

In the House of Representatives, U. S.,

November 30, 2016.

Resolved, That the House agree to the amendment of the Senate to the bill (H.R. 34) entitled “An Act to authorize and strengthen the tsunami detection, forecast, warning, research, and mitigation program of the National Oceanic and Atmospheric Administration, and for other purposes.”, with the following

HOUSE AMENDMENT TO SENATE AMENDMENT:

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 “21st*
3 *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. Improving Medicare local coverage determinations.*
- Sec. 4010. Medicare pharmaceutical and technology ombudsman.*
- Sec. 4011. Medicare site-of-service price transparency.*
- Sec. 4012. 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. Codification of due process for determinations by secretary of veterans affairs of mental capacity of beneficiaries.
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.*

1 ***DIVISION A—21ST CENTURY***2 ***CURES***3 ***SEC. 1000. SHORT TITLE.***

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

1 **TITLE** **I—INNOVATION**
2 **PROJECTS AND STATE RE-**
3 **SPONSES TO OPIOID ABUSE**

4 **SEC. 1001. NIH INNOVATION PROJECTS.**

5 (a) *IN GENERAL.*—*The Director of the National Insti-*
6 *tutes of Health (referred to in this section as the “Director*
7 *of NIH”)* shall use any funds appropriated pursuant to the
8 *authorization of appropriations in subsection (b)(3) to*
9 *carry out the National Institutes of Health innovation*
10 *projects described in subsection (b)(4) (referred to in this*
11 *section as the “NIH Innovation Projects”).*

12 (b) *NATIONAL INSTITUTES OF HEALTH INNOVATION*
13 *ACCOUNT.*—

14 (1) *ESTABLISHMENT OF NIH INNOVATION AC-*
15 *COUNT.*—*There is established in the Treasury an ac-*
16 *count, to be known as the “NIH Innovation Account”*
17 *(referred to in this subsection as the “Account”), for*
18 *purposes of carrying out the NIH Innovation Projects*
19 *described in paragraph (4).*

20 (2) *TRANSFER OF DIRECT SPENDING SAVINGS.*—

21 (A) *IN GENERAL.*—*The following amounts*
22 *shall be transferred to the Account from the gen-*
23 *eral fund of the Treasury:*

24 (i) *For fiscal year 2017, \$352,000,000.*

25 (ii) *For fiscal year 2018, \$496,000,000.*

1 (iii) For fiscal year 2019,
2 \$711,000,000.

3 (iv) For fiscal year 2020,
4 \$492,000,000.

5 (v) For fiscal year 2021, \$404,000,000.

6 (vi) For fiscal year 2022,
7 \$496,000,000.

8 (vii) For fiscal year 2023,
9 \$1,085,000,000.

10 (viii) For fiscal year 2024,
11 \$407,000,000.

12 (ix) For fiscal year 2025,
13 \$127,000,000.

14 (x) For fiscal year 2026, \$226,000,000.

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

20 (3) APPROPRIATIONS.—

21 (A) AUTHORIZATION OF APPROPRIA-
22 TIONS.—For each of the fiscal years 2017
23 through 2026, there is authorized to be appro-
24 priated from the Account to the Director of NIH,
25 for the purpose of carrying out the NIH Innova-

1 *tion Projects, an amount not to exceed the total*
2 *amount transferred to the Account under para-*
3 *graph (2)(A), to remain available until ex-*
4 *pended.*

5 (B) *OFFSETTING FUTURE APPROPRIA-*
6 *TIONS.—For any of fiscal years 2017 through*
7 *2026, for any discretionary appropriation under*
8 *the heading “NIH Innovation Account” provided*
9 *to the Director of NIH pursuant to the author-*
10 *ization of appropriations under subparagraph*
11 *(A) for the purpose of carrying out the NIH In-*
12 *novation Projects, the total amount of such ap-*
13 *propriations for the applicable fiscal year (not to*
14 *exceed the total amount remaining in the Ac-*
15 *count) shall be subtracted from the estimate of*
16 *discretionary budget authority and the resulting*
17 *outlays for any estimate under the Congressional*
18 *Budget and Impoundment Control Act of 1974*
19 *or the Balanced Budget and Emergency Deficit*
20 *Control Act of 1985, and the amount transferred*
21 *to the Account shall be reduced by the same*
22 *amount.*

23 (4) *NIH INNOVATION PROJECTS.—NIH Innova-*
24 *tion Projects authorized to be funded under this sec-*
25 *tion shall consist of the following and, of the total*

1 *amounts authorized to be appropriated under para-*
2 *graph (3), there are authorized to be appropriated to*
3 *each such project a total amount not to exceed the fol-*
4 *lowing, over the period of fiscal years 2017 through*
5 *2026:*

6 *(A) For the Precision Medicine Initiative,*
7 *including for the advancement of a cohort of in-*
8 *dividuals to support the goals of the Precision*
9 *Medicine Initiative, not to exceed a total of*
10 *\$1,455,000,000, as follows:*

11 *(i) For fiscal year 2017, \$40,000,000.*

12 *(ii) For fiscal year 2018, \$100,000,000.*

13 *(iii) For fiscal year 2019,*
14 *\$186,000,000.*

15 *(iv) For fiscal year 2020,*
16 *\$149,000,000.*

17 *(v) For fiscal year 2021, \$109,000,000.*

18 *(vi) For fiscal year 2022,*
19 *\$150,000,000.*

20 *(vii) For fiscal year 2023,*
21 *\$419,000,000.*

22 *(viii) For fiscal year 2024,*
23 *\$235,000,000.*

24 *(ix) For fiscal year 2025, \$36,000,000.*

25 *(x) For fiscal year 2026, \$31,000,000.*

1 (B) *For the Brain Research through Advancing Innovative Neurotechnologies Initiative*
2 *(known as the “BRAIN Initiative”), not to exceed a total of \$1,511,000,000, as follows:*

5 (i) *For fiscal year 2017, \$10,000,000.*

6 (ii) *For fiscal year 2018, \$86,000,000.*

7 (iii) *For fiscal year 2019,*
8 *\$115,000,000.*

9 (iv) *For fiscal year 2020,*
10 *\$140,000,000.*

11 (v) *For fiscal year 2021, \$100,000,000.*

12 (vi) *For fiscal year 2022,*
13 *\$152,000,000.*

14 (vii) *For fiscal year 2023,*
15 *\$450,000,000.*

16 (viii) *For fiscal year 2024,*
17 *\$172,000,000.*

18 (ix) *For fiscal year 2025, \$91,000,000.*

19 (x) *For fiscal year 2026, \$195,000,000.*

20 (C) *To support cancer research, such as the*
21 *development of cancer vaccines, the development*
22 *of more sensitive diagnostic tests for cancer,*
23 *immunotherapy and the development of com-*
24 *bination therapies, and research that has the po-*
25 *tential to transform the scientific field, that has*

1 *inherently higher risk, and that seeks to address*
2 *major challenges related to cancer, not to exceed*
3 *a total of \$1,800,000,000, as follows:*

4 *(i) For fiscal year 2017, \$300,000,000.*

5 *(ii) For fiscal year 2018, \$300,000,000.*

6 *(iii) For fiscal year 2019,*
7 *\$400,000,000.*

8 *(iv) For fiscal year 2020,*
9 *\$195,000,000.*

10 *(v) For fiscal year 2021, \$195,000,000.*

11 *(vi) For fiscal year 2022,*
12 *\$194,000,000.*

13 *(vii) For fiscal year 2023,*
14 *\$216,000,000.*

15 *(D) For the National Institutes of Health,*
16 *in coordination with the Food and Drug Admin-*
17 *istration, to award grants and contracts for clin-*
18 *ical research to further the field of regenerative*
19 *medicine using adult stem cells, including*
20 *autologous stem cells, for which grants and con-*
21 *tracts shall be contingent upon the recipient*
22 *making available non-Federal contributions to-*
23 *ward the costs of such research in an amount not*
24 *less than \$1 for each \$1 of Federal funds pro-*

1 *vided in the award, not to exceed a total of*
2 *\$30,000,000, as follows:*

3 *(i) For fiscal year 2017, \$2,000,000.*

4 *(ii) For each of fiscal years 2018 and*
5 *2019, \$10,000,000.*

6 *(iii) For fiscal year 2020, \$8,000,000.*

7 *(iv) For each of fiscal years 2021*
8 *through 2026, \$0.*

9 *(c) ACCOUNTABILITY AND OVERSIGHT.—*

10 *(1) WORK PLAN.—*

11 *(A) IN GENERAL.—Not later than 180 days*
12 *after the date of enactment of this Act, the Direc-*
13 *tor of NIH shall submit to the Committee on*
14 *Health, Education, Labor, and Pensions and the*
15 *Committee on Appropriations of the Senate and*
16 *the Committee on Energy and Commerce and the*
17 *Committee on Appropriations of the House of*
18 *Representatives, a work plan including the pro-*
19 *posed allocation of funds authorized to be appro-*
20 *priated pursuant to subsection (b)(3) for each of*
21 *fiscal years 2017 through 2026 for the NIH In-*
22 *novation Projects and the contents described in*
23 *subparagraph (B).*

24 *(B) CONTENTS.—The work plan submitted*
25 *under subparagraph (A) shall include—*

1 (i) *recommendations from the Advisory*
2 *Committee described in subparagraph (C);*

3 (ii) *the amount of money to be obli-*
4 *gated or expended in each fiscal year for*
5 *each NIH Innovation Project;*

6 (iii) *a description and justification of*
7 *each such project; and*

8 (iv) *a description of how each such*
9 *project supports the strategic research prior-*
10 *ities identified in the NIH Strategic Plan*
11 *under subsection (m) of section 402 of the*
12 *Public Health Service Act (42 U.S.C. 282),*
13 *as added by section 2031.*

14 (C) *RECOMMENDATIONS.—Prior to submit-*
15 *ting the work plan under this paragraph, the Di-*
16 *rector of NIH shall seek recommendations from*
17 *the Advisory Committee to the Director of NIH*
18 *appointed under section 222 of the Public Health*
19 *Service Act (42 U.S.C. 217a) on—*

20 (i) *the allocations of funds appro-*
21 *priated pursuant to the authorization of ap-*
22 *propriations under subsection (b)(3) for*
23 *each of fiscal years 2017 through 2026; and*

24 (ii) *on the contents of the proposed*
25 *work plan.*

1 (2) *REPORTS.*—

2 (A) *ANNUAL REPORTS.*—Not later than Oc-
3 tober 1 of each of fiscal years 2018 through 2027,
4 the Director of NIH shall submit to the Com-
5 mittee on Health, Education, Labor, and Pen-
6 sions and the Committee on Appropriations of
7 the Senate and the Committee on Energy and
8 Commerce and the Committee on Appropriations
9 of the House of Representatives, a report includ-
10 ing—

11 (i) the amount of money obligated or
12 expended in the prior fiscal year for each
13 NIH Innovation Project;

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

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

24 (B) *ADDITIONAL REPORTS.*—At the request
25 of the Committee on Health, Education, Labor,

1 *and Pensions or the Committee on Appropriations of the Senate, or the Committee on Energy*
2 *and Commerce or the Committee on Appropriations of the House of Representatives, the Director of NIH shall provide an update in the form*
3 *of testimony and any additional reports to the respective congressional committee regarding the*
4 *allocation of funding under this section or the description of the NIH Innovation Projects.*

5 *(d) LIMITATIONS.—Notwithstanding any transfer authority authorized by this Act or any appropriations Act,*
6 *any funds made available pursuant to the authorization of appropriations under subsection (b)(3) may not be used for*
7 *any purpose other than a NIH Innovation Project.*

8 *(e) SUNSET.—This section shall expire on September*
9 *30, 2026.*

10 **SEC. 1002. FDA INNOVATION PROJECTS.**

11 *(a) IN GENERAL.—The Commissioner of Food and Drugs (referred to in this section as the “Commissioner”)*
12 *shall use any funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) to carry*
13 *out the activities described in subsection (b)(4).*

14 *(b) FDA INNOVATION ACCOUNT.—*

15 *(1) ESTABLISHMENT OF FDA INNOVATION ACCOUNT.—There is established in the Treasury an ac-*
16

1 *count, to be known as the “FDA Innovation Account”*
2 *(referred to in this subsection as the “Account”), for*
3 *purposes of carrying out the activities described in*
4 *paragraph (4).*

5 (2) *TRANSFER OF DIRECT SPENDING SAVINGS.—*

6 (A) *IN GENERAL.—For each of fiscal years*
7 *2017 through 2025, the following amounts shall*
8 *be transferred to the Account from the general*
9 *fund of the Treasury:*

10 (i) *For fiscal year 2017, \$20,000,000.*

11 (ii) *For fiscal year 2018, \$60,000,000.*

12 (iii) *For fiscal year 2019, \$70,000,000.*

13 (iv) *For fiscal year 2020, \$75,000,000.*

14 (v) *For fiscal year 2021, \$70,000,000.*

15 (vi) *For fiscal year 2022, \$50,000,000.*

16 (vii) *For fiscal year 2023, \$50,000,000.*

17 (viii) *For fiscal year 2024,*
18 *\$50,000,000.*

19 (ix) *For fiscal year 2025, \$55,000,000.*

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

25 (3) *APPROPRIATIONS.—*

1 (A) *AUTHORIZATION OF APPROPRIA-*
2 *TIONS.—For each of the fiscal years 2017*
3 *through 2025, there is authorized to be appro-*
4 *priated from the Account to the Commissioner,*
5 *for the purpose of carrying out the activities de-*
6 *scribed in paragraph (5), an amount not to ex-*
7 *ceed the total amount transferred to the Account*
8 *under paragraph (2)(A), to remain available*
9 *until expended.*

10 (B) *OFFSETTING FUTURE APPROPRIA-*
11 *TIONS.—For any of fiscal years 2017 through*
12 *2025, for any discretionary appropriation under*
13 *the heading “FDA Innovation Account” provided*
14 *to the Commissioner pursuant to the authoriza-*
15 *tion of appropriations under subparagraph (A)*
16 *for the purpose of carrying out the projects ac-*
17 *tivities described in paragraph (4), the total*
18 *amount of such appropriations in the applicable*
19 *fiscal year (not to exceed the total amount re-*
20 *maining in the Account) shall be subtracted from*
21 *the estimate of discretionary budget authority*
22 *and the resulting outlays for any estimate under*
23 *the Congressional Budget and Impoundment*
24 *Control Act of 1974 or the Balanced Budget and*
25 *Emergency Deficit Control Act of 1985, and the*

1 *amount transferred to the Account shall be re-*
2 *duced by the same amount.*

3 (4) *FDA ACTIVITIES.*—*The activities authorized*
4 *to be funded under this section are the activities*
5 *under subtitles A through F (including the amend-*
6 *ments made by such subtitles) of title III of this Act*
7 *and section 1014 of the Federal Food, Drug, and Cos-*
8 *metic Act, as added by section 3073 of this Act.*

9 (c) *ACCOUNTABILITY AND OVERSIGHT.*—

10 (1) *WORK PLAN.*—

11 (A) *IN GENERAL.*—*Not later than 180 days*
12 *after the date of enactment of this Act, the Com-*
13 *missioner shall submit to the Committee on*
14 *Health, Education, Labor, and Pensions and the*
15 *Committee on Appropriations of the Senate and*
16 *the Committee on Energy and Commerce and the*
17 *Committee on Appropriations of the House of*
18 *Representatives, a work plan including the pro-*
19 *posed allocation of funds appropriated pursuant*
20 *to the authorization of appropriations under*
21 *subsection (b)(3) for each of fiscal years 2017*
22 *through 2025 and the contents described in sub-*
23 *paragraph (B).*

24 (B) *CONTENTS.*—*The work plan submitted*
25 *under subparagraph (A) shall include—*

1 (i) *recommendations from the Advisory*
2 *Committee described in subparagraph (C);*

3 (ii) *the amount of money to be obli-*
4 *gated or expended in each fiscal year for*
5 *each activity described in subsection (b)(4);*
6 *and*

7 (iii) *a description and justification of*
8 *each such project activity.*

9 (C) *RECOMMENDATIONS.*—*Prior to submit-*
10 *ting the work plan under this paragraph, the*
11 *Commissioner shall seek recommendations from*
12 *the Science Board to the Food and Drug Admin-*
13 *istration, on the proposed allocation of funds ap-*
14 *propriated pursuant to the authorization of ap-*
15 *propriations under subsection (b)(3) for each of*
16 *fiscal years 2017 through 2025 and on the con-*
17 *tents of the proposed work plan.*

18 (2) *REPORTS.*—

19 (A) *ANNUAL REPORTS.*—*Not later than Oc-*
20 *tober 1 of each of fiscal years 2018 through 2026,*
21 *the Commissioner shall submit to the Committee*
22 *on Health, Education, Labor, and Pensions and*
23 *the Committee on Appropriations of the Senate*
24 *and the Committee on Energy and Commerce*

1 *and the Committee on Appropriations of the*
2 *House of Representatives, a report including—*

3 *(i) the amount of money obligated or*
4 *expended in the prior fiscal year for each*
5 *activity described in subsection (b)(4);*

6 *(ii) a description of all such activities*
7 *using funds provided pursuant to the au-*
8 *thorization of appropriations under sub-*
9 *section (b)(3); and*

10 *(iii) how the activities are advancing*
11 *public health.*

12 *(B) ADDITIONAL REPORTS.—At the request*
13 *of the Committee on Health, Education, Labor,*
14 *and Pensions or the Committee on Appropria-*
15 *tions of the Senate, or the Committee on Energy*
16 *and Commerce or the Committee on Appropria-*
17 *tions of the House of Representatives, the Com-*
18 *missioner shall provide an update in the form of*
19 *testimony and any additional reports to the re-*
20 *spective congressional committee regarding the*
21 *allocation of funding under this section or the*
22 *description of the activities undertaken with such*
23 *funding.*

24 *(d) LIMITATIONS.—Notwithstanding any transfer au-*
25 *thority authorized by this Act or any appropriations Act,*

1 *any funds made available pursuant to the authorization of*
2 *appropriations in subsection (b)(3) shall not be used for*
3 *any purpose other than an activity described in subsection*
4 *(b)(4).*

5 *(e) SUNSET.—This section shall expire on September*
6 *30, 2025.*

7 **SEC. 1003. ACCOUNT FOR THE STATE RESPONSE TO THE**
8 **OPIOID ABUSE CRISIS.**

9 *(a) IN GENERAL.—The Secretary of Health and*
10 *Human Services (referred to in this section as the “Sec-*
11 *retary”)* shall use any funds appropriated pursuant to the
12 *authorization of appropriations under subsection (b) to*
13 *carry out the grant program described in subsection (c) for*
14 *purposes of addressing the opioid abuse crisis within the*
15 *States.*

16 *(b) ACCOUNT FOR THE STATE RESPONSE TO THE*
17 *OPIOID ABUSE CRISIS.—*

18 *(1) ESTABLISHMENT.—There is established in*
19 *the Treasury an account, to be known as the “Account*
20 *For the State Response to the Opioid Abuse Crisis”*
21 *(referred to in this subsection as the “Account”), to*
22 *carry out the opioid grant program described in sub-*
23 *section (c).*

24 *(2) TRANSFER OF DIRECT SPENDING SAVINGS.—*

1 (A) *IN GENERAL.*—*The following amounts*
2 *shall be transferred to the Account from the gen-*
3 *eral fund of the Treasury:*

4 (i) *For fiscal year 2017, \$500,000,000.*

5 (ii) *For fiscal year 2018, \$500,000,000.*

6 (B) *AMOUNTS DEPOSITED.*—*Any amounts*
7 *transferred under subparagraph (A) shall re-*
8 *main unavailable in the Account until such*
9 *amounts are appropriated pursuant to para-*
10 *graph (3).*

11 (3) *APPROPRIATIONS.*—

12 (A) *AUTHORIZATION OF APPROPRIA-*
13 *TIONS.*—*In each of the fiscal years 2017 and*
14 *2018, there is authorized to be appropriated from*
15 *the Account to the Secretary, for the grant pro-*
16 *gram described in subsection (c), an amount not*
17 *to exceed the total amount transferred to the Ac-*
18 *count under paragraph (2)(A), to remain avail-*
19 *able until expended.*

20 (B) *OFFSETTING FUTURE APPROPRIA-*
21 *TIONS.*—*In each of fiscal years 2017 and 2018,*
22 *for any discretionary appropriation under the*
23 *heading “Account For the State Response to the*
24 *Opioid Abuse Crisis” for the grant program de-*
25 *scribed in subsection (c), the total amount of*

1 *such appropriations in the applicable fiscal year*
2 *(not to exceed the total amount remaining in the*
3 *Account) shall be subtracted from the estimate of*
4 *discretionary budget authority and the resulting*
5 *outlays for any estimate under the Congressional*
6 *Budget and Impoundment Control Act of 1974*
7 *or the Balanced Budget and Emergency Deficit*
8 *Control Act of 1985, and the amount transferred*
9 *to the Account shall be reduced by the same*
10 *amount.*

11 *(c) OPIOID GRANT PROGRAM.—*

12 (1) *STATE RESPONSE TO THE OPIOID ABUSE*
13 *CRISIS.—Subject to the availability of appropriations,*
14 *the Secretary shall award grants to States for the*
15 *purpose of addressing the opioid abuse crisis within*
16 *such States, in accordance with subparagraph (B). In*
17 *awarding such grants, the Secretary shall give pref-*
18 *erence to States with an incidence or prevalence of*
19 *opioid use disorders that is substantially higher rel-*
20 *ative to other States.*

21 (2) *OPIOID GRANTS.—Grants awarded to a State*
22 *under this subsection shall be used for carrying out*
23 *activities that supplement activities pertaining to*
24 *opioids undertaken by the State agency responsible*
25 *for administering the substance abuse prevention and*

1 *treatment block grant under subpart II of part B of*
2 *title XIX of the Public Health Service Act (42 U.S.C.*
3 *300x–21 et seq.), which may include public health-re-*
4 *lated activities such as the following:*

5 (A) *Improving State prescription drug*
6 *monitoring programs.*

7 (B) *Implementing prevention activities, and*
8 *evaluating such activities to identify effective*
9 *strategies to prevent opioid abuse.*

10 (C) *Training for health care practitioners,*
11 *such as best practices for prescribing opioids,*
12 *pain management, recognizing potential cases of*
13 *substance abuse, referral of patients to treatment*
14 *programs, and overdose prevention.*

15 (D) *Supporting access to health care serv-*
16 *ices, including those services provided by Feder-*
17 *ally certified opioid treatment programs or other*
18 *appropriate health care providers to treat sub-*
19 *stance use disorders.*

20 (E) *Other public health-related activities, as*
21 *the State determines appropriate, related to ad-*
22 *dressing the opioid abuse crisis within the State.*

23 (d) *ACCOUNTABILITY AND OVERSIGHT.—A State re-*
24 *ceiving a grant under subsection (c) shall include in a re-*
25 *port related to substance abuse submitted to the Secretary*

1 *pursuant to section 1942 of the Public Health Service Act*
2 *(42 U.S.C. 300x-52), a description of—*

3 *(1) the purposes for which the grant funds re-*
4 *ceived by the State under such subsection for the pre-*
5 *ceding fiscal year were expended and a description of*
6 *the activities of the State under the program; and*

7 *(2) the ultimate recipients of amounts provided*
8 *to the State in the grant.*

9 *(e) LIMITATIONS.—Any funds made available pursu-*
10 *ant to the authorization of appropriations under subsection*
11 *(b)—*

12 *(1) notwithstanding any transfer authority in*
13 *any appropriations Act, shall not be used for any*
14 *purpose other than the grant program in subsection*
15 *(c); and*

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

20 *(f) SUNSET.—This section shall expire on September*
21 *30, 2026.*

22 **SEC. 1004. BUDGETARY TREATMENT.**

23 *(a) STATUTORY PAYGO SCORECARDS.—The budgetary*
24 *effects of division A of this Act shall not be entered on either*

1 *PAYGO scorecard maintained pursuant to section 4(d) of*
 2 *the Statutory Pay-As-You-Go Act of 2010.*

3 (b) *SENATE PAYGO SCORECARDS.*—*The budgetary ef-*
 4 *fects of division A of this Act shall not be entered on any*
 5 *PAYGO scorecard maintained for purposes of section 201*
 6 *of S. Con. Res. 21 (110th Congress).*

7 (c) *RESERVATION OF SAVINGS.*—*None of the funds in*
 8 *the NIH Innovation Account, the FDA Innovation Account,*
 9 *or the Account For the State Response to the Opioid Abuse*
 10 *Crisis established by this title shall be made available except*
 11 *to the extent provided in advance in appropriations Acts,*
 12 *and legislation or an Act that rescinds or reduces amounts*
 13 *in such accounts shall not be estimated as a reduction in*
 14 *direct spending under the Congressional Budget and Im-*
 15 *poundment Control Act of 1974 or the Balanced Budget and*
 16 *Emergency Deficit Control Act of 1985.*

17 **TITLE II—DISCOVERY**

18 **Subtitle A—National Institutes of** 19 **Health Reauthorization**

20 **SEC. 2001. NATIONAL INSTITUTES OF HEALTH REAUTHOR-** 21 **IZATION.**

22 *Section 402A(a)(1) of the Public Health Service Act*
 23 *(42 U.S.C. 282a(a)(1)) is amended—*

24 (1) *in subparagraph (B), by striking “and” at*
 25 *the end;*

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

3 (3) *by adding at the end the following new sub-*
4 *paragraphs:*

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

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

7 *and*

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

9 **SEC. 2002. EUREKA PRIZE COMPETITIONS.**

10 (a) *IN GENERAL.*—*Pursuant to the authorities and*
11 *processes established under section 24 of the Stevenson-*
12 *Wylder Technology Innovation Act of 1980 (15 U.S.C.*
13 *3719), the Director of the National Institutes of Health shall*
14 *support prize competitions for one or both of the following*
15 *goals:*

16 (1) *Identifying and funding areas of biomedical*
17 *science that could realize significant advancements*
18 *through a prize competition.*

19 (2) *Improving health outcomes, particularly with*
20 *respect to human diseases and conditions—*

21 (A) *for which public and private investment*
22 *in research is disproportionately small relative*
23 *to Federal Government expenditures on preven-*
24 *tion and treatment activities with respect to such*

1 diseases and conditions, such that Federal ex-
2 penditures on health programs would be reduced;

3 (B) that are serious and represent a signifi-
4 cant disease burden in the United States; or

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

7 (b) *TRACKING; REPORTING.*—The Director of the Na-
8 tional Institutes of Health shall—

9 (1) collect information on—

10 (A) the effect of innovations funded through
11 the prize competitions under this section in ad-
12 vancing biomedical science or improving health
13 outcomes pursuant to subsection (a); and

14 (B) the effect of the innovations on Federal
15 expenditures; and

16 (2) include the information collected under para-
17 graph (1) in the triennial report under section 403 of
18 the Public Health Service Act (42 U.S.C. 283) (as
19 amended by section 2032).

20 ***Subtitle B—Advancing Precision***
21 ***Medicine***

22 ***SEC. 2011. PRECISION MEDICINE INITIATIVE.***

23 Part H of title IV of the Public Health Service Act
24 (42 U.S.C. 289 et seq.) is amended by adding at the end
25 the following:

1 **“SEC. 498E. PRECISION MEDICINE INITIATIVE.**

2 “(a) *IN GENERAL.*—*The Secretary is encouraged to es-*
3 *tablish and carry out an initiative, to be known as the ‘Pre-*
4 *cision Medicine Initiative’ (in this section referred to as*
5 *the ‘Initiative’), to augment efforts to address disease pre-*
6 *vention, diagnosis, and treatment.*

7 “(b) *COMPONENTS.*—*The Initiative described under*
8 *subsection (a) may include—*

9 “(1) *developing a network of scientists to assist*
10 *in carrying out the purposes of the Initiative;*

11 “(2) *developing new approaches for addressing*
12 *scientific, medical, public health, and regulatory*
13 *science issues;*

14 “(3) *applying genomic technologies, such as*
15 *whole genomic sequencing, to provide data on the mo-*
16 *lecular basis of disease;*

17 “(4) *collecting information voluntarily provided*
18 *by a diverse cohort of individuals that can be used to*
19 *better understand health and disease; and*

20 “(5) *other activities to advance the goals of the*
21 *Initiative, as the Secretary determines appropriate.*

22 “(c) *AUTHORITY OF THE SECRETARY.*—*In carrying*
23 *out this section, the Secretary may—*

24 “(1) *coordinate with the Secretary of Energy,*
25 *private industry, and others, as the Secretary deter-*
26 *mines appropriate, to identify and address the ad-*

1 *vanced supercomputing and other advanced tech-*
2 *nology needs for the Initiative;*

3 *“(2) develop and utilize public-private partner-*
4 *ships; and*

5 *“(3) leverage existing data sources.*

6 *“(d) REQUIREMENTS.—In the implementation of the*
7 *Initiative under subsection (a), the Secretary shall—*

8 *“(1) ensure the collaboration of the National In-*
9 *stitutes of Health, the Food and Drug Administra-*
10 *tion, the Office of the National Coordinator for*
11 *Health Information Technology, and the Office for*
12 *Civil Rights of the Department of Health and Human*
13 *Services;*

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

18 *“(3) implement policies and mechanisms for ap-*
19 *propriate secure data sharing across systems that in-*
20 *clude protections for privacy and security of data;*

21 *“(4) consider the diversity of the cohort to ensure*
22 *inclusion of a broad range of participants, including*
23 *consideration of biological, social, and other deter-*
24 *minants of health that contribute to health dispari-*
25 *ties;*

1 “(5) ensure that only authorized individuals
2 may access controlled or sensitive, identifiable biological
3 material and associated information collected or
4 stored in connection with the Initiative; and

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

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

1 **SEC. 2012. PRIVACY PROTECTION FOR HUMAN RESEARCH**

2 **SUBJECTS.**

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

6 “(d)(1)(A) *If a person is engaged in biomedical, behav-*
7 *ioral, clinical, or other research, in which identifiable, sen-*
8 *sitive information is collected (including research on mental*
9 *health and research on the use and effect of alcohol and*
10 *other psychoactive drugs), the Secretary, in coordination*
11 *with other agencies, as applicable—*

12 “(i) *shall issue to such person a certificate of*
13 *confidentiality to protect the privacy of individuals*
14 *who are the subjects of such research if the research*
15 *is funded wholly or in part by the Federal Govern-*
16 *ment; and*

17 “(ii) *may, upon application by a person engaged*
18 *in research, issue to such person a certificate of con-*
19 *fidentiality to protect the privacy of such individuals*
20 *if the research is not so funded.*

21 “(B) *Except as provided in subparagraph (C), any*
22 *person to whom a certificate is issued under subparagraph*
23 *(A) to protect the privacy of individuals described in such*
24 *subparagraph shall not disclose or provide to any other per-*
25 *son not connected with the research the name of such an*
26 *individual or any information, document, or biospecimen*

1 *that contains identifiable, sensitive information about such*
2 *an individual and that was created or compiled for pur-*
3 *poses of the research.*

4 “(C) *The disclosure prohibition in subparagraph (B)*
5 *shall not apply to disclosure or use that is—*

6 “(i) *required by Federal, State, or local laws, ex-*
7 *cluding instances described in subparagraph (D);*

8 “(ii) *necessary for the medical treatment of the*
9 *individual to whom the information, document, or*
10 *biospecimen pertains and made with the consent of*
11 *such individual;*

12 “(iii) *made with the consent of the individual to*
13 *whom the information, document, or biospecimen per-*
14 *tains; or*

15 “(iv) *made for the purposes of other scientific re-*
16 *search that is in compliance with applicable Federal*
17 *regulations governing the protection of human sub-*
18 *jects in research.*

19 “(D) *Any person to whom a certificate is issued under*
20 *subparagraph (A) to protect the privacy of an individual*
21 *described in such subparagraph shall not, in any Federal,*
22 *State, or local civil, criminal, administrative, legislative,*
23 *or other proceeding, disclose or provide the name of such*
24 *individual or any such information, document, or biospeci-*
25 *men that contains identifiable, sensitive information about*

1 *the individual and that was created or compiled for pur-*
2 *poses of the research, except in the circumstance described*
3 *in subparagraph (C)(iii).*

4 “(E) *Identifiable, sensitive information protected*
5 *under subparagraph (A), and all copies thereof, shall be im-*
6 *mune from the legal process, and shall not, without the con-*
7 *sent of the individual to whom the information pertains,*
8 *be admissible as evidence or used for any purpose in any*
9 *action, suit, or other judicial, legislative, or administrative*
10 *proceeding.*

11 “(F) *Identifiable, sensitive information collected by a*
12 *person to whom a certificate has been issued under subpara-*
13 *graph (A), and all copies thereof, shall be subject to the pro-*
14 *tections afforded by this section for perpetuity.*

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

19 “(2) *The Secretary shall coordinate with the heads of*
20 *other applicable Federal agencies to ensure that such de-*
21 *partments have policies in place with respect to the issuance*
22 *of a certificate of confidentiality pursuant to paragraph (1)*
23 *and other requirements of this subsection.*

24 “(3) *Nothing in this subsection shall be construed to*
25 *limit the access of an individual who is a subject of research*

1 *to information about himself or herself collected during such*
2 *individual’s participation in the research.*

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

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

9 “(B) *for which there is at least a very small risk,*
10 *as determined by current scientific practices or statis-*
11 *tical methods, that some combination of the informa-*
12 *tion, a request for the information, and other avail-*
13 *able data sources could be used to deduce the identity*
14 *of an individual.”.*

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

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

10 *“(A) an individual is identified; or*

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

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

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

24 *“(3) Nothing in this subsection shall be construed to*
25 *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 Health*
5 *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 the*
14 *extent feasible, generated from such National Insti-*
15 *tutes of Health awards in a manner that is consistent*
16 *with all applicable Federal laws and regulations, in-*
17 *cluding such laws and regulations for the protection*
18 *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 States
 6 Code, or section 1905 of title 18, United States Code, or
 7 be construed to require recipients of grants or cooperative
 8 agreements through the National Institutes of Health to
 9 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 by
 16 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 Gen-
 21 eration of Researchers Initiative (referred to in this section
 22 as the ‘Initiative’), through which the Director shall coordi-
 23 nate all policies and programs within the National Insti-
 24 tutes of Health that are focused on promoting and pro-

1 *viding opportunities for new researchers and earlier re-*
2 *search independence.*

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

5 “(1) *promote policies and programs within the*
6 *National Institutes of Health that are focused on im-*
7 *proving opportunities for new researchers and pro-*
8 *moting earlier research independence, including exist-*
9 *ing 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 earlier*
13 *research independence, such as policies to increase op-*
14 *portunities for new researchers to receive funding, en-*
15 *hance training and mentorship programs for re-*
16 *searchers, and enhance workforce diversity;*

17 “(3) *coordinate, as appropriate, with relevant*
18 *agencies, professional and academic associations, aca-*
19 *demical institutions, and others, to improve and update*
20 *existing information on the biomedical research work-*
21 *force in order to inform programs related to the*
22 *training, recruitment, and retention of biomedical re-*
23 *searchers; 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 genera-*
2 *tion of researchers and earlier research independ-*
3 *ence.”.*

4 *(b) CONSIDERATION OF RECOMMENDATIONS.—In car-*
5 *rying 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 recommendations*
8 *made by the National Academies of Sciences, Engineering,*
9 *and Medicine as part of the comprehensive study on policies*
10 *affecting the next generation of researchers under the De-*
11 *partment of Health and Human Services Appropriations*
12 *Act, 2016 (Public Law 114–113), and submit a report to*
13 *the Committee on Health, Education, Labor, and Pensions*
14 *and the Committee on Appropriations of the Senate, and*
15 *the Committee on Energy and Commerce and the Com-*
16 *mittee on Appropriations of the House of Representatives,*
17 *with respect to any actions taken by the National Institutes*
18 *of Health based on the recommendations not later than 2*
19 *years after the completion of the study required pursuant*
20 *to the Department of Health and Human Services Appro-*
21 *priations Act, 2016.*

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

23 *(a) INTRAMURAL LOAN REPAYMENT PROGRAM.—Sec-*
24 *tion 487A of the Public Health Service Act (42 U.S.C. 288–*
25 *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 appro-*
8 *priate and based on workforce and scientific pri-*
9 *orities, carry out a program through the subcat-*
10 *egories listed in subsection (b)(1) (or modified*
11 *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 ac-*
16 *quired immune deficiency syndrome”; and*

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

19 (3) *by redesignating subsection (b) as subsection*
20 *(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 program*
2 *under subsection (a), the Director of the National In-*
3 *stitutes 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 sci-*
13 *entific or workforce need.*

14 “(2) *ELIMINATION OR ESTABLISHMENT OF SUB-*
15 *CATEGORIES.*—*The Director of the National Institutes*
16 *of Health may eliminate one or more subcategories*
17 *provided for in paragraph (1) due to changes in*
18 *workforce or scientific needs related to biomedical re-*
19 *search. The Director may establish other subcategory*
20 *areas based on workforce and scientific priorities if*
21 *the total number of subcategories does not exceed the*
22 *number of subcategories listed in paragraph (1).*

23 “(c) *LIMITATION.*—*The Director of the National Insti-*
24 *tutes of Health may not enter into a contract with a health*
25 *professional pursuant to subsection (a) unless such profes-*

1 sional has a substantial amount of education loans relative
 2 to income (as determined pursuant to guidelines issued by
 3 the Director).”; and

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

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

10 (b) EXTRAMURAL LOAN REPAYMENT PROGRAM.—Sec-
 11 tion 487B of the Public Health Service Act (42 U.S.C. 288-
 12 2) is amended—

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

16 (2) in subsection (a)—

17 (A) by striking “The Secretary, in consulta-
 18 tion with the Director of the Eunice Kennedy
 19 Shriver National Institute of Child Health and
 20 Human Development, shall establish a program”
 21 and inserting “IN GENERAL.—The Director of
 22 the National Institutes of Health shall, as appro-
 23 priate and based on workforce and scientific pri-
 24 orities, carry out a program through the subcat-
 25 egories listed in subsection (b)(1) (or modified

1 *subcategories as provided for in subsection*
2 *(b)(2)),”;*

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

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

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

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

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

14 *“(b) SUBCATEGORIES OF RESEARCH.—*

15 *“(1) IN GENERAL.—In carrying out the program*
16 *under subsection (a), the Director of the National In-*
17 *stitutes of Health—*

18 *“(A) shall continue to focus on—*

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

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

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

25 *“(iv) clinical research; and*

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

5 “(B) *may focus on an area of emerging sci-*
6 *entific or workforce need.*

7 “(2) *ELIMINATION OR ESTABLISHMENT OF SUB-*
8 *CATEGORIES.—The Director of the National Institutes*
9 *of Health may eliminate one or more subcategories*
10 *provided for in paragraph (1) due to changes in*
11 *workforce or scientific needs related to biomedical re-*
12 *search. The Director may establish other subcategory*
13 *areas based on workforce and scientific priorities if*
14 *the total number of subcategories does not exceed the*
15 *number of subcategories listed in paragraph (1).*

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

22 (5) *in subsection (d) (as so redesignated), by*
23 *striking “The provisions” and inserting “APPLICA-*
24 *BILITY OF CERTAIN PROVISIONS REGARDING OBLI-*
25 *GATED SERVICE.—The provisions”;* and

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

4 (c) *TECHNICAL AND CONFORMING AMENDMENTS.—*
5 *Title IV of the Public Health Service Act is amended—*

6 (1) *by striking section 464z-5 (42 U.S.C. 285t-*
7 2);

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

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

10 (4) *by striking section 487F (42 U.S.C. 288-5a),*
11 *as added by section 205 of Public Law 106-505, re-*
12 *lating to loan repayment for clinical researchers; and*

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

16 (d) *GAO REPORT.—Not later than 18 months after the*
17 *date of enactment of this Act, the Comptroller General of*
18 *the United States shall submit to Congress a report on the*
19 *efforts of the National Institutes of Health to attract, retain,*
20 *and develop emerging scientists, including underrepresented*
21 *individuals in the sciences, such as women, racial and eth-*
22 *nic minorities, and other groups. Such report shall include*
23 *an analysis of the impact of the additional authority pro-*
24 *vided to the Secretary of Health and Human Services under*
25 *this Act to address workforce shortages and gaps in priority*

1 *research areas, including which centers and research areas*
2 *offered loan repayment program participants the increased*
3 *award amount.*

4 ***Subtitle D—National Institutes of***
5 ***Health Planning and Adminis-***
6 ***tration***

7 ***SEC. 2031. NATIONAL INSTITUTES OF HEALTH STRATEGIC***
8 ***PLAN.***

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

11 *(1) in subsection (b)(5), by inserting before the*
12 *semicolon the following: “, and through the develop-*
13 *ment, implementation, and updating of the strategic*
14 *plan developed under subsection (m)”;* and

15 *(2) by adding at the end the following:*

16 *“(m) NATIONAL INSTITUTES OF HEALTH STRATEGIC*
17 *PLAN.—*

18 *“(1) IN GENERAL.—Not later than 2 years after*
19 *the date of enactment of the 21st Century Cures Act,*
20 *and at least every 6 years thereafter, the Director of*
21 *the National Institutes of Health shall develop and*
22 *submit to the appropriate committees of Congress and*
23 *post on the Internet website of the National Institutes*
24 *of Health, a coordinated strategy (to be known as the*
25 *‘National Institutes of Health Strategic Plan’) to pro-*

1 *vide direction to the biomedical research investments*
2 *made by the National Institutes of Health, to facili-*
3 *tate collaboration across the institutes and centers, to*
4 *leverage scientific opportunity, and to advance bio-*
5 *medicine.*

6 “(2) *REQUIREMENTS.—The strategy under para-*
7 *graph (1) shall—*

8 “(A) *identify strategic research priorities*
9 *and objectives across biomedical research, includ-*
10 *ing—*

11 “(i) *an assessment of the state of bio-*
12 *medical and behavioral research, including*
13 *areas of opportunity with respect to basic,*
14 *clinical, and translational research;*

15 “(ii) *priorities and objectives to ad-*
16 *vance the treatment, cure, and prevention of*
17 *health conditions;*

18 “(iii) *emerging scientific opportunities,*
19 *rising public health challenges, and sci-*
20 *entific knowledge gaps; and*

21 “(iv) *the identification of near-, mid-,*
22 *and long-term scientific needs;*

23 “(B) *consider, in carrying out subpara-*
24 *graph (A)—*

1 “(i) disease burden in the United
2 States and the potential for return on in-
3 vestment to the United States;

4 “(ii) rare diseases and conditions;

5 “(iii) biological, social, and other de-
6 terminants of health that contribute to
7 health disparities; and

8 “(iv) other factors the Director of Na-
9 tional Institutes of Health determines ap-
10 propriate;

11 “(C) include multi-institute priorities, in-
12 cluding coordination of research among insti-
13 tutes and centers;

14 “(D) include strategic priorities for funding
15 research through the Common Fund, in accord-
16 ance with section 402A(c)(1)(C);

17 “(E) address the National Institutes of
18 Health’s proposed and ongoing activities related
19 to training and the biomedical workforce; and

20 “(F) describe opportunities for collaboration
21 with other agencies and departments, as appro-
22 priate.

23 “(3) USE OF PLANS.—Strategic plans developed
24 and updated by the national research institutes and
25 national centers of the National Institutes of Health

1 *shall be prepared regularly and in such a manner*
2 *that such plans will be informed by the strategic*
3 *plans developed and updated under this subsection.*
4 *Such plans developed by and updated by the national*
5 *research institutes and national centers shall have a*
6 *common template.*

7 “(4) *CONSULTATION.—The Director of National*
8 *Institutes of Health shall develop the strategic plan*
9 *under paragraph (1) in consultation with the direc-*
10 *tors of the national research institutes and national*
11 *centers, researchers, patient advocacy groups, and in-*
12 *dustry leaders.”.*

13 (b) *CONFORMING AMENDMENT.—Section*
14 *402A(c)(1)(C) of the Public Health Service Act (42 U.S.C.*
15 *282a(c)(1)(C)) is amended by striking “Not later than June*
16 *1, 2007, and every 2 years thereafter,” and inserting “As*
17 *part of the National Institutes of Health Strategic Plan re-*
18 *quired under section 402(m),”.*

19 (c) *STRATEGIC PLAN.—Section 492B(a) of the Public*
20 *Health Service Act (42 U.S.C. 289a–2(a)) is amended by*
21 *adding at the end the following:*

22 “(3) *STRATEGIC PLANNING.—*

23 “(A) *IN GENERAL.—The directors of the na-*
24 *tional institutes and national centers shall con-*
25 *sult at least once annually with the Director of*

1 *the National Institute on Minority Health and*
2 *Health Disparities and the Director of the Office*
3 *of Research on Women’s Health regarding objec-*
4 *tives of the national institutes and national cen-*
5 *ters to ensure that future activities by such insti-*
6 *tutes and centers take into account women and*
7 *minorities and are focused on reducing health*
8 *disparities.*

9 “(B) *STRATEGIC PLANS.—Any strategic*
10 *plan issued by a national institute or national*
11 *center shall include details on the objectives de-*
12 *scribed in subparagraph (A).”.*

13 **SEC. 2032. TRIENNIAL REPORTS.**

14 *Section 403 of the Public Health Service Act (42*
15 *U.S.C. 283) is amended—*

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

18 (2) *in subsection (a)—*

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

21 (B) *by amending paragraph (3) to read as*
22 *follows:*

23 “(3) *A description of intra-National Institutes of*
24 *Health activities, including—*

1 “(A) identification of the percentage of
2 funds made available by each national research
3 institute and national center with respect to each
4 applicable fiscal year for conducting or sup-
5 porting research that involves collaboration be-
6 tween the institute or center and 1 or more other
7 national research institutes or national centers;
8 and

9 “(B) recommendations for promoting co-
10 ordination of information among the centers of
11 excellence.”;

12 (C) in paragraph (4)—

13 (i) in subparagraph (B), by striking
14 “demographic variables and other vari-
15 ables” and inserting “demographic vari-
16 ables, including biological and social vari-
17 ables and relevant age categories (such as
18 pediatric subgroups), and determinants of
19 health,”; and

20 (ii) in subparagraph (C)(v)—

21 (I) by striking “demographic
22 variables and such” and inserting “de-
23 mographic variables, including rel-
24 evant age categories (such as pediatric
25 subgroups), information submitted by

1 each national research institute and
2 national center to the Director of Na-
3 tional Institutes of Health under sec-
4 tion 492B(f), and such”; and

5 (II) by striking “(regarding inclu-
6 sion of women and minorities in clin-
7 ical research)” and inserting “and
8 other applicable requirements regard-
9 ing inclusion of demographic groups”;
10 and

11 (D) in paragraph (6)—

12 (i) in the matter preceding subpara-
13 graph (A), by striking “the following:” and
14 inserting “the following—”;

15 (ii) in subparagraph (A)—

16 (I) by striking “An evaluation”
17 and inserting “an evaluation”; and

18 (II) by striking the period and in-
19 serting “; and”;

20 (iii) by striking subparagraphs (B)
21 and (D);

22 (iv) by redesignating subparagraph (C)
23 as subparagraph (B); and

24 (v) in subparagraph (B), as redesign-
25 ated by clause (iv), by striking “Rec-

1 *ommendations” and inserting “rec-*
2 *ommendations”.*

3 **SEC. 2033. INCREASING ACCOUNTABILITY AT THE NA-**
4 **TIONAL INSTITUTES OF HEALTH.**

5 *(a) APPOINTMENT AND TERMS OF DIRECTORS OF NA-*
6 *TIONAL RESEARCH INSTITUTES AND NATIONAL CEN-*
7 *TERS.—Subsection (a) of section 405 of the Public Health*
8 *Service Act (42 U.S.C. 284) is amended to read as follows:*

9 *“(a) APPOINTMENT.—*

10 *“(1) IN GENERAL.—The Director of the National*
11 *Cancer Institute shall be appointed by the President,*
12 *and the Directors of the other national research insti-*
13 *tutes and national centers shall be appointed by the*
14 *Secretary, acting through the Director of National In-*
15 *stitutes of Health. Each Director of a national re-*
16 *search institute or national center shall report di-*
17 *rectly to the Director of National Institutes of Health.*

18 *“(2) APPOINTMENT.—*

19 *“(A) TERM.—A Director of a national re-*
20 *search institute or national center who is ap-*
21 *pointed by the Secretary, acting through the Di-*
22 *rector of National Institutes of Health, shall be*
23 *appointed for 5 years.*

24 *“(B) REAPPOINTMENT.—At the end of the*
25 *term of a Director of a national research insti-*

1 *tute or national center, the Director may be re-*
2 *appointed in accordance with standards applica-*
3 *ble to the relevant appointment mechanism.*
4 *There shall be no limit on the number of terms*
5 *that a Director may serve.*

6 “(C) *VACANCIES.*—*If the office of a Director*
7 *of a national research institute or national cen-*
8 *ter becomes vacant before the end of such Direc-*
9 *tor’s term, the Director appointed to fill the va-*
10 *cancy shall be appointed for a 5-year term start-*
11 *ing on the date of such appointment.*

12 “(D) *CURRENT DIRECTORS.*—*Each Director*
13 *of a national research institute or national cen-*
14 *ter who is serving on the date of enactment of the*
15 *21st Century Cures Act shall be deemed to be ap-*
16 *pointed for a 5-year term under this subsection*
17 *beginning on such date of enactment.*

18 “(E) *RULE OF CONSTRUCTION.*—*Nothing in*
19 *this subsection shall be construed to limit the au-*
20 *thority of the Secretary or the Director of Na-*
21 *tional Institutes of Health to terminate the ap-*
22 *pointment of a director referred to in subpara-*
23 *graph (A) before the expiration of such director’s*
24 *5-year term.*

1 “(F) *NATURE OF APPOINTMENT.*—Appoint-
2 ments and reappointments under this subsection
3 shall be made on the basis of ability and experi-
4 ence as it relates to the mission of the National
5 Institutes of Health and its components, includ-
6 ing compliance with any legal requirement that
7 the Secretary or Director of National Institutes
8 of Health determines relevant.

