the services and  
21 programs specified in subparagraphs (A)  
22 and (B) of paragraph (1), information on  
23 the specific promising, supported, or well-  
24 supported practices the State plans to use

1 to provide the services or programs, includ-  
2 ing a description of—

3 “(I) the services or programs and  
4 whether the practices used are prom-  
5 ising, supported, or well-supported;

6 “(II) how the State plans to im-  
7 plement the services or programs, in-  
8 cluding how implementation of the  
9 services or programs will be continu-  
10 ously monitored to ensure fidelity to  
11 the practice model and to determine  
12 outcomes achieved and how informa-  
13 tion learned from the monitoring will  
14 be used to refine and improve prac-  
15 tices;

16 “(III) how the State selected the  
17 services or programs;

18 “(IV) the target population for  
19 the services or programs; and

20 “(V) how each service or pro-  
21 gram provided will be evaluated  
22 through a well-designed and rigorous  
23 process, which may consist of an on-  
24 going, cross-site evaluation approved  
25 by the Secretary.

1                   “(iv) A description of the consultation  
2                   that the State agencies responsible for ad-  
3                   ministering the State plans under this part  
4                   and part B engage in with other State  
5                   agencies responsible for administering  
6                   health programs, including mental health  
7                   and substance abuse prevention and treat-  
8                   ment services, and with other public and  
9                   private agencies with experience in admin-  
10                  istering child and family services, including  
11                  community-based organizations, in order to  
12                  foster a continuum of care for children de-  
13                  scribed in paragraph (2) and their parents  
14                  or kin caregivers.

15                  “(v) A description of how the State  
16                  shall assess children and their parents or  
17                  kin caregivers to determine eligibility for  
18                  services or programs specified in para-  
19                  graph (1).

20                  “(vi) A description of how the services  
21                  or programs specified in paragraph (1)  
22                  that are provided for or on behalf of a  
23                  child and the parents or kin caregivers of  
24                  the child will be coordinated with other  
25                  child and family services provided to the

1 child and the parents or kin caregivers of  
2 the child under the State plan under part  
3 B.

4 “(vii) Descriptions of steps the State  
5 is taking to support and enhance a com-  
6 petent, skilled, and professional child wel-  
7 fare workforce to deliver trauma-informed  
8 and evidence-based services, including—

9 “(I) ensuring that staff is quali-  
10 fied to provide services or programs  
11 that are consistent with the prom-  
12 ising, supported, or well-supported  
13 practice models selected; and

14 “(II) developing appropriate pre-  
15 vention plans, and conducting the risk  
16 assessments required under clause  
17 (iii).

18 “(viii) A description of how the State  
19 will provide training and support for case-  
20 workers in assessing what children and  
21 their families need, connecting to the fami-  
22 lies served, knowing how to access and de-  
23 liver the needed trauma-informed and evi-  
24 dence-based services, and overseeing and



1           evaluating the continuing appropriateness  
2           of the services.

3           “(ix) A description of how caseload  
4           size and type for prevention caseworkers  
5           will be determined, managed, and overseen.

6           “(x) An assurance that the State will  
7           report to the Secretary such information  
8           and data as the Secretary may require  
9           with respect to the provision of services  
10          and programs specified in paragraph (1),  
11          including information and data necessary  
12          to determine the performance measures for  
13          the State under paragraph (6) and compli-  
14          ance with paragraph (7).

15          “(C) REIMBURSEMENT FOR SERVICES  
16          UNDER THE PREVENTION PLAN COMPONENT.—

17          “(i) LIMITATION.—Except as provided  
18          in subclause (ii), a State may not receive  
19          a Federal payment under this part for a  
20          given promising, supported, or well-sup-  
21          ported practice unless (in accordance with  
22          subparagraph (B)(iii)(V)) the plan includes  
23          a well-designed and rigorous evaluation  
24          strategy for that practice.

1                   “(ii) WAIVER OF LIMITATION.—The  
2                   Secretary may waive the requirement for a  
3                   well-designed and rigorous evaluation of  
4                   any well-supported practice if the Sec-  
5                   retary deems the evidence of the effective-  
6                   ness of the practice to be compelling and  
7                   the State meets the continuous quality im-  
8                   provement requirements included in sub-  
9                   paragraph (B)(iii)(II) with regard to the  
10                  practice.

11                 “(6) PREVENTION SERVICES MEASURES.—

12                   “(A) ESTABLISHMENT; ANNUAL UP-  
13                   DATES.—Beginning with fiscal year 2021, and  
14                   annually thereafter, the Secretary shall estab-  
15                   lish the following prevention services measures  
16                   based on information and data reported by  
17                   States that elect to provide services and pro-  
18                   grams specified in paragraph (1):

19                   “(i) PERCENTAGE OF CANDIDATES  
20                   FOR FOSTER CARE WHO DO NOT ENTER  
21                   FOSTER CARE.—The percentage of can-  
22                   didates for foster care for whom, or on  
23                   whose behalf, the services or programs are  
24                   provided who do not enter foster care, in-  
25                   cluding those placed with a kin caregiver

1 outside of foster care, during the 12-month  
2 period in which the services or programs  
3 are provided and through the end of the  
4 succeeding 12-month-period.

5 “(ii) PER-CHILD SPENDING.—The  
6 total amount of expenditures made for  
7 mental health and substance abuse preven-  
8 tion and treatment services or in-home  
9 parent skill-based programs, respectively,  
10 for, or on behalf of, each child described in  
11 paragraph (2).

12 “(B) DATA.—The Secretary shall establish  
13 and annually update the prevention services  
14 measures—

15 “(i) based on the median State values  
16 of the information reported under each  
17 clause of subparagraph (A) for the 3 then  
18 most recent years; and

19 “(ii) taking into account State dif-  
20 ferences in the price levels of consumption  
21 goods and services using the most recent  
22 regional price parities published by the Bu-  
23 reau of Economic Analysis of the Depart-  
24 ment of Commerce or such other data as  
25 the Secretary determines appropriate.

1           “(C) PUBLICATION OF STATE PREVENTION  
2 SERVICES MEASURES.—The Secretary shall an-  
3 nually make available to the public the preven-  
4 tion services measures of each State.

5           “(7) MAINTENANCE OF EFFORT FOR STATE  
6 FOSTER CARE PREVENTION EXPENDITURES.—

7           “(A) IN GENERAL.—If a State elects to  
8 provide services and programs specified in para-  
9 graph (1) for a fiscal year, the State foster care  
10 prevention expenditures for the fiscal year shall  
11 not be less than the amount of the expenditures  
12 for fiscal year 2014 (or, at the option of a State  
13 described in subparagraph (E), fiscal year 2015  
14 or fiscal year 2016 (whichever the State  
15 elects)).

16           “(B) STATE FOSTER CARE PREVENTION  
17 EXPENDITURES.—The term ‘State foster care  
18 prevention expenditures’ means the following:

19           “(i) TANF; IV-B; SSBG.—State ex-  
20 penditures for foster care prevention serv-  
21 ices and activities under the State program  
22 funded under part A (including from  
23 amounts made available by the Federal  
24 Government), under the State plan devel-  
25 oped under part B (including any such

1 amounts), or under the Social Services  
2 Block Grant Programs under subtitle A of  
3 title XX (including any such amounts).

4 “(ii) OTHER STATE PROGRAMS.—  
5 State expenditures for foster care preven-  
6 tion services and activities under any State  
7 program that is not described in clause (i)  
8 (other than any State expenditures for fos-  
9 ter care prevention services and activities  
10 under the State program under this part  
11 (including under a waiver of the pro-  
12 gram)).

13 “(C) STATE EXPENDITURES.—The term  
14 ‘State expenditures’ means all State or local  
15 funds that are expended by the State or a local  
16 agency including State or local funds that are  
17 matched or reimbursed by the Federal Govern-  
18 ment and State or local funds that are not  
19 matched or reimbursed by the Federal Govern-  
20 ment.

21 “(D) DETERMINATION OF PREVENTION  
22 SERVICES AND ACTIVITIES.—The Secretary  
23 shall require each State that elects to provide  
24 services and programs specified in paragraph  
25 (1) to report the expenditures specified in sub-

1 paragraph (B) for fiscal year 2014 and for such  
2 fiscal years thereafter as are necessary to deter-  
3 mine whether the State is complying with the  
4 maintenance of effort requirement in subpara-  
5 graph (A). The Secretary shall specify the spe-  
6 cific services and activities under each program  
7 referred to in subparagraph (B) that are ‘pre-  
8 vention services and activities’ for purposes of  
9 the reports.

10 “(E) STATE DESCRIBED.—For purposes of  
11 subparagraph (A), a State is described in this  
12 subparagraph if the population of children in  
13 the State in 2014 was less than 200,000 (as de-  
14 termined by the Bureau of the Census).

15 “(8) PROHIBITION AGAINST USE OF STATE FOS-  
16 TER CARE PREVENTION EXPENDITURES AND FED-  
17 ERAL IV–E PREVENTION FUNDS FOR MATCHING OR  
18 EXPENDITURE REQUIREMENT.—A State that elects  
19 to provide services and programs specified in para-  
20 graph (1) shall not use any State foster care preven-  
21 tion expenditures for a fiscal year for the State  
22 share of expenditures under section 474(a)(6) for a  
23 fiscal year.

24 “(9) ADMINISTRATIVE COSTS.—Expenditures  
25 described in section 474(a)(6)(B)—

1           “(A) shall not be eligible for payment  
2           under subparagraph (A), (B), or (E) of section  
3           474(a)(3); and

4           “(B) shall be eligible for payment under  
5           section 474(a)(6)(B) without regard to whether  
6           the expenditures are incurred on behalf of a  
7           child who is, or is potentially, eligible for foster  
8           care maintenance payments under this part.

9           “(10) APPLICATION.—

10           “(A) IN GENERAL.—The provision of serv-  
11           ices or programs under this subsection to or on  
12           behalf of a child described in paragraph (2)  
13           shall not be considered to be receipt of aid or  
14           assistance under the State plan under this part  
15           for purposes of eligibility for any other program  
16           established under this Act.

17           “(B) CANDIDATES IN KINSHIP CARE.—A  
18           child described in paragraph (2) for whom such  
19           services or programs under this subsection are  
20           provided for more than 6 months while in the  
21           home of a kin caregiver, and who would satisfy  
22           the AFDC eligibility requirement of section  
23           472(a)(3)(A)(ii)(II) but for residing in the  
24           home of the caregiver for more than 6 months,  
25           is deemed to satisfy that requirement for pur-

1           poses of determining whether the child is eligi-  
2           ble for foster care maintenance payments under  
3           section 472.”.

4           (b) DEFINITION.—Section 475 of such Act (42  
5 U.S.C. 675) is amended by adding at the end the fol-  
6           lowing:

7           “(13) The term ‘child who is a candidate for  
8           foster care’ means, a child who is identified in a pre-  
9           vention plan under section 471(e)(4)(A) as being at  
10          imminent risk of entering foster care (without re-  
11          gard to whether the child would be eligible for foster  
12          care maintenance payments under section 472 or is  
13          or would be eligible for adoption assistance or kin-  
14          ship guardianship assistance payments under section  
15          473) but who can remain safely in the child’s home  
16          or in a kinship placement as long as services or pro-  
17          grams specified in section 471(e)(1) that are nec-  
18          essary to prevent the entry of the child into foster  
19          care are provided. The term includes a child whose  
20          adoption or guardianship arrangement is at risk of  
21          a disruption or dissolution that would result in a  
22          foster care placement.”.

23          (c) PAYMENTS UNDER TITLE IV–E.—Section 474(a)  
24          of such Act (42 U.S.C. 674(a)) is amended—



1 (1) in paragraph (5), by striking the period at  
2 the end and inserting “; plus”; and

3 (2) by adding at the end the following:

4 “(6) subject to section 471(e)—

5 “(A) for each quarter—

6 “(i) subject to clause (ii)—

7 “(I) beginning after September  
8 30, 2019, and before October 1, 2025,  
9 an amount equal to 50 percent of the  
10 total amount expended during the  
11 quarter for the provision of services or  
12 programs specified in subparagraph  
13 (A) or (B) of section 471(e)(1) that  
14 are provided in accordance with prom-  
15 ising, supported, or well-supported  
16 practices that meet the applicable cri-  
17 teria specified for the practices in sec-  
18 tion 471(e)(4)(C); and

19 “(II) beginning after September  
20 30, 2025, an amount equal to the  
21 Federal medical assistance percentage  
22 (which shall be as defined in section  
23 1905(b), in the case of a State other  
24 than the District of Columbia, or 70  
25 percent, in the case of the District of

1 Columbia) of the total amount ex-  
2 pended during the quarter for the pro-  
3 vision of services or programs speci-  
4 fied in subparagraph (A) or (B) of  
5 section 471(e)(1) that are provided in  
6 accordance with promising, supported,  
7 or well-supported practices that meet  
8 the applicable criteria specified for the  
9 practices in section 471(e)(4)(C) (or,  
10 with respect to the payments made  
11 during the quarter under a coopera-  
12 tive agreement or contract entered  
13 into by the State and an Indian tribe,  
14 tribal organization, or tribal consor-  
15 tium for the administration or pay-  
16 ment of funds under this part, an  
17 amount equal to the Federal medical  
18 assistance percentage that would  
19 apply under section 479B(d) (in this  
20 paragraph referred to as the ‘tribal  
21 FMAP’) if the Indian tribe, tribal or-  
22 ganization, or tribal consortium made  
23 the payments under a program oper-  
24 ated under that section, unless the  
25 tribal FMAP is less than the Federal

1                   medical assistance percentage that ap-  
2                   plies to the State); except that

3                   “(ii) not less than 50 percent of the  
4                   total amount payable to a State under  
5                   clause (i) for a fiscal year shall be for the  
6                   provision of services or programs specified  
7                   in subparagraph (A) or (B) of section  
8                   471(e)(1) that are provided in accordance  
9                   with well-supported practices; plus

10                  “(B) for each quarter specified in subpara-  
11                  graph (A), an amount equal to the sum of the  
12                  following proportions of the total amount ex-  
13                  pended during the quarter:

14                  “(i) 50 percent of so much of the ex-  
15                  penditures as are found necessary by the  
16                  Secretary for the proper and efficient ad-  
17                  ministration of the State plan for the pro-  
18                  vision of services or programs specified in  
19                  section 471(e)(1), including expenditures  
20                  for activities approved by the Secretary  
21                  that promote the development of necessary  
22                  processes and procedures to establish and  
23                  implement the provision of the services and  
24                  programs for individuals who are eligible  
25                  for the services and programs and expendi-

1           tures attributable to data collection and re-  
2           porting; and

3                   “(ii) 50 percent of so much of the ex-  
4           penditures with respect to the provision of  
5           services and programs specified in section  
6           471(e)(1) as are for training of personnel  
7           employed or preparing for employment by  
8           the State agency or by the local agency ad-  
9           ministering the plan in the political sub-  
10          division and of the members of the staff of  
11          State-licensed or State-approved child wel-  
12          fare agencies providing services to children  
13          described in section 471(e)(2) and their  
14          parents or kin caregivers, including on how  
15          to determine who are individuals eligible  
16          for the services or programs, how to iden-  
17          tify and provide appropriate services and  
18          programs, and how to oversee and evaluate  
19          the ongoing appropriateness of the services  
20          and programs.”.

21          (d) TECHNICAL ASSISTANCE AND BEST PRACTICES,  
22          CLEARINGHOUSE, AND DATA COLLECTION AND EVALUA-  
23          TIONS.—Section 476 of such Act (42 U.S.C. 676) is  
24          amended by adding at the end the following:

1           “(d) TECHNICAL ASSISTANCE AND BEST PRACTICES,  
2 CLEARINGHOUSE, DATA COLLECTION, AND EVALUATIONS  
3 RELATING TO PREVENTION SERVICES AND PROGRAMS.—

4           “(1) TECHNICAL ASSISTANCE AND BEST PRACTICES.—The Secretary shall provide to States and,  
5 as applicable, to Indian tribes, tribal organizations,  
6 and tribal consortia, technical assistance regarding  
7 the provision of services and programs described in  
8 section 471(e)(1) and shall disseminate best practices  
9 with respect to the provision of the services and  
10 programs, including how to plan and implement a  
11 well-designed and rigorous evaluation of a promising,  
12 supported, or well-supported practice.  
13

14           “(2) CLEARINGHOUSE OF PROMISING, SUPPORTED,  
15 AND WELL-SUPPORTED PRACTICES.—The  
16 Secretary shall, directly or through grants, contracts,  
17 or interagency agreements, evaluate research  
18 on the practices specified in clauses (iii), (iv), and  
19 (v), respectively, of section 471(e)(4)(C), and programs  
20 that meet the requirements described in section  
21 427(a)(1), including culturally specific, or  
22 location- or population-based adaptations of the  
23 practices, to identify and establish a public clearinghouse  
24 of the practices that satisfy each category described  
25 by such clauses. In addition, the clearing-

1 house shall include information on the specific out-  
2 comes associated with each practice, including  
3 whether the practice has been shown to prevent child  
4 abuse and neglect and reduce the likelihood of foster  
5 care placement by supporting birth families and kin-  
6 ship families and improving targeted supports for  
7 pregnant and parenting youth and their children.

8 “(3) DATA COLLECTION AND EVALUATIONS.—  
9 The Secretary, directly or through grants, contracts,  
10 or interagency agreements, may collect data and  
11 conduct evaluations with respect to the provision of  
12 services and programs described in section 471(e)(1)  
13 for purposes of assessing the extent to which the  
14 provision of the services and programs—

15 “(A) reduces the likelihood of foster care  
16 placement;

17 “(B) increases use of kinship care arrange-  
18 ments; or

19 “(C) improves child well-being.

20 “(4) REPORTS TO CONGRESS.—

21 “(A) IN GENERAL.—The Secretary shall  
22 submit to the Committee on Finance of the  
23 Senate and the Committee on Ways and Means  
24 of the House of Representatives periodic reports  
25 based on the provision of services and programs

1 described in section 471(e)(1) and the activities  
2 carried out under this subsection.

3 “(B) PUBLIC AVAILABILITY.—The Sec-  
4 retary shall make the reports to Congress sub-  
5 mitted under this paragraph publicly available.

6 “(5) APPROPRIATION.—Out of any money in  
7 the Treasury of the United States not otherwise ap-  
8 propriated, there is appropriated to the Secretary  
9 \$1,000,000 for fiscal year 2017 and each fiscal year  
10 thereafter to carry out this subsection.”.