9 “(3) *NONAPPLICATION OF CERTAIN PROVISION.*—
10 The restrictions contained in section 202 of the De-
11 partments of Labor, Health and Human Services,
12 and Education, and Related Agencies Appropriations
13 Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note)
14 related to consultants and individual scientists ap-
15 pointed for limited periods of time shall not apply to
16 Directors appointed under this subsection.”.

17 (b) *REVIEW OF CERTAIN AWARDS BY DIRECTORS.*—
18 Section 405(b) of the Public Health Service Act (42 U.S.C.
19 284(b)) is amended by adding at the end the following:

20 “(3) Before an award is made by a national research
21 institute or by a national center for a grant for a research
22 program or project (commonly referred to as an ‘R-series
23 grant’), other than an award constituting a noncompetitive
24 renewal of such a grant, or a noncompetitive administrative
25 supplement to such a grant, the Director of such national

1 *research institute or national center shall, consistent with*
2 *the peer review process—*

3 “(A) *review and make the final decision with re-*
4 *spect to making the award; and*

5 “(B) *take into consideration, as appropriate—*

6 “(i) *the mission of the national research in-*
7 *stitute or national center and the scientific pri-*
8 *orities identified in the strategic plan under sec-*
9 *tion 402(m);*

10 “(ii) *programs or projects funded by other*
11 *agencies on similar research topics; and*

12 “(iii) *advice by staff and the advisory coun-*
13 *cil or board of such national research institute or*
14 *national center.”.*

15 (c) *REPORT ON DUPLICATION IN FEDERAL BIO-*
16 *MEDICAL RESEARCH.—The Secretary of Health and*
17 *Human Services (referred to in this subsection as the “Sec-*
18 *retary”), shall, not later than 2 years after the date of en-*
19 *actment of this Act, submit a report to Congress on efforts*
20 *to prevent and eliminate duplicative biomedical research*
21 *that is not necessary for scientific purposes. Such report*
22 *shall—*

23 (1) *describe the procedures in place to identify*
24 *such duplicative research, including procedures for*

1 *monitoring research applications and funded research*
2 *awards to prevent unnecessary duplication;*

3 *(2) describe the steps taken to improve the proce-*
4 *dures described in paragraph (1), in response to rel-*
5 *evant recommendations made by the Comptroller Gen-*
6 *eral of the United States;*

7 *(3) describe how the Secretary operationally dis-*
8 *tinguishes necessary and appropriate scientific rep-*
9 *lication from unnecessary duplication; and*

10 *(4) provide examples of instances where the Sec-*
11 *retary has identified unnecessarily duplicative re-*
12 *search and the steps taken to eliminate the unneces-*
13 *sary duplication.*

14 **SEC. 2034. REDUCING ADMINISTRATIVE BURDEN FOR RE-**
15 **SEARCHERS.**

16 *(a) PLAN PREPARATION AND IMPLEMENTATION OF*
17 *MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—*

18 *(1) IN GENERAL.—Not later than 2 years after*
19 *the date of enactment of this Act, the Secretary of*
20 *Health and Human Services (referred to in this sec-*
21 *tion as the “Secretary”) shall—*

22 *(A) lead a review by research funding agen-*
23 *cies of all regulations and policies related to the*
24 *disclosure of financial conflicts of interest, in-*

1 *cluding the minimum threshold for reporting fi-*
2 *nancial conflicts of interest;*

3 *(B) make revisions, as appropriate, to har-*
4 *monize existing policies and reduce administra-*
5 *tive burden on researchers while maintaining the*
6 *integrity and credibility of research findings and*
7 *protections of human participants; and*

8 *(C) confer with the Office of the Inspector*
9 *General about the activities of such office related*
10 *to financial conflicts of interest involving re-*
11 *search funding agencies.*

12 (2) *CONSIDERATIONS.—In updating policies*
13 *under paragraph (1)(B), the Secretary shall con-*
14 *sider—*

15 *(A) modifying the timelines for the report-*
16 *ing of financial conflicts of interest to just-in-*
17 *time information by institutions receiving grant*
18 *or cooperative agreement funding from the Na-*
19 *tional Institutes of Health;*

20 *(B) ensuring that financial interest disclo-*
21 *sure reporting requirements are appropriate for,*
22 *and relevant to, awards that will directly fund*
23 *research, which may include modification of the*
24 *definition of the term “investigator” for purposes*

1 *of the regulations and policies described in sub-*
2 *paragraphs (A) and (B) of paragraph (1); and*
3 *(C) updating any applicable training mod-*
4 *ules of the National Institutes of Health related*
5 *to Federal financial interest disclosure.*

6 **(b) MONITORING OF SUBRECIPIENTS OF FUNDING**
7 **FROM THE NATIONAL INSTITUTES OF HEALTH.—***The Di-*
8 *rector of the National Institutes of Health (referred to in*
9 *this section as the “Director of National Institutes of*
10 *Health”)* shall implement measures to reduce the adminis-
11 *trative burdens related to monitoring of subrecipients of*
12 *grants by primary awardees of funding from the National*
13 *Institutes of Health, which may incorporate findings and*
14 *recommendations from existing and ongoing activities.*
15 *Such measures may include, as appropriate—*

16 *(1) an exemption from subrecipient monitoring*
17 *requirements, upon request from the primary award-*
18 *ees, provided that—*

19 *(A) the subrecipient is subject to Federal*
20 *audit requirements pursuant to the Uniform*
21 *Guidance of the Office of Management and*
22 *Budget;*

23 *(B) the primary awardee conducts, pursu-*
24 *ant to guidance of the National Institutes of*
25 *Health, a pre-award evaluation of each sub-*

1 *recipient's risk of noncompliance with Federal*
2 *statutes and regulations, the conditions of the*
3 *subaward, and any recurring audit findings;*
4 *and*

5 *(C) such exemption does not absolve the pri-*
6 *mary awardee of liability for misconduct by sub-*
7 *recipients; and*

8 *(2) the implementation of alternative grant*
9 *structures that obviate the need for subrecipient moni-*
10 *toring, which may include collaborative grant models*
11 *allowing for multiple primary awardees.*

12 *(c) REPORTING OF FINANCIAL EXPENDITURES.—The*
13 *Secretary, in consultation with the Director of National In-*
14 *stitutes of Health, shall evaluate financial expenditure re-*
15 *porting procedures and requirements for recipients of fund-*
16 *ing from the National Institutes of Health and take action,*
17 *as appropriate, to avoid duplication between department*
18 *and agency procedures and requirements and minimize*
19 *burden to funding recipients.*

20 *(d) ANIMAL CARE AND USE IN RESEARCH.—Not later*
21 *than 2 years after the date of enactment of this Act, the*
22 *Director of National Institutes of Health, in collaboration*
23 *with the Secretary of Agriculture and the Commissioner of*
24 *Food and Drugs, shall complete a review of applicable regu-*
25 *lations and policies for the care and use of laboratory ani-*

1 *mals and make revisions, as appropriate, to reduce admin-*
2 *istrative burden on investigators while maintaining the in-*
3 *tegrity and credibility of research findings and protection*
4 *of research animals. In carrying out this effort, the Director*
5 *of the National Institutes of Health shall seek the input of*
6 *experts, as appropriate. The Director of the National Insti-*
7 *tutes of Health shall—*

8 (1) *identify ways to ensure such regulations and*
9 *policies are not inconsistent, overlapping, or unneces-*
10 *sarily duplicative, including with respect to inspec-*
11 *tion and review requirements by Federal agencies and*
12 *accrediting associations;*

13 (2) *take steps to eliminate or reduce identified*
14 *inconsistencies, overlap, or duplication among such*
15 *regulations and policies; and*

16 (3) *take other actions, as appropriate, to im-*
17 *prove the coordination of regulations and policies*
18 *with respect to research with laboratory animals.*

19 (e) *DOCUMENTATION OF PERSONNEL EXPENSES.—The*
20 *Secretary shall clarify the applicability of the requirements*
21 *under the Office of Management and Budget Uniform Guid-*
22 *ance for management and certification systems adopted by*
23 *entities receiving Federal research grants through the De-*
24 *partment of Health and Human Services regarding docu-*
25 *mentation of personnel expenses, including clarification of*

1 *the extent to which any flexibility to such requirements*
2 *specified in such Uniform Guidance applies to entities re-*
3 *ceiving grants through the Department of Health and*
4 *Human Services.*

5 *(f) RESEARCH POLICY BOARD.—*

6 *(1) ESTABLISHMENT.—Not later than 1 year*
7 *after the date of enactment of this Act, the Director*
8 *of the Office of Management and Budget shall estab-*
9 *lish an advisory committee, to be known as the “Re-*
10 *search Policy Board” (referred to in this subsection as*
11 *the “Board”), to provide Federal Government officials*
12 *with information on the effects of regulations related*
13 *to Federal research requirements.*

14 *(2) MEMBERSHIP.—*

15 *(A) IN GENERAL.—The Board shall include*
16 *not more than 10 Federal members, including*
17 *each of the following Federal members or their*
18 *designees:*

19 *(i) The Administrator of the Office of*
20 *Information and Regulatory Affairs of the*
21 *Office of Management and Budget.*

22 *(ii) The Director of the Office of*
23 *Science and Technology Policy.*

24 *(iii) The Secretary of Health and*
25 *Human Services.*

1 (iv) *The Director of the National*
2 *Science Foundation.*

3 (v) *The secretaries and directors of*
4 *other departments and agencies that sup-*
5 *port or regulate scientific research, as deter-*
6 *mined by the Director of the Office of Man-*
7 *agement and Budget.*

8 (B) *NON-FEDERAL MEMBERS.*—*The Board*
9 *shall be comprised of not less than 9 and not*
10 *more than 12 representatives of academic re-*
11 *search institutions, other private, nonprofit re-*
12 *search institutions, or other nonprofit organiza-*
13 *tions with relevant expertise. Such members shall*
14 *be appointed by a formal process, to be estab-*
15 *lished by the Director of the Office of Manage-*
16 *ment and Budget, in consultation with the Fed-*
17 *eral membership, and that incorporates—*

18 (i) *nomination by members of the non-*
19 *profit scientific research community, in-*
20 *cluding academic research institutions; and*

21 (ii) *procedures to fill membership posi-*
22 *tions vacated before the end of a member's*
23 *term.*

24 (3) *PURPOSE AND RESPONSIBILITIES.*—*The*
25 *Board shall make recommendations regarding the*

1 *modification and harmonization of regulations and*
2 *policies having similar purposes across research fund-*
3 *ing agencies to ensure that the administrative burden*
4 *of such research policy and regulation is minimized*
5 *to the greatest extent possible and consistent with*
6 *maintaining responsible oversight of federally funded*
7 *research. Activities of the Board may include—*

8 *(A) providing thorough and informed anal-*
9 *ysis of regulations and policies;*

10 *(B) identifying negative or adverse con-*
11 *sequences of existing policies and making action-*
12 *able recommendations regarding possible im-*
13 *provement of such policies;*

14 *(C) making recommendations with respect*
15 *to efforts within the Federal Government to im-*
16 *prove coordination of regulation and policy re-*
17 *lated to research;*

18 *(D) creating a forum for the discussion of*
19 *research policy or regulatory gaps, challenges,*
20 *clarification, or harmonization of such policies*
21 *or regulation, and best practices; and*

22 *(E) conducting ongoing assessment and*
23 *evaluation of regulatory burden, including devel-*
24 *opment of metrics, periodic measurement, and*

1 *identification of process improvements and pol-*
2 *icy changes.*

3 (4) *EXPERT SUBCOMMITTEES.*—*The Board may*
4 *form temporary expert subcommittees, as appropriate,*
5 *to develop timely analysis on pressing issues and as-*
6 *ist the Board in anticipating future regulatory chal-*
7 *lenges, including challenges emerging from new sci-*
8 *entific advances.*

9 (5) *REPORTING REQUIREMENTS.*—*Not later than*
10 *2 years after the date of enactment of this Act, and*
11 *once thereafter, the Board shall submit a report to the*
12 *Director of the Office of Management and Budget, the*
13 *Administrator of the Office of Information and Regu-*
14 *latory Affairs of the Office of Management and Budg-*
15 *et, the Director of the Office of Science and Tech-*
16 *nology Policy, the heads of relevant Federal depart-*
17 *ments and agencies, the Committee on Health, Edu-*
18 *cation, Labor, and Pensions of the Senate, and the*
19 *Committee on Energy and Commerce of the House of*
20 *Representatives containing formal recommendations*
21 *on the conceptualization, development, harmonization,*
22 *and reconsideration of scientific research policy, in-*
23 *cluding the regulatory benefits and burdens.*

24 (6) *SUNSET.*—*The Board shall terminate on*
25 *September 30, 2021.*

1 (7) *GAO REPORT.*—Not later than 4 years after
2 the date of enactment of this Act, the Comptroller
3 General of the United States shall conduct an inde-
4 pendent evaluation of the activities carried out by the
5 Board pursuant to this subsection and submit to the
6 appropriate committees of Congress a report regard-
7 ing the results of the independent evaluation. Such re-
8 port shall review and assess the Board’s activities
9 with respect to the responsibilities described in para-
10 graph (3).

11 **SEC. 2035. EXEMPTION FOR THE NATIONAL INSTITUTES OF**
12 **HEALTH FROM THE PAPERWORK REDUCTION**
13 **ACT REQUIREMENTS.**

14 Section 301 of the Public Health Service Act (42
15 U.S.C. 241), as amended by section 2013, is further amend-
16 ed by adding at the end the following:

17 “(g) Subchapter I of chapter 35 of title 44, United
18 States Code, shall not apply to the voluntary collection of
19 information during the conduct of research by the National
20 Institutes of Health.”.

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

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

25 “(n) *UNIQUE RESEARCH INITIATIVES.*—

1 “(1) *IN GENERAL.*—*The Director of NIH may*
2 *approve, after consideration of a proposal under*
3 *paragraph (2)(A), requests by the national research*
4 *institutes and centers, or program officers within the*
5 *Office of the Director to engage in transactions other*
6 *than a contract, grant, or cooperative agreement with*
7 *respect to projects that carry out—*

8 “(A) *the Precision Medicine Initiative*
9 *under section 498E; or*

10 “(B) *section 402(b)(7), except that not more*
11 *than 50 percent of the funds available for a fiscal*
12 *year through the Common Fund under section*
13 *402A(c)(1) for purposes of carrying out such sec-*
14 *tion 402(b)(7) may be used to engage in such*
15 *other transactions.*

16 “(2) *REQUIREMENTS.*—*The authority provided*
17 *under this subsection may be used to conduct or sup-*
18 *port high impact cutting-edge research described in*
19 *paragraph (1) using the other transactions authority*
20 *described in such paragraph if the institute, center, or*
21 *office—*

22 “(A) *submits a proposal to the Director of*
23 *NIH for the use of such authority before con-*
24 *ducting or supporting the research, including*

1 *why the use of such authority is essential to pro-*
2 *moting the success of the project;*

3 “(B) *receives approval for the use of such*
4 *authority from the Director of NIH; and*

5 “(C) *for each year in which the institute,*
6 *center, or office has used such authority in ac-*
7 *cordance with this subsection, submits a report*
8 *to the Director of NIH on the activities of the in-*
9 *stitute, center, or office relating to such re-*
10 *search.”.*

11 **(b) REPORT TO CONGRESS.**—*Not later than September*
12 *30, 2020, the Secretary of Health and Human Services, act-*
13 *ing through the Director of the National Institutes of*
14 *Health, shall conduct an evaluation of the activities under*
15 *subsection (n) of section 402 of the Public Health Service*
16 *Act (42 U.S.C. 282), as added by subsection (a), and submit*
17 *a report to the Committee on Health, Education, Labor,*
18 *and Pensions of the Senate and the Committee on Energy*
19 *and Commerce of the House of Representatives on the re-*
20 *sults of such evaluation.*

21 **(c) DUTIES OF DIRECTORS OF INSTITUTES.**—*Section*
22 *405(b)(1) of the Public Health Service Act (42 U.S.C.*
23 *284(b)(1)) is amended—*

1 (1) by redesignating subparagraphs (C) through
2 (L) as subparagraphs (D) through (M), respectively;
3 and

4 (2) by inserting after subparagraph (B), the fol-
5 lowing:

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

10 **SEC. 2037. NATIONAL CENTER FOR ADVANCING**
11 **TRANSLATIONAL SCIENCES.**

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

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

16 (2) in paragraph (2)—

17 (A) in the matter preceding subparagraph
18 (A), by striking “phase IIB” and inserting
19 “phase III”;

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

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

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

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

3 (1) in subsection (c)—

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

6 (B) in paragraph (5), by striking the period
7 and inserting a semicolon; and

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

9 “(6) the methods and tools, if any, that have
10 been developed since the last biennial report was pre-
11 pared; and

12 “(7) the methods and tools, if any, that have
13 been developed and are being utilized by the Food and
14 Drug Administration to support medical product re-
15 views.”; and

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

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

22 “(e) **RULE OF CONSTRUCTION.**—Nothing in this sec-
23 tion shall be construed as authorizing the Secretary to dis-
24 close any information that is a trade secret, or other privi-
25 leged or confidential information subject to section

1 *552(b)(4) of title 5, United States Code, or section 1905*
 2 *of title 18, United States Code.”.*

3 **SEC. 2038. COLLABORATION AND COORDINATION TO EN-**
 4 **HANCE RESEARCH.**

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

8 *(1) by amending paragraph (4) to read as fol-*
 9 *lows:*

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

12 *“(A) information to better evaluate sci-*
 13 *entific opportunity, public health burdens, and*
 14 *progress in reducing health disparities; and*

15 *“(B) data on study populations of clinical*
 16 *research, funded by or conducted at each na-*
 17 *tional research institute and national center,*
 18 *which—*

19 *“(i) specifies the inclusion of—*

20 *“(I) women;*

21 *“(II) members of minority groups;*

22 *“(III) relevant age categories, in-*
 23 *cluding pediatric subgroups; and*

1 “(IV) other demographic variables
2 as the Director of the National Insti-
3 tutes of Health determines appropriate;

4 “(ii) is disaggregated by research area,
5 condition, and disease categories; and

6 “(iii) is to be made publicly available
7 on the Internet website of the National In-
8 stitutes of Health;”]; and

9 (2) in paragraph (8)—

10 (A) in subparagraph (A), by striking “and”
11 at the end; and

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

13 “(C) foster collaboration between clinical re-
14 search projects funded by the respective national
15 research institutes and national centers that—

16 “(i) conduct research involving human
17 subjects; and

18 “(ii) collect similar data; and

19 “(D) encourage the collaboration described
20 in subparagraph (C) to—

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

23 “(ii) utilize diverse study populations,
24 with special consideration to biological, so-

1 cial, and other determinants of health that
2 contribute to health disparities;”.

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

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

7 (2) *by striking “The advisory council” and in-*
8 *serting the following:*

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

10 (3) *by adding at the end the following:*

11 “*(2) CONTENTS.—Each triennial report pre-*
12 *pared by an advisory council of each national re-*
13 *search institute as described in paragraph (1) shall*
14 *include each of the following:*

15 “*(A) The number of women included as sub-*
16 *jects, and the proportion of subjects that are*
17 *women, in any project of clinical research con-*
18 *ducted during the applicable reporting period,*
19 *disaggregated by categories of research area, con-*
20 *dition, or disease, and accounting for single-sex*
21 *studies.*

22 “*(B) The number of members of minority*
23 *groups included as subjects, and the proportion*
24 *of subjects that are members of minority groups,*
25 *in any project of clinical research conducted dur-*

1 *ing the applicable reporting period,*
2 *disaggregated by categories of research area, con-*
3 *dition, or disease and accounting for single-race*
4 *and single-ethnicity studies.*

5 “(C) *For the applicable reporting period,*
6 *the number of projects of clinical research that*
7 *include women and members of minority groups*
8 *and that—*

9 “(i) *have been completed during such*
10 *reporting period; and*

11 “(ii) *are being carried out during such*
12 *reporting period and have not been com-*
13 *pleted.*

14 “(D) *The number of studies completed dur-*
15 *ing the applicable reporting period for which re-*
16 *porting has been submitted in accordance with*
17 *subsection (c)(2)(A).”.*

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

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

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

2 *“The Director of the National Institutes of Health*
3 *shall, as appropriate, encourage efforts to improve research*
4 *related to the health of sexual and gender minority popu-*
5 *lations, including by—*

6 *“(1) facilitating increased participation of sex-*
7 *ual and gender minority populations in clinical re-*
8 *search supported by the National Institutes of Health,*
9 *and reporting on such participation, as applicable;*

10 *“(2) facilitating the development of valid and re-*
11 *liable methods for research relevant to sexual and gen-*
12 *der minority populations; and*

13 *“(3) addressing methodological challenges.”.*

14 *(e) REPORTING.—*

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

18 *(A) continue to support research for the de-*
19 *velopment of appropriate measures related to re-*
20 *porting health information about sexual and*
21 *gender minority populations; and*

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

25 *(2) NATIONAL ACADEMY OF MEDICINE REC-*
26 *COMMENDATIONS.—In developing the measures de-*

1 scribed in paragraph (1)(A), the Secretary shall take
2 into account recommendations made by the National
3 Academy of Medicine.

4 (f) *IMPROVING COORDINATION RELATED TO MINORITY*
5 *HEALTH AND HEALTH DISPARITIES*.—Section 464z–3 of
6 the Public Health Service Act (42 U.S.C. 285t) is amend-
7 ed—

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

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

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

15 (B) by striking “as the primary Federal of-
16 ficials” and inserting “as the primary Federal
17 official”;

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

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

23 (E) by adding at the end the following:
24 “The Director of the Institute may foster part-
25 nerships between the national research institutes

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

6 *(g) BASIC RESEARCH.—*

7 *(1) DEVELOPING POLICIES.—Not later than 2*
8 *years after the date of enactment of this Act, the Di-*
9 *rector of the National Institutes of Health (referred to*
10 *in this section as the “Director of the National Insti-*
11 *tutes of Health”), taking into consideration the rec-*
12 *ommendations developed under section 2039, shall de-*
13 *velop policies for projects of basic research funded by*
14 *National Institutes of Health to 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 variable*
13 *in basic research, including feedback on when it*
14 *is appropriate for projects of basic research in-*
15 *volving cells, tissues, or animals to include both*
16 *male and female cells, tissues, or animals.*

17 *(4) ADDITIONAL REQUIREMENTS.—The Director*
18 *of the National Institutes of Health shall—*

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

24 *(B) encourage that the results of such re-*
25 *search, when published or reported, be*

1 *disaggregated as appropriate with respect to the*
2 *analysis of any sex differences.*

3 *(h) CLINICAL RESEARCH.—*

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

13 *(2) REQUIREMENTS.—The updated guidelines*
14 *described in paragraph (1) shall—*

15 *(A) reflect the science regarding sex dif-*
16 *ferences;*

17 *(B) improve adherence to the requirements*
18 *under section 492B of the Public Health Service*
19 *Act (42 U.S.C. 289a–2), including the reporting*
20 *requirements under subsection (f) of such section;*
21 *and*

22 *(C) clarify the circumstances under which*
23 *studies should be designed to support the conduct*
24 *of analyses to detect significant differences in the*
25 *intervention effect due to demographic factors re-*

1 *lated to section 492B of the Public Health Serv-*
2 *ice Act, including in the absence of prior studies*
3 *that demonstrate a difference in study outcomes*
4 *on the basis of such factors and considering the*
5 *effects of the absence of such analyses on the*
6 *availability of data related to demographic dif-*
7 *ferences.*

8 *(i) APPROPRIATE AGE GROUPINGS IN CLINICAL RE-*
9 *SEARCH.—*

10 *(1) INPUT FROM EXPERTS.—Not later than 180*
11 *days after the date of enactment of this Act, the Di-*
12 *rector of the National Institutes of Health shall con-*
13 *vene a workshop of experts on pediatric and older*
14 *populations to provide input on—*

15 *(A) appropriate age groups to be included*
16 *in research studies involving human subjects;*
17 *and*

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

21 *(2) POLICY UPDATES.—Not later than 180 days*
22 *after the conclusion of the workshop under paragraph*
23 *(1), the Director of the National Institutes of Health*
24 *shall make a determination with respect to whether*
25 *the policies of the National Institutes of Health on the*

1 *inclusion of relevant age groups in clinical studies*
2 *need to be updated, and shall update such policies as*
3 *appropriate. In making the determination, the Direc-*
4 *tor of the National Institutes of Health shall take into*
5 *consideration whether such policies—*

6 *(A) address the consideration of age as an*
7 *inclusion variable in research involving human*
8 *subjects; and*

9 *(B) identify the criteria for justification for*
10 *any age-related exclusions in such research.*

11 *(3) PUBLIC AVAILABILITY OF FINDINGS AND CON-*
12 *CLUSIONS.—The Director of the National Institutes of*
13 *Health shall—*

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

20 *(B) ensure that age-related data reported in*
21 *the triennial report under section 403 of the*
22 *Public Health Service Act (42 U.S.C. 283) (as*
23 *amended by section 2032) are made available to*
24 *the public on the Internet website of the National*
25 *Institutes of Health.*

1 **SEC. 2039. ENHANCING THE RIGOR AND REPRODUCIBILITY**
2 **OF SCIENTIFIC RESEARCH.**

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

16 (b) *CONSIDERATIONS.*—In developing and issuing rec-
17 ommendations through the Advisory Committee under sub-
18 section (a), the working group established under such sub-
19 section shall consider, as appropriate—

20 (1) *preclinical experiment design, including*
21 *analysis of sex as a biological variable;*

22 (2) *clinical experiment design, including—*

23 (A) *the diversity of populations studied for*
24 *clinical research, with respect to biological, so-*
25 *cial, and other determinants of health that con-*
26 *tribute to health disparities;*

1 (B) *the circumstances under which sum-*
2 *mary information regarding biological, social,*
3 *and other factors that contribute to health dis-*
4 *parities should be reported; and*

5 (C) *the circumstances under which clinical*
6 *studies, including clinical trials, should conduct*
7 *an analysis of the data collected during the*
8 *study on the basis of biological, social, and other*
9 *factors that contribute to health disparities;*

10 (3) *applicable levels of rigor in statistical meth-*
11 *ods, methodology, and analysis;*

12 (4) *data and information sharing in accordance*
13 *with applicable privacy laws and regulations; and*

14 (5) *any other matter the working group deter-*
15 *mines relevant.*

16 (c) *POLICIES.*—*Not later than 18 months after the date*
17 *of enactment of this Act, the Director of the National Insti-*
18 *tutes of Health shall consider the recommendations devel-*
19 *oped by the working group and issued by the Advisory Com-*
20 *mittee under subsection (a) and develop or update policies*
21 *as appropriate.*

22 (d) *REPORT.*—*Not later than 2 years after the date*
23 *of enactment of this Act, the Director of the National Insti-*
24 *tutes of Health shall issue a report to the Secretary of*
25 *Health and Human Services, the Committee on Health,*

1 *Education, Labor, and Pensions of the Senate, and the*
2 *Committee on Energy and Commerce of the House of Rep-*
3 *resentatives regarding recommendations developed under*
4 *subsection (a) and any subsequent policy changes imple-*
5 *mented, to enhance rigor and reproducibility in scientific*
6 *research funded by the National Institutes of Health.*

7 *(e) CONFIDENTIALITY.—Nothing in this section au-*
8 *thorizes the Secretary of Health and Human Services to*
9 *disclose any information that is a trade secret, or other*
10 *privileged or confidential information, described in section*
11 *552(b)(4) of title 5, United States Code, or section 1905*
12 *of title 18, United States Code.*

13 **SEC. 2040. IMPROVING MEDICAL REHABILITATION RE-**
14 **SEARCH AT THE NATIONAL INSTITUTES OF**
15 **HEALTH.**

16 *(a) IN GENERAL.—Section 452 of the Public Health*
17 *Service Act (42 U.S.C. 285g-4) is amended—*

18 *(1) in subsection (b), by striking “conduct and*
19 *support” and inserting “conduct, support, and co-*
20 *ordination”;*

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

23 *(3) in subsection (d)—*

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

4 “(d)(1) The Director of the Center, in consultation
5 with the Director of the Institute, the coordinating com-
6 mittee established under subsection (e), and the advisory
7 board established under subsection (f), shall develop a com-
8 prehensive plan (referred to in this section as the ‘Research
9 Plan’) for the conduct, support, and coordination of medical
10 rehabilitation research.”;

11 (B) in paragraph (2)—

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

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

16 (iii) by adding at the end the fol-
17 lowing:

18 “(C) include goals and objectives for conducting,
19 supporting, and coordinating medical rehabilitation
20 research, consistent with the purpose described in sub-
21 section (b).”;

22 (C) by striking paragraph (4) and inserting
23 the following:

24 “(4) The Director of the Center, in consultation with
25 the Director of the Institute, the coordinating committee es-

1 *tablished under subsection (e), and the advisory board es-*
2 *tablished under subsection (f), shall revise and update the*
3 *Research Plan periodically, as appropriate, or not less than*
4 *every 5 years. Not later than 30 days after the Research*
5 *Plan is so revised and updated, the Director of the Center*
6 *shall transmit the revised and updated Research Plan to*
7 *the President, the Committee on Health, Education, Labor,*
8 *and Pensions of the Senate, and the Committee on Energy*
9 *and Commerce of the House of Representatives.”; and*

10 *(D) by adding at the end the following:*

11 *“(5) The Director of the Center, in consultation with*
12 *the Director of the Institute, shall, prior to revising and*
13 *updating the Research Plan, prepare a report for the co-*
14 *ordinating committee established under subsection (e) and*
15 *the advisory board established under subsection (f) that de-*
16 *scribes and analyzes the progress during the preceding fiscal*
17 *year in achieving the goals and objectives described in para-*
18 *graph (2)(C) and includes expenditures for rehabilitation*
19 *research at the National Institutes of Health. The report*
20 *shall include recommendations for revising and updating*
21 *the Research Plan, and such initiatives as the Director of*
22 *the Center and the Director of the Institute determine ap-*
23 *propriate. In preparing the report, the Director of the Cen-*
24 *ter and the Director of the Institute shall consult with the*
25 *Director of the National Institutes of Health.”;*

1 (4) *in subsection (e)—*

2 (A) *in paragraph (2), by inserting “peri-*
3 *odically host a scientific conference or workshop*
4 *on medical rehabilitation research and” after*
5 *“The Coordinating Committee shall”; and*

6 (B) *in paragraph (3), by inserting “the Di-*
7 *rector of the Division of Program Coordination,*
8 *Planning, and Strategic Initiatives within the*
9 *Office of the Director of the National Institutes*
10 *of Health,” after “shall be composed of”;*

11 (5) *in subsection (f)(3)(B)—*

12 (A) *by redesignating clauses (ix) through*
13 *(xi) as clauses (x) through (xii), respectively; and*

14 (B) *by inserting after clause (viii) the fol-*
15 *lowing:*

16 “*(ix) The Director of the Division of Program*
17 *Coordination, Planning, and Strategic Initiatives.”;*
18 *and*

19 (6) *by adding at the end the following:*

20 “*(g)(1) The Secretary and the heads of other Federal*
21 *agencies shall jointly review the programs carried out (or*
22 *proposed to be carried out) by each such official with respect*
23 *to medical rehabilitation research and, as appropriate,*
24 *enter into agreements preventing duplication among such*
25 *programs.*”

1 “(2) *The Secretary shall, as appropriate, enter into*
 2 *interagency agreements relating to the coordination of med-*
 3 *ical rehabilitation research conducted by agencies of the Na-*
 4 *tional Institutes of Health and other agencies of the Federal*
 5 *Government.*

6 “(h) *For purposes of this section, the term ‘medical re-*
 7 *habilitation research’ means the science of mechanisms and*
 8 *interventions that prevent, improve, restore, or replace lost,*
 9 *underdeveloped, or deteriorating function.’.*”

10 (b) *CONFORMING AMENDMENT.—Section 3 of the Na-*
 11 *tional Institutes of Health Amendments of 1990 (42 U.S.C.*
 12 *285g–4 note) is amended—*

13 (1) *in subsection (a), by striking “IN GEN-*
 14 *ERAL.—”;* and

15 (2) *by striking subsection (b).*

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

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

20 (1) *ESTABLISHMENT.—Not later than 90 days*
 21 *after the date of enactment of this Act, the Secretary*
 22 *of Health and Human Services (referred to in this*
 23 *section as the “Secretary”) shall establish a task force,*
 24 *in accordance with the Federal Advisory Committee*
 25 *Act (5 U.S.C. App.), to be known as the “Task Force*

1 *on Research Specific to Pregnant Women and Lac-*
2 *tating Women” (in this section referred to as the*
3 *“Task Force”).*

4 (2) *DUTIES.—The Task Force shall provide ad-*
5 *vice and guidance to the Secretary regarding Federal*
6 *activities related to identifying and addressing gaps*
7 *in knowledge and research regarding safe and effective*
8 *therapies for pregnant women and lactating women,*
9 *including the development of such therapies and the*
10 *collaboration on and coordination of such activities.*

11 (3) *MEMBERSHIP.—*

12 (A) *FEDERAL MEMBERS.—The Task Force*
13 *shall be composed of each of the following Federal*
14 *members, or the designees of such members:*

15 (i) *The Director of the Centers for Dis-*
16 *ease Control and Prevention.*

17 (ii) *The Director of the National Insti-*
18 *tutes of Health, the Director of the Eunice*
19 *Kennedy Shriver National Institute of*
20 *Child Health and Human Development,*
21 *and the directors of such other appropriate*
22 *national research institutes.*

23 (iii) *The Commissioner of Food and*
24 *Drugs.*

1 (iv) *The Director of the Office on*
2 *Women’s Health.*

3 (v) *The Director of the National Vac-*
4 *cine Program Office.*

5 (vi) *The head of any other research-re-*
6 *lated agency or department not described in*
7 *clauses (i) through (v) that the Secretary*
8 *determines appropriate, which may include*
9 *the Department of Veterans Affairs and the*
10 *Department of Defense.*

11 (B) *NON-FEDERAL MEMBERS.—The Task*
12 *Force shall be composed of each of the following*
13 *non-Federal members, including—*

14 (i) *representatives from relevant med-*
15 *ical societies with subject matter expertise*
16 *on pregnant women, lactating women, or*
17 *children;*

18 (ii) *nonprofit organizations with ex-*
19 *pertise related to the health of women and*
20 *children;*

21 (iii) *relevant industry representatives;*
22 *and*

23 (iv) *other representatives, as appro-*
24 *priate.*

1 (C) *LIMITATIONS.*—*The non-Federal mem-*
2 *bers described in subparagraph (B) shall—*

3 *(i) compose not more than one-half,*
4 *and not less than one-third, of the total*
5 *membership of the Task Force; and*

6 *(ii) be appointed by the Secretary.*

7 (4) *TERMINATION.*—

8 (A) *IN GENERAL.*—*Subject to subparagraph*
9 *(B), the Task Force shall terminate on the date*
10 *that is 2 years after the date on which the Task*
11 *Force is established under paragraph (1).*

12 (B) *EXTENSION.*—*The Secretary may ex-*
13 *tend the operation of the Task Force for one ad-*
14 *ditional 2-year period following the 2-year pe-*
15 *riod described in subparagraph (A), if the Sec-*
16 *retary determines that the extension is appro-*
17 *priate for carrying out the purpose of this sec-*
18 *tion.*

19 (5) *MEETINGS.*—*The Task Force shall meet not*
20 *less than 2 times each year and shall convene public*
21 *meetings, as appropriate, to fulfill its duties under*
22 *paragraph (2).*

23 (6) *TASK FORCE REPORT TO CONGRESS.*—*Not*
24 *later than 18 months after the date on which the Task*
25 *Force is established under paragraph (1), the Task*

1 *Force shall prepare and submit to the Secretary, the*
2 *Committee on Health, Education, Labor, and Pen-*
3 *sions of the Senate, and the Committee on Energy*
4 *and Commerce of the House of Representatives a re-*
5 *port that includes each of the following:*

6 *(A) A plan to identify and address gaps in*
7 *knowledge and research regarding safe and effec-*
8 *tive therapies for pregnant women and lactating*
9 *women, including the development of such thera-*
10 *pies.*

11 *(B) Ethical issues surrounding the inclu-*
12 *sion of pregnant women and lactating women in*
13 *clinical research.*

14 *(C) Effective communication strategies with*
15 *health care providers and the public on informa-*
16 *tion relevant to pregnant women and lactating*
17 *women.*

18 *(D) Identification of Federal activities, in-*
19 *cluding—*

20 *(i) the state of research on pregnancy*
21 *and lactation;*

22 *(ii) recommendations for the coordina-*
23 *tion of, and collaboration on research re-*
24 *lated to pregnant women and lactating*
25 *women;*

1 (iii) dissemination of research findings
2 and information relevant to pregnant
3 women and lactating women to providers
4 and the public; and

5 (iv) existing Federal efforts and pro-
6 grams to improve the scientific under-
7 standing of the health impacts on pregnant
8 women, lactating women, and related birth
9 and pediatric outcomes, including with re-
10 spect to pharmacokinetics,
11 pharmacodynamics, and toxicities.

12 (E) Recommendations to improve the devel-
13 opment of safe and effective therapies for preg-
14 nant women and lactating women.

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

21 (c) UPDATING PROTECTIONS FOR PREGNANT WOMEN
22 AND LACTATING WOMEN IN RESEARCH.—

23 (1) IN GENERAL.—Not later than 2 years after
24 the date of enactment of this Act, the Secretary, con-
25 sidering any recommendations of the Task Force

1 *available at such time and in consultation with the*
2 *heads of relevant agencies of the Department of*
3 *Health and Human Services, shall, as appropriate,*
4 *update regulations and guidance, as applicable, re-*
5 *garding the inclusion of pregnant women and lac-*
6 *tating women in clinical research.*

7 (2) *CRITERIA FOR EXCLUDING PREGNANT OR*
8 *LACTATING WOMEN.—In updating any regulations or*
9 *guidance described in paragraph (1), the Secretary*
10 *shall consider any appropriate criteria to be used by*
11 *institutional review boards and individuals reviewing*
12 *grant proposals for excluding pregnant women or lac-*
13 *tating women as a study population requiring addi-*
14 *tional protections from participating in human sub-*
15 *ject research.*

16 **SEC. 2042. STREAMLINING NATIONAL INSTITUTES OF**
17 **HEALTH REPORTING REQUIREMENTS.**

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

21 (1) *by amending subparagraph (B) to read as*
22 *follows:*

23 “(B) *REPORTING.—Not later than 2 years*
24 *after the date of enactment of 21st Century Cures*
25 *Act, the head of each national research institute*

1 or national center shall submit to the Director of
2 the National Institutes of Health a report, to be
3 included in the triennial report under section
4 403, on the amount made available by the insti-
5 tute or center for conducting or supporting re-
6 search that involves collaboration between the in-
7 stitute or center and 1 or more other national re-
8 search institutes or national centers.”; and

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

11 (b) *FRAUD AND ABUSE REPORTING*.—Section 403B of
12 the Public Health Service Act (42 U.S.C. 283a–1) is amend-
13 ed—

14 (1) by striking subsection (b);

15 (2) by redesignating subsection (c) as subsection
16 (b); and

17 (3) in subsection (b) (as so redesignated), by
18 striking “subsections (a) and (b)” and inserting “sub-
19 section (a)”.

20 (c) *DOCTORAL DEGREES REPORTING*.—Section
21 403C(a)(2) of the Public Health Service Act (42 U.S.C.
22 283a–2(a)(2)) is amended by striking “(not including any
23 leaves of absence)”.

24 (d) *VACCINE REPORTING*.—Section 404B of the Public
25 Health Service Act (42 U.S.C. 283d) is amended—

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

2 (2) *by striking “(a) DEVELOPMENT OF NEW*
3 *VACCINES.—The Secretary” and inserting “The Sec-*
4 *retary”.*

5 (e) *NATIONAL CENTER FOR ADVANCING*
6 *TRANSLATIONAL SCIENCES.—Section 479(c) of the Public*
7 *Health Service Act (42 U.S.C. 287(c)) is amended—*

8 (1) *in the subsection heading, by striking “AN-*
9 *NUAL” and inserting “BIENNIAL”; and*

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

13 (f) *REVIEW OF CENTERS OF EXCELLENCE.—*

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

16 (2) *CONFORMING AMENDMENT.—Section*
17 *399EE(c) of the Public Health Service Act (42 U.S.C.*
18 *280–4(c)) is amended by striking “399CC, 404H,”*
19 *and inserting “399CC”.*

20 (g) *RAPID HIV TEST REPORT.—Section 502(a) of the*
21 *Ryan White CARE Act Amendments of 2000 (42 U.S.C.*
22 *300cc note) is amended—*

23 (1) *by striking paragraph (2); and*

24 (2) *by redesignating paragraph (3) as para-*
25 *graph (2).*

1 (h) *NATIONAL INSTITUTE OF NURSING RESEARCH.*—

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

4 (2) *CONFORMING AMENDMENT.*—*Section 464X(g)*
5 *of the Public Health Service Act (42 U.S.C. 285q–*
6 *2(g)) is amended by striking “biennial report made*
7 *under section 464Y,” and inserting “triennial report*
8 *made under section 403”.*

9 **SEC. 2043. REIMBURSEMENT FOR RESEARCH SUBSTANCES**
10 **AND LIVING ORGANISMS.**

11 *Section 301 of the Public Health Service Act (42*
12 *U.S.C. 241), as amended by section 2035, is further amend-*
13 *ed—*

14 (1) *in the flush matter at the end of subsection*

15 (i) —

16 (A) *by redesignating such matter as sub-*
17 *section (h)(1); and*

18 (B) *by moving such matter so as to appear*
19 *at the end of such section; and*

20 (2) *in subsection (h) (as so redesignated), by*
21 *adding at the end the following:*

22 “*(2) Where research substances and living organisms*
23 *are made available under paragraph (1) through contrac-*
24 *tors, the Secretary may direct such contractors to collect*
25 *payments on behalf of the Secretary for the costs incurred*

1 *to make available such substances and organisms and to*
2 *forward amounts so collected to the Secretary, in the time*
3 *and manner specified by the Secretary.*

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

9 **SEC. 2044. SENSE OF CONGRESS ON INCREASED INCLUSION**
10 **OF UNDERREPRESENTED POPULATIONS IN**
11 **CLINICAL TRIALS.**

12 *It is the sense of Congress that the National Institute*
13 *on Minority Health and Health Disparities should include*
14 *within its strategic plan under section 402(m) of the Public*
15 *Health Service Act (42 U.S.C. 282(m)) ways to increase*
16 *representation of underrepresented populations in clinical*
17 *trials.*

18 ***Subtitle E—Advancement of the Na-***
19 ***tional Institutes of Health Re-***
20 ***search and Data Access***

21 **SEC. 2051. TECHNICAL UPDATES TO CLINICAL TRIALS**
22 **DATABASE.**

23 *Section 402(j)(2)(D) of the Public Health Service Act*
24 *(42 U.S.C. 282(j)(2)(D)) is amended—*

1 (1) *in clause (ii)(I), by inserting before the semi-*
2 *colon “, unless the responsible party affirmatively re-*
3 *quests that the Director of the National Institutes of*
4 *Health publicly post such clinical trial information*
5 *for an applicable device clinical trial prior to such*
6 *date of clearance or approval”;* and

7 (2) *by adding at the end the following:*

8 “(iii) *OPTION TO MAKE CERTAIN CLIN-*
9 *ICAL TRIAL INFORMATION AVAILABLE EAR-*
10 *LIER.—The Director of the National Insti-*
11 *tutes of Health shall inform responsible par-*
12 *ties of the option to request that clinical*
13 *trial information for an applicable device*
14 *clinical trial be publicly posted prior to the*
15 *date of clearance or approval, in accordance*
16 *with clause (ii)(I).*

17 “(iv) *COMBINATION PRODUCTS.—An*
18 *applicable clinical trial for a product that*
19 *is a combination of drug, device, or biologi-*
20 *cal product shall be considered—*

21 “(I) *an applicable drug clinical*
22 *trial, if the Secretary determines under*
23 *section 503(g) of the Federal Food,*
24 *Drug, and Cosmetic Act that the pri-*

1 *mary mode of action of such product is*
2 *that of a drug or biological product; or*
3 *“(II) an applicable device clinical*
4 *trial, if the Secretary determines under*
5 *such section that the primary mode of*
6 *action of such product is that of a de-*
7 *vice.”.*

8 **SEC. 2052. COMPLIANCE ACTIVITIES REPORTS.**

9 *(a) DEFINITIONS.—In this section:*

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

14 *(2) SECRETARY.—The term “Secretary” means*
15 *the Secretary of Health and Human Services.*

16 *(b) REPORT ON ACTIVITIES TO ENCOURAGE COMPLI-*
17 *ANCE.—Not later than 2 years after the date of enactment*
18 *of this Act, the Secretary, acting through the Director of*
19 *the National Institutes of Health and in collaboration with*
20 *the Commissioner of Food and Drugs, shall submit to the*
21 *Committee on Health, Education, Labor, and Pensions of*
22 *the Senate and the Committee on Energy and Commerce*
23 *of the House of Representatives, a report that describes edu-*
24 *cation and outreach, guidance, enforcement, and other ac-*

1 *tivities undertaken to encourage compliance with section*
2 *402(j) of the Public Health Service Act (42 U.S.C. 282(j)).*

3 *(c) REPORTS ON CLINICAL TRIALS.—*

4 *(1) IN GENERAL.—Not later than 2 years after*
5 *the final compliance date under the final rule imple-*
6 *menting section 402(j) of the Public Health Service*
7 *Act, and every 2 years thereafter for the next 4 years,*
8 *the Secretary, acting through the Director of the Na-*
9 *tional Institutes of Health and in collaboration with*
10 *the Commissioner of Food and Drugs, shall submit to*
11 *the Committee on Health, Education, Labor, and*
12 *Pensions of the Senate and the Committee on Energy*
13 *and Commerce of the House of Representatives, a re-*
14 *port describing—*

15 *(A) the total number of applicable clinical*
16 *trials with complete data bank registration in-*
17 *formation registered during the period for which*
18 *the report is being prepared (broken down by*
19 *each year of such reporting period);*

20 *(B) the total number of applicable clinical*
21 *trials registered during the period for which the*
22 *report is being prepared for which results have*
23 *been submitted to the data bank (broken down by*
24 *each year of such reporting period);*

1 (C) the activities undertaken by the Sec-
 2 retary to educate responsible persons about data
 3 bank registration and results submission require-
 4 ments, including through issuance of guidance
 5 documents, informational meetings, and training
 6 sessions; and

7 (D) the activities described in the report
 8 submitted under subsection (b).

9 (2) *ACTIONS TO ENFORCE COMPLIANCE.*—After
 10 the Secretary has undertaken the educational activi-
 11 ties described in paragraph (1)(C), the Secretary shall
 12 include in subsequent reports submitted under para-
 13 graph (1) the number of actions taken by the Sec-
 14 retary during the period for which the report is being
 15 prepared to enforce compliance with data bank reg-
 16 istration and results submission requirements.

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

18 Section 492B(c) of the Public Health Service Act (42
 19 U.S.C. 289a–2(c)) is amended—

20 (1) by striking “In the case” and inserting the
 21 following:

22 “(1) *IN GENERAL.*—In the case”; and

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

24 “(2) *REPORTING REQUIREMENTS.*—For any new
 25 and competing project of clinical research subject to

1 *the requirements under this section that receives a*
2 *grant award 1 year after the date of enactment of the*
3 *21st Century Cures Act, or any date thereafter, for*
4 *which a valid analysis is provided under paragraph*
5 *(1)—*

6 *“(A) and which is an applicable clinical*
7 *trial as defined in section 402(j), the entity con-*
8 *ducting such clinical research shall submit the*
9 *results of such valid analysis to the clinical trial*
10 *registry data bank expanded under section*
11 *402(j)(3), and the Director of the National Insti-*
12 *tutes of Health shall, as appropriate, consider*
13 *whether such entity has complied with the re-*
14 *porting requirement described in this subpara-*
15 *graph in awarding any future grant to such en-*
16 *tity, including pursuant to section*
17 *402(j)(5)(A)(ii) when applicable; and*

18 *“(B) the Director of the National Institutes*
19 *of Health shall encourage the reporting of the re-*
20 *sults of such valid analysis described in para-*
21 *graph (1) through any additional means deter-*
22 *mined appropriate by the Director.”.*

23 **SEC. 2054. CONSULTATION.**

24 *Not later than 90 days after the date of enactment of*
25 *this Act, the Secretary of Health and Human Services shall*

1 *consult with relevant Federal agencies, including the Food*
 2 *and Drug Administration, the Office of the National Coor-*
 3 *dinator for Health Information Technology, and the Na-*
 4 *tional Institutes of Health, as well as other stakeholders (in-*
 5 *cluding patients, researchers, physicians, industry rep-*
 6 *resentatives, and developers of health information tech-*
 7 *nology) to receive recommendations with respect to enhance-*
 8 *ments to the clinical trial registry data bank under section*
 9 *402(j) of the Public Health Service Act (42 U.S.C. 282(j)),*
 10 *including with respect to usability, functionality, and*
 11 *search capability.*

12 ***Subtitle F—Facilitating***
 13 ***Collaborative Research***

14 ***SEC. 2061. NATIONAL NEUROLOGICAL CONDITIONS SUR-***
 15 ***VEILLANCE SYSTEM.***

16 *Part P of title III of the Public Health Service Act*
 17 *(42 U.S.C. 280g et seq.) is amended by inserting after sec-*
 18 *tion 399S the following:*

19 ***“SEC. 399S–1. SURVEILLANCE OF NEUROLOGICAL DISEASES.***

20 *“(a) IN GENERAL.—The Secretary, acting through the*
 21 *Director of the Centers for Disease Control and Prevention*
 22 *and in coordination with other agencies as the Secretary*
 23 *determines, shall, as appropriate—*

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

4 “(2) incorporate information obtained through
5 such activities into an integrated surveillance system,
6 which may consist of or include a registry, to be
7 known as the National Neurological Conditions Sur-
8 veillance System.

9 “(b) RESEARCH.—The Secretary shall ensure that the
10 National Neurological Conditions Surveillance System is
11 designed in a manner that facilitates further research on
12 neurological diseases.

13 “(c) CONTENT.—In carrying out subsection (a), the
14 Secretary—

15 “(1) shall provide for the collection and storage
16 of information on the incidence and prevalence of
17 neurological diseases in the United States;

18 “(2) to the extent practicable, shall provide for
19 the collection and storage of other available informa-
20 tion on neurological diseases, including information
21 related to persons living with neurological diseases
22 who choose to participate, such as—

23 “(A) demographics, such as age, race, eth-
24 nicity, sex, geographic location, family history,
25 and other information, as appropriate;

1 “(B) risk factors that may be associated
2 with neurological diseases, such as genetic and
3 environmental risk factors and other informa-
4 tion, as appropriate; and

5 “(C) diagnosis and progression markers;

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

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

10 “(B) the prevention of the diseases;

11 “(C) the detection, management, and treat-
12 ment approaches for the diseases; and

13 “(D) the development of outcomes measures;

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

16 “(5) initially may address a limited number of
17 neurological diseases.

18 “(d) CONSULTATION.—In carrying out this section, the
19 Secretary shall consult with individuals with appropriate
20 expertise, which may include—

21 “(1) epidemiologists with experience in disease
22 surveillance or registries;

23 “(2) representatives of national voluntary health
24 associations that—

25 “(A) focus on neurological diseases; and

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

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

5 “(4) clinicians with expertise in neurological
6 diseases; and

7 “(5) research scientists with experience con-
8 ducting translational research or utilizing surveil-
9 lance systems for scientific research purposes.

10 “(e) GRANTS.—The Secretary may award grants to,
11 or enter into contracts or cooperative agreements with, pub-
12 lic or private nonprofit entities to carry out activities under
13 this section.

14 “(f) COORDINATION WITH OTHER FEDERAL, STATE,
15 AND LOCAL AGENCIES.—Subject to subsection (h), the Sec-
16 retary shall—

17 “(1) make information and analysis in the Na-
18 tional Neurological Conditions Surveillance System
19 available, as appropriate—

20 “(A) to Federal departments and agencies,
21 such as the National Institutes of Health and the
22 Department of Veterans Affairs; and

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

24 “(2) identify, build upon, leverage, and coordi-
25 nate among existing data and surveillance systems,

1 *surveys, registries, and other Federal public health in-*
2 *frastructure, wherever practicable.*

3 “(g) *PUBLIC ACCESS.*—Subject to subsection (h), the
4 *Secretary shall ensure that information and analysis in the*
5 *National Neurological Conditions Surveillance System are*
6 *available, as appropriate, to the public, including research-*
7 *ers.*

8 “(h) *PRIVACY.*—The Secretary shall ensure that infor-
9 *mation and analysis in the National Neurological Condi-*
10 *tions Surveillance System are made available only to the*
11 *extent permitted by applicable Federal and State law, and*
12 *in a manner that protects personal privacy, to the extent*
13 *required by applicable Federal and State privacy law, at*
14 *a minimum.*

15 “(i) *REPORTS.*—

16 “(1) *REPORT ON INFORMATION AND ANALYSES.*—
17 *Not later than 1 year after the date on which any sys-*
18 *tem is established under this section, the Secretary*
19 *shall submit an interim report to the Committee on*
20 *Health, Education, Labor, and Pensions of the Senate*
21 *and the Committee on Energy and Commerce of the*
22 *House of Representatives regarding aggregate infor-*
23 *mation collected pursuant to this section and epide-*
24 *miological analyses, as appropriate. Such report shall*
25 *be posted on the Internet website of the Department*

1 *of Health and Human Services and shall be updated*
2 *biennially.*

3 “(2) *IMPLEMENTATION REPORT.*—*Not later than*
4 *4 years after the date of the enactment of this section,*
5 *the Secretary shall submit a report to the Congress*
6 *concerning the implementation of this section. Such*
7 *report shall include information on—*

8 “(A) *the development and maintenance of*
9 *the National Neurological Conditions Surveil-*
10 *lance System;*

11 “(B) *the type of information collected and*
12 *stored in the surveillance system;*

13 “(C) *the use and availability of such infor-*
14 *mation, including guidelines for such use; and*

15 “(D) *the use and coordination of databases*
16 *that collect or maintain information on neuro-*
17 *logical diseases.*

18 “(j) *DEFINITION.*—*In this section, the term ‘national*
19 *voluntary health association’ means a national nonprofit*
20 *organization with chapters, other affiliated organizations,*
21 *or networks in States throughout the United States with*
22 *experience serving the population of individuals with neu-*
23 *rological disease and have demonstrated experience in neu-*
24 *rological disease research, care, and patient services.*

1 “(k) *AUTHORIZATION OF APPROPRIATIONS.*—To carry
2 out this section, there is authorized to be appropriated
3 \$5,000,000 for each of fiscal years 2018 through 2022.”.

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

5 (a) *IN GENERAL.*—The Secretary of Health and
6 Human Services (referred to in this section as “the Sec-
7 retary”) shall continue to conduct or support epidemiolog-
8 ical, basic, translational, and clinical research related to
9 vector-borne diseases, including tick-borne diseases.

10 (b) *REPORTS.*—The Secretary shall ensure that each
11 triennial report under section 403 of the Public Health
12 Service Act (42 U.S.C. 283) (as amended by section 2032)
13 includes information on actions undertaken by the National
14 Institutes of Health to carry out subsection (a) with respect
15 to tick-borne diseases.

16 (c) *TICK-BORNE DISEASES WORKING GROUP.*—

17 (1) *ESTABLISHMENT.*—The Secretary shall estab-
18 lish a working group, to be known as the Tick-Borne
19 Disease Working Group (referred to in this section as
20 the “Working Group”), comprised of representatives of
21 appropriate Federal agencies and other non-Federal
22 entities, to provide expertise and to review all efforts
23 within the Department of Health and Human Serv-
24 ices related to all tick-borne diseases, to help ensure

1 *interagency coordination and minimize overlap, and*
2 *to examine research priorities.*

3 (2) *RESPONSIBILITIES.—The working group*
4 *shall—*

5 (A) *not later than 2 years after the date of*
6 *enactment of this Act, develop or update a sum-*
7 *mary of—*

8 (i) *ongoing tick-borne disease research,*
9 *including research related to causes, preven-*
10 *tion, treatment, surveillance, diagnosis,*
11 *diagnostics, duration of illness, and inter-*
12 *vention for individuals with tick-borne dis-*
13 *eases;*

14 (ii) *advances made pursuant to such*
15 *research;*

16 (iii) *Federal activities related to tick-*
17 *borne diseases, including—*

18 (I) *epidemiological activities re-*
19 *lated to tick-borne diseases; and*

20 (II) *basic, clinical, and*
21 *translational tick-borne disease re-*
22 *search related to the pathogenesis, pre-*
23 *vention, diagnosis, and treatment of*
24 *tick-borne diseases;*

1 (iv) gaps in tick-borne disease research
2 described in clause (iii)(II);

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

5 (vi) the comments received by the
6 Working Group;

7 (B) make recommendations to the Secretary
8 regarding any appropriate changes or improve-
9 ments to such activities and research; and

10 (C) solicit input from States, localities, and
11 nongovernmental entities, including organiza-
12 tions representing patients, health care pro-
13 viders, researchers, and industry regarding sci-
14 entific advances, research questions, surveillance
15 activities, and emerging strains in species of
16 pathogenic organisms.

17 (3) MEMBERSHIP.—The members of the working
18 group shall represent a diversity of scientific dis-
19 ciplines and views and shall be composed of the fol-
20 lowing members:

21 (A) FEDERAL MEMBERS.—Seven Federal
22 members, consisting of one or more representa-
23 tives of each of the following:

24 (i) The Office of the Assistant Sec-
25 retary for Health.

1 (ii) *The Food and Drug Administra-*
2 *tion.*

3 (iii) *The Centers for Disease Control*
4 *and Prevention.*

5 (iv) *The National Institutes of Health.*

6 (v) *Such other agencies and offices of*
7 *the Department of Health and Human*
8 *Services as the Secretary determines appro-*
9 *priate.*

10 (B) *NON-FEDERAL PUBLIC MEMBERS.—*

11 *Seven non-Federal public members, consisting of*
12 *representatives of the following categories:*

13 (i) *Physicians and other medical pro-*
14 *viders with experience in diagnosing and*
15 *treating tick-borne diseases.*

16 (ii) *Scientists or researchers with ex-*
17 *pertise.*

18 (iii) *Patients and their family mem-*
19 *bers.*

20 (iv) *Nonprofit organizations that advo-*
21 *cate for patients with respect to tick-borne*
22 *diseases.*

23 (v) *Other individuals whose expertise*
24 *is determined by the Secretary to be bene-*

1 *ficial to the functioning of the Working*
2 *Group.*

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

5 (5) *REPORTING.*—*Not later than 2 years after*
6 *the date of enactment of this Act, and every 2 years*
7 *thereafter until termination of the Working Group*
8 *pursuant to paragraph (7), the Working Group*
9 *shall—*

10 (A) *submit a report on its activities under*
11 *paragraph (2)(A) and any recommendations*
12 *under paragraph (2)(B) to the Secretary, the*
13 *Committee on Energy and Commerce of the*
14 *House of Representatives, and the Committee on*
15 *Health, Education, Labor, and Pensions of the*
16 *Senate; and*

17 (B) *make such report publicly available on*
18 *the Internet website of the Department of Health*
19 *and Human Services.*

20 (6) *APPLICABILITY OF FACA.*—*The Working*
21 *Group shall be treated as an advisory committee sub-*
22 *ject to the Federal Advisory Committee Act (5 U.S.C.*
23 *App.).*

1 (7) *SUNSET.*—*The Working Group under this*
2 *section shall terminate 6 years after the date of enact-*
3 *ment of this Act.*

4 **SEC. 2063. ACCESSING, SHARING, AND USING HEALTH DATA**
5 **FOR RESEARCH PURPOSES.**

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

16 (1) *at a minimum, security and privacy safe-*
17 *guards, consistent with the requirements of the Rule,*
18 *are maintained by the covered entity and the re-*
19 *searcher; and*

20 (2) *the protected health information is not copied*
21 *or otherwise retained by the researcher.*

22 (b) *GUIDANCE RELATED TO STREAMLINING AUTHOR-*
23 *IZATION.*—*Not later than 1 year after the date of enactment*
24 *of this Act, the Secretary shall issue guidance on the fol-*
25 *lowing:*

1 (1) *AUTHORIZATION FOR USE AND DISCLOSURE*
2 *OF HEALTH INFORMATION.*—*Clarification of the cir-*
3 *cumstances under which the authorization for the use*
4 *or disclosure of protected health information, with re-*
5 *spect to an individual, for future research purposes*
6 *contains a sufficient description of the purpose of the*
7 *use or disclosure, such as if the authorization—*

8 (A) *sufficiently describes the purposes such*
9 *that it would be reasonable for the individual to*
10 *expect that the protected health information*
11 *could be used or disclosed for such future re-*
12 *search;*

13 (B) *either—*

14 (i) *states that the authorization will*
15 *expire on a particular date or on the occur-*
16 *rence of a particular event; or*

17 (ii) *states that the authorization will*
18 *remain valid unless and until it is revoked*
19 *by the individual; and*

20 (C) *provides instruction to the individual*
21 *on how to revoke such authorization at any time.*

22 (2) *REMINDER OF THE RIGHT TO REVOKE.*—
23 *Clarification of the circumstances under which it is*
24 *appropriate to provide an individual with an annual*

1 *notice or reminder that the individual has the right*
2 *to revoke such authorization.*

3 (3) *REVOCATION OF AUTHORIZATION.*—*Clarifica-*
4 *tion of appropriate mechanisms by which an indi-*
5 *vidual may revoke an authorization for future re-*
6 *search purposes, such as described in paragraph*
7 *(1)(C).*

8 (c) *WORKING GROUP ON PROTECTED HEALTH INFOR-*
9 *MATION FOR RESEARCH.*—

10 (1) *ESTABLISHMENT.*—*Not later than 1 year*
11 *after the date of enactment of this Act, the Secretary*
12 *shall convene a working group to study and report on*
13 *the uses and disclosures of protected health informa-*
14 *tion for research purposes, under the Health Insur-*
15 *ance Portability and Accountability Act of 1996*
16 *(Public Law 104–191).*

17 (2) *MEMBERS.*—*The working group shall include*
18 *representatives of—*

19 (A) *relevant Federal agencies, including the*
20 *National Institutes of Health, the Centers for*
21 *Disease Control and Prevention, the Food and*
22 *Drug Administration, and the Office for Civil*
23 *Rights;*

24 (B) *the research community;*

25 (C) *patients;*

1 (D) experts in civil rights, such as privacy
2 rights;

3 (E) developers of health information tech-
4 nology;

5 (F) experts in data privacy and security;

6 (G) health care providers;

7 (H) bioethicists; and

8 (I) other experts and entities, as the Sec-
9 retary determines appropriate.

10 (3) *REPORT.*—Not later than 1 year after the
11 date on which the working group is convened under
12 paragraph (1), the working group shall conduct a re-
13 view and submit a report to the Secretary containing
14 recommendations on whether the uses and disclosures
15 of protected health information for research purposes
16 should be modified to allow protected health informa-
17 tion to be available, as appropriate, for research pur-
18 poses, including studies to obtain generalizable knowl-
19 edge, while protecting individuals' privacy rights. In
20 conducting the review and making recommendations,
21 the working group shall—

22 (A) address, at a minimum—

23 (i) the appropriate manner and timing
24 of authorization, including whether addi-
25 tional notification to the individual should

1 *be required when the individual's protected*
2 *health information will be used or disclosed*
3 *for such research;*

4 *(ii) opportunities for individuals to set*
5 *preferences on the manner in which their*
6 *protected health information is used in re-*
7 *search;*

8 *(iii) opportunities for patients to re-*
9 *voke authorization;*

10 *(iv) notification to individuals of a*
11 *breach in privacy;*

12 *(v) existing gaps in statute, regulation,*
13 *or policy related to protecting the privacy of*
14 *individuals, and*

15 *(vi) existing barriers to research re-*
16 *lated to the current restrictions on the uses*
17 *and disclosures of protected health informa-*
18 *tion; and*

19 *(B) consider, at a minimum—*

20 *(i) expectations and preferences on how*
21 *an individual's protected health informa-*
22 *tion is shared and used;*

23 *(ii) issues related to specific subgroups*
24 *of people, such as children, incarcerated in-*
25 *dividuals, and individuals with a cognitive*

1 *or intellectual disability impacting capacity*
2 *to consent;*

3 *(iii) relevant Federal and State laws;*

4 *(iv) models of facilitating data access*
5 *and levels of data access, including data*
6 *segmentation, where applicable;*

7 *(v) potential impacts of disclosure and*
8 *non-disclosure of protected health informa-*
9 *tion on access to health care services; and*

10 *(vi) the potential uses of such data.*

11 *(4) REPORT SUBMISSION.—The Secretary shall*
12 *submit the report under paragraph (3) to the Com-*
13 *mittee on Health, Education, Labor, and Pensions of*
14 *the Senate and the Committee on Energy and Com-*
15 *merce of the House of Representatives, and shall post*
16 *such report on the appropriate Internet website of the*
17 *Department of Health and Human Services.*

18 *(5) TERMINATION.—The working group convened*
19 *under paragraph (1) shall terminate the day after the*
20 *report under paragraph (3) is submitted to Congress*
21 *and made public in accordance with paragraph (4).*

22 *(d) DEFINITIONS.—In this section:*

23 *(1) THE RULE.—References to “the Rule” refer*
24 *to part 160 or part 164, as appropriate, of title 45,*

1 *Code of Federal Regulations (or any successor regula-*
2 *tion).*

3 (2) *PART 164.—References to a specified section*
4 *of “part 164”, refer to such specified section of part*
5 *164 of title 45, Code of Federal Regulations (or any*
6 *successor section).*

7 ***Subtitle G—Promoting Pediatric***
8 ***Research***

9 ***SEC. 2071. NATIONAL PEDIATRIC RESEARCH NETWORK.***

10 *Section 409D(d) of the Public Health Service Act (42*
11 *U.S.C. 284h(d)) is amended—*

12 (1) *in paragraph (1), by striking “in consulta-*
13 *tion with the Director of the Eunice Kennedy Shriver*
14 *National Institute of Child Health and Human De-*
15 *velopment and in collaboration with other appro-*
16 *prate national research institutes and national cen-*
17 *ters that carry out activities involving pediatric re-*
18 *search, may provide for the establishment of” and in-*
19 *serting “in collaboration with the national research*
20 *institutes and national centers that carry out activi-*
21 *ties involving pediatric research, shall support”;* and

22 (2) *in paragraph (2)(A) and the first sentence of*
23 *paragraph (2)(E), by striking “may” each place such*
24 *term appears and inserting “shall”.*

1 **SEC. 2072. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK.**

2 *It is the sense of Congress that—*

3 *(1) the National Institutes of Health should en-*
4 *courage a global pediatric clinical study network by*
5 *providing grants, contracts, or cooperative agreements*
6 *to support new and early stage investigators who par-*
7 *ticipate in the global pediatric clinical study network;*

8 *(2) the Secretary of Health and Human Services*
9 *(referred to in this section as the “Secretary”) should*
10 *engage with clinical investigators and appropriate*
11 *authorities outside of the United States, including au-*
12 *thorities in the European Union, during the forma-*
13 *tion of the global pediatric clinical study network to*
14 *encourage the participation of such investigator and*
15 *authorities; and*

16 *(3) once a global pediatric clinical study network*
17 *is established and becomes operational, the Secretary*
18 *should continue to encourage and facilitate the par-*
19 *ticipation of clinical investigators and appropriate*
20 *authorities outside of the United States, including in*
21 *the European Union, to participate in the network*
22 *with the goal of enhancing the global reach of the net-*
23 *work.*

1 **TITLE III—DEVELOPMENT**
2 **Subtitle A—Patient-Focused Drug**
3 **Development**

4 **SEC. 3001. PATIENT EXPERIENCE DATA.**

5 *Section 569C of the Federal Food, Drug, and Cosmetic*
6 *Act (21 U.S.C. 360bbb–8c) is amended—*

7 *(1) in subsection (a)—*

8 *(A) in the subsection heading, by striking*
9 *“IN GENERAL” and inserting “PATIENT EN-*
10 *GAGEMENT IN DRUGS AND DEVICES”;*

11 *(B) by redesignating paragraphs (1) and*
12 *(2) as subparagraphs (A) and (B), respectively,*
13 *and moving such subparagraphs 2 ems to the*
14 *right; and*

15 *(C) by striking “The Secretary” and insert-*
16 *ing the following:*

17 *“(1) IN GENERAL.—The Secretary”;*

18 *(2) by redesignating subsections (b) through (e)*
19 *as paragraphs (2) through (5), respectively, and mov-*
20 *ing such paragraphs 2 ems to the right; and*

21 *(3) by adding at the end the following:*

22 *“(b) STATEMENT OF PATIENT EXPERIENCE.—*

23 *“(1) IN GENERAL.—Following the approval of an*
24 *application that was submitted under section 505(b)*
25 *of this Act or section 351(a) of the Public Health*

1 *Service Act at least 180 days after the date of enact-*
2 *ment of the 21st Century Cures Act, the Secretary*
3 *shall make public a brief statement regarding the pa-*
4 *tient experience data and related information, if any,*
5 *submitted and reviewed as part of such application.*

6 “(2) *DATA AND INFORMATION.*—*The data and*
7 *information referred to in paragraph (1) are—*

8 “(A) *patient experience data;*

9 “(B) *information on patient-focused drug*
10 *development tools; and*

11 “(C) *other relevant information, as deter-*
12 *mined by the Secretary.*

13 “(c) *PATIENT EXPERIENCE DATA.*—*For purposes of*
14 *this section, the term ‘patient experience data’ includes data*
15 *that—*

16 “(1) *are collected by any persons (including pa-*
17 *tients, family members and caregivers of patients, pa-*
18 *tient advocacy organizations, disease research founda-*
19 *tions, researchers, and drug manufacturers); and*

20 “(2) *are intended to provide information about*
21 *patients’ experiences with a disease or condition, in-*
22 *cluding—*

23 “(A) *the impact of such disease or condi-*
24 *tion, or a related therapy, on patients’ lives; and*

1 “(B) *patient preferences with respect to*
2 *treatment of such disease or condition.*”.

3 **SEC. 3002. PATIENT-FOCUSED DRUG DEVELOPMENT GUID-**
4 **ANCE.**

5 (a) *PUBLICATION OF GUIDANCE DOCUMENTS.*—Not
6 *later than 180 days after the date of enactment of this Act,*
7 *the Secretary of Health and Human Services (referred to*
8 *in this section as the “Secretary”), acting through the Com-*
9 *missioner of Food and Drugs, shall develop a plan to issue*
10 *draft and final versions of one or more guidance documents,*
11 *over a period of 5 years, regarding the collection of patient*
12 *experience data, and the use of such data and related infor-*
13 *mation in drug development. Not later than 18 months after*
14 *the date of enactment of this Act, the Secretary shall issue*
15 *a draft version of at least one such guidance document. Not*
16 *later than 18 months after the public comment period on*
17 *the draft guidance ends, the Secretary shall issue a revised*
18 *draft guidance or final guidance.*

19 (b) *PATIENT EXPERIENCE DATA.*—For purposes of
20 *this section, the term “patient experience data” has the*
21 *meaning given such term in section 569C of the Federal*
22 *Food, Drug, and Cosmetic Act (as added by section 3001).*

23 (c) *CONTENTS.*—The guidance documents described in
24 *subsection (a) shall address—*

1 (1) *methodological approaches that a person*
2 *seeking to collect patient experience data for submis-*
3 *sion to, and proposed use by, the Secretary in regu-*
4 *latory decisionmaking may use, that are relevant and*
5 *objective and ensure that such data are accurate and*
6 *representative of the intended population, including*
7 *methods to collect meaningful patient input through-*
8 *out the drug development process and methodological*
9 *considerations for data collection, reporting, manage-*
10 *ment, and analysis;*

11 (2) *methodological approaches that may be used*
12 *to develop and identify what is most important to pa-*
13 *tients with respect to burden of disease, burden of*
14 *treatment, and the benefits and risks in the manage-*
15 *ment of the patient's disease;*

16 (3) *approaches to identifying and developing*
17 *methods to measure impacts to patients that will help*
18 *facilitate collection of patient experience data in clin-*
19 *ical trials;*

20 (4) *methodologies, standards, and technologies to*
21 *collect and analyze clinical outcome assessments for*
22 *purposes of regulatory decisionmaking;*

23 (5) *how a person seeking to develop and submit*
24 *proposed draft guidance relating to patient experience*

1 *data for consideration by the Secretary may submit*
2 *such proposed draft guidance to the Secretary;*

3 *(6) the format and content required for submis-*
4 *sions under this section to the Secretary, including*
5 *with respect to the information described in para-*
6 *graph (1);*

7 *(7) how the Secretary intends to respond to sub-*
8 *missions of information described in paragraph (1),*
9 *if applicable, including any timeframe for response*
10 *when such submission is not part of a regulatory ap-*
11 *plication or other submission that has an associated*
12 *timeframe for response; and*

13 *(8) how the Secretary, if appropriate, antici-*
14 *pates using relevant patient experience data and re-*
15 *lated information, including with respect to the struc-*
16 *tured risk-benefit assessment framework described in*
17 *section 505(d) of the Federal Food, Drug, and Cos-*
18 *metic Act (21 U.S.C. 355(d)), to inform regulatory*
19 *decisionmaking.*

20 **SEC. 3003. STREAMLINING PATIENT INPUT.**

21 *Chapter 35 of title 44, United States Code, shall not*
22 *apply to the collection of information to which a response*
23 *is voluntary, that is initiated by the Secretary under sec-*
24 *tion 569C of the Federal Food, Drug, and Cosmetic Act (21*

1 *U.S.C. 360bbb–8c) (as amended by section 3001) or section*
2 *3002.*

3 **SEC. 3004. REPORT ON PATIENT EXPERIENCE DRUG DEVEL-**
4 **OPMENT.**

5 *Not later than June 1 of 2021, 2026, and 2031, the*
6 *Secretary of Health and Human Services, acting through*
7 *the Commissioner of Food and Drugs, shall prepare and*
8 *publish on the Internet website of the Food and Drug Ad-*
9 *ministration a report assessing the use of patient experience*
10 *data in regulatory decisionmaking, in particular with re-*
11 *spect to the review of patient experience data and informa-*
12 *tion on patient-focused drug development tools as part of*
13 *applications approved under section 505(c) of the Federal*
14 *Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or section*
15 *351(a) of the Public Health Service Act (42 U.S.C. 262(a)).*

16 **Subtitle B—Advancing New Drug**
17 **Therapies**

18 **SEC. 3011. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.**

19 *(a) IN GENERAL.—Chapter V of the Federal Food,*
20 *Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended*
21 *by inserting after section 506F the following new section:*

22 **“SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.**

23 **“(a) PROCESS FOR QUALIFICATION.—**

1 “(1) *IN GENERAL.*—*The Secretary shall establish*
2 *a process for the qualification of drug development*
3 *tools for a proposed context of use under which—*

4 “(A)(i) *a requestor initiates such process by*
5 *submitting a letter of intent to the Secretary;*
6 *and*

7 “(ii) *the Secretary accepts or declines to ac-*
8 *cept such letter of intent;*

9 “(B)(i) *if the Secretary accepts the letter of*
10 *intent, a requestor submits a qualification plan*
11 *to the Secretary; and*

12 “(ii) *the Secretary accepts or declines to ac-*
13 *cept the qualification plan; and*

14 “(C)(i) *if the Secretary accepts the quali-*
15 *fication plan, the requestor submits to the Sec-*
16 *retary a full qualification package;*

17 “(ii) *the Secretary determines whether to*
18 *accept such qualification package for review; and*

19 “(iii) *if the Secretary accepts such quali-*
20 *fication package for review, the Secretary con-*
21 *ducts such review in accordance with this sec-*
22 *tion.*

23 “(2) *ACCEPTANCE AND REVIEW OF SUBMIS-*
24 *SIONS.*—

1 “(A) *IN GENERAL.*—Subparagraphs (B),
2 (C), and (D) shall apply with respect to the
3 treatment of a letter of intent, a qualification
4 plan, or a full qualification package submitted
5 under paragraph (1) (referred to in this para-
6 graph as ‘qualification submissions’).

7 “(B) *ACCEPTANCE FACTORS; NONACCEPT-*
8 *ANCE.*—The Secretary shall determine whether to
9 accept a qualification submission based on fac-
10 tors which may include the scientific merit of the
11 qualification submission. A determination not to
12 accept a submission under paragraph (1) shall
13 not be construed as a final determination by the
14 Secretary under this section regarding the quali-
15 fication of a drug development tool for its pro-
16 posed context of use.

17 “(C) *PRIORITIZATION OF QUALIFICATION*
18 *REVIEW.*—The Secretary may prioritize the re-
19 view of a full qualification package submitted
20 under paragraph (1) with respect to a drug de-
21 velopment tool, based on factors determined ap-
22 propriate by the Secretary, including—

23 “(i) as applicable, the severity, rarity,
24 or prevalence of the disease or condition
25 targeted by the drug development tool and

1 *the availability or lack of alternative treat-*
2 *ments for such disease or condition; and*

3 “(ii) *the identification, by the Sec-*
4 *retary or by biomedical research consortia*
5 *and other expert stakeholders, of such a*
6 *drug development tool and its proposed con-*
7 *text of use as a public health priority.*

8 “(D) *ENGAGEMENT OF EXTERNAL EX-*
9 *PERTS.—The Secretary may, for purposes of the*
10 *review of qualification submissions, through the*
11 *use of cooperative agreements, grants, or other*
12 *appropriate mechanisms, consult with bio-*
13 *medical research consortia and may consider the*
14 *recommendations of such consortia with respect*
15 *to the review of any qualification plan submitted*
16 *under paragraph (1) or the review of any full*
17 *qualification package under paragraph (3).*

18 “(3) *REVIEW OF FULL QUALIFICATION PACK-*
19 *AGE.—The Secretary shall—*

20 “(A) *conduct a comprehensive review of a*
21 *full qualification package accepted under para-*
22 *graph (1)(C); and*

23 “(B) *determine whether the drug develop-*
24 *ment tool at issue is qualified for its proposed*
25 *context of use.*

1 “(4) *QUALIFICATION.*—*The Secretary shall deter-*
2 *mine whether a drug development tool is qualified for*
3 *a proposed context of use based on the scientific merit*
4 *of a full qualification package reviewed under para-*
5 *graph (3).*

6 “(b) *EFFECT OF QUALIFICATION.*—

7 “(1) *IN GENERAL.*—*A drug development tool de-*
8 *termined to be qualified under subsection (a)(4) for a*
9 *proposed context of use specified by the requestor may*
10 *be used by any person in such context of use for the*
11 *purposes described in paragraph (2).*

12 “(2) *USE OF A DRUG DEVELOPMENT TOOL.*—
13 *Subject to paragraph (3), a drug development tool*
14 *qualified under this section may be used for—*

15 “(A) *supporting or obtaining approval or*
16 *licensure (as applicable) of a drug or biological*
17 *product (including in accordance with section*
18 *506(c)) under section 505 of this Act or section*
19 *351 of the Public Health Service Act; or*

20 “(B) *supporting the investigational use of a*
21 *drug or biological product under section 505(i)*
22 *of this Act or section 351(a)(3) of the Public*
23 *Health Service Act.*

24 “(3) *RESCISSION OR MODIFICATION.*—

1 “(A) *IN GENERAL.*—*The Secretary may re-*
2 *scind or modify a determination under this sec-*
3 *tion to qualify a drug development tool if the*
4 *Secretary determines that the drug development*
5 *tool is not appropriate for the proposed context*
6 *of use specified by the requestor. Such a deter-*
7 *mination may be based on new information that*
8 *calls into question the basis for such qualifica-*
9 *tion.*

10 “(B) *MEETING FOR REVIEW.*—*If the Sec-*
11 *retary rescinds or modifies under subparagraph*
12 *(A) a determination to qualify a drug develop-*
13 *ment tool, the requestor involved shall, on re-*
14 *quest, be granted a meeting with the Secretary to*
15 *discuss the basis of the Secretary’s decision to re-*
16 *scind or modify the determination before the ef-*
17 *fective date of the rescission or modification.*

18 “(c) *TRANSPARENCY.*—

19 “(1) *IN GENERAL.*—*Subject to paragraph (3), the*
20 *Secretary shall make publicly available, and update*
21 *on at least a biannual basis, on the Internet website*
22 *of the Food and Drug Administration the following:*

23 “(A) *Information with respect to each qual-*
24 *ification submission under the qualification*
25 *process under subsection (a), including—*

1 “(i) the stage of the review process ap-
2 plicable to the submission;

3 “(ii) the date of the most recent change
4 in stage status;

5 “(iii) whether external scientific ex-
6 perts were utilized in the development of a
7 qualification plan or the review of a full
8 qualification package; and

9 “(iv) submissions from requestors
10 under the qualification process under sub-
11 section (a), including any data and evi-
12 dence contained in such submissions, and
13 any updates to such submissions.

14 “(B) The Secretary’s formal written deter-
15 minations in response to such qualification sub-
16 missions.

17 “(C) Any rescissions or modifications under
18 subsection (b)(3) of a determination to qualify a
19 drug development tool.

20 “(D) Summary reviews that document con-
21 clusions and recommendations for determina-
22 tions to qualify drug development tools under
23 subsection (a).

24 “(E) A comprehensive list of—

1 “(i) all drug development tools quali-
2 fied under subsection (a); and

3 “(ii) all surrogate endpoints which
4 were the basis of approval or licensure (as
5 applicable) of a drug or biological product
6 (including in accordance with section
7 506(c)) under section 505 of this Act or sec-
8 tion 351 of the Public Health Service Act.

9 “(2) *RELATION TO TRADE SECRETS ACT.*—Infor-
10 mation made publicly available by the Secretary
11 under paragraph (1) shall be considered a disclosure
12 authorized by law for purposes of section 1905 of title
13 18, United States Code.

14 “(3) *APPLICABILITY.*—Nothing in this section
15 shall be construed as authorizing the Secretary to dis-
16 close any information contained in an application
17 submitted under section 505 of this Act or section 351
18 of the Public Health Service Act that is confidential
19 commercial or trade secret information subject to sec-
20 tion 552(b)(4) of title 5, United States Code, or sec-
21 tion 1905 of title 18, United States Code.

22 “(d) *RULE OF CONSTRUCTION.*—Nothing in this sec-
23 tion shall be construed—

24 “(1) to alter the standards of evidence under sub-
25 section (c) or (d) of section 505, including the sub-

1 *stantial evidence standard in such subsection (d), or*
2 *under section 351 of the Public Health Service Act (as*
3 *applicable); or*

4 *“(2) to limit the authority of the Secretary to*
5 *approve or license products under this Act or the Pub-*
6 *lic Health Service Act, as applicable (as in effect be-*
7 *fore the date of the enactment of the 21st Century*
8 *Cures Act).*

9 *“(e) DEFINITIONS.—In this section:*

10 *“(1) BIOMARKER.—The term ‘biomarker’—*

11 *“(A) means a characteristic (such as a*
12 *physiologic, pathologic, or anatomic char-*
13 *acteristic or measurement) that is objectively*
14 *measured and evaluated as an indicator of nor-*
15 *mal biologic processes, pathologic processes, or*
16 *biological responses to a therapeutic intervention;*
17 *and*

18 *“(B) includes a surrogate endpoint.*

19 *“(2) BIOMEDICAL RESEARCH CONSORTIA.—The*
20 *term ‘biomedical research consortia’ means collabo-*
21 *rative groups that may take the form of public-pri-*
22 *vate partnerships and may include government agen-*
23 *cies, institutions of higher education (as defined in*
24 *section 101(a) of the Higher Education Act of 1965),*
25 *patient advocacy groups, industry representatives,*

1 *clinical and scientific experts, and other relevant enti-*
2 *ties and individuals.*

3 “(3) *CLINICAL OUTCOME ASSESSMENT.*—*The*
4 *term ‘clinical outcome assessment’ means—*

5 “(A) *a measurement of a patient’s symp-*
6 *toms, overall mental state, or the effects of a dis-*
7 *ease or condition on how the patient functions;*
8 *and*

9 “(B) *includes a patient-reported outcome.*

10 “(4) *CONTEXT OF USE.*—*The term ‘context of*
11 *use’ means, with respect to a drug development tool,*
12 *the circumstances under which the drug development*
13 *tool is to be used in drug development and regulatory*
14 *review.*

15 “(5) *DRUG DEVELOPMENT TOOL.*—*The term*
16 *‘drug development tool’ includes—*

17 “(A) *a biomarker;*

18 “(B) *a clinical outcome assessment; and*

19 “(C) *any other method, material, or meas-*
20 *ure that the Secretary determines aids drug de-*
21 *velopment and regulatory review for purposes of*
22 *this section.*

23 “(6) *PATIENT-REPORTED OUTCOME.*—*The term*
24 *‘patient-reported outcome’ means a measurement*
25 *based on a report from a patient regarding the status*

1 *of the patient’s health condition without amendment*
2 *or interpretation of the patient’s report by a clinician*
3 *or any other person.*

4 “(7) *QUALIFICATION.*—*The terms ‘qualification’*
5 *and ‘qualified’ mean a determination by the Sec-*
6 *retary that a drug development tool and its proposed*
7 *context of use can be relied upon to have a specific*
8 *interpretation and application in drug development*
9 *and regulatory review under this Act.*

10 “(8) *REQUESTOR.*—*The term ‘requestor’ means*
11 *an entity or entities, including a drug sponsor or a*
12 *biomedical research consortia, seeking to qualify a*
13 *drug development tool for a proposed context of use*
14 *under this section.*

15 “(9) *SURROGATE ENDPOINT.*—*The term ‘surro-*
16 *gate endpoint’ means a marker, such as a laboratory*
17 *measurement, radiographic image, physical sign, or*
18 *other measure, that is not itself a direct measurement*
19 *of clinical benefit, and—*

20 “(A) *is known to predict clinical benefit*
21 *and could be used to support traditional ap-*
22 *proval of a drug or biological product; or*

23 “(B) *is reasonably likely to predict clinical*
24 *benefit and could be used to support the acceler-*

1 *ated approval of a drug or biological product in*
2 *accordance with section 506(c).”.*

3 *(b) GUIDANCE.—*

4 *(1) IN GENERAL.—The Secretary of Health and*
5 *Human Services (referred to in this section as the*
6 *“Secretary”) shall, in consultation with biomedical*
7 *research consortia (as defined in subsection (e) of sec-*
8 *tion 507 of the Federal Food, Drug, and Cosmetic Act*
9 *(as added by subsection (a)) and other interested par-*
10 *ties through a collaborative public process, issue guid-*
11 *ance to implement such section 507 that—*

12 *(A) provides a conceptual framework de-*
13 *scribing appropriate standards and scientific*
14 *approaches to support the development of bio-*
15 *markers delineated under the taxonomy estab-*
16 *lished under paragraph (3);*

17 *(B) with respect to the qualification process*
18 *under such section 507—*

19 *(i) describes the requirements that enti-*
20 *ties seeking to qualify a drug development*
21 *tool under such section shall observe when*
22 *engaging in such process;*

23 *(ii) outlines reasonable timeframes for*
24 *the Secretary’s review of letters, qualifica-*

1 *tion plans, or full qualification packages*
2 *submitted under such process; and*

3 *(iii) establishes a process by which*
4 *such entities or the Secretary may consult*
5 *with biomedical research consortia and*
6 *other individuals and entities with expert*
7 *knowledge and insights that may assist the*
8 *Secretary in the review of qualification*
9 *plans and full qualification submissions*
10 *under such section; and*

11 *(C) includes such other information as the*
12 *Secretary determines appropriate.*

13 *(2) TIMING.—Not later than 3 years after the*
14 *date of the enactment of this Act, the Secretary shall*
15 *issue draft guidance under paragraph (1) on the im-*
16 *plementation of section 507 of the Federal Food,*
17 *Drug, and Cosmetic Act (as added by subsection (a)).*
18 *The Secretary shall issue final guidance on the imple-*
19 *mentation of such section not later than 6 months*
20 *after the date on which the comment period for the*
21 *draft guidance closes.*

22 *(3) TAXONOMY.—*

23 *(A) IN GENERAL.—For purposes of inform-*
24 *ing guidance under this subsection, the Secretary*
25 *shall, in consultation with biomedical research*

1 *consortia and other interested parties through a*
2 *collaborative public process, establish a tax-*
3 *onomy for the classification of biomarkers (and*
4 *related scientific concepts) for use in drug devel-*
5 *opment.*

6 *(B) PUBLIC AVAILABILITY.—Not later than*
7 *2 years after the date of the enactment of this*
8 *Act, the Secretary shall make such taxonomy*
9 *publicly available in draft form for public com-*
10 *ment. The Secretary shall finalize the taxonomy*
11 *not later than 1 year after the close of the public*
12 *comment period.*

13 *(c) MEETING AND REPORT.—*

14 *(1) MEETING.—Not later than 2 years after the*
15 *date of the enactment of this Act, the Secretary shall*
16 *convene a public meeting to describe and solicit pub-*
17 *lic input regarding the qualification process under*
18 *section 507 of the Federal Food, Drug, and Cosmetic*
19 *Act, as added by subsection (a).*

20 *(2) REPORT.—Not later than 5 years after the*
21 *date of the enactment of this Act, the Secretary shall*
22 *make publicly available on the Internet website of the*
23 *Food and Drug Administration a report. Such report*
24 *shall include, with respect to the qualification process*
25 *under section 507 of the Federal Food, Drug, and*

1 *Cosmetic Act, as added by subsection (a), information*
2 *on—*

3 *(A) the number of requests submitted, as a*
4 *letter of intent, for qualification of a drug devel-*
5 *opment tool (as defined in subsection (e) of such*
6 *section 507);*

7 *(B) the number of such requests accepted*
8 *and determined to be eligible for submission of a*
9 *qualification plan or full qualification package*
10 *(as such terms are defined in subsection (e) of*
11 *such section 507), respectively;*

12 *(C) the number of such requests for which*
13 *external scientific experts were utilized in the de-*
14 *velopment of a qualification plan or review of a*
15 *full qualification package;*

16 *(D) the number of qualification plans and*
17 *full qualification packages, respectively, sub-*
18 *mitted to the Secretary; and*

19 *(E) the drug development tools qualified*
20 *through such qualification process, specified by*
21 *type of tool, such as a biomarker or clinical out-*
22 *come assessment (as such terms are defined in*
23 *subsection (e) of such section 507).*

1 **SEC. 3012. TARGETED DRUGS FOR RARE DISEASES.**

2 *Subchapter B of chapter V of the Federal Food, Drug,*
3 *and Cosmetic Act (21 U.S.C. 360aa et seq.) is amended by*
4 *inserting after section 529 the following:*

5 **“SEC. 529A. TARGETED DRUGS FOR RARE DISEASES.**

6 *“(a) PURPOSE.—The purpose of this section, through*
7 *the approach provided for in subsection (b), is to—*

8 *“(1) facilitate the development, review, and ap-*
9 *proval of genetically targeted drugs and variant pro-*
10 *tein targeted drugs to address an unmet medical need*
11 *in one or more patient subgroups, including sub-*
12 *groups of patients with different mutations of a gene,*
13 *with respect to rare diseases or conditions that are se-*
14 *rious or life-threatening; and*

15 *“(2) maximize the use of scientific tools or meth-*
16 *ods, including surrogate endpoints and other bio-*
17 *markers, for such purposes.*

18 *“(b) LEVERAGING OF DATA FROM PREVIOUSLY AP-*
19 *PROVED DRUG APPLICATION OR APPLICATIONS.—The Sec-*
20 *retary may, consistent with applicable standards for ap-*
21 *proval under this Act or section 351(a) of the Public Health*
22 *Service Act, allow the sponsor of an application under sec-*
23 *tion 505(b)(1) of this Act or section 351(a) of the Public*
24 *Health Service Act for a genetically targeted drug or a vari-*
25 *ant protein targeted drug to rely upon data and informa-*
26 *tion—*

1 “(1) previously developed by the same sponsor
2 (or another sponsor that has provided the sponsor
3 with a contractual right of reference to such data and
4 information); and

5 “(2) submitted by a sponsor described in para-
6 graph (1) in support of one or more previously ap-
7 proved applications that were submitted under section
8 505(b)(1) of this Act or section 351(a) of the Public
9 Health Service Act,
10 for a drug that incorporates or utilizes the same or similar
11 genetically targeted technology as the drug or drugs that
12 are the subject of an application or applications described
13 in paragraph (2) or for a variant protein targeted drug
14 that is the same or incorporates or utilizes the same variant
15 protein targeted drug, as the drug or drugs that are the
16 subject of an application or applications described in para-
17 graph (2).

18 “(c) DEFINITIONS.—For purposes of this section—

19 “(1) the term ‘genetically targeted drug’ means a
20 drug that—

21 “(A) is the subject of an application under
22 section 505(b)(1) of this Act or section 351(a) of
23 the Public Health Service Act for the treatment
24 of a rare disease or condition (as such term is

1 *defined in section 526) that is serious or life-*
2 *threatening;*

3 *“(B) may result in the modulation (includ-*
4 *ing suppression, up-regulation, or activation) of*
5 *the function of a gene or its associated gene*
6 *product; and*

7 *“(C) incorporates or utilizes a genetically*
8 *targeted technology;*

9 *“(2) the term ‘genetically targeted technology’*
10 *means a technology comprising non-replicating nu-*
11 *cleic acid or analogous compounds with a common or*
12 *similar chemistry that is intended to treat one or*
13 *more patient subgroups, including subgroups of pa-*
14 *tients with different mutations of a gene, with the*
15 *same disease or condition, including a disease or con-*
16 *dition due to other variants in the same gene; and*

17 *“(3) the term ‘variant protein targeted drug’*
18 *means a drug that—*

19 *“(A) is the subject of an application under*
20 *section 505(b)(1) of this Act or section 351(a) of*
21 *the Public Health Service Act for the treatment*
22 *of a rare disease or condition (as such term is*
23 *defined in section 526) that is serious or life-*
24 *threatening;*

1 “(B) modulates the function of a product of
2 a mutated gene where such mutation is respon-
3 sible in whole or in part for a given disease or
4 condition; and

5 “(C) is intended to treat one or more pa-
6 tient subgroups, including subgroups of patients
7 with different mutations of a gene, with the same
8 disease or condition.

9 “(d) *RULE OF CONSTRUCTION.*—Nothing in this sec-
10 tion shall be construed to—

11 “(1) alter the authority of the Secretary to ap-
12 prove drugs pursuant to this Act or section 351 of the
13 Public Health Service Act (as authorized prior to the
14 date of enactment of the 21st Century Cures Act), in-
15 cluding the standards of evidence, and applicable con-
16 ditions, for approval under such applicable Act; or

17 “(2) confer any new rights, beyond those author-
18 ized under this Act or the Public Health Service Act
19 prior to enactment of this section, with respect to the
20 permissibility of a sponsor referencing information
21 contained in another application submitted under sec-
22 tion 505(b)(1) of this Act or section 351(a) of the
23 Public Health Service Act.”.

1 **SEC. 3013. REAUTHORIZATION OF PROGRAM TO ENCOUR-**
2 **AGE TREATMENTS FOR RARE PEDIATRIC DIS-**
3 **EASES.**

4 (a) *IN GENERAL.*—Section 529(b) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 360ff(b)) is amended
6 by striking paragraph (5) and inserting the following:

7 “(5) *TERMINATION OF AUTHORITY.*—The Sec-
8 retary may not award any priority review vouchers
9 under paragraph (1) after September 30, 2020, unless
10 the rare pediatric disease product application—

11 “(A) is for a drug that, not later than Sep-
12 tember 30, 2020, is designated under subsection
13 (d) as a drug for a rare pediatric disease; and

14 “(B) is, not later than September 30, 2022,
15 approved under section 505(b)(1) of this Act or
16 section 351(a) of the Public Health Service Act.”.

17 (b) *REPORT.*—The Advancing Hope Act of 2016 (Pub-
18 lic Law 114–229) is amended by striking section 3.

19 **SEC. 3014. GAO STUDY OF PRIORITY REVIEW VOUCHER PRO-**
20 **GRAMS.**

21 (a) *STUDY.*—The Comptroller General of the United
22 States (referred to in this section as the “Comptroller Gen-
23 eral”) shall conduct a study addressing the effectiveness and
24 overall impact of the following priority review voucher pro-
25 grams, including any such programs amended or estab-
26 lished by this Act:

1 (1) *The neglected tropical disease priority review*
2 *voucher program under section 524 of the Federal*
3 *Food, Drug, and Cosmetic Act (21 U.S.C. 360n).*

4 (2) *The rare pediatric disease priority review*
5 *voucher program under section 529 of the Federal*
6 *Food, Drug, and Cosmetic Act (21 U.S.C. 360ff).*

7 (3) *The medical countermeasure priority review*
8 *voucher program under section 565A of the Federal*
9 *Food, Drug, and Cosmetic Act, as added by section*
10 *3086.*

11 (b) *ISSUANCE OF REPORT.*—*Not later than January*
12 *31, 2020, the Comptroller General shall submit to the Com-*
13 *mittee on Health, Education, Labor, and Pensions of the*
14 *Senate and the Committee on Energy and Commerce of the*
15 *House of Representatives a report containing the results of*
16 *the study under subsection (a).*

17 (c) *CONTENTS OF REPORTS.*—*The report submitted*
18 *under subsection (b) shall address—*

19 (1) *for each drug for which a priority review*
20 *voucher has been awarded as of initiation of the*
21 *study—*

22 (A) *the indications for which the drug is*
23 *approved under section 505(c) of the Federal*
24 *Food, Drug, and Cosmetic Act (21 U.S.C.*
25 *355(c)), pursuant to an application under sec-*

1 *tion 505(b)(1) of such Act, or licensed under sec-*
2 *tion 351(a) of the Public Health Service Act (42*
3 *U.S.C. 262(a));*

4 *(B) whether, and to what extent, the vouch-*
5 *er impacted the sponsor's decision to develop the*
6 *drug; and*

7 *(C) whether, and to what extent, the ap-*
8 *proval or licensure of the drug, as applicable and*
9 *appropriate—*

10 *(i) addressed a global unmet need re-*
11 *lated to the treatment or prevention of a ne-*
12 *glected tropical disease, including whether*
13 *the sponsor of a drug coordinated with*
14 *international development organizations;*

15 *(ii) addressed an unmet need related to*
16 *the treatment of a rare pediatric disease; or*

17 *(iii) affected the Nation's preparedness*
18 *against a chemical, biological, radiological,*
19 *or nuclear threat, including naturally oc-*
20 *curring threats;*

21 *(2) for each drug for which a priority review*
22 *voucher has been used—*

23 *(A) the indications for which such 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 sec-
3 tion 351(a) of the Public Health Service Act (42
4 U.S.C. 262);

5 (B) the value of the voucher, if transferred;

6 and

7 (C) the length of time between the date on
8 which the voucher was awarded and the date on
9 which the voucher was used; and

10 (3) an analysis of the priority review voucher
11 programs described in subsection (a), including—

12 (A) the resources used by the Food and
13 Drug Administration in reviewing drugs for
14 which vouchers were used, including the effect of
15 the programs on the Food and Drug Administra-
16 tion's review of drugs for which priority review
17 vouchers were not awarded or used;

18 (B) whether any improvements to such pro-
19 grams are necessary to appropriately target in-
20 centives for the development of drugs that would
21 likely not otherwise be developed, or developed in
22 as timely a manner, and, as applicable and ap-
23 propriate—

24 (i) address global unmet needs related
25 to the treatment or prevention of neglected

1 *tropical diseases, including in countries in*
2 *which neglected tropical diseases are en-*
3 *demic; or*

4 *(ii) address unmet needs related to the*
5 *treatment of rare pediatric diseases; and*

6 *(C) whether the sunset of the rare pediatric*
7 *disease program and medical countermeasure*
8 *program has had an impact on the program, in-*
9 *cluding any potential unintended consequences.*

10 *(d) PROTECTION OF NATIONAL SECURITY.—The*
11 *Comptroller General shall conduct the study and issue re-*
12 *ports under this section in a manner that does not com-*
13 *promise national security.*

14 **SEC. 3015. AMENDMENTS TO THE ORPHAN DRUG GRANTS.**

15 *Section 5 of the Orphan Drug Act (21 U.S.C. 360ee)*
16 *is amended—*

17 *(1) in subsection (a), by striking paragraph (1)*
18 *and inserting the following: “(1) defraying the costs*
19 *of developing drugs for rare diseases or conditions, in-*
20 *cluding qualified testing expenses,”; and*

21 *(2) in subsection (b)(1)—*

22 *(A) in subparagraph (A)(ii), by striking*
23 *“and” after the semicolon;*

24 *(B) in subparagraph (B), by striking the*
25 *period and inserting “; and”; and*

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

2 “(C) prospectively planned and designed ob-
3 servational studies and other analyses conducted
4 to assist in the understanding of the natural his-
5 tory of a rare disease or condition and in the de-
6 velopment of a therapy, including studies and
7 analyses to—

8 “(i) develop or validate a drug develop-
9 ment tool related to a rare disease or condi-
10 tion; or

11 “(ii) understand the full spectrum of
12 the disease manifestations, including de-
13 scribing genotypic and phenotypic varia-
14 bility and identifying and defining distinct
15 subpopulations affected by a rare disease or
16 condition.”.