11 (e) APPLICATION TO PROGRAMS OPERATED BY IN-  
12 DIAN TRIBAL ORGANIZATIONS.—

13 (1) IN GENERAL.—Section 479B of such Act  
14 (42 U.S.C. 679e) is amended—

15 (A) in subsection (c)(1)—

16 (i) in subparagraph (C)(i)—

17 (I) in subclause (II), by striking  
18 “and” after the semicolon;

19 (II) in subclause (III), by strik-  
20 ing the period at the end and insert-  
21 ing “; and”; and

22 (III) by adding at the end the  
23 following:

24 “(IV) at the option of the tribe,  
25 organization, or consortium, services

1 and programs specified in section  
2 471(e)(1) to children described in sec-  
3 tion 471(e)(2) and their parents or  
4 kin caregivers, in accordance with sec-  
5 tion 471(e) and subparagraph (E).”;  
6 and

7 (ii) by adding at the end the fol-  
8 lowing:

9 “(E) PREVENTION SERVICES AND PRO-  
10 GRAMS FOR CHILDREN AND THEIR PARENTS  
11 AND KIN CAREGIVERS.—

12 “(i) IN GENERAL.—In the case of a  
13 tribe, organization, or consortium that  
14 elects to provide services and programs  
15 specified in section 471(e)(1) to children  
16 described in section 471(e)(2) and their  
17 parents or kin caregivers under the plan,  
18 the Secretary shall specify the require-  
19 ments applicable to the provision of the  
20 services and programs. The requirements  
21 shall, to the greatest extent practicable, be  
22 consistent with the requirements applicable  
23 to States under section 471(e) and shall  
24 permit the provision of the services and  
25 programs in the form of services and pro-



1           grams that are adapted to the culture and  
2           context of the tribal communities served.

3                   “(ii) PERFORMANCE MEASURES.—The  
4           Secretary shall establish specific perform-  
5           ance measures for each tribe, organization,  
6           or consortium that elects to provide serv-  
7           ices and programs specified in section  
8           471(e)(1). The performance measures  
9           shall, to the greatest extent practicable, be  
10          consistent with the prevention services  
11          measures required for States under section  
12          471(e)(6) but shall allow for consideration  
13          of factors unique to the provision of the  
14          services by tribes, organizations, or con-  
15          sortia.”; and

16                   (B) in subsection (d)(1), by striking “and  
17           (5)” and inserting “(5), and (6)(A)”.

18                   (2) CONFORMING AMENDMENT.—The heading  
19          for subsection (d) of section 479B of such Act (42  
20          U.S.C. 679c) is amended by striking “FOR FOSTER  
21          CARE MAINTENANCE AND ADOPTION ASSISTANCE  
22          PAYMENTS”.

23                   (f) APPLICATION TO PROGRAMS OPERATED BY TER-  
24          RITORIES.—Section 1108(a)(2) of the Social Security Act

1 (42 U.S.C. 1308(a)(2)) is amended by striking “or  
2 413(f)” and inserting “413(f), or 474(a)(6)”.

3 **SEC. 19012. FOSTER CARE MAINTENANCE PAYMENTS FOR**  
4 **CHILDREN WITH PARENTS IN A LICENSED**  
5 **RESIDENTIAL FAMILY-BASED TREATMENT**  
6 **FACILITY FOR SUBSTANCE ABUSE.**

7 (a) IN GENERAL.—Section 472 of the Social Security  
8 Act (42 U.S.C. 672) is amended—

9 (1) in subsection (a)(2)(C), by striking “or”  
10 and inserting “, with a parent residing in a licensed  
11 residential family-based treatment facility, but only  
12 to the extent permitted under subsection (j), or in  
13 a”; and

14 (2) by adding at the end the following:

15 “(j) CHILDREN PLACED WITH A PARENT RESIDING  
16 IN A LICENSED RESIDENTIAL FAMILY-BASED TREAT-  
17 MENT FACILITY FOR SUBSTANCE ABUSE.—

18 “(1) IN GENERAL.—Notwithstanding the pre-  
19 ceding provisions of this section, a child who is eligi-  
20 ble for foster care maintenance payments under this  
21 section, or who would be eligible for the payments if  
22 the eligibility were determined without regard to  
23 paragraphs (1)(B) and (3) of subsection (a), shall be  
24 eligible for the payments for a period of not more  
25 than 12 months during which the child is placed

1 with a parent who is in a licensed residential family-  
2 based treatment facility for substance abuse, but  
3 only if—

4 “(A) the recommendation for the place-  
5 ment is specified in the child’s case plan before  
6 the placement;

7 “(B) the treatment facility provides, as  
8 part of the treatment for substance abuse, par-  
9 enting skills training, parent education, and in-  
10 dividual and family counseling; and

11 “(C) the substance abuse treatment, par-  
12 enting skills training, parent education, and in-  
13 dividual and family counseling is provided  
14 under an organizational structure and treat-  
15 ment framework that involves understanding,  
16 recognizing, and responding to the effects of all  
17 types of trauma and in accordance with recog-  
18 nized principles of a trauma-informed approach  
19 and trauma-specific interventions to address the  
20 consequences of trauma and facilitate healing.

21 “(2) APPLICATION.—With respect to children  
22 for whom foster care maintenance payments are  
23 made under paragraph (1), only the children who  
24 satisfy the requirements of paragraphs (1)(B) and  
25 (3) of subsection (a) shall be considered to be chil-



1 children who are, or are potentially, eligible for fos-  
2 ter care maintenance payments under this part.”.

3 **Subtitle B—Enhanced Support**  
4 **Under Title IV-B**

5 **SEC. 19021. ELIMINATION OF TIME LIMIT FOR FAMILY RE-**  
6 **UNIFICATION SERVICES WHILE IN FOSTER**  
7 **CARE AND PERMITTING TIME-LIMITED FAM-**  
8 **ILY REUNIFICATION SERVICES WHEN A**  
9 **CHILD RETURNS HOME FROM FOSTER CARE.**

10 (a) IN GENERAL.—Section 431(a)(7) of the Social  
11 Security Act (42 U.S.C. 629a(a)(7)) is amended—

12 (1) in the paragraph heading, by striking  
13 “TIME-LIMITED FAMILY” and inserting “FAMILY”;  
14 and

15 (2) in subparagraph (A)—

16 (A) by striking “time-limited family” and  
17 inserting “family”;

18 (B) by inserting “or a child who has been  
19 returned home” after “child care institution”;  
20 and

21 (C) by striking “, but only during the 15-  
22 month period that begins on the date that the  
23 child, pursuant to section 475(5)(F), is consid-  
24 ered to have entered foster care” and inserting  
25 “and to ensure the strength and stability of the

1 reunification. In the case of a child who has  
2 been returned home, the services and activities  
3 shall only be provided during the 15-month pe-  
4 riod that begins on the date that the child re-  
5 turns home”.

6 (b) CONFORMING AMENDMENTS.—

7 (1) Section 430 of such Act (42 U.S.C. 629) is  
8 amended in the matter preceding paragraph (1), by  
9 striking “time-limited”.

10 (2) Subsections (a)(4), (a)(5)(A), and (b)(1) of  
11 section 432 of such Act (42 U.S.C. 629b) are  
12 amended by striking “time-limited” each place it ap-  
13 pears.

14 **SEC. 19022. REDUCING BUREAUCRACY AND UNNECESSARY**  
15 **DELAYS WHEN PLACING CHILDREN IN**  
16 **HOMES ACROSS STATE LINES.**

17 (a) STATE PLAN REQUIREMENT.—Section  
18 471(a)(25) of the Social Security Act (42 U.S.C.  
19 671(a)(25)) is amended—

20 (1) by striking “provide” and insert “provides”;  
21 and

22 (2) by inserting “, which, not later than Octo-  
23 ber 1, 2026, shall include the use of an electronic  
24 interstate case-processing system” before the first  
25 semicolon.

1 (b) GRANTS FOR THE DEVELOPMENT OF AN ELEC-  
2 TRONIC INTERSTATE CASE-PROCESSING SYSTEM TO EX-  
3 PEDITE THE INTERSTATE PLACEMENT OF CHILDREN IN  
4 FOSTER CARE OR GUARDIANSHIP, OR FOR ADOPTION.—  
5 Section 437 of such Act (42 U.S.C. 629g) is amended by  
6 adding at the end the following:

7 “(g) GRANTS FOR THE DEVELOPMENT OF AN ELEC-  
8 TRONIC INTERSTATE CASE-PROCESSING SYSTEM TO EX-  
9 PEDITE THE INTERSTATE PLACEMENT OF CHILDREN IN  
10 FOSTER CARE OR GUARDIANSHIP, OR FOR ADOPTION.—

11 “(1) PURPOSE.—The purpose of this subsection  
12 is to facilitate the development of an electronic inter-  
13 state case-processing system for the exchange of  
14 data and documents to expedite the placements of  
15 children in foster, guardianship, or adoptive homes  
16 across State lines.

17 “(2) APPLICATION REQUIREMENTS.—A State  
18 that desires a grant under this subsection shall sub-  
19 mit to the Secretary an application containing the  
20 following:

21 “(A) A description of the goals and out-  
22 comes to be achieved during the period for  
23 which grant funds are sought, which goals and  
24 outcomes must result in—

1                   “(i) reducing the time it takes for a  
2                   child to be provided with a safe and appro-  
3                   priate permanent living arrangement  
4                   across State lines;

5                   “(ii) improving administrative proc-  
6                   esses and reducing costs in the foster care  
7                   system; and

8                   “(iii) the secure exchange of relevant  
9                   case files and other necessary materials in  
10                  real time, and timely communications and  
11                  placement decisions regarding interstate  
12                  placements of children.

13                  “(B) A description of the activities to be  
14                  funded in whole or in part with the grant  
15                  funds, including the sequencing of the activities.

16                  “(C) A description of the strategies for in-  
17                  tegrating programs and services for children  
18                  who are placed across State lines.

19                  “(D) Such other information as the Sec-  
20                  retary may require.

21                  “(3) GRANT AUTHORITY.—The Secretary may  
22                  make a grant to a State that complies with para-  
23                  graph (2).

24                  “(4) USE OF FUNDS.—A State to which a grant  
25                  is made under this subsection shall use the grant to



1 support the State in connecting with the electronic  
2 interstate case-processing system described in para-  
3 graph (1).

4 “(5) EVALUATIONS.—Not later than 1 year  
5 after the final year in which grants are awarded  
6 under this subsection, the Secretary shall submit to  
7 the Congress, and make available to the general  
8 public by posting on a website, a report that con-  
9 tains the following information:

10 “(A) How using the electronic interstate  
11 case-processing system developed pursuant to  
12 paragraph (4) has changed the time it takes for  
13 children to be placed across State lines.

14 “(B) The number of cases subject to the  
15 Interstate Compact on the Placement of Chil-  
16 dren that were processed through the electronic  
17 interstate case-processing system, and the num-  
18 ber of interstate child placement cases that  
19 were processed outside the electronic interstate  
20 case-processing system, by each State in each  
21 year.

22 “(C) The progress made by States in im-  
23 plementing the electronic interstate case-proc-  
24 essing system.

1           “(D) How using the electronic interstate  
2 case-processing system has affected various  
3 metrics related to child safety and well-being,  
4 including the time it takes for children to be  
5 placed across State lines.

6           “(E) How using the electronic interstate  
7 case-processing system has affected administra-  
8 tive costs and caseworker time spent on placing  
9 children across State lines.

10          “(6) DATA INTEGRATION.—The Secretary, in  
11 consultation with the Secretariat for the Interstate  
12 Compact on the Placement of Children and the  
13 States, shall assess how the electronic interstate  
14 case-processing system developed pursuant to para-  
15 graph (4) could be used to better serve and protect  
16 children that come to the attention of the child wel-  
17 fare system, by—

18           “(A) connecting the system with other  
19 data systems (such as systems operated by  
20 State law enforcement and judicial agencies,  
21 systems operated by the Federal Bureau of In-  
22 vestigation for the purposes of the Innocence  
23 Lost National Initiative, and other systems);

24           “(B) simplifying and improving reporting  
25 related to paragraphs (34) and (35) of section

1           471(a) regarding children or youth who have  
2           been identified as being a sex trafficking victim  
3           or children missing from foster care; and

4                   “(C) improving the ability of States to  
5           quickly comply with background check require-  
6           ments of section 471(a)(20), including checks of  
7           child abuse and neglect registries as required by  
8           section 471(a)(20)(B).”.

9           (c) RESERVATION OF FUNDS TO IMPROVE THE  
10          INTERSTATE PLACEMENT OF CHILDREN.—Section 437(b)  
11          of such Act (42 U.S.C. 629g(b)) is amended by adding  
12          at the end the following:

13                   “(4) IMPROVING THE INTERSTATE PLACEMENT  
14          OF CHILDREN.—The Secretary shall reserve  
15          \$5,000,000 of the amount made available for fiscal  
16          year 2017 for grants under subsection (g), and the  
17          amount so reserved shall remain available through  
18          fiscal year 2021.”.

19          **SEC. 19023. ENHANCEMENTS TO GRANTS TO IMPROVE**  
20                   **WELL-BEING OF FAMILIES AFFECTED BY**  
21                   **SUBSTANCE ABUSE.**

22          Section 437(f) of the Social Security Act (42 U.S.C.  
23          629g(f)) is amended—

24                   (1) in the subsection heading, by striking “IN-  
25          CREASE THE WELL-BEING OF, AND TO IMPROVE

1 THE PERMANENCY OUTCOMES FOR, CHILDREN AF-  
2 FECTED BY” and inserting “IMPLEMENT IV–E PRE-  
3 VENTION SERVICES, AND IMPROVE THE WELL-  
4 BEING OF, AND IMPROVE PERMANENCY OUTCOMES  
5 FOR, CHILDREN AND FAMILIES AFFECTED BY HER-  
6 OIN, OPIOIDS, AND OTHER”;

7 (2) by striking paragraph (2) and inserting the  
8 following:

9 “(2) REGIONAL PARTNERSHIP DEFINED.—In  
10 this subsection, the term ‘regional partnership’  
11 means a collaborative agreement (which may be es-  
12 tablished on an interstate, State, or intrastate basis)  
13 entered into by the following:

14 “(A) MANDATORY PARTNERS FOR ALL  
15 PARTNERSHIP GRANTS.—

16 “(i) The State child welfare agency  
17 that is responsible for the administration  
18 of the State plan under this part and part  
19 E.

20 “(ii) The State agency responsible for  
21 administering the substance abuse preven-  
22 tion and treatment block grant provided  
23 under subpart II of part B of title XIX of  
24 the Public Health Service Act.

1                   “(B) MANDATORY PARTNERS FOR PART-  
2                   NERSHIP GRANTS PROPOSING TO SERVE CHIL-  
3                   DREN IN OUT-OF-HOME PLACEMENTS.—If the  
4                   partnership proposes to serve children in out-of-  
5                   home placements, the Juvenile Court or Admin-  
6                   istrative Office of the Court that is most appro-  
7                   priate to oversee the administration of court  
8                   programs in the region to address the popu-  
9                   lation of families who come to the attention of  
10                  the court due to child abuse or neglect.

11                  “(C) OPTIONAL PARTNERS.—At the option  
12                  of the partnership, any of the following:

13                         “(i) An Indian tribe or tribal consor-  
14                         tium.

15                         “(ii) Nonprofit child welfare service  
16                         providers.

17                         “(iii) For-profit child welfare service  
18                         providers.

19                         “(iv) Community health service pro-  
20                         viders, including substance abuse treat-  
21                         ment providers.

22                         “(v) Community mental health pro-  
23                         viders.

24                         “(vi) Local law enforcement agencies.

25                         “(vii) School personnel.

1           “(viii) Tribal child welfare agencies  
2           (or a consortia of the agencies).

3           “(ix) Any other providers, agencies,  
4           personnel, officials, or entities that are re-  
5           lated to the provision of child and family  
6           services under a State plan approved under  
7           this subpart.

8           “(D) EXCEPTION FOR REGIONAL PART-  
9           NERSHIPS WHERE THE LEAD APPLICANT IS AN  
10          INDIAN TRIBE OR TRIBAL CONSORTIA.—If an  
11          Indian tribe or tribal consortium enters into a  
12          regional partnership for purposes of this sub-  
13          section, the Indian tribe or tribal consortium—

14               “(i) may (but is not required to) in-  
15               clude the State child welfare agency as a  
16               partner in the collaborative agreement;

17               “(ii) may not enter into a collabo-  
18               rative agreement only with tribal child wel-  
19               fare agencies (or a consortium of the agen-  
20               cies); and

21               “(iii) if the condition described in  
22               paragraph (2)(B) applies, may include  
23               tribal court organizations in lieu of other  
24               judicial partners.”;

25               (3) in paragraph (3)—

1 (A) in subparagraph (A)—

2 (i) by striking “2012 through 2016”  
3 and inserting “2017 through 2021”; and

4 (ii) by striking “\$500,000 and not  
5 more than \$1,000,000” and inserting  
6 “\$250,000 and not more than  
7 \$1,000,000”;

8 (B) in subparagraph (B)—

9 (i) in the subparagraph heading, by  
10 inserting “; PLANNING” after “APPROVAL”;

11 (ii) in clause (i), by striking “clause  
12 (ii)” and inserting “clauses (ii) and (iii)”;  
13 and

14 (iii) by adding at the end the fol-  
15 lowing:

16 “(iii) SUFFICIENT PLANNING.—A  
17 grant awarded under this subsection shall  
18 be disbursed in two phases: a planning  
19 phase (not to exceed 2 years); and an im-  
20 plementation phase. The total disburse-  
21 ment to a grantee for the planning phase  
22 may not exceed \$250,000, and may not ex-  
23 ceed the total anticipated funding for the  
24 implementation phase.”; and

25 (C) by adding at the end the following:

- 1           “(D) LIMITATION ON PAYMENT FOR A FIS-
- 2           CAL YEAR.—No payment shall be made under
- 3           subparagraph (A) or (C) for a fiscal year until
- 4           the Secretary determines that the eligible part-
- 5           nership has made sufficient progress in meeting
- 6           the goals of the grant and that the members of
- 7           the eligible partnership are coordinating to a
- 8           reasonable degree with the other members of
- 9           the eligible partnership.”;
- 10          (4) in paragraph (4)—
- 11           (A) in subparagraph (B)—
- 12           (i) in clause (i), by inserting “, par-
- 13           ents, and families” after “children”;
- 14           (ii) in clause (ii), by striking “safety
- 15           and permanence for such children; and”
- 16           and inserting “safe, permanent caregiving
- 17           relationships for the children;”;
- 18           (iii) in clause (iii), by striking “or”
- 19           and inserting “increase reunification rates
- 20           for children who have been placed in out of
- 21           home care, or decrease”; and
- 22           (iv) by redesignating clause (iii) as
- 23           clause (v) and inserting after clause (ii)
- 24           the following:



1                   “(iii) improve the substance abuse  
2                   treatment outcomes for parents including  
3                   retention in treatment and successful com-  
4                   pletion of treatment;

5                   “(iv) facilitate the implementation, de-  
6                   livery, and effectiveness of prevention serv-  
7                   ices and programs under section 471(e);  
8                   and”;

9                   (B) in subparagraph (D), by striking  
10                  “where appropriate,”; and

11                  (C) by striking subparagraphs (E) and (F)  
12                  and inserting the following:

13                  “(E) A description of a plan for sustaining  
14                  the services provided by or activities funded  
15                  under the grant after the conclusion of the  
16                  grant period, including through the use of pre-  
17                  vention services and programs under section  
18                  471(e) and other funds provided to the State  
19                  for child welfare and substance abuse preven-  
20                  tion and treatment services.

21                  “(F) Additional information needed by the  
22                  Secretary to determine that the proposed activi-  
23                  ties and implementation will be consistent with  
24                  research or evaluations showing which practices  
25                  and approaches are most effective.”;

1           (5) in paragraph (5)(A), by striking “abuse  
2           treatment” and inserting “use disorder treatment in-  
3           cluding medication assisted treatment and in-home  
4           substance abuse disorder treatment and recovery”;

5           (6) in paragraph (7)—

6           (A) by striking “and” at the end of sub-  
7           paragraph (C); and

8           (B) by redesignating subparagraph (D) as  
9           subparagraph (E) and inserting after subpara-  
10          graph (C) the following:

11           “(D) demonstrate a track record of suc-  
12          cessful collaboration among child welfare, sub-  
13          stance abuse disorder treatment and mental  
14          health agencies; and”;

15          (7) in paragraph (8)—

16          (A) in subparagraph (A)—

17           (i) by striking “establish indicators  
18           that will be” and inserting “review indica-  
19           tors that are”; and

20           (ii) by striking “in using funds made  
21           available under such grants to achieve the  
22           purpose of this subsection” and inserting  
23           “and establish a set of core indicators re-  
24           lated to child safety, parental recovery,  
25           parenting capacity, and family well-being.

1 In developing the core indicators, to the  
2 extent possible, indicators shall be made  
3 consistent with the outcome measures de-  
4 scribed in section 471(e)(6)”; and

5 (B) in subparagraph (B)—

6 (i) in the matter preceding clause (i),  
7 by inserting “base the performance meas-  
8 ures on lessons learned from prior rounds  
9 of regional partnership grants under this  
10 subsection, and” before “consult”; and

11 (ii) by striking clauses (iii) and (iv)  
12 and inserting the following:

13 “(iii) Other stakeholders or constitu-  
14 encies as determined by the Secretary.”;

15 (8) in paragraph (9)(A), by striking clause (i)  
16 and inserting the following:

17 “(i) SEMIANNUAL REPORTS.—Not  
18 later than September 30 of each fiscal year  
19 in which a recipient of a grant under this  
20 subsection is paid funds under the grant,  
21 and every 6 months thereafter, the grant  
22 recipient shall submit to the Secretary a  
23 report on the services provided and activi-  
24 ties carried out during the reporting pe-  
25 riod, progress made in achieving the goals

1 of the program, the number of children,  
2 adults, and families receiving services, and  
3 such additional information as the Sec-  
4 retary determines is necessary. The report  
5 due not later than September 30 of the  
6 last such fiscal year shall include, at a  
7 minimum, data on each of the performance  
8 indicators included in the evaluation of the  
9 regional partnership.”; and

10 (9) in paragraph (10), by striking “2012  
11 through 2016” and inserting “2017 through 2021”.

## 12 **Subtitle C—Miscellaneous**

### 13 **SEC. 19031. REVIEWING AND IMPROVING LICENSING** 14 **STANDARDS FOR PLACEMENT IN A RELATIVE** 15 **FOSTER FAMILY HOME.**

16 (a) IDENTIFICATION OF REPUTABLE MODEL LI-  
17 CENSING STANDARDS.—Not later than October 1, 2017,  
18 the Secretary of Health and Human Services shall identify  
19 reputable model licensing standards with respect to the li-  
20 censing of foster family homes (as defined in section  
21 472(c)(1) of the Social Security Act).

22 (b) STATE PLAN REQUIREMENT.—Section 471(a) of  
23 the Social Security Act (42 U.S.C. 671(a)) is amended—

24 (1) in paragraph (34)(B), by striking “and”  
25 after the semicolon;

1           (2) in paragraph (35)(B), by striking the period  
2           at the end and inserting a semicolon; and

3           (3) by adding at the end the following:

4           “(36) provides that, not later than April 1,  
5           2018, the State shall submit to the Secretary infor-  
6           mation addressing—

7                   “(A) whether the State licensing standards  
8                   are in accord with model standards identified  
9                   by the Secretary, and if not, the reason for the  
10                  specific deviation and a description as to why  
11                  having a standard that is reasonably in accord  
12                  with the corresponding national model stand-  
13                  ards is not appropriate for the State;

14                   “(B) whether the State has elected to  
15                   waive standards established in 471(a)(10)(A)  
16                   for relative foster family homes (pursuant to  
17                   waiver authority provided by 471(a)(10)(D)), a  
18                   description of which standards the State most  
19                   commonly waives, and if the State has not  
20                   elected to waive the standards, the reason for  
21                   not waiving these standards;

22                   “(C) if the State has elected to waive  
23                   standards specified in subparagraph (B), how  
24                   caseworkers are trained to use the waiver au-  
25                   thority and whether the State has developed a

1 process or provided tools to assist caseworkers  
2 in waiving nonsafety standards per the author-  
3 ity provided in 471(a)(10)(D) to quickly place  
4 children with relatives; and

5 “(D) a description of the steps the State is  
6 taking to improve caseworker training or the  
7 process, if any; and”.

8 **SEC. 19032. DEVELOPMENT OF A STATEWIDE PLAN TO PRE-**  
9 **VENT CHILD ABUSE AND NEGLECT FATALI-**  
10 **TIES.**

11 Section 422(b)(19) of the Social Security Act (42  
12 U.S.C. 622(b)(19)) is amended to read as follows:

13 “(19) document steps taken to track and pre-  
14 vent child maltreatment deaths by including—

15 “(A) a description of the steps the State is  
16 taking to compile complete and accurate infor-  
17 mation on the deaths required by Federal law  
18 to be reported by the State agency referred to  
19 in paragraph (1), including gathering relevant  
20 information on the deaths from the relevant or-  
21 ganizations in the State including entities such  
22 as State vital statistics department, child death  
23 review teams, law enforcement agencies, offices  
24 of medical examiners or coroners; and

1           “(B) a description of the steps the state is  
2           taking to develop and implement of a com-  
3           prehensive, statewide plan to prevent the fatali-  
4           ties that involves and engages relevant public  
5           and private agency partners, including those in  
6           public health, law enforcement, and the  
7           courts.”.

8   **SEC. 19033. MODERNIZING THE TITLE AND PURPOSE OF**  
9                           **TITLE IV-E.**

10          (a) PART HEADING.—The heading for part E of title  
11          IV of the Social Security Act (42 U.S.C. 670 et seq.) is  
12          amended to read as follows:

13               **“PART E—FEDERAL PAYMENTS FOR FOSTER**  
14               **CARE, PREVENTION, AND PERMANENCY”.**

15          (b) PURPOSE.—The first sentence of section 470 of  
16          such Act (42 U.S.C. 670) is amended—

17               (1) by striking “1995) and” and inserting  
18               “1995),”;

19               (2) by inserting “kinship guardianship assist-  
20               ance, and prevention services or programs specified  
21               in section 471(e)(1),” after “needs,”; and

22               (3) by striking “(commencing with the fiscal  
23               year which begins October 1, 1980)”.

24   **SEC. 19034. EFFECTIVE DATES.**

25          (a) EFFECTIVE DATES.—

1           (1) IN GENERAL.—Except as provided in para-  
2           graph (2), subject to subsection (b), the amend-  
3           ments made by this title shall take effect on January  
4           1, 2017.

5           (2) EXCEPTIONS.—The amendments made by  
6           sections 19031 and 19033 shall take effect on the  
7           date of enactment of this Act.

8           (b) TRANSITION RULE.—

9           (1) IN GENERAL.—In the case of a State plan  
10          under part B or E of title IV of the Social Security  
11          Act which the Secretary of Health and Human Serv-  
12          ices determines requires State legislation (other than  
13          legislation appropriating funds) in order for the plan  
14          to meet the additional requirements imposed by the  
15          amendments made by this title, the State plan shall  
16          not be regarded as failing to comply with the re-  
17          quirements of such part solely on the basis of the  
18          failure of the plan to meet such additional require-  
19          ments before the first day of the first calendar quar-  
20          ter beginning after the close of the first regular ses-  
21          sion of the State legislature that begins after the  
22          date of enactment of this Act. For purposes of the  
23          previous sentence, in the case of a State that has a  
24          2-year legislative session, each year of the session



1 shall be deemed to be a separate regular session of  
2 the State legislature.

3 (2) APPLICATION TO PROGRAMS OPERATED BY  
4 INDIAN TRIBAL ORGANIZATIONS.—In the case of an  
5 Indian tribe, tribal organization, or tribal consortium  
6 which the Secretary of Health and Human Services  
7 determines requires time to take action necessary to  
8 comply with the additional requirements imposed by  
9 the amendments made by this title (whether the  
10 tribe, organization, or tribal consortium has a plan  
11 under section 479B of the Social Security Act or a  
12 cooperative agreement or contract entered into with  
13 a State), the Secretary shall provide the tribe, orga-  
14 nization, or tribal consortium with such additional  
15 time as the Secretary determines is necessary for the  
16 tribe, organization, or tribal consortium to take the  
17 action to comply with the additional requirements  
18 before being regarded as failing to comply with the  
19 requirements.

1 **TITLE XX—ENSURING THE NE-**  
2 **CESSITY OF A PLACEMENT**  
3 **THAT IS NOT IN A FOSTER**  
4 **FAMILY HOME**

5 **SEC. 20001. LIMITATION ON FEDERAL FINANCIAL PARTICI-**  
6 **PATION FOR PLACEMENTS THAT ARE NOT IN**  
7 **FOSTER FAMILY HOMES.**

8 (a) LIMITATION ON FEDERAL FINANCIAL PARTICIPA-  
9 TION.—

10 (1) IN GENERAL.—Section 472 of the Social  
11 Security Act (42 U.S.C. 672), as amended by sec-  
12 tion 19012, is amended—

13 (A) in subsection (a)(2)(C), by inserting “,  
14 but only to the extent permitted under sub-  
15 section (k)” after “institution”; and

16 (B) by adding at the end the following:

17 “(k) LIMITATION ON FEDERAL FINANCIAL PARTICI-  
18 PATION.—

19 “(1) IN GENERAL.—Beginning with the third  
20 week for which foster care maintenance payments  
21 are made under this section on behalf of a child  
22 placed in a child-care institution, no Federal pay-  
23 ment shall be made to the State under section  
24 474(a)(1) for amounts expended for foster care

1 maintenance payments on behalf of the child un-  
2 less—

3 “(A) the child is placed in a child-care in-  
4 stitution that is a setting specified in paragraph  
5 (2) (or is placed in a licensed residential family-  
6 based treatment facility consistent with sub-  
7 section (j)); and

8 “(B) in the case of a child placed in a  
9 qualified residential treatment program (as de-  
10 fined in paragraph (4)), the requirements speci-  
11 fied in paragraph (3) and section 475A(c) are  
12 met.

13 “(2) SPECIFIED SETTINGS FOR PLACEMENT.—  
14 The settings for placement specified in this para-  
15 graph are the following:

16 “(A) A qualified residential treatment pro-  
17 gram (as defined in paragraph (4)).

18 “(B) A setting specializing in providing  
19 prenatal, post-partum, or parenting supports  
20 for youth.

21 “(C) In the case of a child who has at-  
22 tained 18 years of age, a supervised setting in  
23 which the child is living independently.

24 “(D) A setting providing high-quality resi-  
25 dential care and supportive services to children

1 and youth who have been found to be, or are  
2 at risk of becoming, sex trafficking victims, in  
3 accordance with section 471(a)(9)(C).

4 “(3) ASSESSMENT TO DETERMINE APPRO-  
5 PRIATENESS OF PLACEMENT IN A QUALIFIED RESI-  
6 DENTIAL TREATMENT PROGRAM.—

7 “(A) DEADLINE FOR ASSESSMENT.—In  
8 the case of a child who is placed in a qualified  
9 residential treatment program, if the assess-  
10 ment required under section 475A(c)(1) is not  
11 completed within 30 days after the placement is  
12 made, no Federal payment shall be made to the  
13 State under section 474(a)(1) for any amounts  
14 expended for foster care maintenance payments  
15 on behalf of the child during the placement.

16 “(B) DEADLINE FOR TRANSITION OUT OF  
17 PLACEMENT.—If the assessment required under  
18 section 475A(c)(1) determines that the place-  
19 ment of a child in a qualified residential treat-  
20 ment program is not appropriate, a court dis-  
21 approves such a placement under section  
22 475A(c)(2), or a child who has been in an ap-  
23 proved placement in a qualified residential  
24 treatment program is going to return home or  
25 be placed with a fit and willing relative, a legal

1 guardian, or an adoptive parent, or in a foster  
2 family home, Federal payments shall be made  
3 to the State under section 474(a)(1) for  
4 amounts expended for foster care maintenance  
5 payments on behalf of the child while the child  
6 remains in the qualified residential treatment  
7 program only during the period necessary for  
8 the child to transition home or to such a place-  
9 ment. In no event shall a State receive Federal  
10 payments under section 474(a)(1) for amounts  
11 expended for foster care maintenance payments  
12 on behalf of a child who remains placed in a  
13 qualified residential treatment program after  
14 the end of the 30-day period that begins on the  
15 date a determination is made that the place-  
16 ment is no longer the recommended or approved  
17 placement for the child.

18 “(4) QUALIFIED RESIDENTIAL TREATMENT  
19 PROGRAM.—For purposes of this part, the term  
20 ‘qualified residential treatment program’ means a  
21 program that—

22 “(A) has a trauma-informed treatment  
23 model that is designed to address the needs, in-  
24 cluding clinical needs as appropriate, of chil-  
25 dren with serious emotional or behavioral dis-

1 orders or disturbances and, with respect to a  
2 child, is able to implement the treatment identi-  
3 fied for the child by the assessment of the child  
4 required under section 475A(c);

5 “(B) subject to paragraph (5), has reg-  
6 istered or licensed nursing staff and other li-  
7 censed clinical staff who—

8 “(i) provide care within the scope of  
9 their practice as defined by State law;

10 “(ii) are on-site during business  
11 hours; and

12 “(iii) are available 24 hours a day and  
13 7 days a week;

14 “(C) to extent appropriate, and in accord-  
15 ance with the child’s best interests, facilitates  
16 participation of family members in the child’s  
17 treatment program;

18 “(D) facilitates outreach to the family  
19 members of the child, including siblings, docu-  
20 ments how the outreach is made (including con-  
21 tact information), and maintains contact infor-  
22 mation for any known biological family and fic-  
23 tive kin of the child;

24 “(E) documents how family members are  
25 integrated into the treatment process for the

1 child, including post-discharge, and how sibling  
2 connections are maintained;

3 “(F) provides discharge planning and fam-  
4 ily-based aftercare support for at least 6  
5 months post-discharge; and

6 “(G) is licensed in accordance with section  
7 471(a)(10) and is accredited by any of the fol-  
8 lowing independent, not-for-profit organizations:

9 “(i) The Commission on Accreditation  
10 of Rehabilitation Facilities (CARF).

11 “(ii) The Joint Commission on Ac-  
12 creditation of Healthcare Organizations  
13 (JCAHO).

14 “(iii) The Council on Accreditation  
15 (COA).

16 “(iv) Any other independent, not-for-  
17 profit accrediting organization approved by  
18 the Secretary.

19 “(5) FLEXIBILITY IN STAFFING REQUIREMENTS  
20 FOR QUALIFIED RESIDENTIAL TREATMENT PRO-  
21 GRAMS.—

22 “(A) IN GENERAL.—In the case of any  
23 State that the Secretary determines is described  
24 in subparagraph (B) and satisfies the require-  
25 ments of subparagraphs (C) and (D), respec-

1           tively, the State may elect to satisfy the re-  
2           quirement of paragraph (4)(B) that a qualified  
3           residential treatment program have registered  
4           or licensed nursing staff and other licensed clin-  
5           ical staff with clinical staff which include staff  
6           licensed to monitor medications and physical  
7           and behavioral health staff with demonstrated  
8           training in child development and trauma, in  
9           lieu of with registered or licensed nursing staff  
10          and other licensed clinical staff.

11                 “(B) STATE DESCRIBED.—Subject to sub-  
12          paragraph (E), a State is described in this sub-  
13          paragraph if for the most recent fiscal year for  
14          which data are available—

15                         “(i) the percentage of children in fos-  
16          ter care under the responsibility of the  
17          State who have been placed in congregate  
18          care settings—

19                                 “(I) is at or below 5 percent for  
20                                 the fiscal year; or

21                                 “(II) has been reduced by at  
22                                 least 20 percent from the preceding  
23                                 fiscal year; and

24                                 “(ii) the average length of stay for  
25                                 children in foster care under the responsi-



1           bility of the State in congregate care set-  
2           tings is at or below 9 months.

3           “(C) DEMONSTRATION OF CAPACITY AND  
4           NEED.—A State described in subparagraph (B)  
5           shall be eligible to use the alternative staffing  
6           model permitted under subparagraph (A) if the  
7           State can demonstrate to the satisfaction of the  
8           Secretary that the qualified residential treat-  
9           ment programs utilizing the alternative staffing  
10          models permitted under subparagraph (A) have  
11          the capacity to serve children and youth whose  
12          treatment plans—

13               “(i) indicate a need for increased su-  
14               pervision based on behavioral history, his-  
15               tory of juvenile delinquency, or history of  
16               sexual offenses; and

17               “(ii) require a placement that con-  
18               forms to the alternative staffing model per-  
19               mitted under subparagraph (A).

20          “(D) EQUITABLE DISTRIBUTION OF CON-  
21          GREGATE CARE POPULATION.—A State de-  
22          scribed in subparagraph (B) shall be eligible to  
23          use the alternative staffing model permitted  
24          under subparagraph (A) if the State annually  
25          demonstrates to the satisfaction of the Sec-

1           retary that the State is reducing the number of  
2           children in foster care under the responsibility  
3           of the State who are in congregate care place-  
4           ments on a general statewide basis and without  
5           wide disparities between rural, suburban, and  
6           urban areas in the rates of such children in  
7           congregate care placements.

8           “(E) ANNUAL DETERMINATION OF STATE  
9           ELIGIBILITY BASED ON AFCARS AND OTHER  
10          DATA.—The Secretary annually shall make the  
11          determinations required under subparagraph  
12          (B) with respect to a State and a fiscal year,  
13          on the basis of data meeting the requirements  
14          of the system established pursuant to section  
15          479, as reported by the State and approved by  
16          the Secretary, and, to the extent the Secretary  
17          determines necessary, on the basis of such other  
18          information reported to the Secretary as the  
19          Secretary may require to determine that a  
20          State is, or continues to be, a State described  
21          in subparagraph (B).

22          “(F) CONGREGATE CARE SETTINGS.—In  
23          this paragraph, the term ‘congregate care set-  
24          tings’ includes any settings described as ‘group  
25          homes’ or ‘institutions’ for purposes of data re-

1           ported in accordance with the requirements of  
2           the system established pursuant to section 479  
3           or any similar placement settings reported in  
4           accordance with such requirements.