17 **SEC. 3016. GRANTS FOR STUDYING CONTINUOUS DRUG**
18 **MANUFACTURING.**

19 (a) *IN GENERAL.*—The Secretary of Health and
20 *Human Services* may award grants to institutions of higher
21 *education and nonprofit organizations for the purpose of*
22 *studying and recommending improvements to the process*
23 *of continuous manufacturing of drugs and biological prod-*
24 *ucts and similar innovative monitoring and control tech-*
25 *niques.*

1 (b) *DEFINITIONS.—In this section—*

2 (1) *the term “drug” has the meaning given such*
3 *term in section 201 of the Federal Food, Drug, and*
4 *Cosmetic Act (21 U.S.C. 321);*

5 (2) *the term “biological product” has the mean-*
6 *ing given such term in section 351(i) of the Public*
7 *Health Service Act (42 U.S.C. 262(i)); and*

8 (3) *the term “institution of higher education”*
9 *has the meaning given such term in section 101(a) of*
10 *the Higher Education Act of 1965 (20 U.S.C.*
11 *1001(a)).*

12 ***Subtitle C—Modern Trial Design***
13 ***and Evidence Development***

14 ***SEC. 3021. NOVEL CLINICAL TRIAL DESIGNS.***

15 (a) *PROPOSALS FOR USE OF NOVEL CLINICAL TRIAL*
16 *DESIGNS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For*
17 *purposes of assisting sponsors in incorporating complex*
18 *adaptive and other novel trial designs into proposed clinical*
19 *protocols and applications for new drugs under section 505*
20 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
21 *355) and biological products under section 351 of the Public*
22 *Health Service Act (42 U.S.C. 262), the Secretary of Health*
23 *and Human Services (referred to in this section as the “Sec-*
24 *retary”)* shall conduct a public meeting and issue guidance
25 *in accordance with subsection (b).*

1 **(b) GUIDANCE ADDRESSING USE OF NOVEL CLINICAL**
2 **TRIAL DESIGNS.**—

3 **(1) IN GENERAL.**—*The Secretary, acting through*
4 *the Commissioner of Food and Drugs, shall update or*
5 *issue guidance addressing the use of complex adaptive*
6 *and other novel trial design in the development and*
7 *regulatory review and approval or licensure for drugs*
8 *and biological products.*

9 **(2) CONTENTS.**—*The guidance under paragraph*
10 *(1) shall address—*

11 **(A)** *the use of complex adaptive and other*
12 *novel trial designs, including how such clinical*
13 *trials proposed or submitted help to satisfy the*
14 *substantial evidence standard under section*
15 *505(d) of the Federal Food, Drug, and Cosmetic*
16 *Act (21 U.S.C. 355(d));*

17 **(B)** *how sponsors may obtain feedback from*
18 *the Secretary on technical issues related to mod-*
19 *eling and simulations prior to—*

20 **(i)** *completion of such modeling or sim-*
21 *ulations; or*

22 **(ii)** *the submission of resulting infor-*
23 *mation to the Secretary;*

1 (C) the types of quantitative and qualitative
2 information that should be submitted for review;
3 and

4 (D) recommended analysis methodologies.

5 (3) *PUBLIC MEETING.*—Prior to updating or
6 issuing the guidance required by paragraph (1), the
7 Secretary shall consult with stakeholders, including
8 representatives of regulated industry, academia, pa-
9 tient advocacy organizations, consumer groups, and
10 disease research foundations, through a public meet-
11 ing to be held not later than 18 months after the date
12 of enactment of this Act.

13 (4) *TIMING.*—The Secretary shall update or issue
14 a draft version of the guidance required by paragraph
15 (1) not later than 18 months after the date of the pub-
16 lic meeting required by paragraph (3) and finalize
17 such guidance not later than 1 year after the date on
18 which the public comment period for the draft guid-
19 ance closes.

20 **SEC. 3022. REAL WORLD EVIDENCE.**

21 Chapter V of the Federal Food, Drug, and Cosmetic
22 Act is amended by inserting after section 505E (21 U.S.C.
23 355f) the following:

1 **“SEC. 505F. UTILIZING REAL WORLD EVIDENCE.**

2 “(a) *IN GENERAL.*—*The Secretary shall establish a*
3 *program to evaluate the potential use of real world evi-*
4 *dence—*

5 “(1) *to help to support the approval of a new in-*
6 *dications for a drug approved under section 505(c);*
7 *and*

8 “(2) *to help to support or satisfy postapproval*
9 *study requirements.*

10 “(b) *REAL WORLD EVIDENCE DEFINED.*—*In this sec-*
11 *tion, the term ‘real world evidence’ means data regarding*
12 *the usage, or the potential benefits or risks, of a drug de-*
13 *rived from sources other than randomized clinical trials.*

14 “(c) *PROGRAM FRAMEWORK.*—

15 “(1) *IN GENERAL.*—*Not later than 2 years after*
16 *the date of enactment of the 21st Century Cures Act,*
17 *the Secretary shall establish a draft framework for*
18 *implementation of the program under this section.*

19 “(2) *CONTENTS OF FRAMEWORK.*—*The frame-*
20 *work shall include information describing—*

21 “(A) *the sources of real world evidence, in-*
22 *cluding ongoing safety surveillance, observational*
23 *studies, registries, claims, and patient-centered*
24 *outcomes research activities;*

25 “(B) *the gaps in data collection activities;*

1 “(C) *the standards and methodologies for*
2 *collection and analysis of real world evidence;*
3 *and*

4 “(D) *the priority areas, remaining chal-*
5 *lenges, and potential pilot opportunities that the*
6 *program established under this section will ad-*
7 *dress.*

8 “(3) *CONSULTATION.—*

9 “(A) *IN GENERAL.—In developing the pro-*
10 *gram framework under this subsection, the Sec-*
11 *retary shall consult with regulated industry, aca-*
12 *demia, medical professional organizations, rep-*
13 *resentatives of patient advocacy organizations,*
14 *consumer organizations, disease research founda-*
15 *tions, and other interested parties.*

16 “(B) *PROCESS.—The consultation under*
17 *subparagraph (A) may be carried out through*
18 *approaches such as—*

19 “(i) *a public-private partnership with*
20 *the entities described in such subparagraph*
21 *in which the Secretary may participate;*

22 “(ii) *a contract, grant, or other ar-*
23 *rangement, as the Secretary determines ap-*
24 *propriate, with such a partnership or an*
25 *independent research organization; or*

1 “(iii) public workshops with the enti-
2 ties described in such subparagraph.

3 “(d) *PROGRAM IMPLEMENTATION.*—The Secretary
4 shall, not later than 2 years after the date of enactment
5 of the 21st Century Cures Act and in accordance with the
6 framework established under subsection (c), implement the
7 program to evaluate the potential use of real world evidence.

8 “(e) *GUIDANCE FOR INDUSTRY.*—The Secretary
9 shall—

10 “(1) utilize the program established under sub-
11 section (a), its activities, and any subsequent pilots or
12 written reports, to inform a guidance for industry
13 on—

14 “(A) the circumstances under which spon-
15 sors of drugs and the Secretary may rely on real
16 world evidence for the purposes described in
17 paragraphs (1) and (2) of subsection (a); and

18 “(B) the appropriate standards and meth-
19 odologies for collection and analysis of real world
20 evidence submitted for such purposes;

21 “(2) not later than 5 years after the date of en-
22 actment of the 21st Century Cures Act, issue draft
23 guidance for industry as described in paragraph (1);
24 and

1 “(3) not later than 18 months after the close of
2 the public comment period for the draft guidance de-
3 scribed in paragraph (2), issue revised draft guidance
4 or final guidance.

5 “(f) *RULE OF CONSTRUCTION.*—

6 “(1) *IN GENERAL.*—Subject to paragraph (2),
7 nothing in this section prohibits the Secretary from
8 using real world evidence for purposes not specified in
9 this section, provided the Secretary determines that
10 sufficient basis exists for any such nonspecified use.

11 “(2) *STANDARDS OF EVIDENCE AND SEC-*
12 *RETARY’S AUTHORITY.*—This section shall not be con-
13 strued to alter—

14 “(A) the standards of evidence under—

15 “(i) subsection (c) or (d) of section 505,
16 including the substantial evidence standard
17 in such subsection (d); or

18 “(ii) section 351(a) of the Public
19 Health Service Act; or

20 “(B) the Secretary’s authority to require
21 postapproval studies or clinical trials, or the
22 standards of evidence under which studies or
23 trials are evaluated.”.

1 **SEC. 3023. PROTECTION OF HUMAN RESEARCH SUBJECTS.**

2 (a) *IN GENERAL.*—*In order to simplify and facilitate*
3 *compliance by researchers with applicable regulations for*
4 *the protection of human subjects in research, the Secretary*
5 *of Health and Human Services (referred to in this section*
6 *as the “Secretary”) shall, to the extent practicable and con-*
7 *sistent with other statutory provisions, harmonize dif-*
8 *ferences between the HHS Human Subject Regulations and*
9 *the FDA Human Subject Regulations in accordance with*
10 *subsection (b).*

11 (b) *AVOIDING REGULATORY DUPLICATION AND UN-*
12 *NECESSARY DELAYS.*—*The Secretary shall, as appro-*
13 *priate—*

14 (1) *make such modifications to the provisions of*
15 *the HHS Human Subject Regulations, the FDA*
16 *Human Subject Regulations, and the vulnerable pop-*
17 *ulations rules as may be necessary—*

18 (A) *to reduce regulatory duplication and*
19 *unnecessary delays;*

20 (B) *to modernize such provisions in the con-*
21 *text of multisite and cooperative research*
22 *projects; and*

23 (C) *to protect vulnerable populations, incor-*
24 *porate local considerations, and support commu-*
25 *nity engagement through mechanisms such as*
26 *consultation with local researchers and human*

1 *research protection programs, in a manner con-*
2 *sistent with subparagraph (B); and*

3 (2) *ensure that human subject research that is*
4 *subject to the HHS Human Subject Regulations and*
5 *to the FDA Human Subject Regulations may—*

6 (A) *use joint or shared review;*

7 (B) *rely upon the review of—*

8 (i) *an independent institutional review*
9 *board; or*

10 (ii) *an institutional review board of an*
11 *entity other than the sponsor of the re-*
12 *search; or*

13 (C) *use similar arrangements to avoid du-*
14 *plication of effort.*

15 (c) *CONSULTATION.—In harmonizing or modifying*
16 *regulations or guidance under this section, the Secretary*
17 *shall consult with stakeholders (including researchers, aca-*
18 *demic organizations, hospitals, institutional research*
19 *boards, pharmaceutical, biotechnology, and medical device*
20 *developers, clinical research organizations, patient groups,*
21 *and others).*

22 (d) *TIMING.—The Secretary shall complete the harmo-*
23 *nization described in subsection (a) not later than 3 years*
24 *after the date of enactment of this Act.*

1 (e) *PROGRESS REPORT.*—Not later than 2 years after
2 the date of enactment of this Act, the Secretary shall submit
3 to Congress a report on the progress made toward com-
4 pleting such harmonization.

5 (f) *DEFINITIONS.*—

6 (1) *HUMAN SUBJECT REGULATIONS.*—In this
7 section:

8 (A) *FDA HUMAN SUBJECT REGULATIONS.*—
9 The term “*FDA Human Subject Regulations*”
10 means the provisions of parts 50, 56, 312, and
11 812 of title 21, Code of Federal Regulations (or
12 any successor regulations).

13 (B) *HHS HUMAN SUBJECT REGULA-*
14 *TIONS.*—The term “*HHS Human Subject Regu-*
15 *lations*” means the provisions of subpart A of
16 part 46 of title 45, Code of Federal Regulations
17 (or any successor regulations).

18 (C) *VULNERABLE POPULATION RULES.*—The
19 term “*vulnerable population rules*” means—

20 (i) except in the case of research de-
21 scribed in clause (ii), the provisions of sub-
22 parts B through D of part 46, Code of Fed-
23 eral Regulations (or any successor regula-
24 tions); and

1 (ii) in the case of research that is sub-
2 ject to FDA Human Subject Regulations,
3 the provisions applicable to vulnerable pop-
4 ulations under part 56 of title 21, Code of
5 Federal Regulations (or any successor regu-
6 lations) and subpart D of part 50 of such
7 title 21 (or any successor regulations).

8 (2) *INSTITUTIONAL REVIEW BOARD DEFINED.*—
9 In this section, the term “institutional review board”
10 has the meaning that applies to the term “institu-
11 tional review board” under the HHS Human Subject
12 Regulations.

13 **SEC. 3024. INFORMED CONSENT WAIVER OR ALTERATION**
14 **FOR CLINICAL INVESTIGATIONS.**

15 (a) *DEVICES.*—Section 520(g)(3) of the Federal Food,
16 *Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3))* is amend-
17 *ed—*

18 (1) in subparagraph (D), by striking “except
19 where subject to such conditions as the Secretary may
20 prescribe, the investigator” and inserting the fol-
21 lowing: “except where, subject to such conditions as
22 the Secretary may prescribe—

23 “(i) the proposed clinical testing poses no
24 more than minimal risk to the human subject
25 and includes appropriate safeguards to protect

1 *the rights, safety, and welfare of the human sub-*
2 *ject; or*

3 “(i) the investigator”; and

4 (2) in the matter following subparagraph (D), by
5 striking “subparagraph (D)” and inserting “subpara-

6 graph (D)(i)”.

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 test-

13 ing poses no more than minimal risk to such human beings
14 and includes appropriate safeguards as prescribed to pro-

15 tect the rights, safety, and welfare of such human beings”.

16 ***Subtitle D—Patient Access to***
17 ***Therapies and Information***

18 ***SEC. 3031. SUMMARY LEVEL REVIEW.***

19 (a) *FFDCA*.—Section 505(c) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 355(c)) is amended by
21 adding at the end the following:

22 “(5)(A) The Secretary may rely upon qualified data
23 summaries to support the approval of a supplemental ap-

24 plication, with respect to a qualified indication for a drug,

1 *submitted under subsection (b), if such supplemental appli-*
2 *cation 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 Pub-*

1 *lic Health Service Act for which the Secretary made*
2 *use of full data sets in addition to the qualified data*
3 *summary.*

4 “(D) *In this paragraph—*

5 “(i) *the term ‘qualified indication’ means an in-*
6 *dications 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 a*
10 *summary of clinical data that demonstrates the safety*
11 *and effectiveness of a drug with respect to a qualified*
12 *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 appli-*
20 *cation complies with the requirements of subparagraph (B)*
21 *of section 505(c)(5) of the Federal Food, Drug, and Cos-*
22 *metic Act.*

23 “(ii) *In this subparagraph, the terms ‘qualified indica-*
24 *tion’ 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, mon-*
11 *itoring, or treatment of one or more serious diseases or con-*
12 *ditions shall make available the policy of the manufacturer*
13 *or distributor on evaluating and responding to requests sub-*
14 *mitted under section 561(b) for provision of such a drug.*

15 *“(b) PUBLIC AVAILABILITY OF EXPANDED ACCESS*
16 *POLICY.—The policies under subsection (a) shall be made*
17 *public and readily available, such as by posting such poli-*
18 *cies on a publicly available Internet website. Such policies*
19 *may be generally applicable to all investigational drugs of*
20 *such manufacturer or distributor.*

21 *“(c) CONTENT OF POLICY.—A policy described in sub-*
22 *section (a) shall include—*

23 *“(1) contact information for the manufacturer or*
24 *distributor to facilitate communication about requests*
25 *described in subsection (a);*

1 “(2) procedures for making such requests;

2 “(3) the general criteria the manufacturer or dis-
3 tributor will use to evaluate such requests for indi-
4 vidual patients, and for responses to such requests;

5 “(4) the length of time the manufacturer or dis-
6 tributor anticipates will be necessary to acknowledge
7 receipt of such requests; and

8 “(5) a hyperlink or other reference to the clinical
9 trial record containing information about the ex-
10 panded access for such drug that is required under
11 section 402(j)(2)(A)(ii)(II)(gg) of the Public Health
12 Service Act.

13 “(d) *NO GUARANTEE OF ACCESS.*—The posting of
14 policies by manufacturers and distributors under subsection
15 (a) shall not serve as a guarantee of access to any specific
16 investigational drug by any individual patient.

17 “(e) *REVISED POLICY.*—Nothing in this section shall
18 prevent a manufacturer or distributor from revising a pol-
19 icy required under this section at any time.

20 “(f) *APPLICATION.*—This section shall apply to a man-
21 ufacturer or distributor with respect to an investigational
22 drug beginning on the later of—

23 “(1) the date that is 60 calendar days after the
24 date of enactment of the 21st Century Cures Act; or

1 “(2) the first initiation of a phase 2 or phase 3
2 study (as such terms are defined in section 312.21(b)
3 and (c) of title 21, Code of Federal Regulations (or
4 any successor regulations)) with respect to such inves-
5 tigational drug.”.

6 **SEC. 3033. ACCELERATED APPROVAL FOR REGENERATIVE**
7 **ADVANCED THERAPIES.**

8 (a) *IN GENERAL.*—Section 506 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

10 (1) by transferring subsection (e) (relating to
11 construction) so that it appears before subsection (f)
12 (relating to awareness efforts); and

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

14 “(g) *REGENERATIVE ADVANCED THERAPY.*—

15 “(1) *IN GENERAL.*—The Secretary, at the request
16 of the sponsor of a drug, shall facilitate an efficient
17 development program for, and expedite review of, such
18 drug if the drug qualifies as a regenerative advanced
19 therapy under the criteria described in paragraph
20 (2).

21 “(2) *CRITERIA.*—A drug is eligible for designa-
22 tion as a regenerative advanced therapy under this
23 subsection if—

24 “(A) the drug is a regenerative medicine
25 therapy (as defined in paragraph (8));

1 “(B) the drug is intended to treat, modify,
2 reverse, or cure a serious or life-threatening dis-
3 ease or condition; and

4 “(C) preliminary clinical evidence indicates
5 that the drug has the potential to address unmet
6 medical needs for such a disease or condition.

7 “(3) *REQUEST FOR DESIGNATION.*—The sponsor
8 of a drug may request the Secretary to designate the
9 drug as a regenerative advanced therapy concurrently
10 with, or at any time after, submission of an applica-
11 tion for the investigation of the drug under section
12 505(i) of this Act or section 351(a)(3) of the Public
13 Health Service Act.

14 “(4) *DESIGNATION.*—Not later than 60 calendar
15 days after the receipt of a request under paragraph
16 (3), the Secretary shall determine whether the drug
17 that is the subject of the request meets the criteria de-
18 scribed in paragraph (2). If the Secretary determines
19 that the drug meets the criteria, the Secretary shall
20 designate the drug as a regenerative advanced therapy
21 and shall take such actions as are appropriate under
22 paragraph (1). If the Secretary determines that a
23 drug does not meet the criteria for such designation,
24 the Secretary shall include with the determination a

1 *written description of the rationale for such deter-*
2 *mination.*

3 “(5) *ACTIONS.*—*The sponsor of a regenerative*
4 *advanced therapy shall be eligible for the actions to*
5 *expedite development and review of such therapy*
6 *under subsection (a)(3)(B), including early inter-*
7 *actions to discuss any potential surrogate or inter-*
8 *mediate endpoint to be used to support the accelerated*
9 *approval of an application for the product under sub-*
10 *section (c).*

11 “(6) *ACCESS TO EXPEDITED APPROVAL PATH-*
12 *WAYS.*—*An application for a regenerative advanced*
13 *therapy under section 505(b)(1) of this Act or section*
14 *351(a) of the Public Health Service Act may be—*

15 “(A) *eligible for priority review, as de-*
16 *scribed in the Manual of Policies and Procedures*
17 *of the Food and Drug Administration and goals*
18 *identified in the letters described in section*
19 *101(b) of the Prescription Drug User Fee*
20 *Amendments of 2012; and*

21 “(B) *eligible for accelerated approval under*
22 *subsection (c), as agreed upon pursuant to sub-*
23 *section (a)(3)(B), through, as appropriate—*

1 “(i) surrogate or intermediate
2 endpoints reasonably likely to predict long-
3 term clinical benefit; or

4 “(ii) reliance upon data obtained from
5 a meaningful number of sites, including
6 through expansion to additional sites, as
7 appropriate.

8 “(7) *POSTAPPROVAL REQUIREMENTS.*—The spon-
9 sor of a regenerative advanced therapy that is granted
10 accelerated approval and is subject to the post-
11 approval requirements under subsection (c) may, as
12 appropriate, fulfill such requirements, as the Sec-
13 retary may require, through—

14 “(A) the submission of clinical evidence,
15 clinical studies, patient registries, or other
16 sources of real world evidence, such as electronic
17 health records;

18 “(B) the collection of larger confirmatory
19 data sets, as agreed upon pursuant to subsection
20 (a)(3)(B); or

21 “(C) postapproval monitoring of all pa-
22 tients treated with such therapy prior to ap-
23 proval of the therapy.

24 “(8) *DEFINITION.*—For purposes of this section,
25 the term ‘regenerative medicine therapy’ includes cell

1 *therapy, therapeutic tissue engineering products,*
2 *human cell and tissue products, and combination*
3 *products using any such therapies or products, except*
4 *for those regulated solely under section 361 of the*
5 *Public Health Service Act and part 1271 of title 21,*
6 *Code of Federal Regulations.”.*

7 ***(b) RULE OF CONSTRUCTION.***—*Nothing in this section*
8 *and the amendments made by this section shall be construed*
9 *to alter the authority of the Secretary of Health and*
10 *Human Services—*

11 *(1) to approve drugs pursuant to the Federal*
12 *Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)*
13 *and section 351 of the Public Health Service Act (42*
14 *U.S.C. 262) as authorized prior to the date of enact-*
15 *ment of the 21st Century Cures Act, including the*
16 *standards of evidence, and applicable conditions, for*
17 *approval under such Acts; or*

18 *(2) to alter the authority of the Secretary to re-*
19 *quire postapproval studies pursuant to such Acts, as*
20 *authorized prior to the date of enactment of the 21st*
21 *Century Cures Act.*

22 ***(c) CONFORMING AMENDMENT.***—*Section 506(e)(1) of*
23 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
24 *356(e)(1)) is amended by inserting “and the 21st Century*

1 *Cures Act*” after “*Food and Drug Administration Safety*
2 *and Innovation Act*”.

3 **SEC. 3034. GUIDANCE REGARDING DEVICES USED IN THE**
4 **RECOVERY, ISOLATION, OR DELIVERY OF RE-**
5 **GENERATIVE ADVANCED THERAPIES.**

6 (a) *DRAFT GUIDANCE.*—Not later than 1 year after
7 the date of enactment of the 21st Century Cures Act, the
8 Secretary of Health and Human Services, acting through
9 the Commissioner of Food and Drugs, shall issue draft guid-
10 ance clarifying how, in the context of regenerative advanced
11 therapies, the Secretary will evaluate devices used in the
12 recovery, isolation, or delivery of regenerative advanced
13 therapies. In doing so, the Secretary shall specifically ad-
14 dress—

15 (1) *how the Food and Drug Administration in-*
16 *tends to simplify and streamline regulatory require-*
17 *ments for combination device and cell or tissue prod-*
18 *ucts;*

19 (2) *what, if any, intended uses or specific at-*
20 *tributes would result in a device used with a regen-*
21 *erative therapy product to be classified as a class III*
22 *device;*

23 (3) *when the Food and Drug Administration*
24 *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 approach
4 to demonstrate how a device may be used with more
5 than one cell type.

6 (b) *FINAL GUIDANCE*.—Not later than 12 months after
7 the close of the period for public comment on the draft guid-
8 ance under subsection (a), the Secretary of Health and
9 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 Services
14 shall, with respect to the previous calendar year, submit a
15 report to the Committee on Health, Education, Labor, and
16 Pensions of the Senate and the Committee on Energy and
17 Commerce of the House of Representatives on—

18 (1) the number and type of applications for ap-
19 proval of regenerative advanced therapies filed, ap-
20 proved or licensed as applicable, withdrawn, or de-
21 nied; and

22 (2) how many of such applications or therapies,
23 as applicable, were granted accelerated approval or
24 priority review.

1 (b) *REGENERATIVE ADVANCED THERAPY.*—*In this sec-*
2 *tion, 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, Drug,*
9 *and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by*
10 *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 manufacturers*
18 *and clinical trial sponsors, contract manufacturers, aca-*
19 *demic institutions, practicing clinicians, regenerative medi-*
20 *cine and advanced therapies industry organizations, and*
21 *standard setting organizations), shall facilitate an effort to*
22 *coordinate and prioritize the development of standards and*
23 *consensus definition of terms, through a public process, to*
24 *support, through regulatory predictability, the development,*
25 *evaluation, and review of regenerative medicine therapies*

1 *and regenerative advanced therapies, including with respect*
2 *to the manufacturing processes and controls of such prod-*
3 *ucts.*

4 “(b) *ACTIVITIES.—*

5 “(1) *IN GENERAL.—In carrying out this section,*
6 *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 de-*
22 *scribed in subsection (a), the Secretary shall review*
23 *relevant regulations and guidance and, through a*
24 *public process, update such regulations and guidance*
25 *as the Secretary determines appropriate.*

1 “(c) *DEFINITIONS.*—For purposes of this section, the
2 terms ‘regenerative medicine therapy’ and ‘regenerative ad-
3 vanced therapy’ have the meanings given such terms in sec-
4 tion 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 “(a)(1)
9 *If its*”;

10 (2) by striking “a formulary committee, or other
11 similar entity, in the course of the committee or the
12 entity carrying out its responsibilities for the selec-
13 tion of drugs for managed care or other similar orga-
14 nizations” and inserting “a payor, formulary com-
15 mittee, or other similar entity with knowledge and ex-
16 pertise in the area of health care economic analysis,
17 carrying out its responsibilities for the selection of
18 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 forth
23 in section 505(a) or in section 351(a) of the Public
24 Health Service Act shall not apply to health care eco-
25 nomic information provided to such a committee or

1 *entity in accordance with this paragraph” and in-*
2 *serting “, is based on competent and reliable scientific*
3 *evidence, and includes, where applicable, a con-*
4 *spicuous and prominent statement describing any*
5 *material differences between the health care economic*
6 *information and the labeling approved for the drug*
7 *under section 505 or under section 351 of the Public*
8 *Health Service Act. The requirements set forth in sec-*
9 *tion 505(a) or in subsections (a) and (k) of section*
10 *351 of the Public Health Service Act shall not apply*
11 *to health care economic information provided to such*
12 *a payor, committee, or entity in accordance with this*
13 *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 or*
20 *comprising the analysis) that identifies, measures, or de-*
21 *scribes the economic consequences, which may be based on*
22 *the separate or aggregated clinical consequences of the rep-*
23 *resented health outcomes, of the use of a drug. Such analysis*
24 *may be comparative to the use of another drug, to another*
25 *health care intervention, or to no intervention.*

1 “(B) Such term does not include any analysis that re-
2 lates only to an indication that is not approved under sec-
3 tion 505 or under section 351 of the Public Health Service
4 Act for such drug.”.

5 **SEC. 3038. COMBINATION PRODUCT INNOVATION.**

6 (a) *IN GENERAL.*—Section 503(g) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 353(g)) is amended—

8 (1) by striking paragraph (3);

9 (2) by redesignating paragraph (2) as para-
10 graph (7);

11 (3) by redesignating paragraphs (4) and (5) as
12 paragraphs (8) and (9), respectively;

13 (4) by striking “(g)(1)” and all that follows
14 through the end of paragraph (1) and inserting the
15 following:

16 “(g)(1)(A) The Secretary shall, in accordance with this
17 subsection, assign a primary agency center to regulate
18 products that constitute a combination of a drug, device,
19 or biological product.

20 “(B) The Secretary shall conduct the premarket review
21 of any combination product under a single application,
22 whenever appropriate.

23 “(C) For purposes of this subsection, the term ‘primary
24 mode of action’ means the single mode of action of a com-
25 bination product expected to make the greatest contribution

1 *to the overall intended therapeutic effects of the combination*
2 *product.*

3 “(D) *The Secretary shall determine the primary mode*
4 *of action of the combination product. If the Secretary deter-*
5 *mines that the primary mode of action is that of—*

6 “(i) *a drug (other than a biological product), the*
7 *agency center charged with premarket review of drugs*
8 *shall have primary jurisdiction;*

9 “(ii) *a device, the agency center charged with*
10 *premarket review of devices shall have primary juris-*
11 *isdiction; or*

12 “(iii) *a biological product, the agency center*
13 *charged with premarket review of biological products*
14 *shall have primary jurisdiction.*

15 “(E) *In determining the primary mode of action of*
16 *a combination product, the Secretary shall not determine*
17 *that the primary mode of action is that of a drug or biologi-*
18 *cal product solely because the combination product has any*
19 *chemical action within or on the human body.*

20 “(F) *If a sponsor of a combination product disagrees*
21 *with the determination under subparagraph (D)—*

22 “(i) *such sponsor may request, and the Secretary*
23 *shall provide, a substantive rationale to such sponsor*
24 *that references scientific evidence provided by the*

1 *sponsor and any other scientific evidence relied upon*
2 *by the Secretary to support such determination; and*

3 *“(i)(I) the sponsor of the combination product*
4 *may propose one or more studies (which may be non-*
5 *clinical, clinical, or both) to establish the relevance, if*
6 *any, of the chemical action in achieving the primary*
7 *mode of action of such product;*

8 *“(II) if the sponsor proposes any such studies,*
9 *the Secretary and the sponsor of such product shall*
10 *collaborate and seek to reach agreement, within a rea-*
11 *sonable time of such proposal, not to exceed 90 cal-*
12 *endar days, on the design of such studies; and*

13 *“(III) if an agreement is reached under sub-*
14 *clause (II) and the sponsor conducts one or more of*
15 *such studies, the Secretary shall consider the data re-*
16 *sulting from any such study when reevaluating the*
17 *determination of the primary mode of action of such*
18 *product, and unless and until such reevaluation has*
19 *occurred and the Secretary issues a new determina-*
20 *tion, the determination of the Secretary under sub-*
21 *paragraph (D) shall remain in effect.*

22 *“(2)(A)(i) To establish clarity and certainty for the*
23 *sponsor, the sponsor of a combination product may request*
24 *a meeting on such combination product. If the Secretary*
25 *concludes that a determination of the primary mode of ac-*

1 *tion pursuant to paragraph (1)(D) is necessary, the sponsor*
2 *may request such meeting only after the Secretary makes*
3 *such determination. If the sponsor submits a written meet-*
4 *ing request, the Secretary shall, not later than 75 calendar*
5 *days after receiving such request, meet with the sponsor of*
6 *such combination product.*

7 *“(ii) A meeting under clause (i) may—*

8 *“(I) address the standards and requirements for*
9 *market approval or clearance of the combination*
10 *product;*

11 *“(II) address other issues relevant to such com-*
12 *bination product, such as requirements related to*
13 *postmarket modification of such combination product*
14 *and good manufacturing practices applicable to such*
15 *combination product; and*

16 *“(III) identify elements under subclauses (I) and*
17 *(II) that may be more appropriate for discussion and*
18 *agreement with the Secretary at a later date given*
19 *that scientific or other information is not available,*
20 *or agreement is otherwise not feasible regarding such*
21 *elements, at the time a request for such meeting is*
22 *made.*

23 *“(iii) Any agreement under this subparagraph shall*
24 *be in writing and made part of the administrative record*
25 *by the Secretary.*

1 “(iv) Any such agreement shall remain in effect, ex-
2 cept—

3 “(I) upon the written agreement of the Secretary
4 and the sponsor or applicant; or

5 “(II) pursuant to a decision by the director of
6 the reviewing division of the primary agency center,
7 or a person more senior than such director, in con-
8 sultation with consulting centers and the Office, as
9 appropriate, that an issue essential to determining
10 whether the standard for market clearance or other
11 applicable standard under this Act or the Public
12 Health Service Act applicable to the combination
13 product has been identified since the agreement was
14 reached, or that deviating from the agreement is oth-
15 erwise justifiable based on scientific evidence, for pub-
16 lic health reasons.

17 “(3) For purposes of conducting the premarket review
18 of a combination product that contains an approved con-
19 stituent part described in paragraph (4), the Secretary may
20 require that the sponsor of such combination product sub-
21 mit to the Secretary only data or information that the Sec-
22 retary determines is necessary to meet the standard for
23 clearance or approval, as applicable, under this Act or the
24 Public Health Service Act, including any incremental risks
25 and benefits posed by such combination product, using a

1 *risk-based approach and taking into account any prior*
2 *finding of safety and effectiveness or substantial equivalence*
3 *for the approved constituent part relied upon by the appli-*
4 *cant in accordance with paragraph (5).*

5 “(4) *For purposes of paragraph (3), an approved con-*
6 *stituent part is—*

7 “(A) *a drug constituent part of a combination*
8 *product being reviewed in a single application or re-*
9 *quest under section 515, 510(k), or 513(f)(2) (sub-*
10 *mitted in accordance with paragraph (5)), that is an*
11 *approved drug, provided such application or request*
12 *complies with paragraph (5);*

13 “(B) *a device constituent part approved under*
14 *section 515 that is referenced by the sponsor and that*
15 *is available for use by the Secretary under section*
16 *520(h)(4); or*

17 “(C) *any constituent part that was previously*
18 *approved, cleared, or classified under section 505,*
19 *510(k), 513(f)(2), or 515 of this Act for which the*
20 *sponsor has a right of reference or any constituent*
21 *part that is a nonprescription drug, as defined in sec-*
22 *tion 760(a)(2).*

23 “(5)(A) *If an application is submitted under section*
24 *515 or 510(k) or a request is submitted under section*
25 *513(f)(2), consistent with any determination made under*

1 *paragraph (1)(D), for a combination product containing as*
2 *a constituent part an approved drug—*

3 *“(i) the application or request shall include the*
4 *certification or statement described in section*
5 *505(b)(2); and*

6 *“(ii) the applicant or requester shall provide no-*
7 *tice as described in section 505(b)(3).*

8 *“(B) For purposes of this paragraph and paragraph*
9 *(4), the term ‘approved drug’ means an active ingredient—*

10 *“(i) that was in an application previously ap-*
11 *proved under section 505(c);*

12 *“(ii) where such application is relied upon by*
13 *the applicant submitting the application or request*
14 *described in subparagraph (A);*

15 *“(iii) for which full reports of investigations that*
16 *have been made to show whether such drug is safe for*
17 *use and whether such drug is effective in use were not*
18 *conducted by or for the applicant submitting the ap-*
19 *plication or request described in subparagraph (A);*
20 *and*

21 *“(iv) for which the applicant submitting the ap-*
22 *plication or request described in subparagraph (A)*
23 *has not obtained a right of reference or use from the*
24 *person by or for whom the investigations described in*
25 *clause (iii) were conducted.*

1 “(C) *The following provisions shall apply with respect*
2 *to an application or request described in subparagraph (A)*
3 *to the same extent and in the same manner as if such appli-*
4 *cation or request were an application described in section*
5 *505(b)(2) that referenced the approved drug:*

6 “(i) *Subparagraphs (A), (B), (C), and (D) of*
7 *section 505(c)(3).*

8 “(ii) *Clauses (ii), (iii), and (iv) of section*
9 *505(c)(3)(E).*

10 “(iii) *Subsections (b) and (c) of section 505A.*

11 “(iv) *Section 505E(a).*

12 “(v) *Section 527(a).*

13 “(D) *Notwithstanding any other provision of this sub-*
14 *section, an application or request for classification for a*
15 *combination product described in subparagraph (A) shall*
16 *be considered an application submitted under section*
17 *505(b)(2) for purposes of section 271(e)(2)(A) of title 35,*
18 *United States Code.*

19 “(6) *Nothing in this subsection shall be construed as*
20 *prohibiting a sponsor from submitting separate applica-*
21 *tions for the constituent parts of a combination product,*
22 *unless the Secretary determines that a single application*
23 *is necessary.”;*

24 (5) *in paragraph (8) (as redesignated by para-*
25 *graph (3))—*

1 (A) in subparagraph (C)—

2 (i) by amending clause (i) to read as
3 follows:

4 “(i) In carrying out this subsection, the Office shall
5 help to ensure timely and effective premarket review that
6 involves more than one agency center by coordinating such
7 reviews, overseeing the timeliness of such reviews, and over-
8 seeing the alignment of feedback regarding such reviews.”;

9 (ii) in clause (ii), by inserting “and
10 alignment” after “the timeliness” each place
11 it appears; and

12 (iii) by adding at the end the following
13 new clauses:

14 “(iii) The Office shall ensure that, with respect to a
15 combination product, a designated person or persons in the
16 primary agency center is the primary point or points of
17 contact for the sponsor of such combination product. The
18 Office shall also coordinate communications to and from
19 any consulting center involved in such premarket review,
20 if requested by such primary agency center or any such con-
21 sulting center. Agency communications and commitments,
22 to the extent consistent with other provisions of law and
23 the requirements of all affected agency centers, from the pri-
24 mary agency center shall be considered as communication

1 *from the Secretary on behalf of all agency centers involved*
2 *in the review.*

3 “(iv) *The Office shall, with respect to the premarket*
4 *review of a combination product—*

5 “(I) *ensure that any meeting between the Sec-*
6 *retary and the sponsor of such product is attended by*
7 *each agency center involved in the review, as appro-*
8 *priate;*

9 “(II) *ensure that each consulting agency center*
10 *has completed its premarket review and provided the*
11 *results of such review to the primary agency center in*
12 *a timely manner; and*

13 “(III) *ensure that each consulting center follows*
14 *the guidance described in clause (vi) and advises, as*
15 *appropriate, on other relevant regulations, guidances,*
16 *and policies.*

17 “(v) *In seeking agency action with respect to a com-*
18 *ination product, the sponsor of such product—*

19 “(I) *shall identify the product as a combination*
20 *product; and*

21 “(II) *may request in writing the participation of*
22 *representatives of the Office in meetings related to*
23 *such combination product, or to have the Office other-*
24 *wise engage on such regulatory matters concerning*
25 *the combination product.*

1 “(vi) Not later than 4 years after the date of enactment
2 of the 21st Century Cures Act, and after a public comment
3 period of not less than 60 calendar days, the Secretary shall
4 issue a final guidance that describes—

5 “(I) the structured process for managing pre-sub-
6 mission interactions with sponsors developing com-
7 bination products;

8 “(II) the best practices for ensuring that the feed-
9 back in such pre-submission interactions represents
10 the Agency’s best advice based on the information pro-
11 vided during such pre-submission interactions;

12 “(III) the information that is required to be sub-
13 mitted with a meeting request under paragraph (2),
14 how such meetings relate to other types of meetings in
15 the Food and Drug Administration, and the form and
16 content of any agreement reached through a meeting
17 under such paragraph (2);”;

18 (B) in subparagraph (G)—

19 (i) in the matter preceding clause (i),
20 by inserting “(except with respect to clause
21 (iv), beginning not later than one year after
22 the date of the enactment of the 21st Cen-
23 tury Cures Act)” after “enactment of this
24 paragraph”;

1 (ii) in clause (ii), by striking “and” at
2 the end;

3 (iii) in clause (iii), by striking the pe-
4 riod at the end and inserting “; and”; and

5 (iv) by adding at the end the following
6 new clause:

7 “(iv) identifying the percentage of combination
8 products for which a dispute resolution, with respect
9 to premarket review, was requested by the combina-
10 tion product’s sponsor.”; and

11 (6) in paragraph (9) (as redesignated by para-
12 graph (3))—

13 (A) in subparagraph (C)—

14 (i) in clause (i), by striking the comma
15 at the end and inserting a semicolon;

16 (ii) in clause (ii), by striking “, and”
17 at the end and inserting a semicolon;

18 (iii) in clause (iii), by striking the pe-
19 riod at the end and inserting “; and”; and

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

21 “(iv) de novo classification under sec-
22 tion 513(a)(1).”; and

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

24 “(D) The terms ‘premarket review’ and ‘reviews’
25 include all activities of the Food and Drug Adminis-

1 *tration conducted prior to approval or clearance of*
2 *an application, notification, or request for classifica-*
3 *tion submitted under section 505, 510(k), 513(f)(2),*
4 *515, or 520 of this Act or under section 351 of the*
5 *Public Health Service Act, including with respect to*
6 *investigational use of the product.”.*

7 *(b) INFORMATION FOR APPROVAL OF COMBINATION*
8 *PRODUCTS.—Section 520(h)(4) of the Federal Food, Drug,*
9 *and Cosmetic Act (21 U.S.C. 360j(h)(4)) is amended—*

10 *(1) in subparagraph (A), by striking “Any infor-*
11 *mation” and inserting “Subject to subparagraph (C),*
12 *any information”; and*

13 *(2) by adding at the end the following new sub-*
14 *paragraph:*

15 *“(C) No information contained in an application for*
16 *premarket approval filed with the Secretary pursuant to*
17 *section 515(c) may be used to approve or clear any applica-*
18 *tion submitted under section 515 or 510(k) or to classify*
19 *a product under section 513(f)(2) for a combination product*
20 *containing as a constituent part an approved drug (as de-*
21 *finied in section 503(g)(5)(B)) unless—*

22 *“(i) the application includes the certification or*
23 *statement referenced in section 503(g)(5)(A);*

24 *“(ii) the applicant provides notice as described*
25 *in section 503(g)(5)(A); and*

1 “(iii) the Secretary’s approval of such applica-
2 tion is subject to the provisions in section
3 503(g)(5)(C).”.

4 (c) *VARIATIONS FROM CGMP STREAMLINED AP-
5 PROACH.*—Not later than 18 months after the date of enact-
6 ment of this Act, the Secretary of Health and Human Serv-
7 ices (referred to in this subsection as the “Secretary”) shall
8 identify types of combination products and manufacturing
9 processes with respect to which the Secretary proposes that
10 good manufacturing processes may be adopted that vary
11 from the requirements set forth in section 4.4 of title 21,
12 Code of Federal Regulations (or any successor regulations)
13 or that the Secretary proposes can satisfy the requirements
14 in section 4.4 through alternative or streamlined mecha-
15 nisms. The Secretary shall identify such types, variations
16 from such requirements, and such mechanisms, in a pro-
17 posed list published in the Federal Register. After a public
18 comment period regarding the appropriate good manufac-
19 turing practices for such types, the Secretary shall publish
20 a final list in the Federal Register, notwithstanding section
21 553 of title 5, United States Code. The Secretary shall
22 evaluate such types, variations, and mechanisms using a
23 risk-based approach. The Secretary shall periodically re-
24 view such final list.

1 ***Subtitle E—Antimicrobial***
2 ***Innovation and Stewardship***

3 **SEC. 3041. ANTIMICROBIAL RESISTANCE MONITORING.**

4 (a) *IN GENERAL.*—Section 319E of the Public Health
5 Service Act (42 U.S.C. 247d–5) is amended—

6 (1) *by redesignating subsections (f) and (g) as*
7 *subsections (l) and (m), respectively; and*

8 (2) *by inserting after subsection (e), the fol-*
9 *lowing:*

10 “(f) *MONITORING AT FEDERAL HEALTH CARE FACILI-*
11 *TIES.*—The Secretary shall encourage reporting on aggre-
12 gate antimicrobial drug use and antimicrobial resistance
13 to antimicrobial drugs and the implementation of anti-
14 microbial stewardship programs by health care facilities of
15 the Department of Defense, the Department of Veterans Af-
16 fairs, and the Indian Health Service and shall provide tech-
17 nical assistance to the Secretary of Defense and the Sec-
18 retary of Veterans Affairs, as appropriate and upon request.

19 “(g) *REPORT ON ANTIMICROBIAL RESISTANCE IN HU-*
20 *MANS AND USE OF ANTIMICROBIAL DRUGS.*—Not later than
21 1 year after the date of enactment of the 21st Century Cures
22 Act, and annually thereafter, the Secretary shall prepare
23 and make publicly available data and information con-
24 cerning—

1 “(1) aggregate national and regional trends of
2 antimicrobial resistance in humans to antimicrobial
3 drugs, including such drugs approved under section
4 506(h) of the Federal Food, Drug, and Cosmetic Act;

5 “(2) antimicrobial stewardship, which may in-
6 clude summaries of State efforts to address anti-
7 microbial resistance in humans to antimicrobial
8 drugs and antimicrobial stewardship; and

9 “(3) coordination between the Director of the
10 Centers for Disease Control and Prevention and the
11 Commissioner of Food and Drugs with respect to the
12 monitoring of—

13 “(A) any applicable resistance under para-
14 graph (1); and

15 “(B) drugs approved under section 506(h)
16 of the Federal Food, Drug, and Cosmetic Act.

17 “(h) *INFORMATION RELATED TO ANTIMICROBIAL*
18 *STEWARDSHIP PROGRAMS.*—The Secretary shall, as appro-
19 priate, disseminate guidance, educational materials, or
20 other appropriate materials related to the development and
21 implementation of evidence-based antimicrobial steward-
22 ship programs or practices at health care facilities, such
23 as nursing homes and other long-term care facilities, ambu-
24 latory surgical centers, dialysis centers, outpatient clinics,
25 and hospitals, including community and rural hospitals.

1 “(i) *SUPPORTING STATE-BASED ACTIVITIES TO COM-*
2 *BAT ANTIMICROBIAL RESISTANCE.*—*The Secretary shall*
3 *continue to work with State and local public health depart-*
4 *ments on statewide or regional programs related to anti-*
5 *microbial resistance. Such efforts may include activities to*
6 *related to—*

7 “(1) *identifying patterns of bacterial and fungal*
8 *resistance in humans to antimicrobial drugs;*

9 “(2) *preventing the spread of bacterial and*
10 *fungal infections that are resistant to antimicrobial*
11 *drugs; and*

12 “(3) *promoting antimicrobial stewardship.*

13 “(j) *ANTIMICROBIAL RESISTANCE AND STEWARDSHIP*
14 *ACTIVITIES.*—

15 “(1) *IN GENERAL.*—*For the purposes of sup-*
16 *porting stewardship activities, examining changes in*
17 *antimicrobial resistance, and evaluating the effective-*
18 *ness of section 506(h) of the Federal Food, Drug, and*
19 *Cosmetic Act, the Secretary shall—*

20 “(A) *provide a mechanism for facilities to*
21 *report data related to their antimicrobial stew-*
22 *ardship activities (including analyzing the out-*
23 *comes of such activities); and*

24 “(B) *evaluate—*

1 “(i) antimicrobial resistance data
2 using a standardized approach; and

3 “(ii) trends in the utilization of drugs
4 approved under such section 506(h) with re-
5 spect to patient populations.

6 “(2) USE OF SYSTEMS.—The Secretary shall use
7 available systems, including the National Healthcare
8 Safety Network or other systems identified by the Sec-
9 retary, to fulfill the requirements or conduct activities
10 under this section.

11 “(k) ANTIMICROBIAL.—For purposes of subsections (f)
12 through (j), the term ‘antimicrobial’ includes any anti-
13 bacterial or antifungal drugs, and may include drugs that
14 eliminate or inhibit the growth of other microorganisms,
15 as appropriate.”.

16 “(b) AVAILABILITY OF DATA.—The Secretary shall
17 make the data collected pursuant to this subsection public.
18 Nothing in this subsection shall be construed as authorizing
19 the Secretary to disclose any information that is a trade
20 secret or confidential information subject to section
21 552(b)(4) of title 5, United States Code, or section 1905
22 of title 18, United States Code.