5           “(6) ADMINISTRATIVE COSTS.—The prohibition  
6           in paragraph (1) on Federal payments under section  
7           474(a)(1) shall not be construed as prohibiting Fed-  
8           eral payments for administrative expenditures in-  
9           curred on behalf of a child placed in a child-care in-  
10          stitution and for which payment is available under  
11          section 474(a)(3).”.

12          (2) CONFORMING AMENDMENT.—Section  
13          474(a)(1) of the Social Security Act (42 U.S.C.  
14          674(a)(1)), as amended by section 19012(b), is  
15          amended by striking “section 472(j)” and inserting  
16          “subsections (j) and (k) of section 472”.

17          (b) DEFINITION OF FOSTER FAMILY HOME, CHILD-  
18          CARE INSTITUTION.—Section 472(c) of such Act (42  
19          U.S.C. 672(c)(1)) is amended to read as follows:

20          “(c) DEFINITIONS.—For purposes of this part:

21                  “(1) FOSTER FAMILY HOME.—

22                          “(A) IN GENERAL.—The term ‘foster fam-  
23                          ily home’ means the home of an individual or  
24                          family—

1           “(i) that is licensed or approved by  
2           the State in which it is situated as a foster  
3           family home that meets the standards es-  
4           tablished for the licensing or approval; and

5           “(ii) in which a child in foster care  
6           has been placed in the care of an indi-  
7           vidual, who resides with the child and who  
8           has been licensed or approved by the State  
9           to be a foster parent—

10           “(I) that the State deems capable  
11           of adhering to the reasonable and pru-  
12           dent parent standard;

13           “(II) that provides 24-hour sub-  
14           stitute care for children placed away  
15           from their parents or other care-  
16           takers; and

17           “(III) that provides the care for  
18           not more than six children in foster  
19           care.

20           “(B) STATE FLEXIBILITY.—The number of  
21           foster children that may be cared for in a home  
22           under subparagraph (A) may exceed the numer-  
23           ical limitation in subparagraph (A)(ii)(III), at  
24           the option of the State, for any of the following  
25           reasons:

1                   “(i) To allow a parenting youth in fos-  
2                   ter care to remain with the child of the  
3                   parenting youth.

4                   “(ii) To allow siblings to remain to-  
5                   gether.

6                   “(iii) To allow a child with an estab-  
7                   lished meaningful relationship with the  
8                   family to remain with the family.

9                   “(iv) To allow a family with special  
10                  training or skills to provide care to a child  
11                  who has a severe disability.

12                  “(C) RULE OF CONSTRUCTION.—Subpara-  
13                  graph (A) shall not be construed as prohibiting  
14                  a foster parent from renting the home in which  
15                  the parent cares for a foster child placed in the  
16                  parent’s care.

17                  “(2) CHILD-CARE INSTITUTION.—

18                  “(A) IN GENERAL.—The term ‘child-care  
19                  institution’ means a private child-care institu-  
20                  tion, or a public child-care institution which ac-  
21                  commodates no more than 25 children, which is  
22                  licensed by the State in which it is situated or  
23                  has been approved by the agency of the State  
24                  responsible for licensing or approval of institu-

1           tions of this type as meeting the standards es-  
2           tablished for the licensing.

3           “(B) SUPERVISED SETTINGS.—In the case  
4           of a child who has attained 18 years of age, the  
5           term shall include a supervised setting in which  
6           the individual is living independently, in accord-  
7           ance with such conditions as the Secretary shall  
8           establish in regulations.

9           “(C) EXCLUSIONS.—The term shall not in-  
10          clude detention facilities, forestry camps, train-  
11          ing schools, or any other facility operated pri-  
12          marily for the detention of children who are de-  
13          termined to be delinquent.”.

14          (c) TRAINING FOR STATE JUDGES, ATTORNEYS, AND  
15          OTHER LEGAL PERSONNEL IN CHILD WELFARE  
16          CASES.—Section 438(b)(1) of such Act (42 U.S.C.  
17          629h(b)(1)) is amended in the matter preceding subpara-  
18          graph (A) by inserting “shall provide for the training of  
19          judges, attorneys, and other legal personnel in child wel-  
20          fare cases on Federal child welfare policies and payment  
21          limitations with respect to children in foster care who are  
22          placed in settings that are not a foster family home,” after  
23          “with respect to the child,”.

24          (d) ASSURANCE OF NONIMPACT ON JUVENILE JUS-  
25          TICE SYSTEM.—

1           (1) STATE PLAN REQUIREMENT.—Section  
2           471(a) of such Act (42 U.S.C. 671(a)), as amended  
3           by section 19031, is further amended by adding at  
4           the end the following:

5           “(37) includes a certification that, in response  
6           to the limitation imposed under section 472(k) with  
7           respect to foster care maintenance payments made  
8           on behalf of any child who is placed in a setting that  
9           is not a foster family home, the State will not enact  
10          or advance policies or practices that would result in  
11          a significant increase in the population of youth in  
12          the State’s juvenile justice system.”.

13          (2) GAO STUDY AND REPORT.—The Comp-  
14          troller General of the United States shall evaluate  
15          the impact, if any, on State juvenile justice systems  
16          of the limitation imposed under section 472(k) of  
17          the Social Security Act (as added by section  
18          19001(a)(1)) on foster care maintenance payments  
19          made on behalf of any child who is placed in a set-  
20          ting that is not a foster family home, in accordance  
21          with the amendments made by subsections (a) and  
22          (b) of this section. In particular, the Comptroller  
23          General shall evaluate the extent to which children  
24          in foster care who also are subject to the juvenile  
25          justice system of the State are placed in a facility

1 under the jurisdiction of the juvenile justice system  
2 and whether the lack of available congregate care  
3 placements under the jurisdiction of the child wel-  
4 fare systems is a contributing factor to that result.  
5 Not later than December 31, 2023, the Comptroller  
6 General shall submit to Congress a report on the re-  
7 sults of the evaluation.

8 **SEC. 20002. ASSESSMENT AND DOCUMENTATION OF THE**  
9 **NEED FOR PLACEMENT IN A QUALIFIED RES-**  
10 **IDENTIAL TREATMENT PROGRAM.**

11 Section 475A of the Social Security Act (42 U.S.C.  
12 675a) is amended by adding at the end the following:

13 “(c) ASSESSMENT, DOCUMENTATION, AND JUDICIAL  
14 DETERMINATION REQUIREMENTS FOR PLACEMENT IN A  
15 QUALIFIED RESIDENTIAL TREATMENT PROGRAM.—In  
16 the case of any child who is placed in a qualified residen-  
17 tial treatment program (as defined in section 472(k)(4)),  
18 the following requirements shall apply for purposes of ap-  
19 proving the case plan for the child and the case system  
20 review procedure for the child:

21 “(1)(A) Within 30 days of the start of each  
22 placement in such a setting, a qualified individual  
23 (as defined in subparagraph (D)) shall—

24 “(i) assess the strengths and needs of the  
25 child using an age-appropriate, evidence-based,



1 validated, functional assessment tool approved  
2 by the Secretary;

3 “(ii) determine whether the needs of the  
4 child can be met with family members or  
5 through placement in a foster family home or,  
6 if not, which setting from among the settings  
7 specified in section 472(k)(2) would provide the  
8 most effective and appropriate level of care for  
9 the child in the least restrictive environment  
10 and be consistent with the short- and long-term  
11 goals for the child, as specified in the perma-  
12 nency plan for the child; and

13 “(iii) develop a list of child-specific short-  
14 and long-term mental and behavioral health  
15 goals.

16 “(B)(i) The State shall assemble a family and  
17 permanency team for the child in accordance with  
18 the requirements of clauses (ii) and (iii). The quali-  
19 fied individual conducting the assessment required  
20 under subparagraph (A) shall work in conjunction  
21 with the family of, and permanency team for, the  
22 child while conducting and making the assessment.

23 “(ii) The family and permanency team shall  
24 consist of all appropriate biological family members,  
25 relative, and fictive kin of the child, as well as, as

1 appropriate, professionals who are a resource to the  
2 family of the child, such as teachers, medical or  
3 mental health providers who have treated the child,  
4 or clergy. In the case of a child who has attained  
5 age 14, the family and permanency team shall in-  
6 clude the members of the permanency planning team  
7 for the child that are selected by the child in accord-  
8 ance with section 475(5)(C)(iv).

9 “(iii) The State shall document in the child’s  
10 case plan—

11 “(I) the reasonable and good faith effort of  
12 the State to identify and include all such indi-  
13 viduals on the family of, and permanency team  
14 for, the child;

15 “(II) all contact information for members  
16 of the family and permanency team, as well as  
17 contact information for other family members  
18 and fictive kin who are not part of the family  
19 and permanency team;

20 “(III) evidence that meetings of the family  
21 and permanency team, including meetings relat-  
22 ing to the assessment required under subpara-  
23 graph (A), are held at a time and place conven-  
24 ient for family;

1           “(IV) if reunification is the goal, evidence  
2           demonstrating that the parent from whom the  
3           child was removed provided input on the mem-  
4           bers of the family and permanency team;

5           “(V) evidence that the assessment required  
6           under subparagraph (A) is determined in con-  
7           junction with the family and permanency team;  
8           and

9           “(VI) the placement preferences of the  
10          family and permanency team relative to the as-  
11          sessment and, if the placement preferences of  
12          the family and permanency team and child are  
13          not the placement setting recommended by the  
14          qualified individual conducting the assessment  
15          under subparagraph (A), the reasons why the  
16          preferences of the team and of the child were  
17          not recommended.

18          “(C) In the case of a child who the qualified in-  
19          dividual conducting the assessment under subpara-  
20          graph (A) determines should not be placed in a fos-  
21          ter family home, the qualified individual shall specify  
22          in writing the reasons why the needs of the child  
23          cannot be met by the family of the child or in a fos-  
24          ter family home. A shortage or lack of foster family  
25          homes shall not be an acceptable reason for deter-

1 mining that a needs of the child cannot be met in  
2 a foster family home. The qualified individual also  
3 shall specify in writing why the recommended place-  
4 ment in a qualified residential treatment program is  
5 the setting that will provide the child with the most  
6 effective and appropriate level of care in the least re-  
7 strictive environment and how that placement is con-  
8 sistent with the short- and long-term goals for the  
9 child, as specified in the permanency plan for the  
10 child.

11 “(D)(i) Subject to clause (ii), in this subsection,  
12 the term ‘qualified individual’ means a trained pro-  
13 fessional or licensed clinician who is not an employee  
14 of the State agency and who is not connected to, or  
15 affiliated with, any placement setting in which chil-  
16 dren are placed by the State.

17 “(ii) The Secretary may approve a request of a  
18 State to waive any requirement in clause (i) upon a  
19 submission by the State, in accordance with criteria  
20 established by the Secretary, that certifies that the  
21 trained professionals or licensed clinicians with re-  
22 sponsibility for performing the assessments de-  
23 scribed in subparagraph (A) shall maintain objec-  
24 tivity with respect to determining the most effective  
25 and appropriate placement for a child.

1           “(2) Within 60 days of the start of each place-  
2           ment in a qualified residential treatment program, a  
3           family or juvenile court or another court (including  
4           a tribal court) of competent jurisdiction, or an ad-  
5           ministrative body appointed or approved by the  
6           court, independently, shall—

7                   “(A) consider the assessment, determina-  
8                   tion, and documentation made by the qualified  
9                   individual conducting the assessment under  
10                  paragraph (1);

11                   “(B) determine whether the needs of the  
12                   child can be met through placement in a foster  
13                   family home or, if not, whether placement of  
14                   the child in a qualified residential treatment  
15                   program provides the most effective and appro-  
16                   priate level of care for the child in the least re-  
17                   strictive environment and whether that place-  
18                   ment is consistent with the short- and long-  
19                   term goals for the child, as specified in the per-  
20                   manency plan for the child; and

21                   “(C) approve or disapprove the placement.

22           “(3) The written documentation made under  
23           paragraph (1)(C) and documentation of the deter-  
24           mination and approval or disapproval of the place-  
25           ment in a qualified residential treatment program by

1 a court or administrative body under paragraph (2)  
2 shall be included in and made part of the case plan  
3 for the child.

4 “(4) As long as a child remains placed in a  
5 qualified residential treatment program, the State  
6 agency shall submit evidence at each status review  
7 and each permanency hearing held with respect to  
8 the child—

9 “(A) demonstrating that ongoing assess-  
10 ment of the strengths and needs of the child  
11 continues to support the determination that the  
12 needs of the child cannot be met through place-  
13 ment in a foster family home, that the place-  
14 ment in a qualified residential treatment pro-  
15 gram provides the most effective and appro-  
16 priate level of care for the child in the least re-  
17 strictive environment, and that the placement is  
18 consistent with the short- and long-term goals  
19 for the child, as specified in the permanency  
20 plan for the child;

21 “(B) documenting the specific treatment or  
22 service needs that will be met for the child in  
23 the placement and the length of time the child  
24 is expected to need the treatment or services;  
25 and

1           “(C) documenting the efforts made by the  
2           State agency to prepare the child to return  
3           home or to be placed with a fit and willing rel-  
4           ative, a legal guardian, or an adoptive parent,  
5           or in a foster family home.

6           “(5) In the case of any child who is placed in  
7           a qualified residential treatment program for more  
8           than 12 consecutive months or 18 nonconsecutive  
9           months (or, in the case of a child who has not at-  
10          tained age 13, for more than 6 consecutive or non-  
11          consecutive months), the State agency shall submit  
12          to the Secretary—

13                 “(A) the most recent versions of the evi-  
14                 dence and documentation specified in paragraph  
15                 (4); and

16                 “(B) the signed approval of the head of  
17                 the State agency for the continued placement of  
18                 the child in that setting.”.

19 **SEC. 20003. PROTOCOLS TO PREVENT INAPPROPRIATE DI-**  
20 **AGNOSES.**

21           (a)     STATE PLAN REQUIREMENT.—Section  
22     422(b)(15)(A) of the Social Security Act (42 U.S.C.  
23     622(b)(15)(A)) is amended—

24                 (1) in clause (vi), by striking “and” after the  
25                 semicolon;

1 (2) by redesignating clause (vii) as clause (viii);

2 and

3 (3) by inserting after clause (vi) the following:

4 “(vii) the procedures and protocols  
5 the State has established to ensure that  
6 children in foster care placements are not  
7 inappropriately diagnosed with mental ill-  
8 ness, other emotional or behavioral dis-  
9 orders, medically fragile conditions, or de-  
10 velopmental disabilities, and placed in set-  
11 tings that are not foster family homes as  
12 a result of the inappropriate diagnoses;  
13 and”.

14 (b) EVALUATION.—Section 476 of such Act (42  
15 U.S.C. 676), as previously amended, is further amended  
16 by adding at the end the following:

17 “(e) EVALUATION OF STATE PROCEDURES AND PRO-  
18 Tocols To Prevent Inappropriate Diagnoses of  
19 Mental Illness or Other Conditions.—The Sec-  
20 retary shall conduct an evaluation of the procedures and  
21 protocols established by States in accordance with the re-  
22 quirements of section 422(b)(15)(A)(vii). The evaluation  
23 shall analyze the extent to which States comply with and  
24 enforce the procedures and protocols and the effectiveness  
25 of various State procedures and protocols and shall iden-



1 tify best practices. Not later than January 1, 2019, the  
2 Secretary shall submit a report on the results of the eval-  
3 uation to Congress.”.

4 **SEC. 20004. ADDITIONAL DATA AND REPORTS REGARDING**  
5 **CHILDREN PLACED IN A SETTING THAT IS**  
6 **NOT A FOSTER FAMILY HOME.**

7 Section 479A(a)(7)(A) of the Social Security Act (42  
8 U.S.C. 679b(a)(7)(A)) is amended by striking clauses (i)  
9 through (vi) and inserting the following:

10 “(i) with respect to each such place-  
11 ment—

12 “(I) the type of the placement  
13 setting, including whether the place-  
14 ment is shelter care, a group home  
15 and if so, the range of the child popu-  
16 lation in the home, a residential treat-  
17 ment facility, a hospital or institution  
18 providing medical, rehabilitative, or  
19 psychiatric care, a setting specializing  
20 in providing prenatal, post-partum or  
21 parenting supports, or some other  
22 kind of child-care institution and if so,  
23 what kind;

24 “(II) the number of children in  
25 the placement setting and the age,

1 race, ethnicity, and gender of each of  
2 the children;

3 “(III) for each child in the place-  
4 ment setting, the length of the place-  
5 ment of the child in the setting,  
6 whether the placement of the child in  
7 the setting is the first placement of  
8 the child and if not, the number and  
9 type of previous placements of the  
10 child, and whether the child has spe-  
11 cial needs or another diagnosed men-  
12 tal or physical illness or condition;  
13 and

14 “(IV) the extent of any special-  
15 ized education, treatment, counseling,  
16 or other services provided in the set-  
17 ting; and

18 “(ii) separately, the number and ages  
19 of children in the placements who have a  
20 permanency plan of another planned per-  
21 manent living arrangement; and”.

22 **SEC. 20005. EFFECTIVE DATES; APPLICATION TO WAIVERS.**

23 (a) **EFFECTIVE DATES.**—

1           (1) IN GENERAL.—Subject to paragraph (2)  
2           and subsections (b) and (c), the amendments made  
3           by this title shall take effect on January 1, 2017.

4           (2) TRANSITION RULE.—In the case of a State  
5           plan under part B or E of title IV of the Social Se-  
6           curity Act which the Secretary of Health and  
7           Human Services determines requires State legisla-  
8           tion (other than legislation appropriating funds) in  
9           order for the plan to meet the additional require-  
10          ments imposed by the amendments made by this  
11          title, the State plan shall not be regarded as failing  
12          to comply with the requirements of such part solely  
13          on the basis of the failure of the plan to meet the  
14          additional requirements before the first day of the  
15          first calendar quarter beginning after the close of  
16          the first regular session of the State legislature that  
17          begins after the date of enactment of this Act. For  
18          purposes of the previous sentence, in the case of a  
19          State that has a 2-year legislative session, each year  
20          of the session shall be deemed to be a separate reg-  
21          ular session of the State legislature.

22          (b) LIMITATION ON FEDERAL FINANCIAL PARTICI-  
23          PATION FOR PLACEMENTS THAT ARE NOT IN FOSTER  
24          FAMILY HOMES AND RELATED PROVISIONS.—

1           (1) IN GENERAL.—The amendments made by  
2 sections 20001(a), 20001(b), 20001(d), and 20002  
3 shall take effect on October 1, 2019.

4           (2) STATE OPTION TO DELAY EFFECTIVE DATE  
5 FOR NOT MORE THAN 2 YEARS.—At the sole discre-  
6 tion of a State and for not more than 2 years, the  
7 Secretary of Health and Human Services shall delay  
8 the effective date provided for in paragraph (1) with  
9 respect to the State. If the effective date is so de-  
10 layed for a period with respect to a State under the  
11 preceding sentence, then—

12           (A) notwithstanding section 1904, the date  
13 that the amendments made by section 19011(c)  
14 take effect with respect to the State shall be de-  
15 layed for the period; and

16           (B) in applying section 474(a)(6) of the  
17 Social Security Act with respect to the State,  
18 “on or after the date this paragraph takes ef-  
19 fect with respect to the State” is deemed to be  
20 substituted for “after September 30, 2019” in  
21 subparagraph (A)(i)(I) of such section.

22           (c) APPLICATION TO STATES WITH WAIVERS.—In  
23 the case of a State that, on the date of enactment of this  
24 Act, has in effect a waiver approved under section 1130  
25 of the Social Security Act (42 U.S.C. 1320a–9), the

1 amendments made by this title shall not apply with respect  
2 to the State before the expiration (determined without re-  
3 gard to any extensions) of the waiver to the extent the  
4 amendments are inconsistent with the terms of the waiver.

5 **TITLE XXI—CONTINUING SUP-**  
6 **PORT FOR CHILD AND FAM-**  
7 **ILY SERVICES**

8 **SEC. 21001. SUPPORTING AND RETAINING FOSTER FAMI-**  
9 **LIES FOR CHILDREN.**

10 (a) SUPPORTING AND RETAINING FOSTER PARENTS  
11 AS A FAMILY SUPPORT SERVICE.—Section 431(a)(2)(B)  
12 of the Social Security Act (42 U.S.C. 631(a)(2)(B)) is  
13 amended by redesignating clauses (iii) through (vi) as  
14 clauses (iv) through (vii), respectively, and inserting after  
15 clause (ii) the following:

16 “(iii) To support and retain foster  
17 families so they can provide quality family-  
18 based settings for children in foster care.”.

19 (b) SUPPORT FOR FOSTER FAMILY HOMES.—Section  
20 436 of such Act (42 U.S.C. 629f) is amended by adding  
21 at the end the following:

22 “(c) SUPPORT FOR FOSTER FAMILY HOMES.—Out  
23 of any money in the Treasury of the United States not  
24 otherwise appropriated, there are appropriated to the Sec-  
25 retary for fiscal year 2018, \$8,000,000 for the Secretary

1 to make competitive grants to States, Indian tribes, or  
2 tribal consortia to support the recruitment and retention  
3 of high-quality foster families to increase their capacity  
4 to place more children in family settings, focused on  
5 States, Indian tribes, or tribal consortia with the highest  
6 percentage of children in non-family settings. The amount  
7 appropriated under this subparagraph shall remain avail-  
8 able through fiscal year 2022.”.

9 **SEC. 21002. EXTENSION OF CHILD AND FAMILY SERVICES**  
10 **PROGRAMS.**

11 (a) **EXTENSION OF STEPHANIE TUBBS JONES CHILD**  
12 **WELFARE SERVICES PROGRAM.**—Section 425 of the So-  
13 cial Security Act (42 U.S.C. 625) is amended by striking  
14 “2012 through 2016” and inserting “2017 through  
15 2021”.

16 (b) **EXTENSION OF PROMOTING SAFE AND STABLE**  
17 **FAMILIES PROGRAM AUTHORIZATIONS.**—

18 (1) **IN GENERAL.**—Section 436(a) of such Act  
19 (42 U.S.C. 629f(a)) is amended by striking all that  
20 follows “\$345,000,000” and inserting “for each of  
21 fiscal years 2017 through 2021.”.

22 (2) **DISCRETIONARY GRANTS.**—Section 437(a)  
23 of such Act (42 U.S.C. 629g(a)) is amended by  
24 striking “2012 through 2016” and inserting “2017  
25 through 2021”.

1           (c) EXTENSION OF FUNDING RESERVATIONS FOR  
2 MONTHLY CASEWORKER VISITS AND REGIONAL PART-  
3 NERSHIP GRANTS.—Section 436(b) of such Act (42  
4 U.S.C. 629f(b)) is amended—

5           (1) in paragraph (4)(A), by striking “2012  
6 through 2016” and inserting “2017 through 2021”;  
7 and

8           (2) in paragraph (5), by striking “2012  
9 through 2016” and inserting “2017 through 2021”.

10          (d) REAUTHORIZATION OF FUNDING FOR STATE  
11 COURTS.—

12           (1) EXTENSION OF PROGRAM.—Section  
13 438(c)(1) of such Act (42 U.S.C. 629h(c)(1)) is  
14 amended by striking “2012 through 2016” and in-  
15 serting “2017 through 2021”.

16           (2) EXTENSION OF FEDERAL SHARE.—Section  
17 438(d) of such Act (42 U.S.C. 629h(d)) is amended  
18 by striking “2012 through 2016” and inserting  
19 “2017 through 2021”.

20          (e) REPEAL OF EXPIRED PROVISIONS.—Section  
21 438(e) of such Act (42 U.S.C. 629h(e)) is repealed.

1 **SEC. 21003. IMPROVEMENTS TO THE JOHN H. CHAFEE FOS-**  
2 **TER CARE INDEPENDENCE PROGRAM AND**  
3 **RELATED PROVISIONS.**

4 (a) **AUTHORITY TO SERVE FORMER FOSTER YOUTH**  
5 **UP TO AGE 23.**—Section 477 of the Social Security Act  
6 (42 U.S.C. 677) is amended—

7 (1) in subsection (a)(5), by inserting “(or 23  
8 years of age, in the case of a State with a certifi-  
9 cation under subsection (b)(3)(A)(ii) to provide as-  
10 sistance and services to youths who have aged out  
11 of foster care and have not attained such age, in ac-  
12 cordance with such subsection)” after “21 years of  
13 age”;

14 (2) in subsection (b)(3)(A)—

15 (A) by inserting “(i)” before “A certifi-  
16 cation”;

17 (B) by striking “children who have left fos-  
18 ter care” and all that follows through the pe-  
19 riod and inserting “youths who have aged out  
20 of foster care and have not attained 21 years of  
21 age.”; and

22 (C) by adding at the end the following:

23 “(ii) If the State has elected under section  
24 475(8)(B) to extend eligibility for foster care to  
25 all children who have not attained 21 years of  
26 age, or if the Secretary determines that the



1 State agency responsible for administering the  
2 State plans under this part and part B uses  
3 State funds or any other funds not provided  
4 under this part to provide services and assist-  
5 ance for youths who have aged out of foster  
6 care that are comparable to the services and as-  
7 sistance the youths would receive if the State  
8 had made such an election, the certification re-  
9 quired under clause (i) may provide that the  
10 State will provide assistance and services to  
11 youths who have aged out of foster care and  
12 have not attained 23 years of age.”; and

13 (3) in subsection (b)(3)(B), by striking “chil-  
14 dren who have left foster care” and all that follows  
15 through the period and inserting “youths who have  
16 aged out of foster care and have not attained 21  
17 years of age (or 23 years of age, in the case of a  
18 State with a certification under subparagraph (A)(i)  
19 to provide assistance and services to youths who  
20 have aged out of foster care and have not attained  
21 such age, in accordance with subparagraph  
22 (A)(ii).”.

23 (b) AUTHORITY TO REDISTRIBUTE UNSPENT  
24 FUNDS.—Section 477(d) of such Act (42 U.S.C. 677(d))  
25 is amended—

1           (1) in paragraph (4), by inserting “or does not  
2           expend allocated funds within the time period speci-  
3           fied under section 477(d)(3)” after “provided by the  
4           Secretary”; and

5           (2) by adding at the end the following:

6           “(5)   REDISTRIBUTION   OF   UNEXPENDED  
7           AMOUNTS.—

8                   “(A) AVAILABILITY OF AMOUNTS.—To the  
9                   extent that amounts paid to States under this  
10                   section in a fiscal year remain unexpended by  
11                   the States at the end of the succeeding fiscal  
12                   year, the Secretary may make the amounts  
13                   available for redistribution in the second suc-  
14                   ceeding fiscal year among the States that apply  
15                   for additional funds under this section for that  
16                   second succeeding fiscal year.

17                   “(B) REDISTRIBUTION.—

18                           “(i) IN GENERAL.—The Secretary  
19                           shall redistribute the amounts made avail-  
20                           able under subparagraph (A) for a fiscal  
21                           year among eligible applicant States. In  
22                           this subparagraph, the term ‘eligible appli-  
23                           cant State’ means a State that has applied  
24                           for additional funds for the fiscal year  
25                           under subparagraph (A) if the Secretary

1 determines that the State will use the  
2 funds for the purpose for which originally  
3 allotted under this section.

4 “(ii) AMOUNT TO BE REDISTRIB-  
5 UTED.—The amount to be redistributed to  
6 each eligible applicant State shall be the  
7 amount so made available multiplied by the  
8 State foster care ratio, (as defined in sub-  
9 section (c)(4), except that, in such sub-  
10 section, ‘all eligible applicant States (as de-  
11 fined in subsection (d)(5)(B)(i))’ shall be  
12 substituted for ‘all States’).

13 “(iii) TREATMENT OF REDISTRIBUTED  
14 AMOUNT.—Any amount made available to  
15 a State under this paragraph shall be re-  
16 garded as part of the allotment of the  
17 State under this section for the fiscal year  
18 in which the redistribution is made.

19 “(C) TRIBES.—For purposes of this para-  
20 graph, the term ‘State’ includes an Indian tribe,  
21 tribal organization, or tribal consortium that re-  
22 ceives an allotment under this section.”.

23 (c) EXPANDING AND CLARIFYING THE USE OF EDU-  
24 CATION AND TRAINING VOUCHERS.—

1           (1) IN GENERAL.—Section 477(i)(3) of such  
2 Act (42 U.S.C. 677(i)(3)) is amended—

3           (A) by striking “on the date” and all that  
4 follows through “23” and inserting “to remain  
5 eligible until they attain 26”; and

6           (B) by inserting “, but in no event may a  
7 youth participate in the program for more than  
8 5 years (whether or not consecutive)” before  
9 the period.

10          (2) CONFORMING AMENDMENT.—Section  
11 477(i)(1) of such Act (42 U.S.C. 677(i)(1)) is  
12 amended by inserting “who have attained 14 years  
13 of age” before the period.

14          (d) OTHER IMPROVEMENTS.—Section 477 of such  
15 Act (42 U.S.C. 677), as amended by subsections (a), (b),  
16 and (c), is amended—

17           (1) in the section heading, by striking “**INDE-**  
18 **PENDENCE PROGRAM**” and inserting “**PROGRAM**  
19 **FOR SUCCESSFUL TRANSITION TO ADULT-**  
20 **HOOD**”;

21           (2) in subsection (a)—

22           (A) in paragraph (1)—

23           (i) by striking “identify children who  
24 are likely to remain in foster care until 18  
25 years of age and to help these children

1 make the transition to self-sufficiency by  
2 providing services” and inserting “support  
3 all youth who have experienced foster care  
4 at age 14 or older in their transition to  
5 adulthood through transitional services”;

6 (ii) by inserting “and post-secondary  
7 education” after “high school diploma”;  
8 and

9 (iii) by striking “training in daily liv-  
10 ing skills, training in budgeting and finan-  
11 cial management skills” and inserting  
12 “training and opportunities to practice  
13 daily living skills (such as financial literacy  
14 training and driving instruction)”;

15 (B) in paragraph (2), by striking “who are  
16 likely to remain in foster care until 18 years of  
17 age receive the education, training, and services  
18 necessary to obtain employment” and inserting  
19 “who have experienced foster care at age 14 or  
20 older achieve meaningful, permanent connec-  
21 tions with a caring adult”;

22 (C) in paragraph (3), by striking “who are  
23 likely to remain in foster care until 18 years of  
24 age prepare for and enter postsecondary train-  
25 ing and education institutions” and inserting

1 “who have experienced foster care at age 14 or  
2 older engage in age or developmentally appro-  
3 priate activities, positive youth development,  
4 and experiential learning that reflects what  
5 their peers in intact families experience”; and

6 (D) by striking paragraph (4) and redesign-  
7 ating paragraphs (5) through (8) as para-  
8 graphs (4) through (7);  
9 (3) in subsection (b)—

10 (A) in paragraph (2)(D), by striking “ado-  
11 lescents” and inserting “youth”; and

12 (B) in paragraph (3)—

13 (i) in subparagraph (D)—

14 (I) by inserting “including train-  
15 ing on youth development” after “to  
16 provide training”; and

17 (II) by striking “adolescents pre-  
18 paring for independent living” and all  
19 that follows through the period and  
20 inserting “youth preparing for a suc-  
21 cessful transition to adulthood and  
22 making a permanent connection with  
23 a caring adult.”;

1 (ii) in subparagraph (H), by striking  
2 “adolescents” each place it appears and in-  
3 sserting “youth”; and

4 (iii) in subparagraph (K)—

5 (I) by striking “an adolescent”  
6 and inserting “a youth”; and

7 (II) by striking “the adolescent”  
8 each place it appears and inserting  
9 “the youth”; and

10 (4) in subsection (f), by striking paragraph (2)  
11 and inserting the following:

12 “(2) REPORT TO CONGRESS.—Not later than  
13 October 1, 2017, the Secretary shall submit to the  
14 Committee on Ways and Means of the House of  
15 Representatives and the Committee on Finance of  
16 the Senate a report on the National Youth in Tran-  
17 sition Database and any other databases in which  
18 States report outcome measures relating to children  
19 in foster care and children who have aged out of fos-  
20 ter care or left foster care for kinship guardianship  
21 or adoption. The report shall include the following:

22 “(A) A description of the reasons for entry  
23 into foster care and of the foster care experi-  
24 ences, such as length of stay, number of place-  
25 ment settings, case goal, and discharge reason

1 of 17-year-olds who are surveyed by the Na-  
2 tional Youth in Transition Database and an  
3 analysis of the comparison of that description  
4 with the reasons for entry and foster care expe-  
5 riences of children of other ages who exit from  
6 foster care before attaining age 17.

7 “(B) A description of the characteristics of  
8 the individuals who report poor outcomes at  
9 ages 19 and 21 to the National Youth in Tran-  
10 sition Database.

11 “(C) Benchmarks for determining what  
12 constitutes a poor outcome for youth who re-  
13 main in or have exited from foster care and  
14 plans the Executive branch will take to incor-  
15 porate these benchmarks in efforts to evaluate  
16 child welfare agency performance in providing  
17 services to children transitioning from foster  
18 care.

19 “(D) An analysis of the association be-  
20 tween types of placement, number of overall  
21 placements, time spent in foster care, and other  
22 factors, and outcomes at ages 19 and 21.

23 “(E) An analysis of the differences in out-  
24 comes for children in and formerly in foster  
25 care at age 19 and 21 among States.”.



1 (e) CLARIFYING DOCUMENTATION PROVIDED TO  
2 FOSTER YOUTH LEAVING FOSTER CARE.—Section  
3 475(5)(I) of such Act (42 U.S.C. 675(5)(I)) is amended  
4 by inserting after “REAL ID Act of 2005” the following:  
5 “, and any official documentation necessary to prove that  
6 the child was previously in foster care”.

7 **TITLE XXII—CONTINUING IN-**  
8 **CENTIVES TO STATES TO**  
9 **PROMOTE ADOPTION AND**  
10 **LEGAL GUARDIANSHIP**

11 **SEC. 22001. REAUTHORIZING ADOPTION AND LEGAL**  
12 **GUARDIANSHIP INCENTIVE PROGRAMS.**

13 Section 473A of the Social Security Act (42 U.S.C.  
14 673b) is amended—

15 (1) in subsection (b)(4), by striking “2013  
16 through 2015” and inserting “2016 through 2020”;

17 (2) in subsection (h)(1)(D), by striking “2016”  
18 and inserting “2021”; and

19 (3) in subsection (h)(2), by striking “2016”  
20 and inserting “2021”.

1                   **TITLE XXIII—TECHNICAL**  
2                   **CORRECTIONS**

3   **SEC. 23001. TECHNICAL CORRECTIONS TO DATA EXCHANGE**  
4                   **STANDARDS TO IMPROVE PROGRAM COORDI-**  
5                   **NATION.**

6           (a) IN GENERAL.—Section 440 of the Social Security  
7 Act (42 U.S.C. 629m) is amended to read as follows:

8   **“SEC. 440. DATA EXCHANGE STANDARDS FOR IMPROVED**  
9                   **INTEROPERABILITY.**

10           “(a) DESIGNATION.—The Secretary shall, in con-  
11 sultation with an interagency work group established by  
12 the Office of Management and Budget and considering  
13 State government perspectives, by rule, designate data ex-  
14 change standards to govern, under this part and part E—

15                   “(1) necessary categories of information that  
16 State agencies operating programs under State  
17 plans approved under this part are required under  
18 applicable Federal law to electronically exchange  
19 with another State agency; and

20                   “(2) Federal reporting and data exchange re-  
21 quired under applicable Federal law.

22           “(b) REQUIREMENTS.—The data exchange standards  
23 required by paragraph (1) shall, to the extent prac-  
24 ticable—

1           “(1) incorporate a widely accepted, non-propri-  
2           etary, searchable, computer-readable format, such as  
3           the eXtensible Markup Language;

4           “(2) contain interoperable standards developed  
5           and maintained by intergovernmental partnerships,  
6           such as the National Information Exchange Model;

7           “(3) incorporate interoperable standards devel-  
8           oped and maintained by Federal entities with au-  
9           thority over contracting and financial assistance;

10          “(4) be consistent with and implement applica-  
11          ble accounting principles;

12          “(5) be implemented in a manner that is cost-  
13          effective and improves program efficiency and effec-  
14          tiveness; and

15          “(6) be capable of being continually upgraded  
16          as necessary.

17          “(c) RULE OF CONSTRUCTION.—Nothing in this sub-  
18          section shall be construed to require a change to existing  
19          data exchange standards found to be effective and effi-  
20          cient.”.

21          (b) EFFECTIVE DATE.—Not later than the date that  
22          is 24 months after the date of the enactment of this sec-  
23          tion, the Secretary of Health and Human Services shall  
24          issue a proposed rule that—

1 (1) identifies federally required data exchanges,  
2 include specification and timing of exchanges to be  
3 standardized, and address the factors used in deter-  
4 mining whether and when to standardize data ex-  
5 changes; and

6 (2) specifies State implementation options and  
7 describes future milestones.

8 **SEC. 23002. TECHNICAL CORRECTIONS TO STATE REQUIRE-**  
9 **MENT TO ADDRESS THE DEVELOPMENTAL**  
10 **NEEDS OF YOUNG CHILDREN.**

11 Section 422(b)(18) of the Social Security Act (42  
12 U.S.C. 622(b)(18)) is amended by striking “such chil-  
13 dren” and inserting “all vulnerable children under 5 years  
14 of age”.

15 **TITLE XXIV—ENSURING STATES**  
16 **REINVEST SAVINGS RESULT-**  
17 **ING FROM INCREASE IN**  
18 **ADOPTION ASSISTANCE**

19 **SEC. 24001. DELAY OF ADOPTION ASSISTANCE PHASE-IN.**

20 (a) IN GENERAL.—The table in section 473(e)(1)(B)  
21 of the Social Security Act (42 U.S.C. 673(e)(1)(B)) is  
22 amended—

23 (1) by striking “2016” and inserting “2016,  
24 2017, 2018, or 2019”;

1 (2) by striking “2017” and inserting “2020”;

2 and

3 (3) by striking “2018” and inserting “2021”.