1 **SEC. 3042. LIMITED POPULATION PATHWAY.**

2 *Section 506 of the Federal Food, Drug, and Cosmetic*
3 *Act (21 U.S.C. 356), as amended by section 3033, is further*
4 *amended by adding at the end the following:*

5 *“(h) LIMITED POPULATION PATHWAY FOR ANTI-*
6 *BACTERIAL AND ANTIFUNGAL DRUGS.—*

7 *“(1) IN GENERAL.—The Secretary may approve*
8 *an antibacterial or antifungal drug, alone or in com-*
9 *bination with one or more other drugs, as a limited*
10 *population drug pursuant to this subsection only if—*

11 *“(A) the drug is intended to treat a serious*
12 *or life-threatening infection in a limited popu-*
13 *lation of patients with unmet needs;*

14 *“(B) the standards for approval under sec-*
15 *tion 505(c) and (d), or the standards for licen-*
16 *sure under section 351 of the Public Health*
17 *Service Act, as applicable, are met; and*

18 *“(C) the Secretary receives a written request*
19 *from the sponsor to approve the drug as a lim-*
20 *ited population drug pursuant to this subsection.*

21 *“(2) BENEFIT-RISK CONSIDERATION.—The Sec-*
22 *retary’s determination of safety and effectiveness of*
23 *an antibacterial or antifungal drug shall reflect the*
24 *benefit-risk profile of such drug in the intended lim-*
25 *ited population, taking into account the severity, rar-*
26 *ity, or prevalence of the infection the drug is intended*

1 *to treat and the availability or lack of alternative*
2 *treatment in such limited population. Such drug may*
3 *be approved under this subsection notwithstanding a*
4 *lack of evidence to fully establish a favorable benefit-*
5 *risk profile in a population that is broader than the*
6 *intended limited population.*

7 *“(3) ADDITIONAL REQUIREMENTS.—A drug ap-*
8 *proved under this subsection shall be subject to the fol-*
9 *lowing requirements, in addition to any other appli-*
10 *cable requirements of this Act:*

11 *“(A) LABELING.—To indicate that the safe-*
12 *ty and effectiveness of a drug approved under*
13 *this subsection has been demonstrated only with*
14 *respect to a limited population—*

15 *“(i) all labeling and advertising of an*
16 *antibacterial or antifungal drug approved*
17 *under this subsection shall contain the*
18 *statement ‘Limited Population’ in a promi-*
19 *nent manner and adjacent to, and not more*
20 *prominent than—*

21 *“(I) the proprietary name of such*
22 *drug, if any; or*

23 *“(II) if there is no proprietary*
24 *name, the established name of the drug,*
25 *if any, as defined in section 503(e)(3),*

1 or, in the case of a drug that is a bio-
2 logical product, the proper name, as
3 defined by regulation; and

4 “(i) the prescribing information for
5 the drug required by section 201.57 of title
6 21, Code of Federal Regulations (or any
7 successor regulation) shall also include the
8 following statement: ‘This drug is indicated
9 for use in a limited and specific population
10 of patients.’.

11 “(B) PROMOTIONAL MATERIAL.—The spon-
12 sor of an antibacterial or antifungal drug subject
13 to this subsection shall submit to the Secretary
14 copies of all promotional materials related to
15 such drug at least 30 calendar days prior to dis-
16 semination of the materials.

17 “(4) OTHER PROGRAMS.—A sponsor of a drug
18 that seeks approval of a drug under this subsection
19 may also seek designation or approval, as applicable,
20 of such drug under other applicable sections or sub-
21 sections of this Act or the Public Health Service Act.

22 “(5) GUIDANCE.—Not later than 18 months after
23 the date of enactment of the 21st Century Cures Act,
24 the Secretary shall issue draft guidance describing
25 criteria, processes, and other general considerations

1 *for demonstrating the safety and effectiveness of lim-*
2 *ited population antibacterial and antifungal drugs.*
3 *The Secretary shall publish final guidance within 18*
4 *months of the close of the public comment period on*
5 *such draft guidance. The Secretary may approve*
6 *antibacterial and antifungal drugs under this sub-*
7 *section prior to issuing guidance under this para-*
8 *graph.*

9 “(6) *ADVICE.—The Secretary shall provide*
10 *prompt advice to the sponsor of a drug for which the*
11 *sponsor seeks approval under this subsection to enable*
12 *the sponsor to plan a development program to obtain*
13 *the necessary data for such approval, and to conduct*
14 *any additional studies that would be required to gain*
15 *approval of such drug for use in a broader popu-*
16 *lation.*

17 “(7) *TERMINATION OF LIMITATIONS.—If, after*
18 *approval of a drug under this subsection, the Sec-*
19 *retary approves a broader indication for such drug*
20 *under section 505(b) or section 351(a) of the Public*
21 *Health Service Act, the Secretary may remove any*
22 *postmarketing conditions, including requirements*
23 *with respect to labeling and review of promotional*
24 *materials under paragraph (3), applicable to the ap-*
25 *proval of the drug under this subsection.*

1 “(8) *RULES OF CONSTRUCTION.*—*Nothing in this*
2 *subsection shall be construed to alter the authority of*
3 *the Secretary to approve drugs pursuant to this Act*
4 *or section 351 of the Public Health Service Act, in-*
5 *cluding the standards of evidence and applicable con-*
6 *ditions for approval under such Acts, the standards of*
7 *approval of a drug under such Acts, or to alter the*
8 *authority of the Secretary to monitor drugs pursuant*
9 *to such Acts.*

10 “(9) *REPORTING AND ACCOUNTABILITY.*—

11 “(A) *BIENNIAL REPORTING.*—*The Secretary*
12 *shall report to Congress not less often than once*
13 *every 2 years on the number of requests for ap-*
14 *proval, and the number of approvals, of an anti-*
15 *bacterial or antifungal drug under this sub-*
16 *section.*

17 “(B) *GAO REPORT.*—*Not later than Decem-*
18 *ber 2021, the Comptroller General of the United*
19 *States shall submit to the Committee on Energy*
20 *and Commerce of the House of Representatives*
21 *and the Committee on Health, Education, Labor*
22 *and Pensions of the Senate a report on the co-*
23 *ordination of activities required under section*
24 *319E of the Public Health Service Act. Such re-*
25 *port shall include a review of such activities, and*

1 *the extent to which the use of the pathway estab-*
2 *lished under this subsection has streamlined pre-*
3 *market approval for antibacterial or antifungal*
4 *drugs for limited populations, if such pathway*
5 *has functioned as intended, if such pathway has*
6 *helped provide for safe and effective treatment*
7 *for patients, if such premarket approval would*
8 *be appropriate for other categories of drugs, and*
9 *if the authorities under this subsection have af-*
10 *ected antibacterial or antifungal resistance.”.*

11 **SEC. 3043. PRESCRIBING AUTHORITY.**

12 *Nothing in this subtitle, or an amendment made by*
13 *this subtitle, shall be construed to restrict the prescribing*
14 *of antimicrobial drugs or other products, including drugs*
15 *approved under subsection (h) of section 506 of the Federal*
16 *Food, Drug, and Cosmetic Act (21 U.S.C. 356) (as added*
17 *by section 3042), by health care professionals, or to limit*
18 *the practice of health care.*

19 **SEC. 3044. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**
20 **FOR MICROORGANISMS; ANTIMICROBIAL SUS-**
21 **CEPTIBILITY TESTING DEVICES.**

22 *(a) IN GENERAL.—Subchapter A of chapter V of the*
23 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et*
24 *seq.) is amended by inserting after section 511 the following:*

1 **“SEC. 511A. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**
2 **FOR MICROORGANISMS.**

3 *“(a) PURPOSE; IDENTIFICATION OF CRITERIA.—*

4 *“(1) PURPOSE.—The purpose of this section is to*
5 *clarify the Secretary’s authority to—*

6 *“(A) efficiently update susceptibility test in-*
7 *terpretive criteria for antimicrobial drugs when*
8 *necessary for public health, due to, among other*
9 *things, the constant evolution of microorganisms*
10 *that leads to the development of resistance to*
11 *drugs that have been effective in decreasing mor-*
12 *bidity and mortality for patients, which war-*
13 *rants unique management of antimicrobial drugs*
14 *that is inappropriate for most other drugs in*
15 *order to delay or prevent the development of fur-*
16 *ther resistance to existing therapies;*

17 *“(B) provide for public notice of the avail-*
18 *ability of recognized interpretive criteria and in-*
19 *terpretive criteria standards; and*

20 *“(C) clear under section 510(k), classify*
21 *under section 513(f)(2), or approve under section*
22 *515, antimicrobial susceptibility testing devices*
23 *utilizing updated, recognized susceptibility test*
24 *interpretive criteria to characterize the in vitro*
25 *susceptibility of particular bacteria, fungi, or*

1 *other microorganisms, as applicable, to anti-*
2 *microbial drugs.*

3 “(2) *IDENTIFICATION OF CRITERIA.*—*The Sec-*
4 *retary shall identify appropriate susceptibility test*
5 *interpretive criteria with respect to antimicrobial*
6 *drugs—*

7 “(A) *if such criteria are available on the*
8 *date of approval of the drug under section 505*
9 *of this Act or licensure of the drug under section*
10 *351 of the Public Health Service Act (as applica-*
11 *ble), upon such approval or licensure; or*

12 “(B) *if such criteria are unavailable on*
13 *such date, on the date on which such criteria are*
14 *available for such drug.*

15 “(3) *BASES FOR INITIAL IDENTIFICATION.*—*The*
16 *Secretary shall identify appropriate susceptibility test*
17 *interpretive criteria under paragraph (2), based on*
18 *the Secretary’s review of, to the extent available and*
19 *relevant—*

20 “(A) *preclinical and clinical data, includ-*
21 *ing pharmacokinetic, pharmacodynamic, and ep-*
22 *idemiological data;*

23 “(B) *the relationship of susceptibility test*
24 *interpretive criteria to morbidity and mortality*

1 *associated with the disease or condition for*
2 *which such drug is used; and*

3 “(C) *such other evidence and information as*
4 *the Secretary considers appropriate.*

5 “(b) *SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA*
6 *WEBSITE.—*

7 “(1) *IN GENERAL.—Not later than 1 year after*
8 *the date of the enactment of the 21st Century Cures*
9 *Act, the Secretary shall establish, and maintain there-*
10 *after, on the website of the Food and Drug Adminis-*
11 *tration, a dedicated website that contains a list of*
12 *any appropriate new or updated susceptibility test*
13 *interpretive criteria standards and interpretive cri-*
14 *teria in accordance with paragraph (2) (referred to in*
15 *this section as the ‘Interpretive Criteria Website’).*

16 “(2) *LISTING OF SUSCEPTIBILITY TEST INTER-*
17 *PRETIVE CRITERIA STANDARDS AND INTERPRETIVE*
18 *CRITERIA.—*

19 “(A) *IN GENERAL.—The list described in*
20 *paragraph (1) shall consist of any new or up-*
21 *dated susceptibility test interpretive criteria*
22 *standards that are—*

23 “(i) *established by a nationally or*
24 *internationally recognized standard devel-*
25 *opment organization that—*

1 “(I) establishes and maintains
2 procedures to address potential con-
3 flicts of interest and ensure trans-
4 parent decisionmaking;

5 “(II) holds open meetings to en-
6 sure that there is an opportunity for
7 public input by interested parties, and
8 establishes and maintains processes to
9 ensure that such input is considered in
10 decisionmaking; and

11 “(III) permits its standards to be
12 made publicly available, through the
13 National Library of Medicine or an-
14 other similar source acceptable to the
15 Secretary; and

16 “(ii) recognized in whole, or in part,
17 by the Secretary under subsection (c).

18 “(B) OTHER LIST.—The Interpretive Cri-
19 teria Website shall, in addition to the list de-
20 scribed in subparagraph (A), include a list of in-
21 terpretive criteria, if any, that the Secretary has
22 determined to be appropriate with respect to le-
23 gally marketed antimicrobial drugs, where—

24 “(i) the Secretary does not recognize,
25 in whole or in part, an interpretive criteria

1 *standard described under subparagraph (A)*
2 *otherwise applicable to such a drug;*

3 “(ii) *the Secretary withdraws under*
4 *subsection (c)(1)(A) recognition of a stand-*
5 *ard, in whole or in part, otherwise applica-*
6 *ble to such a drug;*

7 “(iii) *the Secretary approves an appli-*
8 *cation under section 505 of this Act or sec-*
9 *tion 351 of the Public Health Service Act,*
10 *as applicable, with respect to marketing of*
11 *such a drug for which there are no relevant*
12 *interpretive criteria included in a standard*
13 *recognized by the Secretary under sub-*
14 *section (c); or*

15 “(iv) *because the characteristics of such*
16 *a drug differ from other drugs with the*
17 *same active ingredient, the interpretive cri-*
18 *teria with respect to such drug—*

19 “(I) *differ from otherwise applica-*
20 *ble interpretive criteria included in a*
21 *standard listed under subparagraph*
22 *(A) or interpretive criteria otherwise*
23 *listed under this subparagraph; and*

24 “(II) *are determined by the Sec-*
25 *retary to be appropriate for the drug.*

1 “(C) *REQUIRED STATEMENTS.*—*The Interpretive Criteria Website shall include statements*
2 *conveying—*

3 “(i) *that the website provides information*
4 *about the in vitro susceptibility of bac-*
5 *teria, fungi, or other microorganisms, as*
6 *applicable to a certain drug (or drugs);*

7 “(ii) *that—*

8 “(I) *the safety and efficacy of such*
9 *drugs in treating clinical infections*
10 *due to such bacteria, fungi, or other*
11 *microorganisms, as applicable, may or*
12 *may not have been established in ade-*
13 *quate and well-controlled clinical trials*
14 *in order for the susceptibility informa-*
15 *tion described in clause (i) to be in-*
16 *cluded on the website; and*

17 “(II) *the clinical significance of*
18 *such susceptibility information in such*
19 *instances is unknown;*

20 “(iii) *that the approved product label-*
21 *ing for specific drugs provides the uses for*
22 *which the Secretary has approved the prod-*
23 *uct; and*
24

1 “(iv) any other information that the
2 Secretary determines appropriate to ade-
3 quately convey the meaning of the data sup-
4 porting the recognition or listing of suscep-
5 tibility test interpretive criteria standards
6 or susceptibility test interpretive criteria
7 included on the website.

8 “(3) NOTICE.—Not later than the date on which
9 the Interpretive Criteria Website is established, the
10 Secretary shall publish a notice of that establishment
11 in the Federal Register.

12 “(4) INAPPLICABILITY OF MISBRANDING PROVI-
13 SION.—The inclusion in the approved labeling of an
14 antimicrobial drug of a reference or hyperlink to the
15 Interpretive Criteria Website, in and of itself, shall
16 not cause the drug to be misbranded in violation of
17 section 502.

18 “(5) TRADE SECRETS AND CONFIDENTIAL INFOR-
19 MATION.—Nothing in this section shall be construed
20 as authorizing the Secretary to disclose any informa-
21 tion that is a trade secret or confidential information
22 subject to section 552(b)(4) of title 5, United States
23 Code.

24 “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-
25 PRETIVE CRITERIA.—

1 “(1) *EVALUATION AND PUBLICATION.*—

2 “(A) *IN GENERAL.*—*Beginning on the date*
3 *of the establishment of the Interpretive Criteria*
4 *Website, and at least every 6 months thereafter,*
5 *the Secretary shall—*

6 “(i) *evaluate any appropriate new or*
7 *updated susceptibility test interpretive cri-*
8 *teria standards established by a nationally*
9 *or internationally recognized standard de-*
10 *velopment organization described in sub-*
11 *section (b)(2)(A)(i); and*

12 “(ii) *publish on the public website of*
13 *the Food and Drug Administration a no-*
14 *tice—*

15 “(I) *withdrawing recognition of*
16 *any different susceptibility test inter-*
17 *pretive criteria standard, in whole or*
18 *in part;*

19 “(II) *recognizing the new or up-*
20 *dated standards;*

21 “(III) *recognizing one or more*
22 *parts of the new or updated interpre-*
23 *tive criteria specified in such a stand-*
24 *ard and declining to recognize the re-*
25 *mainder of such standard; and*

1 “(IV) making any necessary up-
2 dates to the lists under subsection
3 (b)(2).

4 “(B) UPON APPROVAL OF A DRUG.—Upon
5 the approval of an initial or supplemental appli-
6 cation for an antimicrobial drug under section
7 505 of this Act or section 351 of the Public
8 Health Service Act, as applicable, where such
9 approval is based on susceptibility test interpre-
10 tive criteria which differ from those contained in
11 a standard recognized, or from those otherwise
12 listed, by the Secretary pursuant to this sub-
13 section, or for which there are no relevant inter-
14 pretive criteria standards recognized, or inter-
15 pretive criteria otherwise listed, by the Secretary
16 pursuant to this subsection, the Secretary shall
17 update the lists under subparagraphs (A) and
18 (B) of subsection (b)(2) to include the suscepti-
19 bility test interpretive criteria upon which such
20 approval was based.

21 “(2) BASES FOR UPDATING INTERPRETIVE CRI-
22 TERIA STANDARDS.—In evaluating new or updated
23 susceptibility test interpretive criteria standards
24 under paragraph (1)(A), the Secretary may con-
25 sider—

1 “(A) the Secretary’s determination that
2 such a standard is not applicable to a particular
3 drug because the characteristics of the drug differ
4 from other drugs with the same active ingredient;

5 “(B) information provided by interested
6 third parties, including public comment on the
7 annual compilation of notices published under
8 paragraph (3);

9 “(C) any bases used to identify suscepti-
10 bility test interpretive criteria under subsection
11 (a)(2); and

12 “(D) such other information or factors as
13 the Secretary determines appropriate.

14 “(3) ANNUAL COMPILATION OF NOTICES.—Each
15 year, the Secretary shall compile the notices published
16 under paragraph (1)(A) and publish such compila-
17 tion in the Federal Register and provide for public
18 comment. If the Secretary receives comments, the Sec-
19 retary shall review such comments and, if the Sec-
20 retary determines appropriate, update pursuant to
21 this subsection susceptibility test interpretive criteria
22 standards or criteria—

23 “(A) recognized by the Secretary under this
24 subsection; or

1 “(B) otherwise listed on the Interpretive
2 Criteria Website under subsection (b)(2).

3 “(4) *RELATION TO SECTION 514(c).*—Any suscep-
4 tibility test interpretive standard recognized under
5 this subsection or any criteria otherwise listed under
6 subsection (b)(2)(B) shall be deemed to be recognized
7 as a standard by the Secretary under section
8 514(c)(1).

9 “(5) *VOLUNTARY USE OF INTERPRETIVE CRI-*
10 *TERIA.*—Nothing in this section prohibits a person
11 from seeking approval or clearance of a drug or de-
12 vice, or changes to the drug or the device, on the basis
13 of susceptibility test interpretive criteria which differ
14 from those contained in a standard recognized, or
15 from those otherwise listed, by the Secretary pursuant
16 to subsection (b)(2).

17 “(d) *ANTIMICROBIAL DRUG LABELING.*—

18 “(1) *DRUGS MARKETED PRIOR TO ESTABLISH-*
19 *MENT OF INTERPRETIVE CRITERIA WEBSITE.*—

20 “(A) *IN GENERAL.*—With respect to an
21 antimicrobial drug lawfully introduced or deliv-
22 ered for introduction into interstate commerce
23 for commercial distribution before the establish-
24 ment of the Interpretive Criteria Website, a hold-
25 er of an approved application under section 505

1 *of this Act or section 351 of the Public Health*
2 *Service Act, as applicable, for each such drug,*
3 *not later than 1 year after establishment of the*
4 *Interpretive Criteria Website described in sub-*
5 *section (b)(1), shall remove susceptibility test in-*
6 *terpretive criteria, if any, and related informa-*
7 *tion from the approved drug labeling and replace*
8 *it with a reference to the Interpretive Criteria*
9 *Website.*

10 “(B) LABELING CHANGES.—*The labeling*
11 *changes required by this section shall be consid-*
12 *ered a minor change under section 314.70 of title*
13 *21, Code of Federal Regulations (or any suc-*
14 *cessor regulations) that may be implemented*
15 *through documentation in the next applicable*
16 *annual report.*

17 “(2) DRUGS MARKETED SUBSEQUENT TO ESTAB-
18 *LISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—*
19 *With respect to antimicrobial drugs approved on or*
20 *after the date of the establishment of the Interpretive*
21 *Criteria Website described in subsection (b)(1), the la-*
22 *beling for such a drug shall include, in lieu of suscep-*
23 *tibility test interpretive criteria and related informa-*
24 *tion, a reference to such Website.*

1 “(e) *SPECIAL CONDITION FOR MARKETING OF ANTI-*
2 *MICROBIAL SUSCEPTIBILITY TESTING DEVICES.*—

3 “(1) *IN GENERAL.*—*Notwithstanding sections*
4 *501, 502, 505, 510, 513, and 515, if the conditions*
5 *specified in paragraph (2) are met (in addition to*
6 *other applicable provisions under this chapter) with*
7 *respect to an antimicrobial susceptibility testing de-*
8 *vice described in subsection (f)(1), the Secretary may*
9 *authorize the marketing of such device for a use de-*
10 *scribed in such subsection.*

11 “(2) *CONDITIONS APPLICABLE TO ANTI-*
12 *MICROBIAL SUSCEPTIBILITY TESTING DEVICES.*—*The*
13 *conditions specified in this paragraph are the fol-*
14 *lowing:*

15 “(A) *The device is used to make a deter-*
16 *mination of susceptibility using susceptibility*
17 *test interpretive criteria that are—*

18 “(i) *included in a standard recognized*
19 *by the Secretary under subsection (c); or*

20 “(ii) *otherwise listed on the Interpre-*
21 *tive Criteria Website under subsection*
22 *(b)(2).*

23 “(B) *The labeling of such device includes*
24 *statements conveying—*

1 “(i) that the device provides informa-
2 tion about the *in vitro* susceptibility of bac-
3 teria, fungi, or other microorganisms, as
4 applicable to antimicrobial drugs;

5 “(ii) that—

6 “(I) the safety and efficacy of such
7 drugs in treating clinical infections
8 due to such bacteria, fungi, or other
9 microorganisms, as applicable, may or
10 may not have been established in ade-
11 quate and well-controlled clinical trials
12 in order for the device to report the
13 susceptibility of such bacteria, fungi,
14 or other microorganisms, as applicable,
15 to such drugs; and

16 “(II) the clinical significance of
17 such susceptibility information in
18 those instances is unknown;

19 “(iii) that the approved labeling for
20 drugs tested using such a device provides
21 the uses for which the Secretary has ap-
22 proved such drugs; and

23 “(iv) any other information the Sec-
24 retary determines appropriate to adequately
25 convey the meaning of the data supporting

1 *the recognition or listing of susceptibility*
2 *test interpretive criteria standards or sus-*
3 *ceptibility test interpretive criteria de-*
4 *scribed in subparagraph (A).*

5 “(C) *The antimicrobial susceptibility test-*
6 *ing device meets all other requirements to be*
7 *cleared under section 510(k), classified under sec-*
8 *tion 513(f)(2), or approved under section 515.*

9 “(f) *DEFINITIONS.—In this section:*

10 “(1) *The term ‘antimicrobial susceptibility test-*
11 *ing device’ means a device that utilizes susceptibility*
12 *test interpretive criteria to determine and report the*
13 *in vitro susceptibility of certain microorganisms to a*
14 *drug (or drugs).*

15 “(2) *The term ‘qualified infectious disease prod-*
16 *uct’ means a qualified infectious disease product des-*
17 *ignated under section 505E(d).*

18 “(3) *The term ‘susceptibility test interpretive cri-*
19 *teria’ means—*

20 “(A) *one or more specific numerical values*
21 *which characterize the susceptibility of bacteria*
22 *or other microorganisms to the drug tested; and*

23 “(B) *related categorizations of such suscep-*
24 *tibility, including categorization of the drug as*

1 *susceptible, intermediate, resistant, or such other*
2 *term as the Secretary determines appropriate.*

3 “(4)(A) *The term ‘antimicrobial drug’ means,*
4 *subject to subparagraph (B), a systemic antibacterial*
5 *or antifungal drug that—*

6 “(i) *is intended for human use in the treat-*
7 *ment of a disease or condition caused by a bac-*
8 *terium or fungus;*

9 “(ii) *may include a qualified infectious dis-*
10 *ease product designated under section 505E(d);*
11 *and*

12 “(iii) *is subject to section 503(b)(1).*

13 “(B) *If provided by the Secretary through regu-*
14 *lations, such term may include—*

15 “(i) *drugs other than systemic antibacterial*
16 *and antifungal drugs; and*

17 “(ii) *biological products (as such term is de-*
18 *finied in section 351 of the Public Health Service*
19 *Act) to the extent such products exhibit anti-*
20 *microbial activity.*

21 “(5) *The term ‘interpretive criteria standard’*
22 *means a compilation of susceptibility test interpretive*
23 *criteria developed by a standard development organi-*
24 *zation that meets the criteria set forth in subsection*
25 *(b)(2)(A)(i).*

1 “(g) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*
2 *tion shall be construed to—*

3 “(1) *alter the standards of evidence under sub-*
4 *section (c) or (d) of section 505 (including the sub-*
5 *stantial evidence standard under section 505(d)) or*
6 *under section 351 of the Public Health Service Act (as*
7 *applicable); or*

8 “(2) *with respect to clearing devices under sec-*
9 *tion 510(k), classifying devices under section*
10 *513(f)(2), or approving devices under section 515—*

11 “(A) *apply with respect to any drug, device,*
12 *or biological product, in any context other than*
13 *an antimicrobial drug and an antimicrobial sus-*
14 *ceptibility testing device that uses susceptibility*
15 *test interpretive criteria to characterize and re-*
16 *port the susceptibility of certain bacteria, fungi,*
17 *or other microorganisms, as applicable, to such*
18 *drug to reflect patient morbidity and mortality*
19 *in accordance with this section; or*

20 “(B) *unless specifically stated, have any ef-*
21 *fect on authorities provided under other sections*
22 *of this Act, including any regulations issued*
23 *under such sections.”.*

24 “(b) *CONFORMING AMENDMENTS.*—

1 (1) *REPEAL OF PRIOR RELATED AUTHORITY.*—
2 *Section 1111 of the Food and Drug Administration*
3 *Amendments Act of 2007 (42 U.S.C. 247d–5a), relat-*
4 *ing to identification of clinically susceptible con-*
5 *centrations of antimicrobials, is repealed.*

6 (2) *ADDITION TO CATEGORIES OF MISBRANDED*
7 *DRUGS.*—*Section 502 of the Federal Food, Drug, and*
8 *Cosmetic Act (21 U.S.C. 352) is amended by adding*
9 *at the end the following:*

10 “(dd) *If it is an antimicrobial drug, as defined in sec-*
11 *tion 511A(f), and its labeling fails to conform with the re-*
12 *quirements under section 511A(d).*”.

13 (3) *RECOGNITION OF INTERPRETIVE CRITERIA*
14 *STANDARD AS DEVICE STANDARD.*—*Section*
15 *514(c)(1)(A) of the Federal Food, Drug, and Cosmetic*
16 *Act (21 U.S.C. 360d(c)(1)(A)) is amended by insert-*
17 *ing after “the Secretary shall, by publication in the*
18 *Federal Register” the following: “(or, with respect to*
19 *a susceptibility test interpretive criteria standard*
20 *under section 511A, by posting on the Interpretive*
21 *Criteria Website in accordance with such section)*”.

22 (c) *REPORT TO CONGRESS.*—*Not later than 2 years*
23 *after the date of enactment of this Act, the Secretary of*
24 *Health and Human Services shall submit to the Committee*
25 *on Health, Education, Labor, and Pensions of the Senate*

1 *and the Committee on Energy and Commerce of the House*
2 *of Representatives a report on the progress made in imple-*
3 *menting section 511A of the Federal Food, Drug, and Cos-*
4 *metic Act (21 U.S.C. 360a), as added by subsection (a).*

5 *(d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-*
6 *TERIA WEBSITE.—Chapter 35 of title 44, United States*
7 *Code, shall not apply to the collection of information from*
8 *interested parties regarding updating the lists established*
9 *under section 511A(b) of the Federal Food, Drug, and Cos-*
10 *metic Act and posted on the Interpretive Criteria Website*
11 *established under section 511A(c) of such Act.*

12 ***Subtitle F—Medical Device*** 13 ***Innovations***

14 ***SEC. 3051. BREAKTHROUGH DEVICES.***

15 *(a) IN GENERAL.—Chapter V of the Federal Food,*
16 *Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended*
17 *by inserting after section 515B, as added by section*
18 *3034(b), the following:*

19 ***“SEC. 515C. BREAKTHROUGH DEVICES.***

20 *“(a) PURPOSE.—The purpose of this section is to en-*
21 *courage the Secretary, and provide the Secretary with suffi-*
22 *cient authority, to apply efficient and flexible approaches*
23 *to expedite the development of, and prioritize the Food and*
24 *Drug Administration’s review of, devices that represent*
25 *breakthrough technologies.*

1 “(b) *ESTABLISHMENT OF PROGRAM.*—*The Secretary*
2 *shall establish a program to expedite the development of,*
3 *and provide for the priority review for, devices, as deter-*
4 *mined by the Secretary—*

5 “(1) *that provide for more effective treatment or*
6 *diagnosis of life-threatening or irreversibly debili-*
7 *tating human disease or conditions; and*

8 “(2)(A) *that represent breakthrough technologies;*

9 “(B) *for which no approved or cleared alter-*
10 *natives exist;*

11 “(C) *that offer significant advantages over exist-*
12 *ing approved or cleared alternatives, including the*
13 *potential, compared to existing approved alternatives,*
14 *to reduce or eliminate the need for hospitalization,*
15 *improve patient quality of life, facilitate patients’*
16 *ability to manage their own care (such as through*
17 *self-directed personal assistance), or establish long-*
18 *term clinical efficiencies; or*

19 “(D) *the availability of which is in the best in-*
20 *terest of patients.*

21 “(c) *REQUEST FOR DESIGNATION.*—*A sponsor of a de-*
22 *vice may request that the Secretary designate such device*
23 *for expedited development and priority review under this*
24 *section. Any such request for designation may be made at*
25 *any time prior to the submission of an application under*

1 *section 515(c), a notification under section 510(k), or a pe-*
2 *tition 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 de-*
8 *scribed in subsection (b). If the Secretary determines*
9 *that the device meets the criteria, the Secretary shall*
10 *designate the device for expedited development and*
11 *priority review.*

12 “(2) *REVIEW.*—*Review of a request under sub-*
13 *section (c) shall be undertaken by a team that is com-*
14 *posed of experienced staff and senior managers of the*
15 *Food and Drug Administration.*

16 “(3) *WITHDRAWAL.*—*The Secretary may not*
17 *withdraw a designation granted under this section on*
18 *the basis of the criteria under subsection (b) no longer*
19 *applying because of the subsequent clearance or ap-*
20 *proval 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 which*
9 *a request is submitted under subsection (c);*

10 “(B) *provide for oversight of the team by*
11 *senior agency personnel to facilitate the efficient*
12 *development of the device and the efficient review*
13 *of any submission described in subsection (c) for*
14 *the device;*

15 “(C) *adopt an efficient process for timely*
16 *dispute resolution;*

17 “(D) *provide for interactive and timely*
18 *communication with the sponsor of the device*
19 *during the development program and review*
20 *process;*

21 “(E) *expedite the Secretary’s review of*
22 *manufacturing and quality systems compliance,*
23 *as applicable;*

24 “(F) *disclose to the sponsor, not less than 5*
25 *business days in advance, the topics of any con-*

1 *sultation the Secretary intends to undertake with*
2 *external experts or an advisory committee con-*
3 *cerning the sponsor’s device and provide the*
4 *sponsor the opportunity to recommend such ex-*
5 *ternal experts;*

6 “(G) provide for advisory committee input,
7 as the Secretary determines appropriate (includ-
8 ing in response to the request of the sponsor) for
9 applications submitted under section 515(c); and

10 “(H) assign staff to be available within a
11 reasonable time to address questions by institu-
12 tional review committees concerning the condi-
13 tions and clinical testing requirements applica-
14 ble to the investigational use of the device pursu-
15 ant to an exemption under section 520(g).

16 “(2) *ADDITIONAL ACTIONS.*—*In addition to the*
17 *actions described in paragraph (1), for purposes of*
18 *expediting the development and review of devices des-*
19 *ignated under subsection (d), the Secretary, in col-*
20 *laboration with the device sponsor, may, as appro-*
21 *priate—*

22 “(A) coordinate with the sponsor regarding
23 early agreement on a data development plan;

1 “(B) take steps to ensure that the design of
2 clinical trials is as efficient and flexible as prac-
3 ticable, when scientifically appropriate;

4 “(C) facilitate, when scientifically appro-
5 priate, expedited and efficient development and
6 review of the device through utilization of timely
7 postmarket data collection with regard to appli-
8 cation for approval under section 515(c); and

9 “(D) agree in writing to clinical protocols
10 that the Secretary will consider binding on the
11 Secretary and the sponsor, subject to—

12 “(i) changes to such protocols agreed to
13 in writing by the sponsor and the Sec-
14 retary; or

15 “(ii) a decision, made by the director
16 of the office responsible for reviewing the de-
17 vice submission, that a substantial scientific
18 issue essential to determining the safety or
19 effectiveness of such device exists, provided
20 that such decision is in writing, and is
21 made only after the Secretary provides to
22 the device sponsor or applicant an oppor-
23 tunity for a meeting at which the director
24 and the sponsor or applicant are present

1 and at which the director documents the
2 substantial scientific issue.

3 “(f) *PRIORITY REVIEW GUIDANCE.*—

4 “(1) *CONTENT.*—Not later than 1 year after the
5 date of enactment of the 21st Century Cures Act, the
6 Secretary shall issue guidance on the implementation
7 of this section. Such guidance shall—

8 “(A) set forth the process by which a person
9 may seek a designation under subsection (d);

10 “(B) provide a template for requests under
11 subsection (c);

12 “(C) identify the criteria the Secretary will
13 use in evaluating a request for designation under
14 this section; and

15 “(D) identify the criteria and processes the
16 Secretary will use to assign a team of staff, in-
17 cluding team leaders, to review devices des-
18 ignated for expedited development and priority
19 review, including any training required for such
20 personnel to ensure effective and efficient review.

21 “(2) *PROCESS.*—Prior to finalizing the guidance
22 under paragraph (1), the Secretary shall seek public
23 comment on a proposed guidance.

24 “(g) *RULE OF CONSTRUCTION.*—Nothing in this sec-
25 tion shall be construed to affect—

1 “(1) the criteria and standards for evaluating an
2 application pursuant to section 515(c), a report and
3 request for classification under section 513(f)(2), or a
4 report under section 510(k), including the recognition
5 of valid scientific evidence as described in section
6 513(a)(3)(B) and consideration and application of
7 the least burdensome means of evaluating device effec-
8 tiveness or demonstrating substantial equivalence be-
9 tween devices with differing technological characteris-
10 tics, as applicable;

11 “(2) the authority of the Secretary with respect
12 to clinical holds under section 520(g)(8)(A);

13 “(3) the authority of the Secretary to act on an
14 application pursuant to section 515(d) before comple-
15 tion of an establishment inspection, as the Secretary
16 determines appropriate; or

17 “(4) the authority of the Secretary with respect
18 to postmarket surveillance under sections 519(h) and
19 522.”.

20 (b) *DOCUMENTATION AND REVIEW OF SIGNIFICANT*
21 *DECISIONS.*—Section 517A(a)(1) of the Federal Food,
22 *Drug, and Cosmetic Act* (21 U.S.C. 360g–1(a)(1)) is
23 amended by inserting “a request for designation under sec-
24 tion 515C,” after “application under section 515,”.

25 (c) *TERMINATION OF PREVIOUS PROGRAM.*—

1 (1) *IN GENERAL.*—Section 515(d) of the Federal
2 *Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)) is*
3 *amended—*

4 (A) *by striking paragraph (5); and*

5 (B) *by redesignating paragraph (6) as*
6 *paragraph (5).*

7 (2) *CONFORMING AMENDMENT.*—Section 737(5)
8 *of the Federal Food, Drug, and Cosmetics Act (21*
9 *U.S.C. 379i(5)) is amended by striking “515(d)(6)”*
10 *and inserting “515(d)(5)”.*

11 (d) *REPORT.*—On January 1, 2019, the Secretary of
12 *Health and Human Services shall issue a report to the*
13 *Committee on Health, Education, Labor, and Pensions of*
14 *the Senate and the Committee on Energy and Commerce*
15 *of the House of Representatives—*

16 (1) *on the program under section 515C of the*
17 *Federal Food, Drug, and Cosmetic Act, as added by*
18 *subsection (a), in bringing safe and effective devices*
19 *included in such program to patients as soon as pos-*
20 *sible; and*

21 (2) *that includes recommendations, if any, to*
22 *strengthen the program to better meet patient device*
23 *needs in a manner as timely as possible.*

1 **SEC. 3052. HUMANITARIAN DEVICE EXEMPTION.**

2 (a) *IN GENERAL.*—Section 520(m) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amend-
4 ed—

5 (1) in paragraph (1) by striking “fewer than
6 4,000” and inserting “not more than 8,000”;

7 (2) in paragraph (2)(A) by striking “fewer than
8 4,000” and inserting “not more than 8,000”; and

9 (3) in paragraph (6)(A)(ii), by striking “4,000”
10 and inserting “8,000”.

11 (b) *GUIDANCE DOCUMENT ON PROBABLE BENEFIT.*—

12 Not later than 18 months after the date of enactment of
13 this Act, the Secretary of Health and Human Services, act-
14 ing through the Commissioner of Food and Drugs, shall
15 publish a draft guidance that defines the criteria for estab-
16 lishing “probable benefit” as that term is used in section
17 520(m)(2)(C) of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 360j(m)(2)(C)).

19 **SEC. 3053. RECOGNITION OF STANDARDS.**

20 (a) *IN GENERAL.*—Section 514(c) of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 360d(c)) is amended—

22 (1) in paragraph (1), by inserting after subpara-
23 graph (B) the following new subparagraphs:

24 “(C)(i) Any person may submit a request for recogni-
25 tion under subparagraph (A) of all or part of an appro-

1 *priate standard established by a nationally or internation-*
2 *ally recognized standard organization.*

3 “(ii) Not later than 60 calendar days after the Sec-
4 retary receives such a request, the Secretary shall—

5 “(I) make a determination to recognize all, part,
6 or none of the standard that is the subject of the re-
7 quest; and

8 “(II) issue to the person who submitted such re-
9 quest a response in writing that states the Secretary’s
10 rationale for that determination, including the sci-
11 entific, technical, regulatory, or other basis for such
12 determination.

13 “(iii) The Secretary shall make a response issued
14 under clause (ii)(II) publicly available, in such a manner
15 as the Secretary determines appropriate.

16 “(iv) The Secretary shall take such actions as may be
17 necessary to implement all or part of a standard recognized
18 under clause (ii)(I), in accordance with subparagraph (A).

19 “(D) The Secretary shall make publicly available, in
20 such manner as the Secretary determines appropriate, the
21 rationale for recognition under subparagraph (A) of all,
22 part, or none of a standard, including the scientific, tech-
23 nical, regulatory, or other basis for the decision regarding
24 such recognition.”; and

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

1 “(4) *The Secretary shall provide to all employees of*
2 *the Food and Drug Administration who review premarket*
3 *submissions for devices periodic training on the concept and*
4 *use of recognized standards for purposes of meeting a pre-*
5 *market submission requirement or other applicable require-*
6 *ment under this Act, including standards relevant to an*
7 *employee’s area of device review.”.*

8 (b) *GUIDANCE.—The Secretary of Health and Human*
9 *Services, acting through the Commissioner of Food and*
10 *Drugs, shall review and update, if necessary, previously*
11 *published guidance and standard operating procedures*
12 *identifying the principles for recognizing standards, and for*
13 *withdrawing the recognition of standards, under section*
14 *514(c) of the Federal Food, Drug, and Cosmetic Act (21*
15 *U.S.C. 360d(c)), taking into account the experience with*
16 *and reliance on a standard by foreign regulatory authori-*
17 *ties and the device industry, and whether recognition of a*
18 *standard will promote harmonization among regulatory*
19 *authorities in the regulation of devices.*

20 **SEC. 3054. CERTAIN CLASS I AND CLASS II DEVICES.**

21 (a) *CLASS I DEVICES.—Section 510(l) of the Federal*
22 *Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amend-*
23 *ed—*

1 (1) *by striking “A report under subsection (k)”*
2 *and inserting “(1) A report under subsection (k)”;*
3 *and*

4 (2) *by adding at the end the following new para-*
5 *graph:*

6 “(2) *Not later than 120 calendar days after the date*
7 *of enactment of the 21st Century Cures Act and at least*
8 *once every 5 years thereafter, as the Secretary determines*
9 *appropriate, the Secretary shall identify, through publica-*
10 *tion in the Federal Register, any type of class I device that*
11 *the Secretary determines no longer requires a report under*
12 *subsection (k) to provide reasonable assurance of safety and*
13 *effectiveness. Upon such publication—*

14 “(A) *each type of class I device so identified shall*
15 *be exempt from the requirement for a report under*
16 *subsection (k); and*

17 “(B) *the classification regulation applicable to*
18 *each such type of device shall be deemed amended to*
19 *incorporate such exemption.”.*

20 (b) *CLASS II DEVICES.—Section 510(m) of the Federal*
21 *Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) is*
22 *amended—*

23 (1) *by striking “(m)(1)” and all that follows*
24 *through “by the Secretary.” and inserting the fol-*
25 *lowing:*

1 “(m)(1) *The Secretary shall—*

2 “(A) *not later than 90 days after the date of en-*
3 *actment of the 21st Century Cures Act and at least*
4 *once every 5 years thereafter, as the Secretary deter-*
5 *mines appropriate—*

6 “(i) *publish in the Federal Register a notice*
7 *that contains a list of each type of class II device*
8 *that the Secretary determines no longer requires*
9 *a report under subsection (k) to provide reason-*
10 *able assurance of safety and effectiveness; and*

11 “(ii) *provide for a period of not less than*
12 *60 calendar days for public comment beginning*
13 *on the date of the publication of such notice; and*

14 “(B) *not later than 210 calendar days after the*
15 *date of enactment of the 21st Century Cures Act, pub-*
16 *lish in the Federal Register a list representing the*
17 *Secretary’s final determination with respect to the de-*
18 *VICES contained in the list published under subpara-*
19 *graph (A).”;* and

20 (2) *in paragraph (2)—*

21 (A) *by striking “1 day after the date of*
22 *publication of a list under this subsection,” and*
23 *inserting “1 calendar day after the date of publi-*
24 *cation of the final list under paragraph (1)(B).”;*
25 and

1 (B) by striking “30-day period” and insert-
2 ing “60-calendar-day period”; and

3 (C) by adding at the end the following new
4 paragraph:

5 “(3) Upon the publication of the final list under para-
6 graph (1)(B)—

7 “(A) each type of class II device so listed shall
8 be exempt from the requirement for a report under
9 subsection (k); and

10 “(B) the classification regulation applicable to
11 each such type of device shall be deemed amended to
12 incorporate such exemption.”.

13 **SEC. 3055. CLASSIFICATION PANELS.**

14 (a) **CLASSIFICATION PANELS.**—Paragraph (5) of sec-
15 tion 513(b) of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 360c(b)) is amended—

17 (1) by striking “(5)” and inserting “(5)(A)”;
18 and

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

20 “(B) When a device is specifically the subject of review
21 by a classification panel, the Secretary shall—

22 “(i) ensure that adequate expertise is represented
23 on the classification panel to assess—

1 “(I) the disease or condition which the de-
2 vice is intended to cure, treat, mitigate, prevent,
3 or diagnose; and

4 “(II) the technology of the device; and

5 “(ii) provide an opportunity for the person
6 whose device is specifically the subject of panel review
7 to provide recommendations on the expertise needed
8 among the voting members of the panel.

9 “(C) For purposes of subparagraph (B)(i), the term
10 ‘adequate expertise’ means that the membership of the clas-
11 sification panel includes—

12 “(i) two or more voting members, with a spe-
13 cialty or other expertise clinically relevant to the de-
14 vice under review; and

15 “(ii) at least one voting member who is knowl-
16 edgeable about the technology of the device.

17 “(D) The Secretary shall provide an annual oppor-
18 tunity for patients, representatives of patients, and spon-
19 sors of medical device submissions to provide recommenda-
20 tions for individuals with appropriate expertise to fill vot-
21 ing member positions on classification panels.”.

22 (b) *PANEL REVIEW PROCESS*.—Section 513(b)(6) of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 360c(b)(6)) is amended—

1 (1) in subparagraph (A)(iii), by inserting before
2 the period at the end “, including, subject to the dis-
3 cretion of the panel chairperson, by designating a
4 representative who will be provided a time during the
5 panel meeting to address the panel for the purpose of
6 correcting misstatements of fact or providing clari-
7 fying information, and permitting the person or rep-
8 resentative to call on experts within the person’s orga-
9 nization to address such specific issues in the time
10 provided”; and

11 (2) by striking subparagraph (B) and inserting
12 the following new subparagraph:

13 “(B)(i) Any meeting of a classification panel with re-
14 spect to the review of a device shall—

15 “(I) provide adequate time for initial presen-
16 tations by the person whose device is specifically the
17 subject of such review and by the Secretary; and

18 “(II) encourage free and open participation by
19 all interested persons.

20 “(ii) Following the initial presentations described in
21 clause (i), the panel may—

22 “(I) pose questions to a designated representative
23 described in subparagraph (A)(iii); and

24 “(II) consider the responses to such questions in
25 the panel’s review of the device.”.

1 **SEC. 3056. INSTITUTIONAL REVIEW BOARD FLEXIBILITY.**

2 *Section 520 of the Federal Food, Drug, and Cosmetic*
3 *Act (21 U.S.C. 360j) is amended—*

4 *(1) in subsection (g)(3)—*

5 *(A) in subparagraph (A)(i)—*

6 *(i) by striking “local”; and*

7 *(ii) by striking “which has been”; and*

8 *(B) in subparagraph (B), by striking “a*
9 *local institutional” and inserting “an institu-*
10 *tional”; and*

11 *(2) in subsection (m)(4)—*

12 *(A) by striking subparagraph (A) and in-*
13 *serting the following:*

14 *“(A) in facilities in which clinical testing of de-*
15 *vices is supervised by an institutional review com-*
16 *mittee established in accordance with the regulations*
17 *of the Secretary; and”;*

18 *(B) in subparagraph (B), by striking “a*
19 *local institutional” and inserting “an institu-*
20 *tional”; and*

21 *(C) in the matter following subparagraph*
22 *(B), by striking “local”.*

23 **SEC. 3057. CLIA WAIVER IMPROVEMENTS.**

24 *(a) DRAFT REVISED GUIDANCE.—Not later than 1*
25 *year after the date of the enactment of this Act, the Sec-*
26 *retary of Health and Human Services, acting through the*

1 *Commissioner of Food and Drugs, shall publish a draft*
2 *guidance that—*

3 (1) *revises “Section V. Demonstrating Insignifi-*
4 *cant Risk of an Erroneous Result – Accuracy” of the*
5 *guidance entitled “Recommendations for Clinical*
6 *Laboratory Improvement Amendments of 1988*
7 *(CLIA) Waiver Applications for Manufacturers of In*
8 *Vitro Diagnostic Devices” and dated January 30,*
9 *2008; and*

10 (2) *includes the appropriate use of comparable*
11 *performance between a waived user and a moderately*
12 *complex laboratory user to demonstrate accuracy.*

13 (b) *FINAL REVISED GUIDANCE.—The Secretary of*
14 *Health and Human Services, acting through the Commis-*
15 *sioner of Food and Drugs, shall finalize the draft guidance*
16 *published under subsection (a) not later than 1 year after*
17 *the comment period for such draft guidance closes.*

18 **SEC. 3058. LEAST BURDENSOME DEVICE REVIEW.**

19 (a) *IN GENERAL.—Section 513 of the Federal Food,*
20 *Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by*
21 *adding at the end the following:*

22 “(j) *TRAINING AND OVERSIGHT OF LEAST BURDEN-*
23 *SOME REQUIREMENTS.—*

24 “(1) *The Secretary shall—*

1 “(A) ensure that each employee of the Food
2 and Drug Administration who is involved in the
3 review of premarket submissions, including su-
4 pervisors, receives training regarding the mean-
5 ing and implementation of the least burdensome
6 requirements under subsections (a)(3)(D) and
7 (i)(1)(D) of this section and section 515(c)(5);
8 and

9 “(B) periodically assess the implementation
10 of the least burdensome requirements, including
11 the employee training under subparagraph (A),
12 to ensure that the least burdensome requirements
13 are fully and consistently applied.

14 “(2) Not later than 18 months after the date of
15 enactment of the 21st Century Cures Act, the ombuds-
16 man for any organizational unit of the Food and
17 Drug Administration responsible for the premarket
18 review of devices shall—

19 “(A) conduct an audit of the training de-
20 scribed in paragraph (1)(A), including the effec-
21 tiveness of such training in implementing the
22 least burdensome requirements;

23 “(B) include in such audit interviews of
24 persons who are representatives of the device in-
25 dustry regarding their experiences in the device

1 premarket review process, including with respect
2 to the application of least burdensome concepts
3 to premarket review and decisionmaking;

4 “(C) include in such audit a list of the
5 measurement tools the Secretary uses to assess
6 the implementation of the least burdensome re-
7 quirements, including under paragraph (1)(B)
8 and section 517A(a)(3), and may also provide
9 feedback on the effectiveness of such tools in the
10 implementation of the least burdensome require-
11 ments;

12 “(D) summarize the findings of such audit
13 in a final audit report; and

14 “(E) within 30 calendar days of completion
15 of such final audit report, make such final audit
16 report available—

17 “(i) to the Committee on Health, Edu-
18 cation, Labor, and Pensions of the Senate
19 and the Committee on Energy and Com-
20 merce of the House of Representatives; and

21 “(ii) on the Internet website of the
22 Food and Drug Administration.”.

23 (b) *PREMARKET APPLICATIONS.*—Section 515(c) of the
24 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c))*
25 is amended by adding at the end the following:

1 “(5)(A) *In requesting additional information with re-*
2 *spect to an application under this section, the Secretary*
3 *shall consider the least burdensome appropriate means nec-*
4 *essary to demonstrate a reasonable assurance of device safe-*
5 *ty and effectiveness.*

6 “(B) *For purposes of subparagraph (A), the term ‘nec-*
7 *essary’ means the minimum required information that*
8 *would support a determination by the Secretary that an*
9 *application provides a reasonable assurance of the safety*
10 *and effectiveness of the device.*

11 “(C) *For purposes of this paragraph, the Secretary*
12 *shall consider the role of postmarket information in deter-*
13 *mining the least burdensome means of demonstrating a rea-*
14 *sonable assurance of device safety and effectiveness.*

15 “(D) *Nothing in this paragraph alters the standards*
16 *for premarket approval of a device.”.*

17 (c) *RATIONALE FOR SIGNIFICANT DECISIONS REGARD-*
18 *ING DEVICES.—Section 517A(a) of the Federal Food, Drug,*
19 *and Cosmetic Act (21 U.S.C. 360g–1(a)) is amended by*
20 *adding at the end the following:*

21 “(3) *APPLICATION OF LEAST BURDENSOME RE-*
22 *QUIREMENTS.—The substantive summary required*
23 *under this subsection shall include a brief statement*
24 *regarding how the least burdensome requirements*
25 *were considered and applied consistent with section*

1 513(i)(1)(D), section 513(a)(3)(D), and section
2 515(c)(5), as applicable.”

3 **SEC. 3059. CLEANING INSTRUCTIONS AND VALIDATION**

4 **DATA REQUIREMENT.**

5 (a) *IN GENERAL.*—Section 510 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 360) is amended by
7 adding at the end the following:

8 “(q) *REUSABLE MEDICAL DEVICES.*—

9 “(1) *IN GENERAL.*—Not later than 180 days
10 after the date of enactment of the 21st Century Cures
11 Act, the Secretary shall identify and publish a list of
12 reusable device types for which reports under sub-
13 section (k) are required to include—

14 “(A) instructions for use, which have been
15 validated in a manner specified by the Sec-
16 retary; and

17 “(B) validation data, the types of which
18 shall be specified by the Secretary;
19 regarding cleaning, disinfection, and sterilization,
20 and for which a substantial equivalence determina-
21 tion may be based.

22 “(2) *REVISION OF LIST.*—The Secretary shall re-
23 vise the list under paragraph (2), as the Secretary de-
24 termines appropriate, with notice in the Federal Reg-
25 ister.

1 “(3) *CONTENT OF REPORTS.*—*Reports under sub-*
2 *section (k) that are submitted after the publication of*
3 *the list described in paragraph (1), for devices or*
4 *types of devices included on such list, shall include*
5 *such instructions for use and validation data.*”.

6 **(b) *DEVICE MODIFICATIONS.***—*The Secretary of Health*
7 *and Human Services, acting through the Commissioner of*
8 *Food and Drugs, shall issue final guidance regarding when*
9 *a premarket notification under section 510(k) of the Federal*
10 *Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is re-*
11 *quired to be submitted for a modification or change to a*
12 *legally marketed device. Such final guidance shall be issued*
13 *not later than 1 year after the date on which the comment*
14 *period closes for the draft guidance on such subject.*

15 **SEC. 3060. CLARIFYING MEDICAL SOFTWARE REGULATION.**

16 **(a) *IN GENERAL.***—*Section 520 of the Federal Food,*
17 *Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by*
18 *adding at the end the following:*

19 **“(o) *REGULATION OF MEDICAL AND CERTAIN DECI-***
20 ***SIONS SUPPORT SOFTWARE.***—

21 **“(1) *The term device, as defined in section***
22 ***201(h), shall not include a software function that is***
23 ***intended—***

24 **“(A) *for administrative support of a health***
25 ***care facility, including the processing and main-***

1 *tenance of financial records, claims or billing in-*
2 *formation, appointment schedules, business ana-*
3 *lytics, information about patient populations,*
4 *admissions, practice and inventory management,*
5 *analysis of historical claims data to predict fu-*
6 *ture utilization or cost-effectiveness, determina-*
7 *tion of health benefit eligibility, population*
8 *health management, and laboratory workflow;*

9 “(B) *for maintaining or encouraging a*
10 *healthy lifestyle and is unrelated to the diag-*
11 *nosis, cure, mitigation, prevention, or treatment*
12 *of a disease or condition;*

13 “(C) *to serve as electronic patient records,*
14 *including patient-provided information, to the*
15 *extent that such records are intended to transfer,*
16 *store, convert formats, or display the equivalent*
17 *of a paper medical chart, so long as—*

18 “(i) *such records were created, stored,*
19 *transferred, or reviewed by health care pro-*
20 *essionals, or by individuals working under*
21 *supervision of such professionals;*

22 “(ii) *such records are part of health in-*
23 *formation technology that is certified under*
24 *section 3001(c)(5) of the Public Health*
25 *Service Act; and*

1 “(iii) such function is not intended to
2 interpret or analyze patient records, includ-
3 ing medical image data, for the purpose of
4 the diagnosis, cure, mitigation, prevention,
5 or treatment of a disease or condition;

6 “(D) for transferring, storing, converting
7 formats, or displaying clinical laboratory test or
8 other device data and results, findings by a
9 health care professional with respect to such data
10 and results, general information about such find-
11 ings, and general background information about
12 such laboratory test or other device, unless such
13 function is intended to interpret or analyze clin-
14 ical laboratory test or other device data, results,
15 and findings; or

16 “(E) unless the function is intended to ac-
17 quire, process, or analyze a medical image or a
18 signal from an *in vitro* diagnostic device or a
19 pattern or signal from a signal acquisition sys-
20 tem, for the purpose of—

21 “(i) displaying, analyzing, or printing
22 medical information about a patient or
23 other medical information (such as peer-re-
24 viewed clinical studies and clinical practice
25 guidelines);

1 “(ii) supporting or providing rec-
2 ommendations to a health care professional
3 about prevention, diagnosis, or treatment of
4 a disease or condition; and

5 “(iii) enabling such health care profes-
6 sional to independently review the basis for
7 such recommendations that such software
8 presents so that it is not the intent that
9 such health care professional rely primarily
10 on any of such recommendations to make a
11 clinical diagnosis or treatment decision re-
12 garding an individual patient.

13 “(2) In the case of a product with multiple func-
14 tions that contains—

15 “(A) at least one software function that
16 meets the criteria under paragraph (1) or that
17 otherwise does not meet the definition of device
18 under section 201(h); and

19 “(B) at least one function that does not
20 meet the criteria under paragraph (1) and that
21 otherwise meets the definition of a device under
22 section 201(h),

23 the Secretary shall not regulate the software function
24 of such product described in subparagraph (A) as a
25 device. Notwithstanding the preceding sentence, when

1 *assessing the safety and effectiveness of the device*
2 *function or functions of such product described in*
3 *subparagraph (B), the Secretary may assess the im-*
4 *act that the software function or functions described*
5 *in subparagraph (A) have on such device function or*
6 *functions.*

7 “(3)(A) *Notwithstanding paragraph (1), a soft-*
8 *ware function described in subparagraph (C), (D), or*
9 *(E) of paragraph (1) shall not be excluded from the*
10 *definition of device under section 201(h) if—*

11 “(i) *the Secretary makes a finding that use*
12 *of such software function would be reasonably*
13 *likely to have serious adverse health con-*
14 *sequences; and*

15 “(ii) *the software function has been identi-*
16 *fied in a final order issued by the Secretary*
17 *under subparagraph (B).*

18 “(B) *Subparagraph (A) shall apply only if the*
19 *Secretary—*

20 “(i) *publishes a notification and proposed*
21 *order in the Federal Register;*

22 “(ii) *includes in such notification the Sec-*
23 *retary’s finding, including the rationale and*
24 *identification of the evidence on which such find-*

1 *ing was based, as described in subparagraph*
2 *(A)(i); and*

3 *“(iii) provides for a period of not less than*
4 *30 calendar days for public comment before*
5 *issuing a final order or withdrawing such pro-*
6 *posed order.*

7 *“(C) In making a finding under subparagraph*
8 *(A)(i) with respect to a software function, the Sec-*
9 *retary shall consider—*

10 *“(i) the likelihood and severity of patient*
11 *harm if the software function were to not per-*
12 *form as intended;*

13 *“(ii) the extent to which the software func-*
14 *tion is intended to support the clinical judgment*
15 *of a health care professional;*

16 *“(iii) whether there is a reasonable oppor-*
17 *tunity for a health care professional to review*
18 *the basis of the information or treatment rec-*
19 *ommendation provided by the software function;*
20 *and*

21 *“(iv) the intended user and user environ-*
22 *ment, such as whether a health care professional*
23 *will use a software function of a type described*
24 *in subparagraph (E) of paragraph (1).*

1 “(4) Nothing in this subsection shall be construed
2 as limiting the authority of the Secretary to—

3 “(A) exercise enforcement discretion as to
4 any device subject to regulation under this Act;

5 “(B) regulate software used in the manufac-
6 ture and transfusion of blood and blood compo-
7 nents to assist in the prevention of disease in hu-
8 mans; or

9 “(C) regulate software as a device under
10 this Act if such software meets the criteria under
11 section 513(a)(1)(C).”.

12 (b) *REPORTS.*—The Secretary of Health and Human
13 Services (referred to in this subsection as the “Secretary”),
14 after consultation with agencies and offices of the Depart-
15 ment of Health and Human Services involved in health in-
16 formation technology, shall publish a report, not later than
17 2 years after the date of enactment of this Act and every
18 2 years thereafter, that—

19 (1) includes input from outside experts, such as
20 representatives of patients, consumers, health care
21 providers, startup companies, health plans or other
22 third-party payers, venture capital investors, infor-
23 mation technology vendors, health information tech-
24 nology vendors, small businesses, purchasers, employ-

1 *ers, and other stakeholders with relevant expertise, as*
2 *determined by the Secretary;*

3 *(2) examines information available to the Sec-*
4 *retary on any risks and benefits to health associated*
5 *with software functions described in section 520(o)(1)*
6 *of the Federal Food, Drug, and Cosmetic Act (21*
7 *U.S.C. 360j) (as amended by subsection (a)); and*

8 *(3) summarizes findings regarding the impact of*
9 *such software functions on patient safety, including*
10 *best practices to promote safety, education, and com-*
11 *petency related to such functions.*

12 *(c) CLASSIFICATION OF ACCESSORIES.—Section*
13 *513(b) of the Federal Food, Drug, and Cosmetic Act (21*
14 *U.S.C. 360c(b)) is amended by adding at the end the fol-*
15 *lowing:*

16 *“(9) The Secretary shall classify an accessory under*
17 *this section based on the intended use of the accessory, not-*
18 *withstanding the classification of any other device with*
19 *which such accessory is intended to be used.”.*

20 *(d) CONFORMING AMENDMENT.—Section 201(h) of the*
21 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))*
22 *is amended by adding at the end the following: “The term*
23 *‘device’ does not include software functions excluded pursu-*
24 *ant 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 “RE-*
11 ***SEARCH****”;*

12 *(2) in subsection (a)—*

13 *(A) in paragraph (1), by striking “Silvio O.*
14 *Conte Senior Biomedical Research Service, not*
15 *to exceed 500 members” and inserting “Silvio O.*
16 *Conte Senior Biomedical Research and Bio-*
17 *medical Product Assessment Service (in this sec-*
18 *tion referred to as the ‘Service’), not to exceed*
19 *2,000 members, the purpose of which is to recruit*
20 *and retain outstanding and qualified scientific*
21 *and technical experts in the fields of biomedical*
22 *research, clinical research evaluation, and bio-*
23 *medical 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 num-*
3 *ber of employees serving under any other employment sys-*
4 *tem in order to offset the number of members serving in*
5 *the Service.”; and*

6 *(C) by adding at the end the following:*

7 “(3) *The Secretary shall assign experts under this sec-*
8 *tion to agencies within the Department of Health and*
9 *Human Services taking into account the need for the exper-*
10 *tise 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 Executive*
22 *Schedule unless approved by the President under sec-*
23 *tion 5377(d)(2) of title 5, United States Code” and*
24 *inserting “and shall not exceed the amount of annual*

1 *compensation (excluding expenses) specified in section*
2 *102 of title 3, United States 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 Pub-*
10 *lic Health Service Act (42 U.S.C. 237) made by sub-*
11 *section (a) and the impact of such amendments, if*
12 *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 Com-*
16 *mittee on Health, Education, Labor, and Pensions of*
17 *the Senate and the Committee on Energy and Com-*
18 *merce 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 oth-*

1 *erwise have been affected by the amendments to sec-*
2 *tion 228 of the Public Health Service Act (42 U.S.C.*
3 *237) made by subsection (a), including by deter-*
4 *mining, during the period between the date of enact-*
5 *ment of this Act and the completion of the study—*

6 *(A) the total number of members recruited*
7 *and retained under the Senior Biomedical Re-*
8 *search and Biomedical Product Assessment Serv-*
9 *ice under such section 228, and the effect of in-*
10 *creasing the number of members eligible for such*
11 *Service;*

12 *(B) the number of members of such Senior*
13 *Biomedical Research and Biomedical Product*
14 *Assessment Service hired with a doctoral level*
15 *degree in biomedicine or a related field, and the*
16 *number of such members hired with a doctoral or*
17 *master's level degree in engineering,*
18 *bioinformatics, or a related or emerging field;*
19 *and*

20 *(C) the number of Senior Biomedical Re-*
21 *search and Biomedical Product Assessment Serv-*
22 *ice members that have been hired by each agency*
23 *or department of the Department of Health and*
24 *Human Services, and how such Department as-*

1 *signs such members to each agency or depart-*
2 *ment.*

3 **SEC. 3072. HIRING AUTHORITY FOR SCIENTIFIC, TECH-**
4 **NICAL, AND PROFESSIONAL PERSONNEL.**

5 *(a) IN GENERAL.—The Federal Food, Drug, and Cos-*
6 *metic Act is amended by inserting after section 714 (21*
7 *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 regula-*
15 *tion of medical products. Such positions shall be within the*
16 *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 subchapter*
21 *III of chapter 53 of title 5, United States Code, and*
22 *consistent with the requirements of paragraph (2), the*
23 *Commissioner of Food and Drugs may determine and*
24 *set—*

1 “(A) the annual rate of pay of any indi-
2 vidual appointed under subsection (a); and

3 “(B) for purposes of retaining qualified em-
4 ployees, the annual rate of pay for any qualified
5 scientific, technical, or professional personnel ap-
6 pointed to a position described in subsection (a)
7 before the date of enactment of the 21st Century
8 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 of
15 pay provided to an individual in accordance with
16 this section shall be publicly available information.

17 “(c) *RULE OF CONSTRUCTION.*—The authorities under
18 this section shall not be construed to affect the authority
19 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 Cures
23 Act, the Secretary shall submit a report on workforce
24 planning to the Committee on Health, Education,
25 Labor, and Pensions of the Senate and the Committee

1 *on Energy and Commerce of the House of Representa-*
2 *tives that examines the extent to which the Food and*
3 *Drug Administration has a critical need for qualified*
4 *individuals for scientific, technical, or professional*
5 *positions, including—*

6 *“(A) an analysis of the workforce needs at*
7 *the Food and Drug Administration and the Sec-*
8 *retary’s strategic plan for addressing such needs,*
9 *including through use of the authority under this*
10 *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 help*
6 *the Food and Drug Administration to better recruit*
7 *and retain qualified individuals for scientific, tech-*
8 *nical, 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 ability*
12 *of the Food and Drug Administration to hire, train,*
13 *and retain qualified scientific, technical, and profes-*
14 *sional staff, not including contractors, necessary to*
15 *fulfill the mission of the Food and Drug Administra-*
16 *tion to protect and promote public health. Not later*
17 *than January 1, 2022, the Comptroller General shall*
18 *submit a report on such study to the Committee on*
19 *Health, Education, Labor, and Pensions of the Senate*
20 *and the Committee on Energy and Commerce of the*
21 *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 bio-*
5 *medical research, clinical research evaluation,*
6 *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 and*
16 *retention; and*

17 (D) recommendations for potential improve-
18 ments that would address staffing needs of the
19 *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 amended*
24 *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 ‘Institute’)*
6 *for a major disease area or areas. With respect to the major*
7 *disease area of focus of an Institute, such Institute shall*
8 *develop and implement processes for coordination of activi-*
9 *ties, as applicable to such major disease area or areas,*
10 *among the Center for Drug Evaluation and Research, the*
11 *Center for Biologics Evaluation and Research, and the Cen-*
12 *ter for Devices and Radiological Health (for the purposes*
13 *of this section, referred to as the ‘Centers’). Such activities*
14 *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 the*
19 *Institute;*

20 “(2) *streamlining, where appropriate, the review*
21 *of medical products to diagnose, cure, mitigate, treat,*
22 *or prevent the specific diseases relevant to the major*
23 *disease area of focus of the Institute, applying rel-*
24 *evant standards under sections 505, 510(k), 513(f)(2),*
25 *and 515 of this Act and section 351 of the Public*
26 *Health Service Act, and other applicable authorities;*

1 “(3) *promotion of scientific programs within the*
2 *Centers related to the major disease area of focus of*
3 *the Institute;*

4 “(4) *development of programs and enhancement*
5 *of strategies to recruit, train, and provide continuing*
6 *education opportunities for the personnel of the Cen-*
7 *ters with expertise related to the major disease area*
8 *of focus of the Institute;*

9 “(5) *enhancement of the interactions of the Cen-*
10 *ters with patients, sponsors, and the external bio-*
11 *medical community regarding the major disease area*
12 *of focus of the Institute; and*

13 “(6) *facilitation of the collaborative relationships*
14 *of the Centers with other agencies within the Depart-*
15 *ment of Health and Human Services regarding the*
16 *major disease area of focus of the Institute.*

17 “(b) *PUBLIC PROCESS.—The Secretary shall provide*
18 *a period for public comment during the time that each In-*
19 *stitute is being implemented.*

20 “(c) *TIMING.—The Secretary shall establish at least*
21 *one Institute under subsection (a) before the date that is*
22 *1 year after the date of enactment of the 21st Century Cures*
23 *Act.*

24 “(d) *TERMINATION OF INSTITUTES.—The Secretary*
25 *may terminate any Institute established pursuant to this*

1 *section if the Secretary determines such Institute is no*
2 *longer benefitting the public health. Not less than 60 days*
3 *prior to so terminating an Institute, the Secretary shall*
4 *provide public notice, including the rationale for such ter-*
5 *mination.”.*

6 (b) *TECHNICAL AMENDMENTS.—Chapter X of the Fed-*
7 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.)*
8 *is amended—*

9 (1) *by redesignating section 1012 as section*
10 *1013; and*

11 (2) *by redesignating the second section 1011*
12 *(with respect to improving the training of State,*
13 *local, territorial, and tribal food safety officials), as*
14 *added by section 209(a) of the FDA Food Safety Mod-*
15 *ernization Act (Public Law 111–353), as section*
16 *1012.*

17 **SEC. 3074. SCIENTIFIC ENGAGEMENT.**

18 (a) *IN GENERAL.—Scientific meetings that are at-*
19 *tended by scientific or medical personnel, or other profes-*
20 *sionals, of the Department of Health and Human Services*
21 *for whom attendance at such meeting is directly related to*
22 *their professional duties and the mission of the Depart-*
23 *ment—*

24 (1) *shall not be considered conferences for the*
25 *purposes of complying with Federal reporting require-*

1 *ments contained in annual appropriations Acts or in*
2 *this section; and*

3 *(2) shall not be considered conferences for pur-*
4 *poses of a restriction contained in an annual appro-*
5 *priations Act, based on Office of Management and*
6 *Budget Memorandum M-12-12 or any other regula-*
7 *tion restricting travel to such meeting.*

8 *(b) LIMITATION.—Nothing in this section shall be con-*
9 *strued to exempt travel for scientific meetings from Federal*
10 *regulations relating to travel.*

11 *(c) REPORTS.—Not later than 90 days after the end*
12 *of the fiscal year, each operating division of the Department*
13 *of Health and Human Services shall prepare, and post on*
14 *an Internet website of the operating division, an annual*
15 *report on scientific meeting attendance and related travel*
16 *spending for each fiscal year. Such report shall include—*

17 *(1) general information concerning the scientific*
18 *meeting activities involved;*

19 *(2) information concerning the total amount ex-*
20 *pended for such meetings;*

21 *(3) a description of all such meetings that were*
22 *attended by scientific or medical personnel, or other*
23 *professionals, of each such operating division where*
24 *the total amount expended by the operating division*

1 associated with each such meeting were in excess of
2 \$30,000, including—

3 (A) the total amount of meeting expenses
4 incurred by the operating division for such meet-
5 ing;

6 (B) the location of such meeting;

7 (C) the date of such meeting;

8 (D) a brief explanation on how such meet-
9 ing advanced the mission of the operating divi-
10 sion; and

11 (E) the total number of individuals whose
12 travel expenses or other scientific meeting ex-
13 penses were paid by the operating division; and

14 (4) with respect to any such meeting where the
15 total expenses to the operating division exceeded
16 \$150,000, a description of the exceptional cir-
17 cumstances that necessitated the expenditure of such
18 amounts.

19 **SEC. 3075. DRUG SURVEILLANCE.**

20 (a) **NEW DRUGS.**—Section 505(k)(5) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)(5)), as
22 amended by section 2074, is further amended—

23 (1) in subparagraph (A), by striking “, bi-weekly
24 screening” and inserting “screenings”;

1 (2) in subparagraph (B), as redesignated by sec-
2 tion 2074(1)(C), by striking the period at the end and
3 inserting “; and”; and

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

5 “(C) make available on the Internet website of
6 the Food and Drug Administration—

7 “(i) guidelines, developed with input from
8 experts qualified by scientific training and expe-
9 rience to evaluate the safety and effectiveness of
10 drugs, that detail best practices for drug safety
11 surveillance using the Adverse Event Reporting
12 System; and

13 “(ii) criteria for public posting of adverse
14 event signals.”.

15 (b) *FAERS REVISION*.—Section 505(r)(2)(D) of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 355(r)(2)(D)) is amended by striking “, by 18 months” and
18 all that follows through the semicolon at the end of the sub-
19 paragraph and inserting “and making publicly available
20 on the Internet website established under paragraph (1) best
21 practices for drug safety surveillance activities for drugs
22 approved under this section or section 351 of the Public
23 Health Service Act;”.

1 (c) *RISK EVALUATION AND MITIGATION STRATE-*
2 *GIES.*—Section 505–1(f)(5) of the Federal Food, Drug, and
3 *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 “(or
6 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 Cosmetic
14 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 “(i) *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 total*
8 *voting members of the Board (including*
9 *members whose positions are established by*
10 *such amendment) are representatives of the*
11 *general pharmaceutical, device, food, cos-*
12 *metic, and biotechnology industries.”; and*
13 *(C) in clause (iii)(I), as redesignated by*
14 *subparagraph (A), by striking “The ex officio*
15 *members shall ensure” and inserting “The ex*
16 *officio members, acting pursuant to clause (i),*
17 *and the Board, acting pursuant to clause (ii),*
18 *shall ensure”.*

19 (2) *FEDERAL EMPLOYEES ALLOWED TO SERVE*
20 *ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C) of*
21 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
22 *379dd(d)(1)(C)), as redesignated by paragraph*
23 *(1)(A), is amended by adding at the end the fol-*
24 *lowing: “For purposes of this section, the term ‘em-*
25 *ployee of the Federal Government’ does not include a*

1 *special Government employee, as that term is defined*
2 *in section 202(a) of title 18, United States Code.”.*

3 (3) *STAGGERED TERMS.—Subparagraph (A) of*
4 *section 770(d)(3) of the Federal Food, Drug, and Cos-*
5 *metic Act (21 U.S.C. 379dd(d)(3)) is amended to read*
6 *as follows:*

7 “(A) *TERM.—The term of office of each*
8 *member of the Board appointed under para-*
9 *graph (1)(C)(i), and the term of office of any*
10 *member of the Board whose position is estab-*
11 *lished pursuant to paragraph (1)(C)(ii), shall be*
12 *4 years, except that—*

13 “(i) *the terms of offices for the members*
14 *of the Board initially appointed under*
15 *paragraph (1)(C)(i) shall expire on a stag-*
16 *gered basis as determined by the ex officio*
17 *members; and*

18 “(ii) *the terms of office for the persons*
19 *initially appointed to positions established*
20 *pursuant to paragraph (1)(C)(ii) may be*
21 *made to expire on a staggered basis, as de-*
22 *termined by the individuals who, as of the*
23 *date of the amendment establishing such po-*
24 *sitions, are members of the Board.”.*

1 *section (c)), including for such products in the stock-*
2 *pile.”; and*

3 *(2) in subsection (g)—*

4 *(A) by amending paragraph (4) to read as*
5 *follows:*

6 *“(4) REPORT ON SECURITY COUNTERMEASURE*
7 *PROCUREMENT.—Not later than March 1 of each year*
8 *in which the Secretary determines that the amount of*
9 *funds available for procurement of security counter-*
10 *measures is less than \$1,500,000,000, the Secretary*
11 *shall submit to the Committee on Appropriations and*
12 *the Committee on Health, Education, Labor, and*
13 *Pensions of the Senate and the Committee on Appro-*
14 *priations and the Committee on Energy and Com-*
15 *merce of the House of Representatives a report detail-*
16 *ing the amount of such funds available for procure-*
17 *ment and the impact such amount of funding will*
18 *have—*

19 *“(A) in meeting the security countermeasure*
20 *needs identified under this section; and*

21 *“(B) on the annual Public Health Emer-*
22 *gency Medical Countermeasures Enterprise and*
23 *Strategy Implementation Plan (pursuant to sec-*
24 *tion 2811(d)).”.*

1 **SEC. 3082. CLARIFYING BARDA CONTRACTING AUTHORITY.**

2 (a) *IN GENERAL.*—Section 319F–2(g) of the Public
3 Health Service Act (42 U.S.C. 247d–6b(g)) is amended by
4 adding at the end the following:

5 “(5) *CLARIFICATION ON CONTRACTING AUTHOR-*
6 *ITY.*—The Secretary, acting through the Director of
7 the Biomedical Advanced Research and Development
8 Authority, shall carry out the programs funded by the
9 special reserve fund (for the procurement of security
10 countermeasures under subsection (c) and for car-
11 rying out section 319L), including the execution of
12 procurement contracts, grants, and cooperative agree-
13 ments pursuant to this section and section 319L.”.

14 (b) *BARDA CONTRACTING AUTHORITY.*—Section
15 319L(c)(3) of the Public Health Service Act (42 U.S.C.
16 247d–7c) is amended by inserting “, including the execution
17 of procurement contracts, grants, and cooperative agree-
18 ments pursuant to this section” before the period.

19 **SEC. 3083. COUNTERMEASURE BUDGET PLAN.**

20 Section 2811(b)(7) of the Public Health Service Act
21 (42 U.S.C. 300hh–10(b)(7)) is amended—

22 (1) in the matter preceding subparagraph (A),
23 by striking the first sentence and inserting “Develop,
24 and update not later than March 1 of each year, a
25 coordinated 5-year budget plan based on the medical
26 countermeasure priorities described in subsection (d),

1 *including with respect to chemical, biological, radio-*
2 *logical, and nuclear agent or agents that may present*
3 *a threat to the Nation, including such agents that are*
4 *novel or emerging infectious diseases, and the cor-*
5 *responding efforts to develop qualified counter-*
6 *measures (as defined in section 319F-1), security*
7 *countermeasures (as defined in section 319F-2), and*
8 *qualified pandemic or epidemic products (as defined*
9 *in section 319F-3) for each such threat.”;*

10 (2) *in subparagraph (C), by striking “; and”*
11 *and inserting a semicolon;*

12 (3) *in subparagraph (D), by striking “to the ap-*
13 *propriate committees of Congress upon request.” and*
14 *inserting “, not later than March 15 of each year, to*
15 *the Committee on Appropriations and the Committee*
16 *on Health, Education, Labor, and Pensions of the*
17 *Senate and the Committee on Appropriations and the*
18 *Committee on Energy and Commerce of the House of*
19 *Representatives; and”;* and

20 (4) *by adding at the end the following:*

21 “(E) *not later than March 15 of each year,*
22 *be made publicly available in a manner that*
23 *does not compromise national security.”.*

1 **SEC. 3084. MEDICAL COUNTERMEASURES INNOVATION.**

2 *Section 319L(c)(4) of the Public Health Service Act*
3 *(42 U.S.C. 247d-7e(c)(4)) is amended by adding at the end*
4 *the following:*

5 *“(E) MEDICAL COUNTERMEASURES INNOVA-*
6 *TION PARTNER.—*

7 *“(i) IN GENERAL.—To support the*
8 *purposes described in paragraph (2), the*
9 *Secretary, acting through the Director of*
10 *BARDA, may enter into an agreement (in-*
11 *cluding through the use of grants, contracts,*
12 *cooperative agreements, or other trans-*
13 *actions as described in paragraph (5)) with*
14 *an independent, nonprofit entity to—*

15 *“(I) foster and accelerate the de-*
16 *velopment and innovation of medical*
17 *countermeasures and technologies that*
18 *may assist advanced research and the*
19 *development of qualified counter-*
20 *measures and qualified pandemic or*
21 *epidemic products, including through*
22 *the use of strategic venture capital*
23 *practices and methods;*

24 *“(II) promote the development of*
25 *new and promising technologies that*

1 address urgent medical countermeasure
2 needs, as identified by the Secretary;

3 “(III) address unmet public
4 health needs that are directly related to
5 medical countermeasure requirements,
6 such as novel antimicrobials for
7 multidrug resistant organisms and
8 multiuse platform technologies for
9 diagnostics, prophylaxis, vaccines, and
10 therapeutics; and

11 “(IV) provide expert consultation
12 and advice to foster viable medical
13 countermeasure innovators, including
14 helping qualified countermeasure
15 innovators navigate unique industry
16 challenges with respect to developing
17 chemical, biological, radiological, and
18 nuclear countermeasure products.

19 “(i) *ELIGIBILITY*.—

20 “(I) *IN GENERAL*.—To be eligible
21 to enter into an agreement under
22 clause (i) an entity shall—

23 “(aa) be an independent,
24 nonprofit entity;

1 “(bb) have a demonstrated
2 record of being able to create link-
3 ages between innovators and in-
4 vestors and leverage such partner-
5 ships and resources for the pur-
6 pose of addressing identified stra-
7 tegic needs of the Federal Govern-
8 ment;

9 “(cc) have experience in pro-
10 moting novel technology innova-
11 tion;

12 “(dd) be problem-driven and
13 solution-focused based on the
14 needs, requirements, and problems
15 identified by the Secretary under
16 clause (iv);

17 “(ee) demonstrate the ability,
18 or the potential ability, to pro-
19 mote the development of medical
20 countermeasure products;

21 “(ff) demonstrate expertise,
22 or the capacity to develop or ac-
23 quire expertise, related to tech-
24 nical and regulatory consider-

1 *ations with respect to medical*
2 *countermeasures; and*

3 *“(gg) not be within the De-*
4 *partment of Health and Human*
5 *Services.*

6 *“(II) PARTNERING EXPERI-*
7 *ENCE.—In selecting an entity with*
8 *which to enter into an agreement*
9 *under clause (i), the Secretary shall*
10 *place a high value on the demonstrated*
11 *experience of the entity in partnering*
12 *with the Federal Government to meet*
13 *identified strategic needs.*

14 *“(iii) NOT AGENCY.—An entity that*
15 *enters into an agreement under clause (i)*
16 *shall not be deemed to be a Federal agency*
17 *for any purpose, including for any purpose*
18 *under title 5, United States Code.*

19 *“(iv) DIRECTION.—Pursuant to an*
20 *agreement entered into under this subpara-*
21 *graph, the Secretary, acting through the Di-*
22 *rector of BARDA, shall provide direction to*
23 *the entity that enters into an agreement*
24 *under clause (i). As part of this agreement*
25 *the Director of BARDA shall—*

1 “(I) communicate the medical
2 countermeasure needs, requirements,
3 and problems to be addressed by the
4 entity under the agreement;

5 “(II) develop a description of
6 work to be performed by the entity
7 under the agreement;

8 “(III) provide technical feedback
9 and appropriate oversight over work
10 carried out by the entity under the
11 agreement, including subsequent devel-
12 opment and partnerships consistent
13 with the needs and requirements set
14 forth in this subparagraph;

15 “(IV) ensure fair consideration of
16 products developed under the agree-
17 ment in order to maintain competition
18 to the maximum practical extent, as
19 applicable and appropriate under ap-
20 plicable provisions of this section; and

21 “(V) ensure, as a condition of the
22 agreement that the entity—

23 “(aa) has in place a com-
24 prehensive set of policies that

1 demonstrate a commitment to
2 transparency and accountability;

3 “(bb) protects against con-
4 flicts of interest through a com-
5 prehensive set of policies that ad-
6 dress potential conflicts of inter-
7 est, ethics, disclosure, and report-
8 ing requirements;

9 “(cc) provides monthly ac-
10 counting on the use of funds pro-
11 vided under such agreement; and

12 “(dd) provides on a quarterly
13 basis, reports regarding the
14 progress made toward meeting the
15 identified needs set forth in the
16 agreement.

17 “(v) SUPPLEMENT NOT SUPPLANT.—
18 Activities carried out under this subpara-
19 graph shall supplement, and not supplant,
20 other activities carried out under this sec-
21 tion.

22 “(vi) NO ESTABLISHMENT OF ENTI-
23 TY.—To prevent unnecessary duplication
24 and target resources effectively, nothing in
25 this subparagraph shall be construed to au-

1 *thorize the Secretary to establish within the*
2 *Department of Health and Human Services*
3 *an entity for the purposes of carrying out*
4 *this subparagraph.*

5 “(vii) *TRANSPARENCY AND OVER-*
6 *SIGHT.—Upon request, the Secretary shall*
7 *provide to Congress the information pro-*
8 *vided to the Secretary under clause*
9 *(iv)(V)(dd).*

10 “(viii) *INDEPENDENT EVALUATION.—*
11 *Not later than 4 years after the date of en-*
12 *actment of the 21st Century Cures Act, the*
13 *Comptroller General of the United States*
14 *shall conduct an independent evaluation,*
15 *and submit to the Secretary and the appro-*
16 *priate committees of Congress a report, con-*
17 *cerning the activities conducted under this*
18 *subparagraph. Such report shall include*
19 *recommendations with respect to any agree-*
20 *ment or activities carried out pursuant to*
21 *this subparagraph.*

22 “(ix) *SUNSET.—This subparagraph*
23 *shall have no force or effect after September*
24 *30, 2022.”.*

1 **SEC. 3085. STREAMLINING PROJECT BIOSHIELD PROCURE-**
2 **MENT.**

3 *Section 319F–2(c) of the Public Health Service Act (42*
4 *U.S.C. 247d–6b(c)) is amended—*

5 *(1) in paragraph (4)(A)(ii), by striking “make a*
6 *recommendation under paragraph (6) that the special*
7 *reserve fund as defined in subsection (h) be made*
8 *available for the procurement of such countermeasure”*
9 *and inserting “and subject to the availability of ap-*
10 *propriations, make available the special reserve fund*
11 *as defined in subsection (h) for procurement of such*
12 *countermeasure, as applicable”;*

13 *(2) in paragraph (6)—*

14 *(A) by striking subparagraphs (A), (B), and*
15 *(E);*

16 *(B) by redesignating subparagraphs (C)*
17 *and (D) as subparagraphs (A) and (B), respec-*
18 *tively;*

19 *(C) by amending subparagraph (A), as so*
20 *redesignated, to read as follows:*

21 *“(A) NOTICE TO APPROPRIATE CONGRES-*
22 *SIONAL COMMITTEES.—The Secretary shall no-*
23 *tify the Committee on Appropriations and the*
24 *Committee on Health, Education, Labor, and*
25 *Pensions of the Senate and the Committee on*
26 *Appropriations and the Committee on Energy*

1 *and Commerce of the House of Representatives of*
2 *each decision to make available the special re-*
3 *serve fund as defined in subsection (h) for pro-*
4 *urement of a security countermeasure, includ-*
5 *ing, where available, the number of, the nature*
6 *of, and other information concerning potential*
7 *suppliers of such countermeasure, and whether*
8 *other potential suppliers of the same or similar*
9 *countermeasures were considered and rejected for*
10 *procurement under this section and the reasons*
11 *for each such rejection.”; and*

12 *(D) in the heading, by striking “REC-*
13 *COMMENDATION FOR PRESIDENT’S APPROVAL”*
14 *and inserting “RECOMMENDATIONS FOR PRO-*
15 *CUREMENT”;* and

16 *(3) in paragraph (7)—*

17 *(A) by striking subparagraphs (A) and (B)*
18 *and inserting the following:*

19 *“(A) PAYMENTS FROM SPECIAL RESERVE*
20 *FUND.—The special reserve fund as defined in*
21 *subsection (h) shall be available for payments*
22 *made by the Secretary to a vendor for procure-*
23 *ment of a security countermeasure in accordance*
24 *with the provisions of this paragraph.”; and*

1 (B) by redesignating subparagraph (C) as
2 subparagraph (B).

3 **SEC. 3086. ENCOURAGING TREATMENTS FOR AGENTS THAT**
4 **PRESENT A NATIONAL SECURITY THREAT.**

5 Subchapter E of chapter V of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended
7 by inserting after section 565 the following:

8 **“SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREAT-**
9 **MENTS FOR AGENTS THAT PRESENT NA-**
10 **TIONAL SECURITY THREATS.**

11 “(a) *DEFINITIONS.*—In this section:

12 “(1) *HUMAN DRUG APPLICATION.*—The term
13 ‘human drug application’ has the meaning given such
14 term in section 735(1).

15 “(2) *PRIORITY REVIEW.*—The term ‘priority re-
16 view’, with respect to a human drug application,
17 means review and action by the Secretary on such
18 application not later than 6 months after receipt by
19 the Secretary of such application, as described in the
20 *Manual of Policies and Procedures in the Food and*
21 *Drug Administration* and goals identified in the let-
22 *ters described in section 101(b) of the Food and Drug*
23 *Administration Safety and Innovation Act.*

24 “(3) *PRIORITY REVIEW VOUCHER.*—The term
25 ‘priority review voucher’ means a voucher issued by

1 *the Secretary to the sponsor of a material threat med-*
2 *ical countermeasure application that entitles the hold-*
3 *er of such voucher to priority review of a single*
4 *human drug application submitted under section*
5 *505(b)(1) or section 351(a) of the Public Health Serv-*
6 *ice Act after the date of approval of the material*
7 *threat medical countermeasure application.*

8 “(4) *MATERIAL THREAT MEDICAL COUNTER-*
9 *MEASURE APPLICATION.—The term ‘material threat*
10 *medical countermeasure application’ means an appli-*
11 *cation that—*

12 “(A) *is a human drug application for a*
13 *drug intended for use—*

14 “(i) *to prevent, or treat harm from a*
15 *biological, chemical, radiological, or nuclear*
16 *agent identified as a material threat under*
17 *section 319F–2(c)(2)(A)(ii) of the Public*
18 *Health Service Act; or*

19 “(ii) *to mitigate, prevent, or treat*
20 *harm from a condition that may result in*
21 *adverse health consequences or death and*
22 *may be caused by administering a drug, or*
23 *biological product against such agent; and*

24 “(B) *the Secretary determines eligible for*
25 *priority review;*

1 “(C) is approved after the date of enactment
2 of the 21st Century Cures Act; and

3 “(D) is for a human drug, no active ingre-
4 dient (including any ester or salt of the active
5 ingredient) of which has been approved in any
6 other application under section 505(b)(1) or sec-
7 tion 351(a) of the Public Health Service Act.

8 “(b) *PRIORITY REVIEW VOUCHER.*—

9 “(1) *IN GENERAL.*—The Secretary shall award a
10 priority review voucher to the sponsor of a material
11 threat medical countermeasure application upon ap-
12 proval by the Secretary of such material threat med-
13 ical countermeasure application.

14 “(2) *TRANSFERABILITY.*—The sponsor of a mate-
15 rial threat medical countermeasure application that
16 receives a priority review voucher under this section
17 may transfer (including by sale) the entitlement to
18 such voucher to a sponsor of a human drug for which
19 an application under section 505(b)(1) or section
20 351(a) of the Public Health Service Act will be sub-
21 mitted after the date of the approval of the material
22 threat medical countermeasure application. There is
23 no limit on the number of times a priority review
24 voucher may be transferred before such voucher is
25 used.

1 “(3) *NOTIFICATION.*—

2 “(A) *IN GENERAL.*—*The sponsor of a*
3 *human drug application shall notify the Sec-*
4 *retary not later than 90 calendar days prior to*
5 *submission of the human drug application that*
6 *is the subject of a priority review voucher of an*
7 *intent to submit the human drug application,*
8 *including the date on which the sponsor intends*
9 *to submit the application. Such notification*
10 *shall be a legally binding commitment to pay for*
11 *the user fee to be assessed in accordance with this*
12 *section.*

13 “(B) *TRANSFER AFTER NOTICE.*—*The spon-*
14 *sor of a human drug application that provides*
15 *notification of the intent of such sponsor to use*
16 *the voucher for the human drug application*
17 *under subparagraph (A) may transfer the vouch-*
18 *er after such notification is provided, if such*
19 *sponsor has not yet submitted the human drug*
20 *application described in the notification.*

21 “(c) *PRIORITY REVIEW USER FEE.*—

22 “(1) *IN GENERAL.*—*The Secretary shall establish*
23 *a user fee program under which a sponsor of a*
24 *human drug application that is the subject of a pri-*
25 *ority review voucher shall pay to the Secretary a fee*

1 *determined under paragraph (2). Such fee shall be in*
2 *addition to any fee required to be submitted by the*
3 *sponsor under chapter VII.*

4 “(2) *FEE AMOUNT.*—*The amount of the priority*
5 *review user fee shall be determined each fiscal year by*
6 *the Secretary and based on the average cost incurred*
7 *by the agency in the review of a human drug applica-*
8 *tion subject to priority review in the previous fiscal*
9 *year.*

10 “(3) *ANNUAL FEE SETTING.*—*The Secretary shall*
11 *establish, before the beginning of each fiscal year be-*
12 *ginning after September 30, 2016, for that fiscal year,*
13 *the amount of the priority review user fee.*

14 “(4) *PAYMENT.*—

15 “(A) *IN GENERAL.*—*The priority review*
16 *user fee required by this subsection shall be due*
17 *upon the submission of a human drug applica-*
18 *tion under section 505(b)(1) or section 351(a) of*
19 *the Public Health Service Act for which the pri-*
20 *ority review voucher is used.*

21 “(B) *COMPLETE APPLICATION.*—*An appli-*
22 *cation described under subparagraph (A) for*
23 *which the sponsor requests the use of a priority*
24 *review voucher shall be considered incomplete if*
25 *the fee required by this subsection and all other*

1 *applicable user fees are not paid in accordance*
2 *with the Secretary's procedures for paying such*
3 *fees.*

4 “(C) *NO WAIVERS, EXEMPTIONS, REDUC-*
5 *TIONS, OR REFUNDS.—The Secretary may not*
6 *grant a waiver, exemption, reduction, or refund*
7 *of any fees due and payable under this section.*

8 “(5) *OFFSETTING COLLECTIONS.—Fees collected*
9 *pursuant to this subsection for any fiscal year—*

10 *“(A) shall be deposited and credited as off-*
11 *setting collections to the account providing ap-*
12 *propriations to the Food and Drug Administra-*
13 *tion; and*

14 *“(6) shall not be collected for any fiscal year ex-*
15 *cept to the extent provided in advance in appropria-*
16 *tion Acts.*

17 “(d) *NOTICE OF ISSUANCE OF VOUCHER AND AP-*
18 *PROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary*
19 *shall publish a notice in the Federal Register and on the*
20 *Internet website of the Food and Drug Administration not*
21 *later than 30 calendar days after the occurrence of each of*
22 *the following:*

23 “(1) *The Secretary issues a priority review*
24 *voucher under this section.*

1 “(2) *The Secretary approves a drug pursuant to*
2 *an application submitted under section 505(b) of this*
3 *Act or section 351(a) of the Public Health Service Act*
4 *for which the sponsor of the application used a pri-*
5 *ority review voucher issued under this section.*

6 “(e) *ELIGIBILITY FOR OTHER PROGRAMS.—Nothing*
7 *in this section precludes a sponsor who seeks a priority re-*
8 *view voucher under this section from participating in any*
9 *other incentive program, including under this Act, except*
10 *that no sponsor of a material threat medical counter-*
11 *measure application may receive more than one priority*
12 *review voucher issued under any section of this Act with*
13 *respect to such drug.*

14 “(f) *RELATION TO OTHER PROVISIONS.—The provi-*
15 *sions of this section shall supplement, not supplant, any*
16 *other provisions of this Act or the Public Health Service*
17 *Act that encourage the development of medical counter-*
18 *measures.*

19 “(g) *SUNSET.—The Secretary may not award any pri-*
20 *ority review vouchers under subsection (b) after October 1,*
21 *2023.”.*

1 **SEC. 3087. PAPERWORK REDUCTION ACT WAIVER DURING A**
2 **PUBLIC HEALTH EMERGENCY.**

3 *Section 319 of the Public Health Service Act (42*
4 *U.S.C. 247d) is amended by adding at the end the fol-*
5 *lowing:*

6 *“(f) DETERMINATION WITH RESPECT TO PAPERWORK*
7 *REDUCTION ACT WAIVER DURING A PUBLIC HEALTH*
8 *EMERGENCY.—*

9 *“(1) DETERMINATION.—If the Secretary deter-*
10 *mines, after consultation with such public health offi-*
11 *cial as may be necessary, that—*

12 *“(A)(i) the criteria set forth for a public*
13 *health emergency under paragraph (1) or (2) of*
14 *subsection (a) has been met; or*

15 *“(ii) a disease or disorder, including a*
16 *novel and emerging public health threat, is sig-*
17 *nificantly likely to become a public health emer-*
18 *gency; and*

19 *“(B) the circumstances of such public health*
20 *emergency, or potential for such significantly*
21 *likely public health emergency, including the spe-*
22 *cific preparation for and response to such public*
23 *health emergency or threat, necessitate a waiver*
24 *from the requirements of subchapter I of chapter*
25 *35 of title 44, United States Code (commonly re-*
26 *ferred to as the Paperwork Reduction Act),*

1 *then the requirements of such subchapter I with re-*
2 *spect to voluntary collection of information shall not*
3 *be applicable during the immediate investigation of,*
4 *and response to, such public health emergency during*
5 *the period of such public health emergency or the pe-*
6 *riod of time necessary to determine if a disease or dis-*
7 *order, including a novel and emerging public health*
8 *threat, will become a public health emergency as pro-*
9 *vided for in this paragraph. The requirements of such*
10 *subchapter I with respect to voluntary collection of*
11 *information shall not be applicable during the imme-*
12 *diate postresponse review regarding such public health*
13 *emergency if such immediate postresponse review does*
14 *not exceed a reasonable length of time.*

15 *“(2) TRANSPARENCY.—If the Secretary deter-*
16 *mines that a waiver is necessary under paragraph*
17 *(1), the Secretary shall promptly post on the Internet*
18 *website of the Department of Health and Human*
19 *Services a brief justification for such waiver, the an-*
20 *ticipated period of time such waiver will be in effect,*
21 *and the agencies and offices within the Department of*
22 *Health and Human Services to which such waiver*
23 *shall apply, and update such information posted on*
24 *the Internet website of the Department of Health and*
25 *Human Services, as applicable.*

1 “(3) *EFFECTIVENESS OF WAIVER.*—Any waiver
2 under this subsection shall take effect on the date on
3 which the Secretary posts information on the Internet
4 website as provided for in this subsection.

5 “(4) *TERMINATION OF WAIVER.*—Upon deter-
6 mining that the circumstances necessitating a waiver
7 under paragraph (1) no longer exist, the Secretary
8 shall promptly update the Internet website of the De-
9 partment of Health and Human Services to reflect the
10 termination of such waiver.

11 “(5) *LIMITATIONS.*—

12 “(A) *PERIOD OF WAIVER.*—The period of a
13 waiver under paragraph (1) shall not exceed the
14 period of time for the related public health emer-
15 gency, including a public health emergency de-
16 clared pursuant to subsection (a), and any im-
17 mediate postresponse review regarding the public
18 health emergency consistent with the require-
19 ments of this subsection.