4 (b) SPECIAL RULE.—Section 473(e) of the Social Se-  
5 curity Act (42 U.S.C. 673(e)) is amended by adding at  
6 the end the following new paragraph:

7 “(3) ADDITIONAL EXCEPTION.—Notwith-  
8 standing paragraph (1) of this subsection, during  
9 the period that begins on October 1, 2016, and ends  
10 on December 31, 2016, such term shall include a  
11 child—

12 “(A) who satisfies the requirements for  
13 being considered an applicable child under para-  
14 graph (1) (as in effect during that period);

15 “(B) who meets the requirements of sub-  
16 section (a)(2)(A)(ii); and

17 “(C) on whose behalf an adoption assist-  
18 ance agreement is entered into under this sec-  
19 tion during that period.”.

20 (c) EFFECTIVE DATE.—The amendments made by  
21 this section take effect on January 1, 2017.

1 **SEC. 24002. GAO STUDY AND REPORT ON STATE REINVEST-**  
2 **MENT OF SAVINGS RESULTING FROM IN-**  
3 **CREASE IN ADOPTION ASSISTANCE.**

4 (a) STUDY.—The Comptroller General of the United  
5 States shall study the extent to which States are com-  
6 plying with the requirements of section 473(a)(8) of the  
7 Social Security Act relating to the effects of phasing out  
8 the AFDC income eligibility requirements for adoption as-  
9 sistance payments under section 473 of the Social Security  
10 Act, as enacted by section 402 of the Fostering Conne-  
11 ctions to Success and Increasing Adoptions Act of 2008  
12 (Public Law 110–351; 122 Stat. 3975) and amended by  
13 section 206 of the Preventing Sex Trafficking and  
14 Strengthening Families Act (Public Law 113–183; 128  
15 Stat. 1919). In particular, the Comptroller General shall  
16 analyze the extent to which States are complying with the  
17 following requirements under section 473(a)(8)(D) of the  
18 Social Security Act:

19 (1) The requirement to spend an amount equal  
20 to the amount of the savings (if any) in State ex-  
21 penditures under part E of title IV of the Social Se-  
22 curity resulting from phasing out the AFDC income  
23 eligibility requirements for adoption assistance pay-  
24 ments under section 473 of such Act to provide to  
25 children of families any service that may be provided  
26 under part B or E of title IV of such Act.

1           (2) The requirement that a State shall spend  
2           not less than 30 percent of the amount of any sav-  
3           ings described in subparagraph (A) on post-adoption  
4           services, post-guardianship services, and services to  
5           support and sustain positive permanent outcomes for  
6           children who otherwise might enter into foster care  
7           under the responsibility of the State, with at least  $\frac{2}{3}$   
8           of the spending by the State to comply with the 30  
9           percent requirement being spent on post-adoption  
10          and post-guardianship services.

11          (b) REPORT.—The Comptroller General of the  
12          United States shall submit to the Committee on Finance  
13          of the Senate, the Committee on Ways and Means of the  
14          House of Representatives, and the Secretary of Health  
15          and Human Services a report that contains the results of  
16          the study required by subsection (a), including rec-  
17          ommendations to ensure compliance with laws referred to  
18          in subsection (a).

19          **TITLE    XXV—SOCIAL    IMPACT**  
20                **PARTNERSHIPS TO PAY FOR**  
21                **RESULTS**

22          **SEC. 25001. SHORT TITLE.**

23           This title may be cited as the “Social Impact Part-  
24          nership to Pay for Results Act”.

1 **SEC. 25002. SOCIAL IMPACT PARTNERSHIPS TO PAY FOR**  
2 **RESULTS.**

3 Section 403 of the Social Security Act (42 U.S.C.  
4 603) is amended by adding at the end the following:

5 “(c) SOCIAL IMPACT DEMONSTRATION PROJECTS.—

6 “(1) PURPOSES.—The purposes of this sub-  
7 section are the following:

8 “(A) To improve the lives of families and  
9 individuals in need in the United States by  
10 funding social programs that achieve real re-  
11 sults.

12 “(B) To redirect funds away from pro-  
13 grams that, based on objective data, are ineffec-  
14 tive, and into programs that achieve demon-  
15 strable, measurable results.

16 “(C) To ensure Federal funds are used ef-  
17 fectively on social services to produce positive  
18 outcomes for both service recipients and tax-  
19 payers.

20 “(D) To establish the use of social impact  
21 partnerships to address some of our Nation’s  
22 most pressing problems.

23 “(E) To facilitate the creation of public-  
24 private partnerships that bundle philanthropic  
25 or other private resources with existing public  
26 spending to scale up effective social interven-



1           tions already being implemented by private or-  
2           ganizations, nonprofits, charitable organiza-  
3           tions, and State and local governments across  
4           the country.

5           “(F) To bring pay-for-performance to the  
6           social sector, allowing the United States to im-  
7           prove the impact and effectiveness of vital social  
8           services programs while redirecting inefficient  
9           or duplicative spending.

10          “(G) To incorporate outcomes measure-  
11          ment and randomized controlled trials or other  
12          rigorous methodologies for assessing program  
13          impact.

14          “(2) SOCIAL IMPACT PARTNERSHIP APPLICA-  
15          TION.—

16          “(A) NOTICE.—Not later than 1 year after  
17          the date of the enactment of this subsection,  
18          the Secretary of the Treasury, in consultation  
19          with the Federal Interagency Council on Social  
20          Impact Partnerships, shall publish in the Fed-  
21          eral Register a request for proposals from  
22          States or local governments for social impact  
23          partnership projects in accordance with this  
24          paragraph.

1           “(B) REQUIRED OUTCOMES FOR SOCIAL  
2           IMPACT PARTNERSHIP PROJECT.—To qualify as  
3           a social impact partnership project under this  
4           subsection, a project must produce one or more  
5           measurable, clearly defined outcomes that result  
6           in social benefit and Federal, State, or local  
7           savings through any of the following:

8                   “(i) Increasing work and earnings by  
9                   individuals in the United States who are  
10                  unemployed for more than 6 consecutive  
11                  months.

12                  “(ii) Increasing employment and earn-  
13                  ings of individuals who have attained 16  
14                  years of age but not 25 years of age.

15                  “(iii) Increasing employment among  
16                  individuals receiving Federal disability ben-  
17                  efits.

18                  “(iv) Reducing the dependence of low-  
19                  income families on Federal means-tested  
20                  benefits.

21                  “(v) Improving rates of high school  
22                  graduation.

23                  “(vi) Reducing teen and unplanned  
24                  pregnancies.

1                   “(vii) Improving birth outcomes and  
2                   early childhood health and development  
3                   among low-income families and individuals.

4                   “(viii) Reducing rates of asthma, dia-  
5                   betes, or other preventable diseases among  
6                   low-income families and individuals to re-  
7                   duce the utilization of emergency and other  
8                   high-cost care.

9                   “(ix) Increasing the proportion of chil-  
10                  dren living in two-parent families.

11                  “(x) Reducing incidences and adverse  
12                  consequences of child abuse and neglect.

13                  “(xi) Reducing the number of youth  
14                  in foster care by increasing adoptions, per-  
15                  manent guardianship arrangements, reuni-  
16                  fications, or placements with a fit and will-  
17                  ing relative, or by avoiding placing children  
18                  in foster care by ensuring they can be  
19                  cared for safely in their own homes.

20                  “(xii) Reducing the number of chil-  
21                  dren and youth in foster care residing in  
22                  group homes, child care institutions, agen-  
23                  cy-operated foster homes, or other non-  
24                  family foster homes, unless it is deter-  
25                  mined that it is in the interest of the

1 child's long-term health, safety, or psycho-  
2 logical well-being to not be placed in a  
3 family foster home.

4 “(xiii) Reducing the number of chil-  
5 dren returning to foster care.

6 “(xiv) Reducing recidivism among ju-  
7 venile offenders, individuals released from  
8 prison, or other high-risk populations.

9 “(xv) Reducing the rate of homeless-  
10 ness among our most vulnerable popu-  
11 lations.

12 “(xvi) Improving the health and well-  
13 being of those with mental, emotional, and  
14 behavioral health needs.

15 “(xvii) Improving the educational out-  
16 comes of special-needs or low-income chil-  
17 dren.

18 “(xviii) Improving the employment  
19 and well-being of returning United States  
20 military members.

21 “(xix) Increasing the financial sta-  
22 bility of low-income families.

23 “(xx) Increasing the independence and  
24 employability of individuals who are phys-  
25 ically or mentally disabled.

1           “(xxi) Other measurable outcomes de-  
2           fined by the State or local government that  
3           result in positive social outcomes and Fed-  
4           eral savings.

5           “(C) APPLICATION REQUIRED.—The notice  
6           described in subparagraph (A) shall require a  
7           State or local government to submit an applica-  
8           tion for the social impact partnership project  
9           that addresses the following:

10           “(i) The outcome goals of the project.

11           “(ii) A description of each interven-  
12           tion in the project and anticipated out-  
13           comes of the intervention.

14           “(iii) Rigorous evidence demonstrating  
15           that the intervention can be expected to  
16           produce the desired outcomes.

17           “(iv) The target population that will  
18           be served by the project.

19           “(v) The expected social benefits to  
20           participants who receive the intervention  
21           and others who may be impacted.

22           “(vi) Projected Federal, State, and  
23           local government costs and other costs to  
24           conduct the project.

1                   “(vii) Projected Federal, State, and  
2                   local government savings and other sav-  
3                   ings, including an estimate of the savings  
4                   to the Federal Government, on a program-  
5                   by-program basis and in the aggregate, if  
6                   the project is implemented and the out-  
7                   comes are achieved as a result of the inter-  
8                   vention.

9                   “(viii) If savings resulting from the  
10                  successful completion of the project are es-  
11                  timated to accrue to the State or local gov-  
12                  ernment, the likelihood of the State or  
13                  local government to realize those savings.

14                  “(ix) A plan for delivering the inter-  
15                  vention through a social impact partner-  
16                  ship model.

17                  “(x) A description of the expertise of  
18                  each service provider that will administer  
19                  the intervention, including a summary of  
20                  the experience of the service provider in  
21                  delivering the proposed intervention or a  
22                  similar intervention, or demonstrating that  
23                  the service provider has the expertise nec-  
24                  essary to deliver the proposed intervention.

1                   “(xi) An explanation of the experience  
2                   of the State or local government, the inter-  
3                   mediary, or the service provider in raising  
4                   private and philanthropic capital to fund  
5                   social service investments.

6                   “(xii) The detailed roles and respon-  
7                   sibilities of each entity involved in the  
8                   project, including any State or local gov-  
9                   ernment entity, intermediary, service pro-  
10                  vider, independent evaluator, investor, or  
11                  other stakeholder.

12                  “(xiii) A summary of the experience of  
13                  the service provider in delivering the pro-  
14                  posed intervention or a similar interven-  
15                  tion, or a summary demonstrating the  
16                  service provider has the expertise necessary  
17                  to deliver the proposed intervention.

18                  “(xiv) A summary of the unmet need  
19                  in the area where the intervention will be  
20                  delivered or among the target population  
21                  who will receive the intervention.

22                  “(xv) The proposed payment terms,  
23                  the methodology used to calculate outcome  
24                  payments, the payment schedule, and per-  
25                  formance thresholds.

1                   “(xvi) The project budget.

2                   “(xvii) The project timeline.

3                   “(xviii) The criteria used to determine  
4 the eligibility of an individual for the  
5 project, including how selected populations  
6 will be identified, how they will be referred  
7 to the project, and how they will be en-  
8 rolled in the project.

9                   “(xix) The evaluation design.

10                  “(xx) The metrics that will be used in  
11 the evaluation to determine whether the  
12 outcomes have been achieved as a result of  
13 the intervention and how the metrics will  
14 be measured.

15                  “(xxi) An explanation of how the  
16 metrics used in the evaluation to determine  
17 whether the outcomes achieved as a result  
18 of the intervention are independent, objec-  
19 tive indicators of impact and are not sub-  
20 ject to manipulation by the service pro-  
21 vider, intermediary, or investor.

22                  “(xxii) A summary explaining the  
23 independence of the evaluator from the  
24 other entities involved in the project and  
25 the evaluator’s experience in conducting



1 rigorous evaluations of program effective-  
2 ness including, where available, well-imple-  
3 mented randomized controlled trials on the  
4 intervention or similar interventions.

5 “(xxiii) The capacity of the service  
6 provider to deliver the intervention to the  
7 number of participants the State or local  
8 government proposes to serve in the  
9 project.

10 “(xxiv) A description of whether and  
11 how the State or local government and  
12 service providers plan to sustain the inter-  
13 vention, if it is timely and appropriate to  
14 do so, to ensure that successful interven-  
15 tions continue to operate after the period  
16 of the social impact partnership.

17 “(D) PROJECT INTERMEDIARY INFORMA-  
18 TION REQUIRED.—The application described in  
19 subparagraph (C) shall also contain the fol-  
20 lowing information about any intermediary for  
21 the social impact partnership project (whether  
22 an intermediary is a service provider or other  
23 entity):

1                   “(i) Experience and capacity for pro-  
2                   viding or facilitating the provision of the  
3                   type of intervention proposed.

4                   “(ii) The mission and goals.

5                   “(iii) Information on whether the  
6                   intermediary is already working with serv-  
7                   ice providers that provide this intervention  
8                   or an explanation of the capacity of the  
9                   intermediary to begin working with service  
10                  providers to provide the intervention.

11                  “(iv) Experience working in a collabo-  
12                  rative environment across government and  
13                  nongovernmental entities.

14                  “(v) Previous experience collaborating  
15                  with public or private entities to implement  
16                  evidence-based programs.

17                  “(vi) Ability to raise or provide fund-  
18                  ing to cover operating costs (if applicable  
19                  to the project).

20                  “(vii) Capacity and infrastructure to  
21                  track outcomes and measure results, in-  
22                  cluding—

23                                 “(I) capacity to track and ana-  
24                                 lyze program performance and assess  
25                                 program impact; and

1                   “(II) experience with perform-  
2                   ance-based awards or performance-  
3                   based contracting and achieving  
4                   project milestones and targets.

5                   “(viii) Role in delivering the interven-  
6                   tion.

7                   “(ix) How the intermediary would  
8                   monitor program success, including a de-  
9                   scription of the interim benchmarks and  
10                  outcome measures.

11                  “(E) FEASIBILITY STUDIES FUNDED  
12                  THROUGH OTHER SOURCES.—The notice de-  
13                  scribed in subparagraph (A) shall permit a  
14                  State or local government to submit an applica-  
15                  tion for social impact partnership funding that  
16                  contains information from a feasibility study  
17                  developed for purposes other than applying for  
18                  funding under this subsection.

19                  “(3) AWARDING SOCIAL IMPACT PARTNERSHIP  
20                  AGREEMENTS.—

21                  “(A) TIMELINE IN AWARDING AGREE-  
22                  MENT.—Not later than 6 months after receiving  
23                  an application in accordance with paragraph  
24                  (2), the Secretary, in consultation with the Fed-  
25                  eral Interagency Council on Social Impact Part-

1           nerships, shall determine whether to enter into  
2           an agreement for a social impact partnership  
3           project with a State or local government.

4           “(B) CONSIDERATIONS IN AWARDING  
5           AGREEMENT.—In determining whether to enter  
6           into an agreement for a social impact partner-  
7           ship project (the application for which was sub-  
8           mitted under paragraph (2)) the Secretary, in  
9           consultation with the Federal Interagency  
10          Council on Social Impact Partnerships (estab-  
11          lished by paragraph (6)) and the head of any  
12          Federal agency administering a similar inter-  
13          vention or serving a population similar to that  
14          served by the project, shall consider each of the  
15          following:

16                 “(i) The recommendations made by  
17                 the Commission on Social Impact Partner-  
18                 ships.

19                 “(ii) The value to the Federal Govern-  
20                 ment of the outcomes expected to be  
21                 achieved if the outcomes specified in the  
22                 agreement are achieved as a result of the  
23                 intervention.

24                 “(iii) The likelihood, based on evi-  
25                 dence provided in the application and other

1 evidence, that the State or local govern-  
2 ment in collaboration with the inter-  
3 mediary and the service providers will  
4 achieve the outcomes.

5 “(iv) The savings to the Federal Gov-  
6 ernment if the outcomes specified in the  
7 agreement are achieved as a result of the  
8 intervention.

9 “(v) The savings to the State and  
10 local governments if the outcomes specified  
11 in the agreement are achieved as a result  
12 of the intervention.

13 “(vi) The expected quality of the eval-  
14 uation that would be conducted with re-  
15 spect to the agreement.

16 “(vii) The capacity and commitment  
17 of the State or local government to sustain  
18 the intervention, if appropriate and timely  
19 and if the intervention is successful, be-  
20 yond the period of the social impact part-  
21 nership.

22 “(C) AGREEMENT AUTHORITY.—

23 “(i) AGREEMENT REQUIREMENTS.—

24 In accordance with this paragraph, the  
25 Secretary, in consultation with the Federal

1 Interagency Council on Social Impact  
2 Partnerships and the head of any Federal  
3 agency administering a similar intervention  
4 or serving a population similar to that  
5 served by the project, may enter into an  
6 agreement for a social impact partnership  
7 project with a State or local government if  
8 the Secretary, in consultation with the  
9 Federal Interagency Council on Social Im-  
10 pact Partnerships, determines that each of  
11 the following requirements are met:

12 “(I) The State or local govern-  
13 ment agrees to achieve one or more  
14 outcomes as a result of the interven-  
15 tion, as specified in the agreement  
16 and validated by independent evalua-  
17 tion, in order to receive payment.

18 “(II) The Federal payment to the  
19 State or local government for each  
20 specified outcome achieved as a result  
21 of the intervention is less than or  
22 equal to the value of the outcome to  
23 the Federal Government over a period  
24 not to exceed 10 years, as determined

1 by the Secretary, in consultation with  
2 the State or local government.

3 “(III) The duration of the  
4 project does not exceed 10 years.

5 “(IV) The State or local govern-  
6 ment has demonstrated, through the  
7 application submitted under para-  
8 graph (2), that, based on prior rig-  
9 orous experimental evaluations or rig-  
10 orous quasi-experimental studies, the  
11 intervention can be expected to  
12 achieve each outcome specified in the  
13 agreement.

14 “(V) The State, local govern-  
15 ment, intermediary, or service pro-  
16 vider has experience raising private or  
17 philanthropic capital to fund social  
18 service investments (if applicable to  
19 the project).

20 “(VI) The State or local govern-  
21 ment has shown that each service pro-  
22 vider has experience delivering the  
23 intervention, a similar intervention, or  
24 has otherwise demonstrated the exper-

1                   tise necessary to deliver the interven-  
2                   tion.