20 “(B) *SUBSEQUENT COMPLIANCE.*—An ini-
21 tiative subject to a waiver under paragraph (1)
22 that is ongoing after the date on which the waiv-
23 er expires, shall be subject to the requirements of
24 subchapter I of chapter 35 of title 44, United
25 States Code, and the Secretary shall ensure that

1 *compliance with such requirements occurs in as*
 2 *timely a manner as possible based on the appli-*
 3 *cable circumstances, but not to exceed 30 cal-*
 4 *endar days after the expiration of the applicable*
 5 *waiver.”.*

6 **SEC. 3088. CLARIFYING FOOD AND DRUG ADMINISTRATION**
 7 **EMERGENCY USE AUTHORIZATION.**

8 *(a) AUTHORIZATION FOR MEDICAL PRODUCTS FOR*
 9 *USE IN EMERGENCIES.—Section 564 of the Federal Food,*
 10 *Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amend-*
 11 *ed—*

12 *(1) in subsection (a)(2)—*

13 *(A) in subparagraph (A)—*

14 *(i) by striking “or 515” and inserting*
 15 *“512, or 515”; and*

16 *(ii) by inserting “or conditionally ap-*
 17 *proved under section 571 of this Act” after*
 18 *“Public Health Service Act”; and*

19 *(B) in subparagraph (B), by inserting*
 20 *“conditionally approved under section 571,”*
 21 *after “approved,” each place the term appears;*

22 *(2) in subsection (b)(4), by striking the second*
 23 *comma after “determination”;*

1 (3) in subsection (e)(3)(B), by striking “section
2 503(b)” and inserting “subsection (b) or (f) of section
3 503 or under section 504”;

4 (4) in subsection (f)(2)—

5 (A) by inserting “, or an animal to which,”
6 after “to a patient to whom”; and

7 (B) by inserting “or by the veterinarian
8 caring for such animal, as applicable” after “at-
9 tending physician”;

10 (5) in subsection (g)(1), by inserting “condi-
11 tional approval under section 571,” after “approval,”;

12 (6) in subsection (h)(1), by striking “or section
13 520(g)” and inserting “512(j), or 520(g)”; and

14 (7) in subsection (k), by striking “section
15 520(g),” and inserting “512(j), or 520(g)”.

16 (b) *NEW ANIMAL DRUGS.*—Section 512(a)(1) of the
17 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C.
18 *360b(a)(1)*) is amended—

19 (1) in subparagraph (B), by striking “or” at the
20 end;

21 (2) in subparagraph (C), by striking the period
22 and inserting “; or”; and

23 (3) by inserting after subparagraph (C) the fol-
24 lowing:

1 “(D) there is in effect an authorization pursuant
2 to section 564 with respect to such use or intended use
3 of such drug, and such drug, its labeling, and such
4 use conform to any conditions of such authorization.”.

5 (c) *EMERGENCY USE OF MEDICAL PRODUCTS*.—Sec-
6 tion 564A of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 360bbb–3a) is amended—

8 (1) in subsection (a)(1)(A), by inserting “, con-
9 ditionally approved under section 571,” after “chap-
10 ter”; and

11 (2) in subsection (d), by striking “sections 503(b)
12 and 520(e)” and inserting “subsections (b) and (f) of
13 section 503, section 504, and section 520(e)”.

14 (d) *PRODUCTS HELD FOR EMERGENCY USE*.—Section
15 564B(2) of the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 360bbb–3b(2)) is amended—

17 (1) in subparagraph (A)—

18 (A) by inserting “or conditionally approved
19 under section 571 of this Act” after “Public
20 Health Service Act”; and

21 (B) by striking “or 515” and inserting
22 “512, or 515”; and

23 (2) in subparagraph (B), by striking “or 520”
24 and inserting “512, or 520”.

1 ***Subtitle I—Vaccine Access,***
2 ***Certainty, and Innovation***

3 ***SEC. 3091. PREDICTABLE REVIEW TIMELINES OF VACCINES***
4 ***BY THE ADVISORY COMMITTEE ON IMMUNIZA-***
5 ***TION PRACTICES.***

6 (a) *CONSIDERATION OF NEW VACCINES.*—Upon the li-
7 *censure of any vaccine or any new indication for a vaccine,*
8 *the Advisory Committee on Immunization Practices (in this*
9 *section referred to as the “Advisory Committee”) shall, as*
10 *appropriate, consider the use of the vaccine at its next regu-*
11 *larly scheduled meeting.*

12 (b) *ADDITIONAL INFORMATION.*—If the Advisory Com-
13 *mittee does not make a recommendation with respect to the*
14 *use of a vaccine at the Advisory Committee’s first regularly*
15 *scheduled meeting after the licensure of the vaccine or any*
16 *new indication for the vaccine, the Advisory Committee*
17 *shall provide an update on the status of such committee’s*
18 *review.*

19 (c) *CONSIDERATION FOR BREAKTHROUGH THERAPIES*
20 *AND FOR POTENTIAL USE DURING PUBLIC HEALTH EMER-*
21 *GENCY.*—The Advisory Committee shall make recommenda-
22 *tions with respect to the use of certain vaccines in a timely*
23 *manner, as appropriate, including vaccines that—*

24 (1) *are designated as a breakthrough therapy*
25 *under section 506 of the Federal Food, Drug, and*

1 *Cosmetic Act (21 U.S.C. 356) and licensed under sec-*
2 *tion 351 of the Public Health Service Act (42 U.S.C.*
3 *262); or*

4 *(2) could be used in a public health emergency.*

5 *(d) DEFINITION.—In this section, the terms “Advisory*
6 *Committee on Immunization Practices” and “Advisory*
7 *Committee” mean the Advisory Committee on Immuniza-*
8 *tion Practices established by the Secretary pursuant to sec-*
9 *tion 222 of the Public Health Service Act (42 U.S.C. 217a),*
10 *acting through the Director of the Centers for Disease Con-*
11 *trol and Prevention.”.*

12 **SEC. 3092. REVIEW OF PROCESSES AND CONSISTENCY OF**
13 **ADVISORY COMMITTEE ON IMMUNIZATION**
14 **PRACTICES RECOMMENDATIONS.**

15 *(a) REVIEW.—The Director of the Centers for Disease*
16 *Control and Prevention shall conduct a review of the proc-*
17 *esses used by the Advisory Committee on Immunization*
18 *Practices in formulating and issuing recommendations per-*
19 *taining to vaccines, including with respect to consistency.*

20 *(b) CONSIDERATIONS.—The review under subsection*
21 *(a) shall include an assessment of—*

22 *(1) the criteria used to evaluate new and existing*
23 *vaccines, including the identification of any areas for*
24 *which flexibility in evaluating such criteria is nec-*
25 *essary and the reason for such flexibility;*

1 (2) *the Grading of Recommendations, Assess-*
2 *ment, Development, and Evaluation (GRADE) ap-*
3 *proach to the review and analysis of scientific and*
4 *economic data, including the scientific basis for such*
5 *approach; and*

6 (3) *the extent to which the processes used by the*
7 *work groups of the Advisory Committee on Immuni-*
8 *zation Practices are consistent among such groups,*
9 *including the identification of reasons for any vari-*
10 *ation.*

11 (c) *STAKEHOLDERS.—In carrying out the review*
12 *under subsection (a), the Director of the Centers for Disease*
13 *Control and Prevention shall solicit input from vaccine*
14 *stakeholders.*

15 (d) *REPORT.—Not later than 18 months after the date*
16 *of enactment of this Act, the Director of the Centers for Dis-*
17 *ease Control and Prevention shall submit to the appropriate*
18 *committees of the Congress, and make publicly available,*
19 *a report on the results of the review under subsection (a),*
20 *including any recommendations on improving the consist-*
21 *ency of the processes described in such subsection.*

22 (e) *DEFINITION.—In this section, the term “Advisory*
23 *Committee on Immunization Practices” means the Advi-*
24 *sory Committee on Immunization Practices established by*
25 *the Secretary of Health and Human Services pursuant to*

1 *section 222 of the Public Health Service Act (42 U.S.C.*
2 *217a), acting through the Director of the Centers for Disease*
3 *Control and Prevention.*

4 **SEC. 3093. ENCOURAGING VACCINE INNOVATION.**

5 (a) *VACCINE MEETINGS.*—*The Director of the Centers*
6 *for Disease Control and Prevention shall ensure that appro-*
7 *priate staff within the relevant centers and divisions of the*
8 *Office of Infectious Diseases, and others, as appropriate, co-*
9 *ordinate with respect to the public health needs, epidemi-*
10 *ology, and program planning and implementation consid-*
11 *erations related to immunization, including with regard to*
12 *meetings with stakeholders related to such topics.*

13 (b) *REPORT ON VACCINE INNOVATION.*—

14 (1) *IN GENERAL.*—*Not later than 1 year after*
15 *the date of enactment of this Act, the Secretary of*
16 *Health and Human Services (referred to in this sec-*
17 *tion as the “Secretary”), in collaboration with appro-*
18 *priate agencies or offices within the Department of*
19 *Health and Human Services, including the National*
20 *Institutes of Health, the Centers for Disease Control*
21 *and Prevention, the Food and Drug Administration,*
22 *and the Biomedical Advanced Research and Develop-*
23 *ment Authority, shall submit to the Committee on*
24 *Health, Education, Labor, and Pensions of the Senate*
25 *and the Committee on Energy and Commerce of the*

1 *House of Representatives, and post publicly on the*
2 *Internet website of the Department of Health and*
3 *Human Services, a report on ways to promote inno-*
4 *vation in the development of vaccines that minimize*
5 *the burden of infectious disease.*

6 (2) *CONTENTS.—The report described in para-*
7 *graph (1) shall review the current status of vaccine*
8 *development and, as appropriate—*

9 (A) *consider the optimal process to deter-*
10 *mine which vaccines would be beneficial to pub-*
11 *lic health and how information on such vaccines*
12 *is disseminated to key stakeholders;*

13 (B) *examine and identify whether obstacles*
14 *exist that inhibit the development of beneficial*
15 *vaccines; and*

16 (C) *make recommendations about how best*
17 *to remove any obstacles identified under sub-*
18 *paragraph (B) in order to promote and*
19 *incentivize vaccine innovation and development.*

20 (3) *CONSULTATION.—In preparing the report*
21 *under this subsection, the Secretary may consult*
22 *with—*

23 (A) *representatives of relevant Federal agen-*
24 *cies and departments, including the Department*

1 *of Defense and the Department of Veterans Af-*
2 *fairs;*

3 *(B) academic researchers;*

4 *(C) developers and manufacturers of vac-*
5 *cines;*

6 *(D) medical and public health practitioners;*

7 *(E) representatives of patient, policy, and*
8 *advocacy organizations; and*

9 *(F) representatives of other entities, as the*
10 *Secretary determines appropriate.*

11 *(c) UPDATES RELATED TO MATERNAL IMMUNIZA-*
12 *TION.—*

13 *(1) ADDITIONAL VACCINES.—Section 2114(e) of*
14 *the Public Health Service Act (42 U.S.C. 300aa-*
15 *14(e)) is amended by adding at the end the following:*

16 “(3) VACCINES RECOMMENDED FOR USE IN
17 PREGNANT WOMEN.—The Secretary shall revise the
18 Vaccine Injury Table included in subsection (a),
19 through the process described in subsection (c), to in-
20 clude vaccines recommended by the Centers for Dis-
21 ease Control and Prevention for routine administra-
22 tion in pregnant women and the information de-
23 scribed in subparagraphs (B) and (C) of paragraph
24 (2) with respect to such vaccines.”.

1 (2) *PETITION CONTENT.*—Section 2111 of the
2 *Public Health Service Act (42 U.S.C. 300aa–11)* is
3 *amended by adding at the end the following:*

4 “(f) *MATERNAL IMMUNIZATION.*—

5 “(1) *IN GENERAL.*—Notwithstanding any other
6 *provision of law, for purposes of this subtitle, both a*
7 *woman who received a covered vaccine while pregnant*
8 *and any child who was in utero at the time such*
9 *woman received the vaccine shall be considered per-*
10 *sons to whom the covered vaccine was administered*
11 *and persons who received the covered vaccine.*

12 “(2) *DEFINITION.*—As used in this subsection,
13 *the term ‘child’ shall have the meaning given that*
14 *term by subsections (a) and (b) of section 8 of title*
15 *1, United States Code, except that, for purposes of*
16 *this subsection, such section 8 shall be applied as if*
17 *the term ‘include’ in subsection (a) of such section*
18 *were replaced with the term ‘mean’.*”.

19 (3) *PETITIONERS.*—Section 2111(b)(2) of the
20 *Public Health Service Act (42 U.S.C. 300aa–11(b)(2))*
21 *is amended by adding “A covered vaccine adminis-*
22 *tered to a pregnant woman shall constitute more than*
23 *one administration, one to the mother and one to each*
24 *child (as such term is defined in subsection (f)(2))*

1 *who was in utero at the time such woman was ad-*
2 *ministered the vaccine.” at the end.*

3 ***Subtitle J—Technical Corrections***

4 ***SEC. 3101. TECHNICAL CORRECTIONS.***

5 *(a) FFDCA.—*

6 *(1) REFERENCES.—Except as otherwise expressly*
7 *provided, whenever in this subsection an amendment*
8 *is expressed in terms of an amendment to a section*
9 *or other provision, the reference shall be considered to*
10 *be made to that section or other provision of the Fed-*
11 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et*
12 *seq.).*

13 *(2) AMENDMENTS.—*

14 *(A) PROHIBITED ACTS.—Section 301(r) (21*
15 *U.S.C. 331(r)) is amended by inserting “, drug,”*
16 *after “device” each place the term appears.*

17 *(B) NEW DRUGS.—Section 505 (21 U.S.C.*
18 *355) is amended—*

19 *(i) in subsection (d), in the last sen-*
20 *tence, by striking “premarket approval”*
21 *and inserting “marketing approval”; and*

22 *(ii) in subsection (q)(5)(A), by striking*
23 *“subsection (b)(2) or (j) of the Act or*
24 *351(k)” and inserting “subsection (b)(2) or*
25 *(j) of this section or section 351(k)”.*

1 (C) *RISK EVALUATION AND MITIGATION*
2 *STRATEGIES.*—Section 505–1(h)(21 U.S.C. 355–
3 1(h)) is amended—

4 (i) in paragraph (2)(A)(iii)—
5 (I) in the clause heading, by strik-
6 ing “LABEL” and inserting “LABEL-
7 ING”;

8 (II) by striking “label” each place
9 the term appears and inserting “label-
10 ing”; and

11 (III) by striking “sponsor” and
12 inserting “responsible person”; and

13 (ii) in paragraph (8), by striking “and
14 (7).” and inserting “and (7)”.

15 (D) *PEDIATRIC STUDY PLANS.*—Section
16 505B (21 U.S.C. 355c) is amended—

17 (i) in subsection (e)—

18 (I) in paragraph (2)—

19 (aa) in subparagraph (A), by
20 inserting “study” after “initial
21 pediatric” each place the term ap-
22 pears; and

23 (bb) in subparagraph (B), in
24 the subparagraph heading, by
25 striking “INITIAL PLAN” and in-

1 serting “INITIAL PEDIATRIC
2 STUDY PLAN”;

3 (II) in paragraph (5), in the
4 paragraph heading, by inserting
5 “AGREED INITIAL PEDIATRIC STUDY”
6 before “PLAN”; and

7 (III) in paragraph (6), by strik-
8 ing “agreed initial pediatric plan”
9 and inserting “agreed initial pediatric
10 study plan”; and

11 (ii) in subsection (f)(1), by inserting
12 “and any significant amendments to such
13 plans,” after “agreed initial pediatric study
14 plans,”.

15 (E) DISCONTINUANCE OR INTERRUPTION IN
16 THE PRODUCTION OF LIVE-SAVING DRUGS.—Sec-
17 tion 506C (21 U.S.C. 356c) is amended—

18 (i) in subsection (c), by striking “dis-
19 continuation” and inserting “discontinu-
20 ance”; and

21 (ii) in subsection (g)(1), by striking
22 “section 505(j) that could help” and insert-
23 ing “section 505(j), that could help”.

1 (F) ANNUAL REPORTING ON DRUG SHORT-
2 AGES.—Section 506C–1(a) (21 U.S.C. 331(a)) is
3 amended, in the matter before paragraph (1)—

4 (i) by striking “Not later than the end
5 of calendar year 2013, and not later than
6 the end of each calendar year thereafter,”
7 and inserting “Not later than March 31 of
8 each calendar year;”; and

9 (ii) by inserting “, with respect to the
10 preceding calendar year,” after “a report”.

11 (G) DRUG SHORTAGE LIST.—Section
12 506E(b)(3)(E) (21 U.S.C. 356e(b)(3)(E)) is
13 amended by striking “discontinuation” and in-
14 sserting “discontinuance”.

15 (H) INSPECTIONS OF ESTABLISHMENTS.—
16 Section 510(h) (21 U.S.C. 360(h)) is amended—

17 (i) in paragraph (4), in the matter
18 preceding subparagraph (A), by striking
19 “establishing the risk-based scheduled” and
20 inserting “establishing a risk-based sched-
21 ule”; and

22 (ii) in paragraph (6)—

23 (I) in subparagraph (A), by strik-
24 ing “fiscal” and inserting “calendar”
25 each place the term appears; and

1 (II) *in subparagraph (B), by*
2 *striking “an active ingredient of a*
3 *drug, a finished drug product, or an*
4 *excipient of a drug” and inserting “an*
5 *active ingredient of a drug or a fin-*
6 *ished drug product”.*

7 (I) *CLASSIFICATION OF DEVICES INTENDED*
8 *FOR HUMAN USE.—Section 513(f)(2)(A) (21*
9 *U.S.C. 360c(f)(2)(A)) is amended—*

10 *(i) in clause (i), by striking “within*
11 *30 days”; and*

12 *(ii) in clause (iv), by striking “low-*
13 *moderate” and inserting “low to moderate”.*

14 (J) *PREMARKET APPROVAL.—Section*
15 *515(a)(1) (21 U.S.C. 360e(a)(1)) is amended by*
16 *striking “subject to a an order” and inserting*
17 *“subject to an order”.*

18 (K) *PROGRAM TO IMPROVE THE DEVICE RE-*
19 *CALL SYSTEM.—Section 518A (21 U.S.C. 360h-*
20 *1) is amended—*

21 *(i) by striking subsection (c); and*

22 *(ii) by redesignating subsection (d) as*
23 *subsection (c).*

24 (L) *UNIQUE DEVICE IDENTIFIER.—Section*
25 *519(f) (21 U.S.C. 360i(f)) is amended by strik-*

1 ing “and life sustaining” and inserting “or life
2 sustaining”.

3 (M) *PRIORITY REVIEW TO ENCOURAGE*
4 *TREATMENTS FOR TROPICAL DISEASES.*—Section
5 524(c)(4)(A) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 360n(c)(4)(A)) is amended
7 by striking “Services Act” and inserting “Serv-
8 ice Act”.

9 (N) *PRIORITY REVIEW FOR QUALIFIED IN-*
10 *FECTIONOUS DISEASE PRODUCTS.*—Section 524A
11 (21 U.S.C. 360n–1) is amended—

12 (i) by striking “If the Secretary” and
13 inserting the following:

14 “(a) *IN GENERAL.*—If the Secretary”;

15 (ii) by striking “any” and inserting
16 “the first”; and

17 (iii) by adding at the end the fol-
18 lowing:

19 “(b) *CONSTRUCTION.*—Nothing in this section shall
20 prohibit the Secretary from giving priority review to a
21 human drug application or efficacy supplement submitted
22 for approval under section 505(b) that otherwise meets the
23 criteria for the Secretary to grant priority review.”.

24 (O) *CONSULTATION WITH EXTERNAL EX-*
25 *PERTS ON RARE DISEASES, TARGETED THERA-*

1 *PIES, AND GENETIC TARGETING OF TREAT-*
2 *MENTS.—Section 569(a)(2)(A) (21 U.S.C.*
3 *360bbb–8(a)(2)(A)) is amended, in the first sen-*
4 *tence, by striking “subsection (c)” and inserting*
5 *“subsection (b)”.*

6 *(P) OPTIMIZING GLOBAL CLINICAL*
7 *TRIALS.—Section 569A(c) (21 U.S.C. 360bbb–*
8 *8a(c)) is amended by inserting “or under the*
9 *Public Health Service Act” after “this Act”.*

10 *(Q) USE OF CLINICAL INVESTIGATION DATA*
11 *FROM OUTSIDE THE UNITED STATES.—Section*
12 *569B (21 U.S.C. 360bbb–8b) is amended by*
13 *striking “drug or device” and inserting “drug,*
14 *biological product, or device” each place the term*
15 *appears.*

16 *(R) MEDICAL GASES DEFINITIONS.—Section*
17 *575(1)(H) (21 U.S.C. 360ddd(1)(H)) is amend-*
18 *ed—*

19 *(i) by inserting “for a new drug” after*
20 *“any period of exclusivity”; and*

21 *(ii) by inserting “or any period of ex-*
22 *clusivity for a new animal drug under sec-*
23 *tion 512(c)(2)(F),” after “section 505A,”.*

1 (S) *REGULATION OF MEDICAL GASES.*—*Sec-*
2 tion 576(a) (21 U.S.C. 360ddd–1(a)) is amend-
3 ed—

4 (i) in the matter preceding subpara-
5 graph (A) of paragraph (1), by inserting
6 “who seeks to initially introduce or deliver
7 for introduction a designated medical gas
8 into interstate commerce” after “any per-
9 son”; and

10 (ii) in paragraph (3)—

11 (I) in subparagraph (A)—

12 (aa) in clause (i)(VIII), by
13 inserting “for a new drug” after
14 “any period of exclusivity”; and

15 (bb) in clause (ii), in the
16 matter preceding subclause (I), by
17 inserting “the” before “final use”;
18 and

19 (II) in subparagraph (B)—

20 (aa) in clause (i), by insert-
21 ing “for a new drug” after “any
22 period of exclusivity”; and

23 (bb) in clause (ii), by insert-
24 ing a comma after “drug prod-
25 uct”.

1 (T) *INAPPLICABILITY OF DRUG FEES TO*
2 *DESIGNATED MEDICAL GASES.*—Section 577 (21
3 *U.S.C. 360ddd–2*) is amended by inserting “or
4 *740(a)*” after “*section 736(a)*”.

5 (U) *CONFLICTS OF INTEREST.*—Section
6 *712(e)(1)(B)* (21 *U.S.C. 379d–1(e)(1)(B)*) is
7 amended by striking “*services*” and inserting
8 “*service*”.

9 (V) *AUTHORITY TO ASSESS AND USE BIO-*
10 *SIMILAR BIOLOGICAL PRODUCT FEES.*—Section
11 *744H(a)* (21 *U.S.C. 379j–52(a)*) is amended—

12 (i) in paragraph (1)(A)(v), by striking
13 “*Biosimilars User Fee Act of 2012*” and in-
14 serting “*Biosimilar User Fee Act of 2012*”;
15 and

16 (ii) in paragraph (2)(B), by striking
17 “*Biosimilars User Fee Act of 2012*” and in-
18 serting “*Biosimilar User Fee Act of 2012*”.

19 (W) *REGISTRATION OF COMMERCIAL IM-*
20 *PORTERS.*—

21 (i) *AMENDMENT.*—Section 801(s)(2)
22 (21 *U.S.C. 381(s)(2)*) is amended by adding
23 at the end the following:

24 “(D) *EFFECTIVE DATE.*—In establishing the
25 effective date of the regulations under subpara-

1 *graph (A), the Secretary shall, in consultation*
2 *with the Secretary of Homeland Security acting*
3 *through U.S. Customs and Border Protection, as*
4 *determined appropriate by the Secretary of*
5 *Health and Human Services, provide a reason-*
6 *able period of time for an importer of a drug to*
7 *comply with good importer practices, taking into*
8 *account differences among importers and types*
9 *of imports, including based on the level of risk*
10 *posed by the imported product.”.*

11 (ii) *CONFORMING AMENDMENT.—Sec-*
12 *tion 714 of the Food and Drug Administra-*
13 *tion Safety and Innovation Act (Public*
14 *Law 112–144; 126 Stat. 1074) is amended*
15 *by striking subsection (d).*

16 (X) *RECOGNITION OF FOREIGN GOVERN-*
17 *MENT INSPECTIONS.—Section 809(a)(2) (21*
18 *U.S.C. 384e(a)(2)) is amended by striking “con-*
19 *duction” and inserting “conducting”.*

20 (b) *FDASIA.—*

21 (1) *FINDINGS RELATING TO DRUG APPROVAL.—*
22 *Section 901(a)(1)(A) of the Food and Drug Adminis-*
23 *tration Safety and Innovation Act (Public Law 112–*
24 *144; 21 U.S.C. 356 note) is amended by striking “se-*

1 *rious and life-threatening diseases” and inserting “se-*
2 *rious or life-threatening diseases”.*

3 (2) *REPORTING OF INCLUSION OF DEMOGRAPHIC*
4 *SUBGROUPS.—Section 907 of the Food and Drug Ad-*
5 *ministration Safety and Innovation Act (Public Law*
6 *112–144; 126 Stat. 1092, 1093) is amended—*

7 (A) *in the section heading, by striking*
8 *“BIOLOGICS” in the heading and inserting*
9 *“BIOLOGICAL PRODUCTS”; and*

10 (B) *in subsection (a)(2)(B), by striking*
11 *“applications for new drug applications” and*
12 *inserting “new drug applications”.*

13 (3) *COMBATING PRESCRIPTION DRUG ABUSE.—*
14 *Section 1122 of the Food and Drug Administration*
15 *Safety and Innovation Act (Public Law 112–144; 126*
16 *Stat. 1112, 1113) is amended—*

17 (A) *in subsection (a)(2), by striking*
18 *“dependance” and inserting “dependence”; and*

19 (B) *in subsection (c), by striking “promul-*
20 *gate” and inserting “issue”.*

21 **SEC. 3102. COMPLETED STUDIES.**

22 *The Federal Food, Drug, and Cosmetic Act is amend-*
23 *ed—*

24 (1) *in section 505(k)(5) (21 U.S.C. 355(k)(5))—*

1 (A) in subparagraph (A), by inserting
2 “and” after the semicolon;

3 (B) by striking subparagraph (B); and

4 (C) by redesignating subparagraph (C) as
5 subparagraph (B);

6 (2) in section 505A (21 U.S.C. 355a), by striking
7 subsection (p);

8 (3) in section 505B (21 U.S.C. 355c)—

9 (A) by striking subsection (l); and

10 (B) by redesignating subsection (m) as sub-
11 section (l); and

12 (4) in section 523 (21 U.S.C. 360m), by striking
13 subsection (d).

14 **TITLE IV—DELIVERY**

15 **SEC. 4001. ASSISTING DOCTORS AND HOSPITALS IN IM-** 16 **PROVING QUALITY OF CARE FOR PATIENTS.**

17 (a) *IN GENERAL.*—*The Health Information Tech-*
18 *nology for Economic and Clinical Health Act (title XIII*
19 *of division A of Public Law 111–5) is amended—*

20 (1) *by adding at the end of part 1 of subtitle A*
21 *the following:*

22 **“SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IM-** 23 **PROVING QUALITY OF CARE FOR PATIENTS.**

24 “(a) *REDUCTION IN BURDENS GOAL.*—*The Secretary*
25 *of Health and Human Services (referred to in this section*

1 *as the ‘Secretary’), in consultation with providers of health*
2 *services, health care suppliers of services, health care payers,*
3 *health professional societies, health information technology*
4 *developers, health care quality organizations, health care*
5 *accreditation organizations, public health entities, States,*
6 *and other appropriate entities, shall, in accordance with*
7 *subsection (b)—*

8 “(1) *establish a goal with respect to the reduction*
9 *of regulatory or administrative burdens (such as doc-*
10 *umentation requirements) relating to the use of elec-*
11 *tronic health records;*

12 “(2) *develop a strategy for meeting the goal es-*
13 *tablished under paragraph (1); and*

14 “(3) *develop recommendations for meeting the*
15 *goal established under paragraph (1).*

16 “(b) *STRATEGY AND RECOMMENDATIONS.—*

17 “(1) *IN GENERAL.—To achieve the goal estab-*
18 *lished under subsection (a)(1), the Secretary, in con-*
19 *sultation with the entities described in such sub-*
20 *section, shall, not later than 1 year after the date of*
21 *enactment of the 21st Century Cures Act, develop a*
22 *strategy and recommendations to meet the goal in ac-*
23 *cordance with this subsection.*

24 “(2) *STRATEGY.—The strategy developed under*
25 *paragraph (1) shall address the regulatory and ad-*

1 *ministrative burdens (such as documentation require-*
2 *ments) relating to the use of electronic health records.*
3 *Such strategy shall include broad public comment*
4 *and shall prioritize—*

5 *“(A)(i) incentives for meaningful use of cer-*
6 *tified EHR technology for eligible professionals*
7 *and hospitals under sections 1848(a)(7) and*
8 *1886(b)(3)(B)(ix), respectively, of the Social Se-*
9 *curity Act (42 U.S.C. 1395w–4(a)(7),*
10 *1395ww(b)(3)(B)(ix));*

11 *“(i) the program for making payments*
12 *under section 1903(a)(3)(F) of the Social Secu-*
13 *rity Act (42 U.S.C. 1396b(a)(3)(F)) to encourage*
14 *the adoption and use of certified EHR tech-*
15 *nology by Medicaid providers;*

16 *“(iii) the Merit-based Incentive Payment*
17 *System under section 1848(q) of the Social Secu-*
18 *rity Act (42 U.S.C. 1395w–4(q));*

19 *“(iv) alternative payment models (as de-*
20 *finied in section 1833(z)(3)(C) of the Social Secu-*
21 *rity Act (42 U.S.C. 1395l(z)(3)(C));*

22 *“(v) the Hospital Value-Based Purchasing*
23 *Program under section 1886(o) of the Social Se-*
24 *curity Act (42 U.S.C. 1395ww(o)); and*

1 “(vi) other value-based payment programs,
2 as the Secretary determines appropriate;

3 “(B) health information technology certifi-
4 cation;

5 “(C) standards and implementation speci-
6 fications, as appropriate;

7 “(D) activities that provide individuals ac-
8 cess to their electronic health information;

9 “(E) activities related to protecting the pri-
10 vacy of electronic health information;

11 “(F) activities related to protecting the se-
12 curity of electronic health information;

13 “(G) activities related to facilitating health
14 and clinical research;

15 “(H) activities related to public health;

16 “(I) activities related to aligning and sim-
17 plifying quality measures across Federal pro-
18 grams and other payers;

19 “(J) activities related to reporting clinical
20 data for administrative purposes; and

21 “(K) other areas, as the Secretary deter-
22 mines appropriate.

23 “(3) *RECOMMENDATIONS.*—The recommenda-
24 tions developed under paragraph (1) shall address—

1 “(A) actions that improve the clinical docu-
2 mentation experience;

3 “(B) actions that improve patient care;

4 “(C) actions to be taken by the Secretary
5 and by other entities; and

6 “(D) other areas, as the Secretary deter-
7 mines appropriate, to reduce the reporting bur-
8 den required of health care providers.

9 “(4) FACA.—The Federal Advisory Committee
10 Act (5 U.S.C. App.) shall not apply to the develop-
11 ment of the goal, strategies, or recommendations de-
12 scribed in this section.

13 “(c) APPLICATION OF CERTAIN REGULATORY RE-
14 QUIREMENTS.—A physician (as defined in section
15 1861(r)(1) of the Social Security Act), to the extent con-
16 sistent with applicable State law, may delegate electronic
17 medical record documentation requirements specified in
18 regulations promulgated by the Centers for Medicare &
19 Medicaid Services to a person performing a scribe function
20 who is not such physician if such physician has signed and
21 verified the documentation.”; and

22 (2) in the table of contents in section 13001(b),
23 by inserting after the item relating to section 13102
24 the following:

 “13103. Assisting doctors and hospitals in improving the quality and care for pa-
 tients.”.

1 (b) *CERTIFICATION OF HEALTH INFORMATION TECH-*
2 *NOLOGY FOR MEDICAL SPECIALTIES AND SITES OF SERV-*
3 *ICE.*—Section 3001(c)(5) of the Public Health Service Act
4 (42 U.S.C. 300jj–11(c)(5)) is amended by adding at the end
5 the following:

6 “(C) *HEALTH INFORMATION TECHNOLOGY*
7 *FOR MEDICAL SPECIALTIES AND SITES OF SERV-*
8 *ICE.*—

9 “(i) *IN GENERAL.*—*The National Coor-*
10 *dinator shall encourage, keep, or recognize,*
11 *through existing authorities, the voluntary*
12 *certification of health information tech-*
13 *nology under the program developed under*
14 *subparagraph (A) for use in medical spe-*
15 *cialties and sites of service for which no*
16 *such technology is available or where more*
17 *technological advancement or integration is*
18 *needed.*

19 “(ii) *SPECIFIC MEDICAL SPECIAL-*
20 *TIES.*—*The Secretary shall accept public*
21 *comment on specific medical specialties and*
22 *sites of service, in addition to those de-*
23 *scribed in clause (i), for the purpose of se-*
24 *lecting additional specialties and sites of*
25 *service as necessary.*

1 “(iii) *HEALTH INFORMATION TECH-*
2 *NOLOGY FOR PEDIATRICS.*—Not later than
3 18 months after the date of enactment of the
4 21st Century Cures Act, the Secretary, in
5 consultation with relevant stakeholders,
6 shall make recommendations for the vol-
7 untary certification of health information
8 technology for use by pediatric health pro-
9 viders to support the health care of children.
10 Not later than 2 years after the date of en-
11 actment of the 21st Century Cures Act, the
12 Secretary shall adopt certification criteria
13 under section 3004 to support the voluntary
14 certification of health information tech-
15 nology for use by pediatric health providers
16 to support the health care of children.”.

17 (c) *MEANINGFUL USE STATISTICS.*—

18 (1) *IN GENERAL.*—Not later than 6 months after
19 the date of enactment of this Act, the Secretary of
20 Health and Human Services shall submit to the HIT
21 Advisory Committee of the Office of the National Co-
22 ordinator for Health Information Technology, a re-
23 port concerning attestation statistics for the Medicare
24 and Medicaid EHR Meaningful Use Incentive pro-
25 grams to assist in informing standards adoption and

1 *related practices. Such statistics shall include attesta-*
2 *tion information delineated by State, including, to*
3 *the extent practicable, the number of providers who*
4 *did not meet the minimum criteria necessary to attest*
5 *for the Medicare and Medicaid EHR Meaningful Use*
6 *Incentive programs for a calendar year, and shall be*
7 *made publicly available on the Internet website of the*
8 *Secretary on at least a quarterly basis.*

9 (2) *AUTHORITY TO ALTER FORMAT.—The Sec-*
10 *retary of Health and Human Services may alter the*
11 *format of the reports on the attestation of eligible*
12 *health care professionals following the first perform-*
13 *ance year of the Merit-based Incentive Payment Sys-*
14 *tem to account for changes arising from the imple-*
15 *mentation of such payment system.*

16 **SEC. 4002. TRANSPARENT REPORTING ON USABILITY, SECU-**
17 **RITY, AND FUNCTIONALITY.**

18 (a) *ENHANCEMENTS TO CERTIFICATION.—Section*
19 *3001(c)(5) of the Public Health Service Act (42 U.S.C.*
20 *300jj–11), as amended by section 4001(b), is further amend-*
21 *ed by adding at the end the following:*

22 *“(D) CONDITIONS OF CERTIFICATION.—Not*
23 *later than 1 year after the date of enactment of*
24 *the 21st Century Cures Act, the Secretary,*
25 *through notice and comment rulemaking, shall*

1 *require, as a condition of certification and*
2 *maintenance of certification for programs main-*
3 *tained or recognized under this paragraph, con-*
4 *sistent with other conditions and requirements*
5 *under this title, that the health information tech-*
6 *nology developer or entity—*

7 *“(i) does not take any action that con-*
8 *stitutes information blocking as defined in*
9 *section 3022(a);*

10 *“(ii) provides assurances satisfactory*
11 *to the Secretary that such developer or enti-*
12 *ty, unless for legitimate purposes specified*
13 *by the Secretary, will not take any action*
14 *described in clause (i) or any other action*
15 *that may inhibit the appropriate exchange,*
16 *access, and use of electronic health informa-*
17 *tion;*

18 *“(iii) does not prohibit or restrict com-*
19 *munication regarding—*

20 *“(I) the usability of the health in-*
21 *formation technology;*

22 *“(II) the interoperability of the*
23 *health information technology;*

24 *“(III) the security of the health*
25 *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 electronic
7 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 electronic
20 health record to the extent permissible under
21 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 the
6 conduct described in clause (i);

7 “(II) has provided assurances sat-
8 isfactory to the Secretary in accord-
9 ance with clause (ii);

10 “(III) does not prohibit or restrict
11 communication as described in clause
12 (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.—***Section*
7 *1848(a)(7)(B) of the Social Security Act (42*
8 *U.S.C. 1395w–4(a)(7)(B)) is amended by insert-*
9 *ing after the first sentence the following new sen-*
10 *tence: “The Secretary shall exempt an eligible*
11 *professional from the application of the payment*
12 *adjustment under subparagraph (A) with respect*
13 *to a year, subject to annual renewal, if the Sec-*
14 *retary determines that compliance with the re-*
15 *quirement for being a meaningful EHR user is*
16 *not possible because the certified EHR technology*
17 *used by such professional has been decertified*
18 *under a program kept or recognized pursuant to*
19 *section 3001(c)(5) of the Public Health Service*
20 *Act.”.*

21 **(B) CONTINUED APPLICATION UNDER**
22 **MIPS.—***Section 1848(o)(2)(D) of the Social Secu-*
23 *rity Act (42 U.S.C. 1395w–4(o)(2)(D)) is*
24 *amended by adding at the end the following new*
25 *sentence: “The provisions of subparagraphs (B)*

1 *and (D) of subsection (a)(7), shall apply to as-*
2 *essments of MIPS eligible professionals under*
3 *subsection (q) with respect to the performance*
4 *category described in subsection (q)(2)(A)(iv) in*
5 *an appropriate manner which may be similar to*
6 *the manner in which such provisions apply with*
7 *respect to payment adjustments made under sub-*
8 *section (a)(7)(A).”.*

9 (2) *APPLICATION TO ELIGIBLE HOSPITALS.—Sec-*
10 *tion 1886(b)(3)(B)(ix)(II) of the Social Security Act*
11 *(42 U.S.C. 1395ww(b)(3)(B)(ix)(II)) is amended by*
12 *inserting after the first sentence the following new*
13 *sentence: “The Secretary shall exempt an eligible hos-*
14 *pital from the application of the payment adjustment*
15 *under subclause (I) with respect to a fiscal year, sub-*
16 *ject to annual renewal, if the Secretary determines*
17 *that compliance with the requirement for being a*
18 *meaningful EHR user is not possible because the cer-*
19 *tified EHR technology used by such hospital is decer-*
20 *tified under a program kept or recognized pursuant*
21 *to section 3001(c)(5) of the Public Health Service*
22 *Act.”.*

23 (c) *ELECTRONIC HEALTH RECORD REPORTING PRO-*
24 *GRAM.—Subtitle A of title XXX of the Public Health Service*

1 *Act (42 U.S.C. 300jj–11 et seq.) is amended by adding at*
2 *the end the following:*

3 **“SEC. 3009A. ELECTRONIC HEALTH RECORD REPORTING**
4 **PROGRAM.**

5 *“(a) REPORTING CRITERIA.—*

6 *“(1) CONVENING OF STAKEHOLDERS.—Not later*
7 *than 1 year after the date of enactment of the 21st*
8 *Century Cures Act, the Secretary shall convene stake-*
9 *holders, as described in paragraph (2), for the pur-*
10 *pose of developing the reporting criteria in accordance*
11 *with paragraph (3).*

12 *“(2) DEVELOPMENT OF REPORTING CRITERIA.—*
13 *The reporting criteria under this subsection shall be*
14 *developed through a public, transparent process that*
15 *reflects input from relevant stakeholders, including—*

16 *“(A) health care providers, including pri-*
17 *mary care and specialty care health care profes-*
18 *sionals;*

19 *“(B) hospitals and hospital systems;*

20 *“(C) health information technology devel-*
21 *opers;*

22 *“(D) patients, consumers, and their advo-*
23 *cates;*

24 *“(E) data sharing networks, such as health*
25 *information exchanges;*

1 “(F) authorized certification bodies and
2 testing laboratories;

3 “(G) security experts;

4 “(H) relevant manufacturers of medical de-
5 vices;

6 “(I) experts in health information tech-
7 nology market economics;

8 “(J) public and private entities engaged in
9 the evaluation of health information technology
10 performance;

11 “(K) quality organizations, including the
12 consensus based entity described in section 1890
13 of the Social Security Act;

14 “(L) experts in human factors engineering
15 and the measurement of user-centered design;
16 and

17 “(M) other entities or individuals, as the
18 Secretary determines appropriate.

19 “(3) CONSIDERATIONS FOR REPORTING CRI-
20 TERIA.—The reporting criteria developed under this
21 subsection—

22 “(A) shall include measures that reflect cat-
23 egories including—

24 “(i) security;

1 “(ii) usability and user-centered de-
2 sign;

3 “(iii) interoperability;

4 “(iv) conformance to certification test-
5 ing; and

6 “(v) other categories, as appropriate to
7 measure the performance of electronic health
8 record technology;

9 “(B) may include categories such as—

10 “(i) enabling the user to order and
11 view the results of laboratory tests, imaging
12 tests, and other diagnostic tests;

13 “(ii) submitting, editing, and retriev-
14 ing data from registries such as clinician-
15 led clinical data registries;

16 “(iii) accessing and exchanging infor-
17 mation and data from and through health
18 information exchanges;

19 “(iv) accessing and exchanging infor-
20 mation and data from medical devices;

21 “(v) accessing and exchanging infor-
22 mation and data held by Federal, State,
23 and local agencies and other applicable en-
24 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 ex-*
14 *changing such information, and avoiding*
15 *the duplication of patients records; and*

16 *“(x) other categories regarding per-*
17 *formance, accessibility, as the Secretary de-*
18 *termines appropriate; and*

19 *“(C) shall be designed to ensure that small*
20 *and startup health information technology devel-*
21 *opers are not unduly disadvantaged by the re-*
22 *porting 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(c)(5)(D), a developer of cer-*
6 *tified electronic health records shall submit to an appro-*
7 *priate recipient of a grant, contract, or agreement under*
8 *subsection (c)(1) responses to the criteria developed under*
9 *subsection (a), with respect to all certified technology offered*
10 *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 Act,*
14 *the Secretary shall award grants, contracts, or agree-*
15 *ments to independent entities on a competitive basis*
16 *to support the convening of stakeholders as described*
17 *in subsection (a)(2), collect the information required*
18 *to be reported in accordance with the criteria estab-*
19 *lished as described subsection (a)(3), and develop and*
20 *implement a process in accordance with paragraph*
21 *(5) and report such information to the Secretary.*

22 “(2) *APPLICATIONS.*—*An independent entity*
23 *that seeks a grant, contract, or agreement under this*
24 *subsection shall submit an application to the Sec-*
25 *retary at such time, in such manner, and containing*

1 *such information as the Secretary may reasonably re-*
2 *quire, including a description of—*

3 *“(A) the proposed method for reviewing and*
4 *summarizing information gathered based on re-*
5 *porting criteria established under subsection (a);*

6 *“(B) if applicable, the intended focus on a*
7 *specific subset of certified electronic health record*
8 *technology users, such as health care providers,*
9 *including primary care, specialty care, and care*
10 *provided in rural settings; hospitals and hospital*
11 *systems; and patients, consumers, and patients*
12 *and consumer advocates;*

13 *“(C) the plan for widely distributing re-*
14 *ports described in paragraph (6);*

15 *“(D) the period for which the grant, con-*
16 *tract, or agreement is requested, which may be*
17 *up to 2 years; and*

18 *“(E) the budget for reporting program par-*
19 *ticipation, and whether the eligible independent*
20 *entity intends to continue participation after the*
21 *period of the grant, contract, or agreement.*

22 *“(3) CONSIDERATIONS FOR INDEPENDENT ENTI-*
23 *TIES.—In awarding grants, contracts, and agree-*
24 *ments under paragraph (1), the Secretary shall give*
25 *priority to independent entities with appropriate ex-*

1 *expertise in health information technology usability,*
2 *interoperability, and security (especially entities with*
3 *such expertise in electronic health records) with re-*
4 *spect to—*

5 *“(A) health care providers, including pri-*
6 *mary care, specialty care, and care provided in*
7 *rural settings;*

8 *“(B) hospitals and hospital systems; and*

9 *“(C) patients, consumers, and patient and*
10 *consumer advocates.*

11 *“(4) LIMITATIONS.—*

12 *“(A) ASSESSMENT AND REDETERMINA-*
13 *TION.—Not later than 4 years after the date of*
14 *enactment of the 21st Century Cures Act and*
15 *every 2 years thereafter, the Secretary, in con-*
16 *sultation with stakeholders, shall—*

17 *“(i) assess performance of the recipi-*
18 *ents of the grants, contracts, and agreements*
19 *under paragraph (1) based on quality and*
20 *usability of reports described in paragraph*
21 *(6); and*

22 *“(ii) re-determine grants, contracts,*
23 *and agreements as necessary.*

24 *“(B) PROHIBITIONS ON PARTICIPATION.—*

25 *The Secretary may not award a grant, contract,*

1 or cooperative agreement under paragraph (1)
2 to—

3 “(i) a proprietor of certified health in-
4 formation technology or a business affiliate
5 of such a proprietor;

6 “(ii) a developer of certified health in-
7 formation technology; or

8 “(iii) a State or local government
9 agency.

10 “(5) *FEEDBACK*.—Based on reporting criteria
11 established under subsection (a), the recipients of
12 grants, contracts, and agreements under paragraph
13 (1) shall develop and implement a process to collect
14 and verify confidential feedback on such criteria
15 from—

16 “(A) health care providers, patients, and
17 other users of certified electronic health record
18 technology; and

19 “(B) developers of certified electronic health
20 record technology.

21 “(6) *REPORTS*.—

22 “(A) *DEVELOPMENT OF REPORTS*.—Each
23 recipient of a grant, contract, or agreement
24 under paragraph (1) shall report on the infor-
25 mation reported to such recipient pursuant to

1 *subsection (a) and the user feedback collected*
2 *under paragraph (5) by preparing summary re-*
3 *ports and detailed reports of such information.*

4 *“(B) DISTRIBUTION OF REPORTS.—Each*
5 *recipient of a grant, contract, or agreement*
6 *under paragraph (1) shall submit the reports*
7 *prepared under subparagraph (A) to the Sec-*
8 *retary for public distribution in accordance with*
9 *subsection (d).*

10 *“(d) PUBLICATION.—The Secretary shall distribute*
11 *widely, as appropriate, and publish, on the Internet website*
12 *of the Office of the National Coordinator—*

13 *“(1) the reporting criteria developed under sub-*
14 *section (a); and*

15 *“(2) the summary and detailed reports under*
16 *subsection (c)(6).*

17 *“(e) REVIEW.—Each recipient of a grant, contract, or*
18 *agreement under paragraph (1) shall develop and imple-*
19 *ment a process through which participating electronic*
20 *health record technology developers may review and rec-*
21 *ommend changes to the reports created under subsection*
22 *(c)(6) for products developed by such developer prior to the*
23 *publication of such report under subsection (d).*

24 *“(f) ADDITIONAL RESOURCES.—The Secretary may*
25 *provide additional resources on the Internet website of the*

1 *Office of the National Coordinator to better inform con-*
2 *sumers of health information technology. Such reports may*
3 *be carried out through partnerships with private organiza-*
4 *tions with appropriate expertise.”.*

5 (d) *AUTHORIZATION OF APPROPRIATIONS.—There is*
6 *authorized to be appropriated \$15,000,000 for purposes of*
7 *carrying out subparagraph (D) of section 3001(c)(5) of the*
8 *Public Health Service Act (42 U.S.C. 300jj–11) (as added*
9 *by subsection (a)) and section 3009A of the Public Health*
10 *Service Act (as added by subsection (b)), including for pur-*
11 *poses of administering any contracts, grants, or agreements,*
12 *to remain available until expended.*

13 **SEC. 4003. INTEROPERABILITY.**

14 (a) *DEFINITION.—Section 3000 of the Public Health*
15 *Service Act (42 U.S.C. 300jj) is amended—*

16 (1) *by redesignating paragraphs (10) through*
17 *(14), as paragraphs (11) through (15), respectively;*
18 *and*

19 (2) *by inserting after paragraph (9) the fol-*
20 *lowing:*

21 “(10) *INTEROPERABILITY.—The term ‘interoper-*
22 *ability’, with respect to health information technology,*
23 *means such health information technology that—*

24 “(A) *enables the secure exchange of elec-*
25 *tronic health information with, and use of elec-*

1 *tronic health information from, other health in-*
2 *formation technology without special effort on*
3 *the part of the user;*

4 *“(B) allows for complete access, exchange,*
5 *and use of all electronically accessible health in-*
6 *formation for authorized use under applicable*
7 *State or Federal law; and*

8 *“(C) does not constitute information block-*
9 *ing as defined in section 3022(a).”.*

10 *(b) SUPPORT FOR INTEROPERABLE NETWORK EX-*
11 *CHANGE.—Section 3001(c) of the Public Health Service Act*
12 *(42 U.S.C. 300jj–11(c)) is amended by adding at the end*
13 *the following:*

14 *“(9) SUPPORT FOR INTEROPERABLE NETWORKS*
15 *EXCHANGE.—*

16 *“(A) IN GENERAL.—The National Coordi-*
17 *nator shall, in collaboration with the National*
18 *Institute of Standards and Technology and other*
19 *relevant agencies within the Department of*
20 *Health and Human Services, for the purpose of*
21 *ensuring full network-to-network exchange of*
22 *health information, convene public-private and*
23 *public-public partnerships to build consensus*
24 *and develop or support a trusted exchange*
25 *framework, including a common agreement*

1 *among health information networks nationally.*
2 *Such convention may occur at a frequency deter-*
3 *mined appropriate by the Secretary.*

4 “(B) *ESTABLISHING A TRUSTED EXCHANGE*
5 *FRAMEWORK.—*

6 “(i) *IN GENERAL.—Not later than 6*
7 *months after the date of enactment of the*
8 *21st Century Cures Act, the National Coor-*
9 *dinator shall convene appropriate public*
10 *and private stakeholders to develop or sup-*
11 *port a trusted exchange framework for trust*
12 *policies and practices and for a common*
13 *agreement for exchange between health in-*
14 *formation networks. The common agreement*
15 *may include—*

16 “(I) *a common method for au-*
17 *thenticating trusted health information*
18 *network participants;*

19 “(II) *a common set of rules for*
20 *trusted exchange;*

21 “(III) *organizational and oper-*
22 *ational policies to enable the exchange*
23 *of health information among networks,*
24 *including minimum conditions for*
25 *such exchange to occur; and*

1 “(IV) a process for filing and ad-
2 judicating noncompliance with the
3 terms of the common agreement.