3                   “(ii) PAYMENT.—The Secretary shall  
4                   pay the State or local government only if  
5                   the independent evaluator described in  
6                   paragraph (5) determines that the social  
7                   impact partnership project has met the re-  
8                   quirements specified in the agreement and  
9                   achieved an outcome as a result of the  
10                  intervention, as specified in the agreement  
11                  and validated by independent evaluation.

12                  “(D) NOTICE OF AGREEMENT AWARD.—  
13                  Not later than 30 days after entering into an  
14                  agreement under this paragraph, the Secretary  
15                  shall publish a notice in the Federal Register  
16                  that includes, with regard to the agreement, the  
17                  following:

18                         “(i) The outcome goals of the social  
19                         impact partnership project.

20                         “(ii) A description of each interven-  
21                         tion in the project.

22                         “(iii) The target population that will  
23                         be served by the project.



1                   “(iv) The expected social benefits to  
2 participants who receive the intervention  
3 and others who may be impacted.

4                   “(v) The detailed roles, responsibil-  
5 ities, and purposes of each Federal, State,  
6 or local government entity, intermediary,  
7 service provider, independent evaluator, in-  
8 vestor, or other stakeholder.

9                   “(vi) The payment terms, the method-  
10 ology used to calculate outcome payments,  
11 the payment schedule, and performance  
12 thresholds.

13                   “(vii) The project budget.

14                   “(viii) The project timeline.

15                   “(ix) The project eligibility criteria.

16                   “(x) The evaluation design.

17                   “(xi) The metrics that will be used in  
18 the evaluation to determine whether the  
19 outcomes have been achieved as a result of  
20 each intervention and how these metrics  
21 will be measured.

22                   “(xii) The estimate of the savings to  
23 the Federal, State, and local government,  
24 on a program-by-program basis and in the  
25 aggregate, if the agreement is entered into

1           and implemented and the outcomes are  
2           achieved as a result of each intervention.

3           “(E) AUTHORITY TO TRANSFER ADMINIS-  
4           TRATION OF AGREEMENT.—The Secretary may  
5           transfer to the head of another Federal agency  
6           the authority to administer (including making  
7           payments under) an agreement entered into  
8           under subparagraph (C), and any funds nec-  
9           essary to do so.

10          “(F) REQUIREMENT ON FUNDING USED TO  
11          BENEFIT CHILDREN.—Not less than 50 percent  
12          of all Federal payments made to carry out  
13          agreements under this paragraph shall be used  
14          for initiatives that directly benefit children.

15          “(4) FEASIBILITY STUDY FUNDING.—

16          “(A) REQUESTS FOR FUNDING FOR FEASI-  
17          BILITY STUDIES.—The Secretary shall reserve a  
18          portion of the amount reserved to carry out this  
19          subsection to assist States or local governments  
20          in developing feasibility studies to apply for so-  
21          cial impact partnership funding under para-  
22          graph (2). To be eligible to receive funding to  
23          assist with completing a feasibility study, a  
24          State or local government shall submit an appli-

1 cation for feasibility study funding addressing  
2 the following:

3 “(i) A description of the outcome  
4 goals of the social impact partnership  
5 project.

6 “(ii) A description of the intervention,  
7 including anticipated program design, tar-  
8 get population, an estimate regarding the  
9 number of individuals to be served, and  
10 setting for the intervention.

11 “(iii) Evidence to support the likeli-  
12 hood that the intervention will produce the  
13 desired outcomes.

14 “(iv) A description of the potential  
15 metrics to be used.

16 “(v) The expected social benefits to  
17 participants who receive the intervention  
18 and others who may be impacted.

19 “(vi) Estimated costs to conduct the  
20 project.

21 “(vii) Estimates of Federal, State,  
22 and local government savings and other  
23 savings if the project is implemented and  
24 the outcomes are achieved as a result of  
25 each intervention.

1                   “(viii) An estimated timeline for im-  
2                   plementation and completion of the  
3                   project, which shall not exceed 10 years.

4                   “(ix) With respect to a project for  
5                   which the State or local government selects  
6                   an intermediary to operate the project, any  
7                   partnerships needed to successfully execute  
8                   the project and the ability of the inter-  
9                   mediary to foster the partnerships.

10                   “(x) The expected resources needed to  
11                   complete the feasibility study for the State  
12                   or local government to apply for social im-  
13                   pact partnership funding under paragraph  
14                   (2).

15                   “(B) FEDERAL SELECTION OF APPLICA-  
16                   TIONS FOR FEASIBILITY STUDY.—Not later  
17                   than 6 months after receiving an application for  
18                   feasibility study funding under subparagraph  
19                   (A), the Secretary, in consultation with the  
20                   Federal Interagency Council on Social Impact  
21                   Partnerships and the head of any Federal agen-  
22                   cy administering a similar intervention or serv-  
23                   ing a population similar to that served by the  
24                   project, shall select State or local government

1 feasibility study proposals for funding based on  
2 the following:

3 “(i) The recommendations made by  
4 the Commission on Social Impact Partner-  
5 ships.

6 “(ii) The likelihood that the proposal  
7 will achieve the desired outcomes.

8 “(iii) The value of the outcomes ex-  
9 pected to be achieved as a result of each  
10 intervention.

11 “(iv) The potential savings to the  
12 Federal Government if the social impact  
13 partnership project is successful.

14 “(v) The potential savings to the  
15 State and local governments if the project  
16 is successful.

17 “(C) PUBLIC DISCLOSURE.—Not later  
18 than 30 days after selecting a State or local  
19 government for feasibility study funding under  
20 this paragraph, the Secretary shall cause to be  
21 published on the website of the Federal Inter-  
22 agency Council on Social Impact Partnerships  
23 information explaining why a State or local gov-  
24 ernment was granted feasibility study funding.

25 “(D) FUNDING RESTRICTION.—

1                   “(i) FEASIBILITY STUDY RESTRIC-  
2                   TION.—The Secretary may not provide fea-  
3                   sibility study funding under this paragraph  
4                   for more than 50 percent of the estimated  
5                   total cost of the feasibility study reported  
6                   in the State or local government applica-  
7                   tion submitted under subparagraph (A).

8                   “(ii) AGGREGATE RESTRICTION.—Of  
9                   the total amount reserved to carry out this  
10                  subsection, the Secretary may not use  
11                  more than \$10,000,000 to provide feasi-  
12                  bility study funding to States or local gov-  
13                  ernments under this paragraph.

14                  “(iii) NO GUARANTEE OF FUNDING.—  
15                  The Secretary shall have the option to  
16                  award no funding under this paragraph.

17                  “(E) SUBMISSION OF FEASIBILITY STUDY  
18                  REQUIRED.—Not later than 9 months after the  
19                  receipt of feasibility study funding under this  
20                  paragraph, a State or local government receiv-  
21                  ing the funding shall complete the feasibility  
22                  study and submit the study to the Federal  
23                  Interagency Council on Social Impact Partner-  
24                  ships.

1           “(F) DELEGATION OF AUTHORITY.—The  
2           Secretary may transfer to the head of another  
3           Federal agency the authorities provided in this  
4           paragraph and any funds necessary to exercise  
5           the authorities.

6           “(5) EVALUATIONS.—

7           “(A) AUTHORITY TO ENTER INTO AGREE-  
8           MENTS.—For each State or local government  
9           awarded a social impact partnership project ap-  
10          proved by the Secretary under this subsection,  
11          the head of the relevant agency, as rec-  
12          ommended by the Federal Interagency Council  
13          on Social Impact Partnerships and determined  
14          by the Secretary, shall enter into an agreement  
15          with the State or local government to pay for  
16          all or part of the independent evaluation to de-  
17          termine whether the State or local government  
18          project has achieved a specific outcome as a re-  
19          sult of the intervention in order for the State  
20          or local government to receive outcome pay-  
21          ments under this subsection.

22          “(B) EVALUATOR QUALIFICATIONS.—The  
23          head of the relevant agency may not enter into  
24          an agreement with a State or local government  
25          unless the head determines that the evaluator is

1 independent of the other parties to the agree-  
2 ment and has demonstrated substantial experi-  
3 ence in conducting rigorous evaluations of pro-  
4 gram effectiveness including, where available  
5 and appropriate, well-implemented randomized  
6 controlled trials on the intervention or similar  
7 interventions.

8 “(C) **METHODOLOGIES TO BE USED.**—The  
9 evaluation used to determine whether a State or  
10 local government will receive outcome payments  
11 under this subsection shall use experimental de-  
12 signs using random assignment or other reli-  
13 able, evidence-based research methodologies, as  
14 certified by the Federal Interagency Council on  
15 Social Impact Partnerships, that allow for the  
16 strongest possible causal inferences when ran-  
17 dom assignment is not feasible.

18 “(D) **PROGRESS REPORT.**—

19 “(i) **SUBMISSION OF REPORT.**—The  
20 independent evaluator shall—

21 “(I) not later than 2 years after  
22 a project has been approved by the  
23 Secretary and biannually thereafter  
24 until the project is concluded, submit  
25 to the head of the relevant agency and



1 the Federal Interagency Council on  
2 Social Impact Partnerships a written  
3 report summarizing the progress that  
4 has been made in achieving each out-  
5 come specified in the agreement; and

6 “(II) before the scheduled time of  
7 the first outcome payment and before  
8 the scheduled time of each subsequent  
9 payment, submit to the head of the  
10 relevant agency and the Federal  
11 Interagency Council on Social Impact  
12 Partnerships a written report that in-  
13 cludes the results of the evaluation  
14 conducted to determine whether an  
15 outcome payment should be made  
16 along with information on the unique  
17 factors that contributed to achieving  
18 or failing to achieve the outcome, the  
19 challenges faced in attempting to  
20 achieve the outcome, and information  
21 on the improved future delivery of this  
22 or similar interventions.

23 “(ii) SUBMISSION TO THE SECRETARY  
24 AND CONGRESS.—Not later than 30 days  
25 after receipt of the written report pursuant

1 to clause (i)(II), the Federal Interagency  
2 Council on Social Impact Partnerships  
3 shall submit the report to the Secretary  
4 and each committee of jurisdiction in the  
5 House of Representatives and the Senate.

6 “(E) FINAL REPORT.—

7 “(i) SUBMISSION OF REPORT.—Within  
8 6 months after the social impact partner-  
9 ship project is completed, the independent  
10 evaluator shall—

11 “(I) evaluate the effects of the  
12 activities undertaken pursuant to the  
13 agreement with regard to each out-  
14 come specified in the agreement; and

15 “(II) submit to the head of the  
16 relevant agency and the Federal  
17 Interagency Council on Social Impact  
18 Partnerships a written report that in-  
19 cludes the results of the evaluation  
20 and the conclusion of the evaluator as  
21 to whether the State or local govern-  
22 ment has fulfilled each obligation of  
23 the agreement, along with information  
24 on the unique factors that contributed  
25 to the success or failure of the project,

1 the challenges faced in attempting to  
2 achieve the outcome, and information  
3 on the improved future delivery of this  
4 or similar interventions.

5 “(ii) SUBMISSION TO THE SECRETARY  
6 AND CONGRESS.—Not later than 30 days  
7 after receipt of the written report pursuant  
8 to clause (i)(II), the Federal Interagency  
9 Council on Social Impact Partnerships  
10 shall submit the report to the Secretary  
11 and each committee of jurisdiction in the  
12 House of Representatives and the Senate.

13 “(F) LIMITATION ON COST OF EVALUA-  
14 TIONS.—Of the amount reserved under this  
15 subsection for social impact partnership  
16 projects, the Secretary may not obligate more  
17 than 15 percent to evaluate the implementation  
18 and outcomes of the projects.

19 “(G) DELEGATION OF AUTHORITY.—The  
20 Secretary may transfer to the head of another  
21 Federal agency the authorities provided in this  
22 paragraph and any funds necessary to exercise  
23 the authorities.

24 “(6) FEDERAL INTERAGENCY COUNCIL ON SO-  
25 CIAL IMPACT PARTNERSHIPS.—

1           “(A) ESTABLISHMENT.—There is estab-  
2           lished the Federal Interagency Council on So-  
3           cial Impact Partnerships (in this paragraph re-  
4           ferred to as the ‘Council’) to—

5                   “(i) coordinate with the Secretary on  
6                   the efforts of social impact partnership  
7                   projects funded under this subsection;

8                   “(ii) advise and assist the Secretary in  
9                   the development and implementation of the  
10                  projects;

11                  “(iii) advise the Secretary on specific  
12                  programmatic and policy matter related to  
13                  the projects;

14                  “(iv) provide subject-matter expertise  
15                  to the Secretary with regard to the  
16                  projects;

17                  “(v) certify to the Secretary that each  
18                  State or local government that has entered  
19                  into an agreement with the Secretary for a  
20                  social impact partnership project under  
21                  this subsection and each evaluator selected  
22                  by the head of the relevant agency under  
23                  paragraph (5) has access to Federal ad-  
24                  ministrative data to assist the State or  
25                  local government and the evaluator in eval-

1 uating the performance and outcomes of  
2 the project;

3 “(vi) address issues that will influence  
4 the future of social impact partnership  
5 projects in the United States;

6 “(vii) provide guidance to the execu-  
7 tive branch on the future of social impact  
8 partnership projects in the United States;

9 “(viii) prior to approval by the Sec-  
10 retary, certify that each State and local  
11 government application for a social impact  
12 partnership contains rigorous, independent  
13 data and reliable, evidence-based research  
14 methodologies to support the conclusion  
15 that the project will yield savings to the  
16 State or local government or the Federal  
17 Government if the project outcomes are  
18 achieved;

19 “(ix) certify to the Secretary, in the  
20 case of each approved social impact part-  
21 nership that is expected to yield savings to  
22 the Federal Government, that the project  
23 will yield a projected savings to the Fed-  
24 eral Government if the project outcomes  
25 are achieved, and coordinate with the rel-

1           evant Federal agency to produce an after-  
2           action accounting once the project is com-  
3           plete to determine the actual Federal sav-  
4           ings realized, and the extent to which ac-  
5           tual savings aligned with projected savings;  
6           and

7           “(x) provide periodic reports to the  
8           Secretary and make available reports peri-  
9           odically to Congress and the public on the  
10          implementation of this subsection.

11          “(B) COMPOSITION OF COUNCIL.—The  
12          Council shall have 11 members, as follows:

13                 “(i) CHAIR.—The Chair of the Coun-  
14                 cil shall be the Director of the Office of  
15                 Management and Budget.

16                 “(ii) OTHER MEMBERS.—The head of  
17                 each of the following entities shall des-  
18                 ignate one officer or employee of the entity  
19                 to be a Council member:

20                         “(I) The Department of Labor.

21                         “(II) The Department of Health  
22                         and Human Services.

23                         “(III) The Social Security Ad-  
24                         ministration.

1                   “(IV) The Department of Agri-  
2                   culture.

3                   “(V) The Department of Justice.

4                   “(VI) The Department of Hous-  
5                   ing and Urban Development.

6                   “(VII) The Department of Edu-  
7                   cation.

8                   “(VIII) The Department of Vet-  
9                   erans Affairs.

10                  “(IX) The Department of the  
11                  Treasury.

12                  “(X) The Corporation for Na-  
13                  tional and Community Service.

14                  “(7) COMMISSION ON SOCIAL IMPACT PARTNER-  
15                  SHIPS.—

16                  “(A) ESTABLISHMENT.—There is estab-  
17                  lished the Commission on Social Impact Part-  
18                  nerships (in this paragraph referred to as the  
19                  ‘Commission’).

20                  “(B) DUTIES.—The duties of the Commis-  
21                  sion shall be to—

22                  “(i) assist the Secretary and the Fed-  
23                  eral Interagency Council on Social Impact  
24                  Partnerships in reviewing applications for  
25                  funding under this subsection;

1                   “(ii) make recommendations to the  
2                   Secretary and the Federal Interagency  
3                   Council on Social Impact Partnerships re-  
4                   garding the funding of social impact part-  
5                   nership agreements and feasibility studies;  
6                   and

7                   “(iii) provide other assistance and in-  
8                   formation as requested by the Secretary or  
9                   the Federal Interagency Council on Social  
10                  Impact Partnerships.

11                  “(C) COMPOSITION.—The Commission  
12                  shall be composed of nine members, of whom—

13                  “(i) one shall be appointed by the  
14                  President, who will serve as the Chair of  
15                  the Commission;

16                  “(ii) one shall be appointed by the  
17                  Majority Leader of the Senate;

18                  “(iii) one shall be appointed by the  
19                  Minority Leader of the Senate;

20                  “(iv) one shall be appointed by the  
21                  Speaker of the House of Representatives;

22                  “(v) one shall be appointed by the Mi-  
23                  nority Leader of the House of Representa-  
24                  tives;



1                   “(vi) one shall be appointed by the  
2                   Chairman of the Committee on Finance of  
3                   the Senate;

4                   “(vii) one shall be appointed by the  
5                   ranking member of the Committee on Fi-  
6                   nance of the Senate;

7                   “(viii) one member shall be appointed  
8                   by the Chairman of the Committee on  
9                   Ways and Means of the House of Rep-  
10                  resentatives; and

11                  “(ix) one shall be appointed by the  
12                  ranking member of the Committee on  
13                  Ways and Means of the House of Rep-  
14                  resentatives.

15                  “(D) QUALIFICATIONS OF COMMISSION  
16                  MEMBERS.—The members of the Commission  
17                  shall—

18                         “(i) be experienced in finance, eco-  
19                         nomics, pay for performance, or program  
20                         evaluation;

21                         “(ii) have relevant professional or per-  
22                         sonal experience in a field related to one or  
23                         more of the outcomes listed in this sub-  
24                         section; or

1           “(iii) be qualified to review applica-  
2           tions for social impact partnership projects  
3           to determine whether the proposed metrics  
4           and evaluation methodologies are appro-  
5           priately rigorous and reliant upon inde-  
6           pendent data and evidence-based research.

7           “(E) TIMING OF APPOINTMENTS.—The ap-  
8           pointments of the members of the Commission  
9           shall be made not later than 120 days after the  
10          date of the enactment of this subsection, or, in  
11          the event of a vacancy, not later than 90 days  
12          after the date the vacancy arises. If a member  
13          of Congress fails to appoint a member by that  
14          date, the President may select a member of the  
15          President’s choice on behalf of the member of  
16          Congress. Notwithstanding the preceding sen-  
17          tence, if not all appointments have been made  
18          to the Commission as of that date, the Commis-  
19          sion may operate with no fewer than five mem-  
20          bers until all appointments have been made.

21          “(F) TERM OF APPOINTMENTS.—

22                 “(i) IN GENERAL.—The members ap-  
23                 pointed under subparagraph (C) shall serve  
24                 as follows:

1                   “(I) Three members shall serve  
2                   for 2 years.

3                   “(II) Three members shall serve  
4                   for 3 years.

5                   “(III) Three members (one of  
6                   which shall be Chair of the Commis-  
7                   sion appointed by the President) shall  
8                   serve for 4 years.

9                   “(ii) ASSIGNMENT OF TERMS.—The  
10                  Commission shall designate the term  
11                  length that each member appointed under  
12                  subparagraph (C) shall serve by unani-  
13                  mous agreement. In the event that unani-  
14                  mous agreement cannot be reached, term  
15                  lengths shall be assigned to the members  
16                  by a random process.

17                  “(G) VACANCIES.—Subject to subpara-  
18                  graph (E), in the event of a vacancy in the  
19                  Commission, whether due to the resignation of  
20                  a member, the expiration of a member’s term,  
21                  or any other reason, the vacancy shall be filled  
22                  in the manner in which the original appoint-  
23                  ment was made and shall not affect the powers  
24                  of the Commission.

1           “(H) APPOINTMENT POWER.—Members of  
2           the Commission appointed under subparagraph  
3           (C) shall not be subject to confirmation by the  
4           Senate.

5           “(8) LIMITATION ON USE OF FUNDS.—Of the  
6           amounts reserved to carry out this subsection, the  
7           Secretary may not use more than \$2,000,000 in any  
8           fiscal year to support the review, approval, and over-  
9           sight of social impact partnership projects, including  
10          activities conducted by—

11           “(A) the Federal Interagency Council on  
12          Social Impact Partnerships; and

13           “(B) any other agency consulted by the  
14          Secretary before approving a social impact part-  
15          nership project or a feasibility study under  
16          paragraph (4).

17           “(9) NO FEDERAL FUNDING FOR CREDIT EN-  
18          HANCEMENTS.—No amount reserved to carry out  
19          this subsection may be used to provide any insur-  
20          ance, guarantee, or other credit enhancement to a  
21          State or local government under which a Federal  
22          payment would be made to a State or local govern-  
23          ment as the result of a State or local government  
24          failing to achieve an outcome specified in a contract.

1           “(10) AVAILABILITY OF FUNDS.—Amounts re-  
2 served to carry out this subsection shall remain  
3 available until 10 years after the date of the enact-  
4 ment of this subsection.

5           “(11) WEBSITE.—The Federal Interagency  
6 Council on Social Impact Partnerships shall estab-  
7 lish and maintain a public website that shall display  
8 the following:

9                   “(A) A copy of, or method of accessing,  
10 each notice published regarding a social impact  
11 partnership project pursuant to this subsection.

12                   “(B) A copy of each feasibility study fund-  
13 ed under this subsection.

14                   “(C) For each State or local government  
15 that has entered into an agreement with the  
16 Secretary for a social impact partnership  
17 project, the website shall contain the following  
18 information:

19                           “(i) The outcome goals of the project.

20                           “(ii) A description of each interven-  
21 tion in the project.

22                           “(iii) The target population that will  
23 be served by the project.

1                   “(iv) The expected social benefits to  
2 participants who receive the intervention  
3 and others who may be impacted.

4                   “(v) The detailed roles, responsibil-  
5 ities, and purposes of each Federal, State,  
6 or local government entity, intermediary,  
7 service provider, independent evaluator, in-  
8 vestor, or other stakeholder.

9                   “(vi) The payment terms, method-  
10 ology used to calculate outcome payments,  
11 the payment schedule, and performance  
12 thresholds.

13                   “(vii) The project budget.

14                   “(viii) The project timeline.

15                   “(ix) The project eligibility criteria.

16                   “(x) The evaluation design.

17                   “(xi) The metrics used to determine  
18 whether the proposed outcomes have been  
19 achieved and how these metrics are meas-  
20 ured.

21                   “(D) A copy of the progress reports and  
22 the final reports relating to each social impact  
23 partnership project.

24                   “(E) An estimate of the savings to the  
25 Federal, State, and local government, on a pro-

1           gram-by-program basis and in the aggregate,  
2           resulting from the successful completion of the  
3           social impact partnership project.

4           “(12) REGULATIONS.—The Secretary, in con-  
5           sultation with the Federal Interagency Council on  
6           Social Impact Partnerships, may issue regulations as  
7           necessary to carry out this subsection.

8           “(13) DEFINITIONS.—In this subsection:

9                   “(A) AGENCY.—The term ‘agency’ has the  
10                  meaning given that term in section 551 of title  
11                  5, United States Code.

12                  “(B) INTERVENTION.—The term ‘interven-  
13                  tion’ means a specific service delivered to  
14                  achieve an impact through a social impact part-  
15                  nership project.

16                  “(C) SECRETARY.—The term ‘Secretary’  
17                  means the Secretary of the Treasury.

18                  “(D) SOCIAL IMPACT PARTNERSHIP  
19                  PROJECT.—The term ‘social impact partnership  
20                  project’ means a project that finances social  
21                  services using a social impact partnership  
22                  model.

23                  “(E) SOCIAL IMPACT PARTNERSHIP  
24                  MODEL.—The term ‘social impact partnership

1 model’ means a method of financing social serv-  
2 ices in which—

3 “(i) Federal funds are awarded to a  
4 State or local government only if a State  
5 or local government achieves certain out-  
6 comes agreed on by the State or local gov-  
7 ernment and the Secretary; and

8 “(ii) the State or local government co-  
9 ordinates with service providers, investors  
10 (if applicable to the project), and (if nec-  
11 essary) an intermediary to identify—

12 “(I) an intervention expected to  
13 produce the outcome;

14 “(II) a service provider to deliver  
15 the intervention to the target popu-  
16 lation; and

17 “(III) investors to fund the deliv-  
18 ery of the intervention.

19 “(F) STATE.—The term ‘State’ means  
20 each State of the United States, the District of  
21 Columbia, each commonwealth, territory or pos-  
22 session of the United States, and each federally  
23 recognized Indian tribe.

24 “(14) FUNDING.—Of the amounts made avail-  
25 able to carry out subsection (b) for fiscal year 2017,



1 the Secretary shall reserve \$100,000,000 to carry  
2 out this subsection.”.

3 **SEC. 25003. EXTENSION OF TANF PROGRAM.**

4 (a) FAMILY ASSISTANCE GRANTS.—Section  
5 403(a)(1) of the Social Security Act (42 U.S.C. 603(a)(1))  
6 is amended in each of subparagraphs (A) and (C), by  
7 striking “2012” and inserting “2017”.

8 (b) HEALTHY MARRIAGE PROMOTION AND RESPON-  
9 SIBLE FATHERHOOD GRANTS.—Section 403(a)(2)(D) of  
10 such Act (42 U.S.C. 603(a)(2)(D)) is amended by striking  
11 “2012” each place it appears and inserting “2017”.

12 (c) TRIBAL GRANTS.—Section 412(a) of such Act (42  
13 U.S.C. 612(a)) is amended in each of paragraphs (1)(A)  
14 and (2)(A) by striking “2012” and inserting “2017”.

15 (d) CHILD CARE ENTITLEMENT.—Section 418(a)(3)  
16 of such Act (42 U.S.C. 618(a)(3)) is amended by striking  
17 “2012” and inserting “2017”.

18 (e) GRANTS TO THE TERRITORIES.—Section  
19 1108(b)(2) of such Act (42 U.S.C. 1308(b)(2)) is amend-  
20 ed by striking “2012” and inserting “2017”.

21 **SEC. 25004. STRENGTHENING WELFARE RESEARCH AND**  
22 **EVALUATION AND DEVELOPMENT OF A WHAT**  
23 **WORKS CLEARINGHOUSE.**

24 (a) IN GENERAL.—Section 413 of the Social Security  
25 Act (42 U.S.C. 613) is amended to read as follows:

1 **“SEC. 413. EVALUATION OF TEMPORARY ASSISTANCE FOR**  
2 **NEEDY FAMILIES AND RELATED PROGRAMS.**

3 “(a) **EVALUATION OF THE IMPACTS OF TANF.**—The  
4 Secretary shall conduct research on the effect of State pro-  
5 grams funded under this part and any other State pro-  
6 gram funded with qualified State expenditures (as defined  
7 in section 409(a)(7)(B)(i)) on employment, self-suffi-  
8 ciency, child well-being, unmarried births, marriage, pov-  
9 erty, economic mobility, and other factors as determined  
10 by the Secretary.

11 “(b) **EVALUATION OF GRANTS TO IMPROVE CHILD**  
12 **WELL-BEING BY PROMOTING HEALTHY MARRIAGE AND**  
13 **RESPONSIBLE FATHERHOOD.**—The Secretary shall con-  
14 duct research to determine the effects of the grants made  
15 under section 403(a)(2) on child well-being, marriage,  
16 family stability, economic mobility, poverty, and other fac-  
17 tors as determined by the Secretary.

18 “(c) **DISSEMINATION OF INFORMATION.**—The Sec-  
19 retary shall, in consultation with States receiving funds  
20 provided under this part, develop methods of dissemi-  
21 nating information on any research, evaluation, or study  
22 conducted under this section, including facilitating the  
23 sharing of information and best practices among States  
24 and localities.

25 “(d) **STATE-INITIATED EVALUATIONS.**—A State  
26 shall be eligible to receive funding to evaluate the State

1 program funded under this part or any other State pro-  
2 gram funded with qualified State expenditures (as defined  
3 in section 409(a)(7)(B)(i)) if—

4 “(1) the State submits to the Secretary a de-  
5 scription of the proposed evaluation;

6 “(2) the Secretary determines that the design  
7 and approach of the proposed evaluation is rigorous  
8 and is likely to yield information that is credible and  
9 will be useful to other States; and

10 “(3) unless waived by the Secretary, the State  
11 contributes to the cost of the evaluation, from non-  
12 Federal sources, an amount equal to at least 25 per-  
13 cent of the cost of the proposed evaluation.

14 “(e) CENSUS BUREAU RESEARCH.—

15 “(1) The Bureau of the Census shall implement  
16 or enhance household surveys of program participa-  
17 tion, in consultation with the Secretary and the Bu-  
18 reau of Labor Statistics and made available to inter-  
19 ested parties, to allow for the assessment of the out-  
20 comes of continued welfare reform on the economic  
21 and child well-being of low-income families with chil-  
22 dren, including those who received assistance or  
23 services from a State program funded under this  
24 part or any other State program funded with quali-  
25 fied State expenditures (as defined in section

1       409(a)(7)(B)(i)). The content of the surveys should  
2       include such information as may be necessary to ex-  
3       amine the issues of unmarried childbearing, mar-  
4       riage, welfare dependency and compliance with work  
5       requirements, the beginning and ending of spells of  
6       assistance, work, earnings and employment stability,  
7       and the well-being of children.

8               “(2) To carry out the activities specified in  
9       paragraph (1), the Bureau of the Census, the Sec-  
10       retary, and the Bureau of Labor Statistics shall con-  
11       sider ways to improve the surveys and data derived  
12       from the surveys to—

13               “(A) address under reporting of the receipt  
14       of means-tested benefits and tax benefits for  
15       low-income individuals and families;

16               “(B) increase understanding of poverty  
17       spells and long-term poverty, including by facili-  
18       tating the matching of information to better un-  
19       derstand intergenerational poverty;

20               “(C) generate a better geographical under-  
21       standing of poverty such as through State-  
22       based estimates and measures of neighborhood  
23       poverty;

24               “(D) increase understanding of the effects  
25       of means-tested benefits and tax benefits on the

1 earnings and incomes of low-income families;  
2 and

3 “(E) improve how poverty and economic  
4 well-being are measured, including through the  
5 use of consumption measures, material depriv-  
6 ation measures, social exclusion measures, and  
7 economic and social mobility measures.

8 “(f) RESEARCH AND EVALUATION CONDUCTED  
9 UNDER THIS SECTION.—Research and evaluation con-  
10 ducted under this section designed to determine the effects  
11 of a program or policy (other than research conducted  
12 under subsection (e)) shall use experimental designs using  
13 random assignment or other reliable, evidence-based re-  
14 search methodologies that allow for the strongest possible  
15 causal inferences when random assignment is not feasible.

16 “(g) DEVELOPMENT OF WHAT WORKS CLEARING-  
17 HOUSE OF PROVEN AND PROMISING APPROACHES TO  
18 MOVE WELFARE RECIPIENTS INTO WORK.—

19 “(1) IN GENERAL.—The Secretary, in consulta-  
20 tion with the Secretary of Labor, shall develop a  
21 database (which shall be referred to as the ‘What  
22 Works Clearinghouse of Proven and Promising  
23 Projects to Move Welfare Recipients into Work’) of  
24 the projects that used a proven approach or a prom-  
25 ising approach in moving welfare recipients into

1 work, based on independent, rigorous evaluations of  
2 the projects. The database shall include a separate  
3 listing of projects that used a developmental ap-  
4 proach in delivering services and a further separate  
5 listing of the projects with no or negative effects.  
6 The Secretary shall add to the What Works Clear-  
7 ingshouse of Proven and Promising Projects to Move  
8 Welfare Recipients into Work data about the  
9 projects that, based on an independent, well-con-  
10 ducted experimental evaluation of a program or  
11 project, using random assignment or other research  
12 methodologies that allow for the strongest possible  
13 causal inferences, have shown they are proven,  
14 promising, developmental, or ineffective approaches.

15 “(2) CRITERIA FOR EVIDENCE OF EFFECTIVE-  
16 NESS OF APPROACH.—The Secretary, in consultation  
17 with the Secretary of Labor and organizations with  
18 experience in evaluating research on the effective-  
19 ness of various approaches in delivering services to  
20 move welfare recipients into work, shall—

21 “(A) establish criteria for evidence of effec-  
22 tiveness; and

23 “(B) ensure that the process for estab-  
24 lishing the criteria—

25 “(i) is transparent;

1 “(ii) is consistent across agencies;

2 “(iii) provides opportunity for public  
3 comment; and

4 “(iv) takes into account efforts of  
5 Federal agencies to identify and publicize  
6 effective interventions, including efforts at  
7 the Department of Health and Human  
8 Services, the Department of Education,  
9 and the Department of Justice.

10 “(3) DEFINITIONS.—In this subsection:

11 “(A) APPROACH.—The term ‘approach’  
12 means a process, product, strategy, or practice  
13 that is—

14 “(i) research-based, based on the re-  
15 sults of one or more empirical studies, and  
16 linked to program-determined outcomes;  
17 and

18 “(ii) evaluated using rigorous research  
19 designs.

20 “(B) PROVEN APPROACH.—The term  
21 ‘proven approach’ means an approach that—

22 “(i) meets the requirements of a  
23 promising approach; and

24 “(ii) has demonstrated significant and  
25 substantively important positive outcomes

1 at more than one site in terms of increas-  
2 ing work and earnings of participants, re-  
3 ducing poverty and dependence, improving  
4 child well-being, or strengthening families.

5 “(C) PROMISING APPROACH.—The term  
6 ‘promising approach’ means an approach—

7 “(i) that meets the requirements of  
8 subparagraph (D)(i);

9 “(ii) that has been evaluated using  
10 well-designed and rigorous randomized  
11 controlled trials (or, if not available, rig-  
12 orous quasi-experimental research designs);

13 “(iii) that has demonstrated signifi-  
14 cant and substantively important positive  
15 outcomes at one site in terms of increasing  
16 work and earnings of participants, reduc-  
17 ing poverty and dependence, improving  
18 child well-being, or strengthening families;  
19 and

20 “(iv) under which the benefits of the  
21 positive outcomes have exceeded the costs  
22 of achieving the outcomes.

23 “(D) DEVELOPMENTAL APPROACH.—The  
24 term ‘developmental approach’ means an ap-  
25 proach that—



1 “(i) is research-based, grounded in  
2 relevant empirically-based knowledge, and  
3 linked to program-determined outcomes;

4 “(ii) is evaluated using rigorous re-  
5 search designs; and

6 “(iii) has yet to demonstrate a signifi-  
7 cant positive outcome in terms of increas-  
8 ing work and earnings of participants in a  
9 cost-effective way.

10 “(h) APPROPRIATION.—

11 “(1) IN GENERAL.—Of the amount appro-  
12 priated by section 403(a)(1) for each fiscal year,  
13 0.33 percent shall be available for research, technical  
14 assistance, and evaluation under this section.

15 “(2) ALLOCATION.—Of the amount made avail-  
16 able under paragraph (1) for each fiscal year, the  
17 Secretary shall make available \$10,000,000 plus  
18 such additional amount as the Secretary deems nec-  
19 essary and appropriate, to carry out subsection  
20 (e).”.

21 (b) CONFORMING AMENDMENT.—Section  
22 403(a)(1)(B) of such Act (42 U.S.C. 603(a)(1)(B)) is  
23 amended by inserting “, reduced by the percentage speci-  
24 fied in section 413(h) with respect to the fiscal year,” be-  
25 fore “as the amount”.

1 **SEC. 25005. TECHNICAL CORRECTIONS TO DATA EXCHANGE**  
2 **STANDARDS TO IMPROVE PROGRAM COORDI-**  
3 **NATION.**

4 (a) IN GENERAL.—Section 411(d) of the Social Secu-  
5 rity Act (42 U.S.C. 611(d)) is amended to read as follows:

6 “(d) DATA EXCHANGE STANDARDS FOR IMPROVED  
7 INTEROPERABILITY.—

8 “(1) DESIGNATION.—The Secretary shall, in  
9 consultation with an interagency work group estab-  
10 lished by the Office of Management and Budget and  
11 considering State government perspectives, by rule,  
12 designate data exchange standards to govern, under  
13 this part—

14 “(A) necessary categories of information  
15 that State agencies operating programs under  
16 State plans approved under this part are re-  
17 quired under applicable Federal law to elec-  
18 tronically exchange with another State agency;  
19 and

20 “(B) Federal reporting and data exchange  
21 required under applicable Federal law.

22 “(2) REQUIREMENTS.—The data exchange  
23 standards required by paragraph (1) shall, to the ex-  
24 tent practicable—

1           “(A) incorporate a widely accepted, non-  
2           proprietary, searchable, computer-readable for-  
3           mat, such as the eXtensible Markup Language;

4           “(B) contain interoperable standards devel-  
5           oped and maintained by intergovernmental  
6           partnerships, such as the National Information  
7           Exchange Model;

8           “(C) incorporate interoperable standards  
9           developed and maintained by Federal entities  
10          with authority over contracting and financial  
11          assistance;

12          “(D) be consistent with and implement ap-  
13          plicable accounting principles;

14          “(E) be implemented in a manner that is  
15          cost-effective and improves program efficiency  
16          and effectiveness; and

17          “(F) be capable of being continually up-  
18          graded as necessary.

19          “(3) RULE OF CONSTRUCTION.—Nothing in  
20          this subsection shall be construed to require a  
21          change to existing data exchange standards found to  
22          be effective and efficient.”.

23          (b) EFFECTIVE DATE.—Not later than the date that  
24          is 24 months after the date of the enactment of this sec-

1 tion, the Secretary of Health and Human Services shall  
2 issue a proposed rule that—

3           (1) identifies federally required data exchanges,  
4           include specification and timing of exchanges to be  
5           standardized, and address the factors used in deter-  
6           mining whether and when to standardize data ex-  
7           changes; and

8           (2) specifies State implementation options and  
9           describes future milestones.