4 “(ii) *TECHNICAL ASSISTANCE.*—The
5 National Coordinator, in collaboration with
6 the National Institute of Standards and
7 Technology, shall provide technical assist-
8 ance on how to implement the trusted ex-
9 change framework and common agreement
10 under this paragraph.

11 “(iii) *PILOT TESTING.*—The National
12 Coordinator, in consultation with the Na-
13 tional Institute of Standards and Tech-
14 nology, shall provide for the pilot testing of
15 the trusted exchange framework and com-
16 mon agreement established or supported
17 under this subsection (as authorized under
18 section 13201 of the Health Information
19 Technology for Economic and Clinical
20 Health Act). The National Coordinator, in
21 consultation with the National Institute of
22 Standards and Technology, may delegate
23 pilot testing activities under this clause to
24 independent entities with appropriate ex-
25 pertise.

1 “(C) *PUBLICATION OF A TRUSTED EX-*
2 *CHANGE FRAMEWORK AND COMMON AGREE-*
3 *MENT.—Not later than 1 year after convening*
4 *stakeholders under subparagraph (A), the Na-*
5 *tional Coordinator shall publish on its public*
6 *Internet website, and in the Federal register, the*
7 *trusted exchange framework and common agree-*
8 *ment developed or supported under subpara-*
9 *graph (B). Such trusted exchange framework and*
10 *common agreement shall be published in a man-*
11 *ner that protects proprietary and security infor-*
12 *mation, including trade secrets and any other*
13 *protected intellectual property.*

14 “(D) *DIRECTORY OF PARTICIPATING*
15 *HEALTH INFORMATION NETWORKS.—*

16 “(i) *IN GENERAL.—Not later than 2*
17 *years after convening stakeholders under*
18 *subparagraph (A), and annually thereafter,*
19 *the National Coordinator shall publish on*
20 *its public Internet website a list of the*
21 *health information networks that have*
22 *adopted the common agreement and are ca-*
23 *pable of trusted exchange pursuant to the*
24 *common agreement developed or supported*
25 *under paragraph (B).*

1 “(i) *PROCESS.*—*The Secretary shall,*
2 *through notice and comment rulemaking, es-*
3 *tablish a process for health information net-*
4 *works that voluntarily elect to adopt the*
5 *trusted exchange framework and common*
6 *agreement to attest to such adoption of the*
7 *framework and agreement.*

8 “(E) *APPLICATION OF THE TRUSTED EX-*
9 *CHANGE FRAMEWORK AND COMMON AGREE-*
10 *MENT.*—*As appropriate, Federal agencies con-*
11 *tracting or entering into agreements with health*
12 *information exchange networks may require that*
13 *as each such network upgrades health informa-*
14 *tion technology or trust and operational prac-*
15 *tices, such network may adopt, where available,*
16 *the trusted exchange framework and common*
17 *agreement published under subparagraph (C).*

18 “(F) *RULE OF CONSTRUCTION.*—

19 “(i) *GENERAL ADOPTION.*—*Nothing in*
20 *this paragraph shall be construed to require*
21 *a health information network to adopt the*
22 *trusted exchange framework or common*
23 *agreement.*

24 “(ii) *ADOPTION WHEN EXCHANGE OF*
25 *INFORMATION IS WITHIN NETWORK.*—*Noth-*

1 *ing in this paragraph shall be construed to*
2 *require a health information network to*
3 *adopt the trusted exchange framework or*
4 *common agreement for the exchange of elec-*
5 *tronic health information between partici-*
6 *pants of the same network.*

7 *“(iii) EXISTING FRAMEWORKS AND*
8 *AGREEMENTS.—The trusted exchange frame-*
9 *work and common agreement published*
10 *under subparagraph (C) shall take into ac-*
11 *count existing trusted exchange frameworks*
12 *and agreements used by health information*
13 *networks to avoid the disruption of existing*
14 *exchanges between participants of health in-*
15 *formation networks.*

16 *“(iv) APPLICATION BY FEDERAL AGEN-*
17 *CIES.—Notwithstanding clauses (i), (ii),*
18 *and (iii), Federal agencies may require the*
19 *adoption of the trusted exchange framework*
20 *and common agreement published under*
21 *subparagraph (C) for health information ex-*
22 *changes contracting with or entering into*
23 *agreements pursuant to subparagraph (E).*

24 *“(v) CONSIDERATION OF ONGOING*
25 *WORK.—In carrying out this paragraph, the*

1 *Secretary shall ensure the consideration of*
2 *activities carried out by public and private*
3 *organizations related to exchange between*
4 *health information exchanges to avoid du-*
5 *plication of efforts.”.*

6 (c) *PROVIDER DIGITAL CONTACT INFORMATION*
7 *INDEX.—*

8 (1) *IN GENERAL.—Not later than 3 years after*
9 *the date of enactment of this Act, the Secretary of*
10 *Health and Human Services (referred to in this sub-*
11 *section as the “Secretary”) shall, directly or through*
12 *a partnership with a private entity, establish a pro-*
13 *vider digital contact information index to provide*
14 *digital contact information for health professionals*
15 *and health facilities.*

16 (2) *USE OF EXISTING INDEX.—In establishing*
17 *the initial index under paragraph (1), the Secretary*
18 *may utilize an existing provider directory to make*
19 *such digital contact information available.*

20 (3) *CONTACT INFORMATION.—An index estab-*
21 *lished under this subsection shall ensure that contact*
22 *information is available at the individual health care*
23 *provider level and at the health facility or practice*
24 *level.*

25 (4) *RULE OF CONSTRUCTION.—*

1 (A) *IN GENERAL.*—*The purpose of this sub-*
2 *section is to encourage the exchange of electronic*
3 *health information by providing the most useful,*
4 *reliable, and comprehensive index of providers*
5 *possible. In furthering such purpose, the Sec-*
6 *retary shall include all health professionals and*
7 *health facilities applicable to provide a useful,*
8 *reliable, and comprehensive index for use in the*
9 *exchange of health information.*

10 (B) *LIMITATION.*—*In no case shall exclusion*
11 *from the index of providers be used as a measure*
12 *to achieve objectives other the objectives described*
13 *in subparagraph (A).*

14 (d) *STANDARDS DEVELOPMENT ORGANIZATIONS.*—
15 *Section 3004 of the Public Health Service Act (42 U.S.C.*
16 *300jj–14) is amended by adding at the end the following:*

17 “*(c) DEFERENCE TO STANDARDS DEVELOPMENT OR-*
18 *GANIZATIONS.*—*In adopting and implementing standards*
19 *under this section, the Secretary shall give deference to*
20 *standards published by standards development organiza-*
21 *tions and voluntary consensus-based standards bodies.”.*

22 (e) *HEALTH INFORMATION TECHNOLOGY ADVISORY*
23 *COMMITTEE.*—

24 (1) *IN GENERAL.*—*Title XXX of the Public*
25 *Health Service Act (42 U.S.C. 300jj et seq.) is amend-*

1 *ed by striking sections 3002 (42 U.S.C. 300jj–12) and*
2 *3003 (42 U.S.C. 300jj–13) and inserting the fol-*
3 *lowing:*

4 **“SEC. 3002. HEALTH INFORMATION TECHNOLOGY ADVI-**
5 **SORY COMMITTEE.**

6 *“(a) ESTABLISHMENT.—There is established a Health*
7 *Information Technology Advisory Committee (referred to in*
8 *this section as the ‘HIT Advisory Committee’) to rec-*
9 *ommend to the National Coordinator, consistent with the*
10 *implementation of the strategic plan described in section*
11 *3001(c)(3), policies, and, for purposes of adoption under*
12 *section 3004, standards, implementation specifications, and*
13 *certification criteria, relating to the implementation of a*
14 *health information technology infrastructure, nationally*
15 *and locally, that advances the electronic access, exchange,*
16 *and use of health information. Such Committee shall serve*
17 *to unify the roles of, and replace, the HIT Policy Committee*
18 *and the HIT Standards Committee, as in existence before*
19 *the date of the enactment of the 21st Century Cures Act.*

20 *“(b) DUTIES.—*

21 *“(1) RECOMMENDATIONS ON POLICY FRAMEWORK*
22 *TO ADVANCE AN INTEROPERABLE HEALTH INFORMA-*
23 *TION TECHNOLOGY INFRASTRUCTURE.—*

24 *“(A) IN GENERAL.—The HIT Advisory*
25 *Committee shall recommend to the National Co-*

1 *ordinator a policy framework for adoption by*
2 *the Secretary consistent with the strategic plan*
3 *under section 3001(c)(3) for advancing the target*
4 *areas described in this subsection. Such policy*
5 *framework shall seek to prioritize achieving ad-*
6 *vancements in the target areas specified in sub-*
7 *paragraph (B) of paragraph (2) and may, to the*
8 *extent consistent with this section, incorporate*
9 *policy recommendations made by the HIT Policy*
10 *Committee, as in existence before the date of the*
11 *enactment of the 21st Century Cures Act.*

12 *“(B) UPDATES.—The HIT Advisory Com-*
13 *mittee shall propose updates to such rec-*
14 *ommendations to the policy framework and make*
15 *new recommendations, as appropriate.*

16 *“(2) GENERAL DUTIES AND TARGET AREAS.—*

17 *“(A) IN GENERAL.—The HIT Advisory*
18 *Committee shall recommend to the National Co-*
19 *ordinator for purposes of adoption under section*
20 *3004, standards, implementation specifications,*
21 *and certification criteria and an order of pri-*
22 *ority for the development, harmonization, and*
23 *recognition of such standards, specifications, and*
24 *certification criteria. Such recommendations*
25 *shall include recommended standards, architec-*

1 *tures, and software schemes for access to elec-*
2 *tronic individually identifiable health informa-*
3 *tion across disparate systems including user vet-*
4 *ting, authentication, privilege management, and*
5 *access control.*

6 “(B) *PRIORITY TARGET AREAS.*—*For pur-*
7 *poses of this section, the HIT Advisory Com-*
8 *mittee shall make recommendations under sub-*
9 *paragraph (A) with respect to at least each of the*
10 *following target areas:*

11 “(i) *Achieving a health information*
12 *technology infrastructure, nationally and*
13 *locally, that allows for the electronic access,*
14 *exchange, and use of health information, in-*
15 *cluding through technology that provides ac-*
16 *curate patient information for the correct*
17 *patient, including exchanging such infor-*
18 *mation, and avoids the duplication of pa-*
19 *tient records.*

20 “(ii) *The promotion and protection of*
21 *privacy and security of health information*
22 *in health information technology, including*
23 *technologies that allow for an accounting of*
24 *disclosures and protections against disclo-*
25 *tures of individually identifiable health in-*

1 *formation made by a covered entity for pur-*
2 *poses of treatment, payment, and health*
3 *care operations (as such terms are defined*
4 *for purposes of the regulation promulgated*
5 *under section 264(c) of the Health Insur-*
6 *ance Portability and Accountability Act of*
7 *1996), including for the segmentation and*
8 *protection from disclosure of specific and*
9 *sensitive individually identifiable health in-*
10 *formation with the goal of minimizing the*
11 *reluctance of patients to seek care.*

12 *“(iii) The facilitation of secure access*
13 *by an individual to such individual’s pro-*
14 *TECTED health information and access to such*
15 *information by a family member, caregiver,*
16 *or guardian acting on behalf of a patient,*
17 *including due to age-related and other dis-*
18 *ability, cognitive impairment, or dementia.*

19 *“(iv) Subject to subparagraph (D), any*
20 *other target area that the HIT Advisory*
21 *Committee identifies as an appropriate tar-*
22 *get area to be considered under this sub-*
23 *paragraph.*

24 *“(C) ADDITIONAL TARGET AREAS.—For*
25 *purposes of this section, the HIT Advisory Com-*

1 *mittee may make recommendations under sub-*
2 *paragraph (A), in addition to areas described in*
3 *subparagraph (B), with respect to any of the fol-*
4 *lowing areas:*

5 *“(i) The use of health information tech-*
6 *nology to improve the quality of health care,*
7 *such as by promoting the coordination of*
8 *health care and improving continuity of*
9 *health care among health care providers, re-*
10 *ducing medical errors, improving popu-*
11 *lation health, reducing chronic disease, and*
12 *advancing research and education.*

13 *“(ii) The use of technologies that ad-*
14 *dress the needs of children and other vulner-*
15 *able populations.*

16 *“(iii) The use of electronic systems to*
17 *ensure the comprehensive collection of pa-*
18 *tient demographic data, including at a*
19 *minimum, race, ethnicity, primary lan-*
20 *guage, and gender information.*

21 *“(iv) The use of self-service, telemedi-*
22 *cine, home health care, and remote moni-*
23 *toring technologies.*

24 *“(v) The use of technologies that meet*
25 *the needs of diverse populations.*

1 “(vi) *The use of technologies that sup-*
2 *port—*

3 “(I) *data for use in quality and*
4 *public reporting programs;*

5 “(II) *public health; or*

6 “(III) *drug safety.*

7 “(vii) *The use of technologies that*
8 *allow individually identifiable health infor-*
9 *mation to be rendered unusable, unreadable,*
10 *or indecipherable to unauthorized individ-*
11 *uals when such information is transmitted*
12 *in a health information network or trans-*
13 *ported outside of the secure facilities or sys-*
14 *tems where the disclosing covered entity is*
15 *responsible for security conditions.*

16 “(viii) *The use of a certified health in-*
17 *formation technology for each individual in*
18 *the United States.*

19 “(D) *AUTHORITY FOR TEMPORARY ADDI-*
20 *TIONAL PRIORITY TARGET AREAS.—For purposes*
21 *of subparagraph (B)(iv), the HIT Advisory Com-*
22 *mittee may identify an area to be considered for*
23 *purposes of recommendations under this sub-*
24 *section as a target area described in subpara-*
25 *graph (B) if—*

1 “(i) the area is so identified for pur-
2 poses of responding to new circumstances
3 that have arisen in the health information
4 technology community that affect the inter-
5 operability, privacy, or security of health
6 information, or affect patient safety; and

7 “(ii) at least 30 days prior to treating
8 such area as if it were a target area de-
9 scribed in subparagraph (B), the National
10 Coordinator provides adequate notice to
11 Congress of the intent to treat such area as
12 so described.

13 “(E) *FOCUS OF COMMITTEE WORK.*—It is
14 the sense of Congress that the HIT Advisory
15 Committee shall focus its work on the priority
16 areas described in subparagraph (B) before pro-
17 ceeding to other work under subparagraph (C).

18 “(3) *RULES RELATING TO RECOMMENDATIONS*
19 *FOR STANDARDS, IMPLEMENTATION SPECIFICATIONS,*
20 *AND CERTIFICATION CRITERIA.*—

21 “(A) *IN GENERAL.*—The HIT Advisory
22 Committee shall recommend to the National Co-
23 ordinator standards, implementation specifica-
24 tions, and certification criteria described in sub-
25 section (a), which may include standards, imple-

1 *mentation specifications, and certification cri-*
2 *teria that have been developed, harmonized, or*
3 *recognized by the HIT Advisory Committee or*
4 *predecessor committee. The HIT Advisory Com-*
5 *mittee shall update such recommendations and*
6 *make new recommendations as appropriate, in-*
7 *cluding in response to a notification sent under*
8 *section 3004(a)(2)(B). Such recommendations*
9 *shall be consistent with the latest recommenda-*
10 *tions made by the Committee.*

11 *“(B) HARMONIZATION.—The HIT Advisory*
12 *Committee may recognize harmonized or up-*
13 *dated standards from an entity or entities for the*
14 *purpose of harmonizing or updating standards*
15 *and implementation specifications in order to*
16 *achieve uniform and consistent implementation*
17 *of the standards and implementation specifica-*
18 *tion.*

19 *“(C) PILOT TESTING OF STANDARDS AND*
20 *IMPLEMENTATION SPECIFICATIONS.—In the de-*
21 *velopment, harmonization, or recognition of*
22 *standards and implementation specifications, the*
23 *HIT Advisory Committee for purposes of rec-*
24 *ommendations under paragraph (2)(B), shall, as*
25 *appropriate, provide for the testing of such*

1 standards and specifications by the National In-
2 stitute for Standards and Technology under sec-
3 tion 13201(a) of the Health Information Tech-
4 nology for Economic and Clinical Health Act.

5 “(D) *CONSISTENCY*.—The standards, imple-
6 mentation specifications, and certification cri-
7 teria recommended under paragraph (2)(B) shall
8 be consistent with the standards for information
9 transactions and data elements adopted pursu-
10 ant to section 1173 of the Social Security Act.

11 “(E) *SPECIAL RULE RELATED TO INTER-*
12 *OPERABILITY*.—Any recommendation made by
13 the HIT Advisory Committee after the date of
14 the enactment of this subparagraph with respect
15 to interoperability of health information tech-
16 nology shall be consistent with interoperability
17 as described in section 3000.

18 “(4) *FORUM*.—The HIT Advisory Committee
19 shall serve as a forum for the participation of a broad
20 range of stakeholders with specific expertise in poli-
21 cies, including technical expertise, relating to the
22 matters described in paragraphs (1), (2), and (3) to
23 provide input on the development, harmonization,
24 and recognition of standards, implementation speci-
25 fications, and certification criteria necessary for the

1 *development and adoption of health information tech-*
2 *nology infrastructure nationally and locally that al-*
3 *lows for the electronic access, exchange, and use of*
4 *health information.*

5 *“(5) SCHEDULE.—Not later than 30 days after*
6 *the date on which the HIT Advisory Committee first*
7 *meets, such HIT Advisory Committee shall develop a*
8 *schedule for the assessment of policy recommendations*
9 *developed under paragraph (1). The HIT Advisory*
10 *Committee shall update such schedule annually. The*
11 *Secretary shall publish such schedule in the Federal*
12 *Register.*

13 *“(6) PUBLIC INPUT.—The HIT Advisory Com-*
14 *mittee shall conduct open public meetings and develop*
15 *a process to allow for public comment on the schedule*
16 *described in paragraph (5) and recommendations de-*
17 *scribed in this subsection. Under such process com-*
18 *ments shall be submitted in a timely manner after the*
19 *date of publication of a recommendation under this*
20 *subsection.*

21 *“(c) MEASURED PROGRESS IN ADVANCING PRIORITY*
22 *AREAS.—*

23 *“(1) IN GENERAL.—For purposes of this section,*
24 *the National Coordinator, in collaboration with the*
25 *Secretary, shall establish, and update as appropriate,*

1 *objectives and benchmarks for advancing and meas-*
2 *uring the advancement of the priority target areas de-*
3 *scribed in subsection (b)(2)(B).*

4 “(2) ANNUAL PROGRESS REPORTS ON ADVANCING
5 INTEROPERABILITY.—

6 “(A) IN GENERAL.—*The HIT Advisory*
7 *Committee, in consultation with the National*
8 *Coordinator, shall annually submit to the Sec-*
9 *retary and Congress a report on the progress*
10 *made during the preceding fiscal year in—*

11 “(i) *achieving a health information*
12 *technology infrastructure, nationally and*
13 *locally, that allows for the electronic access,*
14 *exchange, and use of health information;*
15 *and*

16 “(ii) *meeting the objectives and bench-*
17 *marks described in paragraph (1).*

18 “(B) CONTENT.—*Each such report shall in-*
19 *clude, for a fiscal year—*

20 “(i) *a description of the work con-*
21 *ducted by the HIT Advisory Committee*
22 *during the preceding fiscal year with re-*
23 *spect to the areas described in subsection*
24 *(b)(2)(B);*

1 “(ii) an assessment of the status of the
2 infrastructure described in subparagraph
3 (A), including the extent to which electronic
4 health information is appropriately and
5 readily available to enhance the access, ex-
6 change, and the use of electronic health in-
7 formation between users and across tech-
8 nology offered by different developers;

9 “(iii) the extent to which advancements
10 have been achieved with respect to areas de-
11 scribed in subsection (b)(2)(B);

12 “(iv) an analysis identifying existing
13 gaps in policies and resources for—

14 “(I) achieving the objectives and
15 benchmarks established under para-
16 graph (1); and

17 “(II) furthering interoperability
18 throughout the health information tech-
19 nology infrastructure;

20 “(v) recommendations for addressing
21 the gaps identified in clause (iii); and

22 “(vi) a description of additional ini-
23 tiatives as the HIT Advisory Committee
24 and National Coordinator determine appro-
25 priate.

1 “(3) *SIGNIFICANT ADVANCEMENT DETERMINA-*
2 *TION.—The Secretary shall periodically, based on the*
3 *reports submitted under this subsection, review the*
4 *target areas described in subsection (b)(2)(B), and,*
5 *based on the objectives and benchmarks established*
6 *under paragraph (1), the Secretary shall determine if*
7 *significant advancement has been achieved with re-*
8 *spect to such an area. Such determination shall be*
9 *taken into consideration by the HIT Advisory Com-*
10 *mittee when determining to what extent the Com-*
11 *mittee makes recommendations for an area other than*
12 *an area described in subsection (b)(2)(B).*

13 “(d) *MEMBERSHIP AND OPERATIONS.—*

14 “(1) *IN GENERAL.—The National Coordinator*
15 *shall take a leading position in the establishment and*
16 *operations of the HIT Advisory Committee.*

17 “(2) *MEMBERSHIP.—The membership of the HIT*
18 *Advisory Committee shall—*

19 “(A) *include at least 25 members, of*
20 *which—*

21 “(i) *no fewer than 2 members are ad-*
22 *vocates for patients or consumers of health*
23 *information technology;*

24 “(ii) *3 members are appointed by the*
25 *Secretary, 1 of whom shall be appointed to*

1 *represent the Department of Health and*
2 *Human Services and 1 of whom shall be a*
3 *public health official;*

4 *“(iii) 2 members are appointed by the*
5 *majority leader of the Senate;*

6 *“(iv) 2 members are appointed by the*
7 *minority leader of the Senate;*

8 *“(v) 2 members are appointed by the*
9 *Speaker of the House of Representatives;*

10 *“(vi) 2 members are appointed by the*
11 *minority leader of the House of Representa-*
12 *tives; and*

13 *“(vii) such other members are ap-*
14 *pointed by the Comptroller General of the*
15 *United States; and*

16 *“(B) at least reflect providers, ancillary*
17 *health care workers, consumers, purchasers,*
18 *health plans, health information technology de-*
19 *velopers, researchers, patients, relevant Federal*
20 *agencies, and individuals with technical exper-*
21 *tise on health care quality, system functions, pri-*
22 *vacancy, security, and on the electronic exchange*
23 *and use of health information, including the use*
24 *standards for such activity.*

1 “(3) *PARTICIPATION.*—*The members of the HIT*
2 *Advisory Committee shall represent a balance among*
3 *various sectors of the health care system so that no*
4 *single sector unduly influences the recommendations*
5 *of the Committee.*

6 “(4) *TERMS.*—

7 “(A) *IN GENERAL.*—*The terms of the mem-*
8 *bers of the HIT Advisory Committee shall be for*
9 *3 years, except that the Secretary shall designate*
10 *staggered terms of the members first appointed.*

11 “(B) *VACANCIES.*—*Any member appointed*
12 *to fill a vacancy in the membership of the HIT*
13 *Advisory Committee that occurs prior to the ex-*
14 *piration of the term for which the member’s*
15 *predecessor was appointed shall be appointed*
16 *only for the remainder of that term. A member*
17 *may serve after the expiration of that member’s*
18 *term until a successor has been appointed. A va-*
19 *cancy in the HIT Advisory Committee shall be*
20 *filled in the manner in which the original ap-*
21 *pointment was made.*

22 “(C) *LIMITS.*—*Members of the HIT Advi-*
23 *sory Committee shall be limited to two 3-year*
24 *terms, for a total of not to exceed 6 years of serv-*
25 *ice on the Committee.*

1 “(5) *OUTSIDE INVOLVEMENT.*—*The HIT Advisory*
2 *Committee shall ensure an opportunity for the*
3 *participation in activities of the Committee of outside*
4 *advisors, including individuals with expertise in the*
5 *development of policies and standards for the elec-*
6 *tronic exchange and use of health information, in-*
7 *cluding in the areas of health information privacy*
8 *and security.*

9 “(6) *QUORUM.*—*A majority of the members of*
10 *the HIT Advisory Committee shall constitute a*
11 *quorum for purposes of voting, but a lesser number of*
12 *members may meet and hold hearings.*

13 “(7) *CONSIDERATION.*—*The National Coordi-*
14 *nator shall ensure that the relevant and available rec-*
15 *ommendations and comments from the National Com-*
16 *mittee on Vital and Health Statistics are considered*
17 *in the development of policies.*

18 “(8) *ASSISTANCE.*—*For the purposes of carrying*
19 *out this section, the Secretary may provide or ensure*
20 *that financial assistance is provided by the HIT Ad-*
21 *visory Committee to defray in whole or in part any*
22 *membership fees or dues charged by such Committee*
23 *to those consumer advocacy groups and not-for-profit*
24 *entities that work in the public interest as a party of*
25 *their mission.*

1 “(e) *APPLICATION OF FACCA.*—*The Federal Advisory*
2 *Committee Act (5 U.S.C. App.), other than section 14 of*
3 *such Act, shall apply to the HIT Advisory Committee.*

4 “(f) *PUBLICATION.*—*The Secretary shall provide for*
5 *publication in the Federal Register and the posting on the*
6 *Internet website of the Office of the National Coordinator*
7 *for Health Information Technology of all policy rec-*
8 *ommendations made by the HIT Advisory Committee under*
9 *this section.*”.

10 (2) *TECHNICAL AND CONFORMING AMEND-*
11 *MENTS.*—*Title XXX of the Public Health Service Act*
12 *(42 U.S.C. 300jj et seq.) is amended—*

13 (A) *by striking—*

14 (i) *“HIT Policy Committee” and*
15 *“HIT Standards Committee” each place*
16 *that such terms appear (other than within*
17 *the term “HIT Policy Committee and the*
18 *HIT Standards Committee” or within the*
19 *term “HIT Policy Committee or the HIT*
20 *Standards Committee”)* and inserting
21 *“HIT Advisory Committee”;*

22 (ii) *“HIT Policy Committee and the*
23 *HIT Standards Committee” each place that*
24 *such term appears and inserting “HIT Ad-*
25 *visory Committee”;* and

1 (iii) “HIT Policy Committee or the
2 HIT Standards Committee” each place that
3 such term appears and inserting “HIT Ad-
4 visory Committee”;

5 (B) in section 3000 (42 U.S.C. 300jj)—

6 (i) by striking paragraphs (7) and (8)
7 and redesignating paragraphs (9) through
8 (14) as paragraphs (8) through (13), respec-
9 tively; and

10 (ii) by inserting after paragraph (6)
11 the following paragraph:

12 “(7) HIT ADVISORY COMMITTEE.—The term
13 ‘HIT Advisory Committee’ means such Committee es-
14 tablished under section 3002(a).”;

15 (C) in section 3001(c) (42 U.S.C. 300jj–
16 11(c))—

17 (i) in paragraph (1)(A), by striking
18 “under section 3003” and inserting “under
19 section 3002”;

20 (ii) in paragraph (2), by striking sub-
21 paragraph (B) and inserting the following:

22 “(B) HIT ADVISORY COMMITTEE.—The Na-
23 tional Coordinator shall be a leading member in
24 the establishment and operations of the HIT Ad-
25 visory Committee and shall serve as a liaison be-

1 *tween that Committee and the Federal Govern-*
2 *ment.”;*

3 *(D) in section 3004(b)(3) (42 U.S.C. 300jj–*
4 *14(b)(3)), by striking “3003(b)(2)” and inserting*
5 *“3002(b)(4)”;*

6 *(E) in section 3007(b) (42 U.S.C. 300jj–*
7 *17(b)), by striking “3003(a)” and inserting*
8 *“3002(a)(2)”;* and

9 *(F) in section 3008 (42 U.S.C. 300jj–18)—*
10 *(i) in subsection (b), by striking “or*
11 *3003”;* and

12 *(ii) in subsection (c), by striking*
13 *“3003(b)(1)(A)” and inserting*
14 *“3002(b)(2)”.*

15 *(3) TRANSITION TO THE HIT ADVISORY COM-*
16 *MITTEE.—The Secretary of Health and Human Serv-*
17 *ices shall provide for an orderly and timely transition*
18 *to the HIT Advisory Committee established under*
19 *amendments made by this section.*

20 *(f) PRIORITIES FOR ADOPTION OF STANDARDS, IMPLE-*
21 *MENTATION SPECIFICATIONS, AND CERTIFICATION CRI-*
22 *TERIA.—Title XXX of the Public Health Service Act (42*
23 *U.S.C. 300jj et seq.), as amended by subsection (e), is fur-*
24 *ther amended by inserting after section 3002 the following:*

1 **“SEC. 3003. SETTING PRIORITIES FOR STANDARDS ADOPT-**
2 **ION.**

3 *“(a) IDENTIFYING PRIORITIES.—*

4 *“(1) IN GENERAL.—Not later than 6 months*
5 *after the date on which the HIT Advisory Committee*
6 *first meets, the National Coordinator shall periodi-*
7 *cally convene the HIT Advisory Committee to—*

8 *“(A) identify priority uses of health infor-*
9 *mation technology, focusing on priorities—*

10 *“(i) arising from the implementation*
11 *of the incentive programs for the meaning-*
12 *ful use of certified EHR technology, the*
13 *Merit-based Incentive Payment System, Al-*
14 *ternative Payment Models, the Hospital*
15 *Value-Based Purchasing Program, and any*
16 *other value-based payment program deter-*
17 *mined appropriate by the Secretary;*

18 *“(ii) related to the quality of patient*
19 *care;*

20 *“(iii) related to public health;*

21 *“(iv) related to clinical research;*

22 *“(v) related to the privacy and security*
23 *of electronic health information;*

24 *“(vi) related to innovation in the field*
25 *of health information technology;*

26 *“(vii) related to patient safety;*

1 “(viii) related to the usability of health
2 information technology;

3 “(ix) related to individuals’ access to
4 electronic health information; and

5 “(x) other priorities determined appro-
6 priate by the Secretary;

7 “(B) identify existing standards and imple-
8 mentation specifications that support the use
9 and exchange of electronic health information
10 needed to meet the priorities identified in sub-
11 paragraph (A); and

12 “(C) publish a report summarizing the
13 findings of the analysis conducted under sub-
14 paragraphs (A) and (B) and make appropriate
15 recommendations.

16 “(2) *PRIORITIZATION.*—In identifying such
17 standards and implementation specifications under
18 paragraph (1)(B), the HIT Advisory Committee shall
19 prioritize standards and implementation specifica-
20 tions developed by consensus-based standards develop-
21 ment organizations.

22 “(3) *GUIDELINES FOR REVIEW OF EXISTING*
23 *STANDARDS AND SPECIFICATIONS.*—In consultation
24 with the consensus-based entity described in section
25 1890 of the Social Security Act and other appropriate

1 *Federal agencies, the analysis of existing standards*
2 *under paragraph (1)(B) shall include an evaluation*
3 *of the need for a core set of common data elements*
4 *and associated value sets to enhance the ability of cer-*
5 *tified health information technology to capture, use,*
6 *and exchange structured electronic health informa-*
7 *tion.*

8 *“(b) REVIEW OF ADOPTED STANDARDS.—*

9 *“(1) IN GENERAL.—Beginning 5 years after the*
10 *date of enactment of the 21st Century Cures Act and*
11 *every 3 years thereafter, the National Coordinator*
12 *shall convene stakeholders to review the existing set of*
13 *adopted standards and implementation specifications*
14 *and make recommendations with respect to whether*
15 *to—*

16 *“(A) maintain the use of such standards*
17 *and implementation specifications; or*

18 *“(B) phase out such standards and imple-*
19 *mentation specifications.*

20 *“(2) PRIORITIES.—The HIT Advisory Com-*
21 *mittee, in collaboration with the National Institute*
22 *for Standards and Technology, shall annually and*
23 *through the use of public input, review and publish*
24 *priorities for the use of health information technology,*

1 standards, and implementation specifications to sup-
2 port those priorities.

3 “(c) *RULE OF CONSTRUCTION.*—Nothing in this sec-
4 tion shall be construed to prevent the use or adoption of
5 novel standards that improve upon the existing health in-
6 formation technology infrastructure and facilitate the se-
7 cure exchange of health information.”.

8 **SEC. 4004. INFORMATION BLOCKING.**

9 Subtitle C of title XXX of the Public Health Service
10 Act (42 U.S.C. 300jj–51 et seq.) is amended by adding at
11 the end the following:

12 **“SEC. 3022. INFORMATION BLOCKING.**

13 “(a) *DEFINITION.*—

14 “(1) *IN GENERAL.*—In this section, the term ‘in-
15 formation blocking’ means a practice that—

16 “(A) except as required by law or specified
17 by the Secretary pursuant to rulemaking under
18 paragraph (3), is likely to interfere with, pre-
19 vent, or materially discourage access, exchange,
20 or use of electronic health information; and

21 “(B)(i) if conducted by a health informa-
22 tion technology developer, exchange, or network,
23 such developer, exchange, or network knows, or
24 should know, that such practice is likely to inter-
25 fere with, prevent, or materially discourage the

1 *access, exchange, or use of electronic health infor-*
2 *mation; or*

3 *“(i) if conducted by a health care provider,*
4 *such provider knows that such practice is unrea-*
5 *sonable and is likely to interfere with, prevent,*
6 *or materially discourage access, exchange, or use*
7 *of electronic health information.*

8 *“(2) PRACTICES DESCRIBED.—The information*
9 *blocking practices described in paragraph (1) may in-*
10 *clude—*

11 *“(A) practices that restrict authorized ac-*
12 *cess, exchange, or use under applicable State or*
13 *Federal law of such information for treatment*
14 *and other permitted purposes under such appli-*
15 *cable law, including transitions between certified*
16 *health information technologies;*

17 *“(B) implementing health information tech-*
18 *nology in nonstandard ways that are likely to*
19 *substantially increase the complexity or burden*
20 *of accessing, exchanging, or using electronic*
21 *health information; and*

22 *“(C) implementing health information tech-*
23 *nology in ways that are likely to—*

24 *“(i) restrict the access, exchange, or use*
25 *of electronic health information with respect*

1 to exporting complete information sets or in
2 transitioning between health information
3 technology systems; or

4 “(i) lead to fraud, waste, or abuse, or
5 impede innovations and advancements in
6 health information access, exchange, and
7 use, including care delivery enabled by
8 health information technology.

9 “(3) *RULEMAKING.*—The Secretary, through
10 rulemaking, shall identify reasonable and necessary
11 activities that do not constitute information blocking
12 for purposes of paragraph (1).

13 “(4) *NO ENFORCEMENT BEFORE EXCEPTION*
14 *IDENTIFIED.*—The term ‘information blocking’ does
15 not include any practice or conduct occurring prior
16 to the date that is 30 days after the date of enactment
17 of the 21st Century Cures Act.

18 “(5) *CONSULTATION.*—The Secretary may con-
19 sult with the Federal Trade Commission in promul-
20 gating regulations under this subsection, to the extent
21 that such regulations define practices that are nec-
22 essary to promote competition and consumer welfare.

23 “(6) *APPLICATION.*—The term ‘information
24 blocking’, with respect to an individual or entity,

1 *shall not include an act or practice other than an act*
2 *or practice committed by such individual or entity.*

3 “(7) *CLARIFICATION.—In carrying out this sec-*
4 *tion, the Secretary shall ensure that health care pro-*
5 *viders are not penalized for the failure of developers*
6 *of health information technology or other entities of-*
7 *fering health information technology to such providers*
8 *to ensure that such technology meets the requirements*
9 *to be certified under this title.*

10 “(b) *INSPECTOR GENERAL AUTHORITY.—*

11 “(1) *IN GENERAL.—The inspector general of the*
12 *Department of Health and Human Services (referred*
13 *to in this section as the ‘Inspector General’) may in-*
14 *vestigate any claim that—*

15 “(A) *a health information technology devel-*
16 *oper of certified health information technology or*
17 *other entity offering certified health information*
18 *technology—*

19 “(i) *submitted a false attestation under*
20 *section 3001(c)(5)(D)(vi); or*

21 “(ii) *engaged in information blocking;*

22 “(B) *a health care provider engaged in in-*
23 *formation blocking; or*

24 “(C) *a health information exchange or net-*
25 *work engaged in information blocking.*

1 “(2) *PENALTIES.*—

2 “(A) *DEVELOPERS, NETWORKS, AND EX-*
3 *CHANGES.*—*Any individual or entity described*
4 *in subparagraph (A) or (C) of paragraph (1)*
5 *that the Inspector General, following an inves-*
6 *tigation conducted under this subsection, deter-*
7 *mines to have committed information blocking*
8 *shall be subject to a civil monetary penalty de-*
9 *termined by the Secretary for all such violations*
10 *identified through such investigation, which may*
11 *not exceed \$1,000,000 per violation. Such deter-*
12 *mination shall take into account factors such as*
13 *the nature and extent of the information blocking*
14 *and harm resulting from such information block-*
15 *ing, including, where applicable, the number of*
16 *patients affected, the number of providers af-*
17 *ected, and the number of days the information*
18 *blocking persisted.*

19 “(B) *PROVIDERS.*—*Any individual or enti-*
20 *ty described in subparagraph (B) of paragraph*
21 *(1) determined by the Inspector General to have*
22 *committed information blocking shall be referred*
23 *to the appropriate agency to be subject to appro-*
24 *priate disincentives using authorities under ap-*

1 *plicable Federal law, as the Secretary sets forth*
2 *through notice and comment rulemaking.*

3 “(C) *PROCEDURE.*—*The provisions of sec-*
4 *tion 1128A of the Social Security Act (other*
5 *than subsections (a) and (b) of such section)*
6 *shall apply to a civil money penalty applied*
7 *under this paragraph in the same manner as*
8 *such provisions apply to a civil money penalty*
9 *or proceeding under such section 1128A(a).*

10 “(D) *RECOVERED PENALTY FUNDS.*—*The*
11 *amounts recovered under this paragraph shall be*
12 *allocated as follows:*

13 “(i) *ANNUAL OPERATING EXPENSES.*—
14 *Each year following the establishment of the*
15 *authority under this subsection, the Office of*
16 *the Inspector General shall provide to the*
17 *Secretary an estimate of the costs to carry*
18 *out investigations under this section. Such*
19 *estimate may include reasonable reserves to*
20 *account for variance in annual amounts re-*
21 *covered under this paragraph. There is au-*
22 *thorized to be appropriated for purposes of*
23 *carrying out this section an amount equal*
24 *to the amount specified in such estimate for*
25 *the fiscal year.*

1 “(i) *APPLICATION TO OTHER PRO-*
2 *GRAMS.—The amounts recovered under this*
3 *paragraph and remaining after amounts*
4 *are made available under clause (i) shall be*
5 *transferred to the Federal Hospital Insur-*
6 *ance Trust Fund under section 1817 of the*
7 *Social Security Act and the Federal Sup-*
8 *plementary Medical Insurance Trust Fund*
9 *under section 1841 of such Act, in such pro-*
10 *portion as the Secretary determines appro-*
11 *priate.*

12 “(E) *AUTHORIZATION OF APPROPRIA-*
13 *TIONS.—There is authorized to be appropriated*
14 *to the Office of the Inspector General to carry*
15 *out this section \$10,000,000, to remain available*
16 *until expended.*

17 “(3) *RESOLUTION OF CLAIMS.—*

18 “(A) *IN GENERAL.—The Office of the In-*
19 *pector General, if such Office determines that a*
20 *consultation regarding the health privacy and se-*
21 *curity rules promulgated under section 264(c) of*
22 *the Health Insurance Portability and Account-*
23 *ability Act of 1996 (42 U.S.C. 1320d–2 note)*
24 *will resolve an information blocking claim, may*
25 *refer such instances of information blocking to*

1 *the Office for Civil Rights of the Department of*
2 *Health and Human Services for resolution.*

3 “(B) *LIMITATION ON LIABILITY.*—*If a*
4 *health care provider or health information tech-*
5 *nology developer makes information available*
6 *based on a good faith reliance on consultations*
7 *with the Office for Civil Rights of the Depart-*
8 *ment of Health and Human Services pursuant*
9 *to a referral under subparagraph (A), with re-*
10 *spect to such information, the health care pro-*
11 *vider or developer shall not be liable for such dis-*
12 *closure or disclosures made pursuant to subpara-*
13 *graph (A).*

14 “(c) *IDENTIFYING BARRIERS TO EXCHANGE OF CER-*
15 *TIFIED HEALTH INFORMATION TECHNOLOGY.*—

16 “(1) *TRUSTED EXCHANGE DEFINED.*—*In this*
17 *section, the term ‘trusted exchange’ with respect to*
18 *certified electronic health records means that the cer-*
19 *tified electronic health record technology has the tech-*
20 *nicol capability to enable secure health information*
21 *exchange between users and multiple certified elec-*
22 *tronic health record technology systems.*

23 “(2) *GUIDANCE.*—*The National Coordinator, in*
24 *consultation with the Office for Civil Rights of the*
25 *Department of Health and Human Services, shall*

1 *issue guidance on common legal, governance, and se-*
2 *curity barriers that prevent the trusted exchange of*
3 *electronic health information.*

4 “(3) *REFERRAL.*—*The National Coordinator and*
5 *the Office for Civil Rights of the Department of*
6 *Health and Human Services may refer to the Inspec-*
7 *tor General instances or patterns of refusal to ex-*
8 *change health information with an individual or enti-*
9 *ty using certified electronic health record technology*
10 *that is technically capable of trusted exchange and*
11 *under conditions when exchange is legally permis-*
12 *sible.*

13 “(d) *ADDITIONAL PROVISIONS.*—

14 “(1) *INFORMATION SHARING PROVISIONS.*—*The*
15 *National Coordinator may serve as a technical con-*
16 *sultant to the Inspector General and the Federal*
17 *Trade Commission for purposes of carrying out this*
18 *section. The National Coordinator may, notwith-*
19 *standing any other provision of law, share informa-*
20 *tion related to claims or investigations under sub-*
21 *section (b) with the Federal Trade Commission for*
22 *purposes of such investigations and shall share infor-*
23 *mation with the Inspector General, as required by*
24 *law.*

1 “(2) *PROTECTION FROM DISCLOSURE OF INFOR-*
2 *MATION.—Any information that is received by the*
3 *National Coordinator in connection with a claim or*
4 *suggestion of possible information blocking and that*
5 *could reasonably be expected to facilitate identifica-*
6 *tion of the source of the information—*

7 “(A) *shall not be disclosed by the National*
8 *Coordinator except as may be necessary to carry*
9 *out the purpose of this section;*

10 “(B) *shall be exempt from mandatory dis-*
11 *closure under section 552 of title 5, United*
12 *States Code, as provided by subsection (b)(3) of*
13 *such section; and*

14 “(C) *may be used by the Inspector General*
15 *or Federal Trade Commission for reporting pur-*
16 *poses to the extent that such information could*
17 *not reasonably be expected to facilitate identi-*
18 *fication of the source of such information.*

19 “(3) *STANDARDIZED PROCESS.—*

20 “(A) *IN GENERAL.—The National Coordi-*
21 *nator shall implement a standardized process for*
22 *the public to submit reports on claims of—*

23 “(i) *health information technology*
24 *products or developers of such products (or*
25 *other entities offering such products to*

1 health care providers) not being interoper-
2 able or resulting in information blocking;

3 “(ii) actions described in subsection
4 (b)(1) that result in information blocking as
5 described in subsection (a); and

6 “(iii) any other act described in sub-
7 section (a).

8 “(B) *COLLECTION OF INFORMATION.*—The
9 standardized process implemented under sub-
10 paragraph (A) shall provide for the collection of
11 such information as the originating institution,
12 location, type of transaction, system and version,
13 timestamp, terminating institution, locations,
14 system and version, failure notice, and other re-
15 lated information.

16 “(4) *NONDUPLICATION OF PENALTY STRUC-*
17 *TURES.*—In carrying out this subsection, the Sec-
18 retary shall, to the extent possible, ensure that pen-
19 alties do not duplicate penalty structures that would
20 otherwise apply with respect to information blocking
21 and the type of individual or entity involved as of the
22 day before the date of the enactment of this section.”.

23 **SEC. 4005. LEVERAGING ELECTRONIC HEALTH RECORDS TO**
24 **IMPROVE PATIENT CARE.**

25 (a) *REQUIREMENT RELATING TO REGISTRIES.*—

1 (1) *IN GENERAL.*—*To be certified in accordance*
2 *with title XXX of the Public Health Service Act (42*
3 *U.S.C. 300jj et seq.), electronic health records shall be*
4 *capable of transmitting to, and where applicable, re-*
5 *ceiving and accepting data from, registries in accord-*
6 *ance with standards recognized by the Office of the*
7 *National Coordinator for Health Information Tech-*
8 *nology, including clinician-led clinical data reg-*
9 *istries, that are also certified to be technically capable*
10 *of receiving and accepting from, and where applica-*
11 *ble, transmitting data to certified electronic health*
12 *record technology in accordance with such standards.*

13 (2) *RULE OF CONSTRUCTION.*—*Nothing in this*
14 *subsection shall be construed to require the certifi-*
15 *cation of registries beyond the technical capability to*
16 *exchange data in accordance with applicable recog-*
17 *nized standards.*

18 (b) *DEFINITION.*—*For purposes of this Act, the term*
19 *“clinician-led clinical data registry” means a clinical data*
20 *repository—*

21 (1) *that is established and operated by a clini-*
22 *cian-led or controlled, tax-exempt (pursuant to section*
23 *501(c) of the Internal Revenue Code of 1986), profes-*
24 *sional society or other similar clinician-led or -con-*
25 *trolled organization, or such organization’s controlled*

1 *affiliate, devoted to the care of a population defined*
2 *by a particular disease, condition, exposure or ther-*
3 *apy;*

4 *(2) that is designed to collect detailed, standard-*
5 *ized data on an ongoing basis for medical procedures,*
6 *services, or therapies for particular diseases, condi-*
7 *tions, or exposures;*

8 *(3) that provides feedback to participants who*
9 *submit reports to the repository;*

10 *(4) that meets standards for data quality includ-*
11 *ing—*

12 *(A) systematically collecting clinical and*
13 *other health care data, using standardized data*
14 *elements and having procedures in place to*
15 *verify the completeness and validity of those*
16 *data; and*

17 *(B) being subject to regular data checks or*
18 *audits to verify completeness and validity; and*

19 *(5) that provides ongoing participant training*
20 *and support.*

21 *(c) TREATMENT OF HEALTH INFORMATION TECH-*
22 *NOLOGY DEVELOPERS WITH RESPECT TO PATIENT SAFETY*
23 *ORGANIZATIONS.—*

24 *(1) IN GENERAL.—In applying part C of title IX*
25 *of the Public Health Service Act (42 U.S.C. 299b–21*

1 *et seq.*), a health information technology developer
2 shall be treated as a provider (as defined in section
3 921 of such Act) for purposes of reporting and con-
4 ducting patient safety activities concerning improv-
5 ing clinical care through the use of health information
6 technology that could result in improved patient safe-
7 ty, health care quality, or health care outcomes.

8 (2) *REPORT.*—Not later than 4 years after the
9 date of enactment of this Act, the Secretary of Health
10 and Human Services shall submit to the Committee
11 on Health, Education, Labor, and Pensions of the
12 Senate and the Committee on Energy and Commerce
13 of the House of Representatives, a report concerning
14 best practices and current trends voluntarily pro-
15 vided, without identifying individual providers or
16 disclosing or using protected health information or
17 individually identifiable information, by patient safe-
18 ty organizations to improve the integration of health
19 information technology into clinical practice.

20 **SEC. 4006. EMPOWERING PATIENTS AND IMPROVING PA-**
21 **TIENT ACCESS TO THEIR ELECTRONIC**
22 **HEALTH INFORMATION.**

23 (a) *USE OF HEALTH INFORMATION EXCHANGES FOR*
24 *PATIENT ACCESS.*—Section 3009 of the Public Health Serv-

1 *ice Act (42 U.S.C. 300jj–19) is amended by adding at the*
2 *end the following:*

3 “(c) *PROMOTING PATIENT ACCESS TO ELECTRONIC*
4 *HEALTH INFORMATION THROUGH HEALTH INFORMATION*
5 *EXCHANGES* .—

6 “(1) *IN GENERAL*.—*The Secretary shall use ex-*
7 *isting authorities to encourage partnerships between*
8 *health information exchange organizations and net-*
9 *works and health care providers, health plans, and*
10 *other appropriate entities with the goal of offering pa-*
11 *tients access to their electronic health information in*
12 *a single, longitudinal format that is easy to under-*
13 *stand, secure, and may be updated automatically.*

14 “(2) *EDUCATION OF PROVIDERS*.—*The Secretary,*
15 *in coordination with the Office for Civil Rights of the*
16 *Department of Health and Human Services, shall—*

17 “(A) *educate health care providers on ways*
18 *of leveraging the capabilities of health informa-*
19 *tion exchanges (or other relevant platforms) to*
20 *provide patients with access to their electronic*
21 *health information;*

22 “(B) *clarify misunderstandings by health*
23 *care providers about using health information*
24 *exchanges (or other relevant platforms) for pa-*
25 *tient access to electronic health information; and*

1 “(C) to the extent practicable, educate pro-
2 viders about health information exchanges (or
3 other relevant platforms) that employ some or all
4 of the capabilities described in paragraph (1).

5 “(3) *REQUIREMENTS.*—In carrying out para-
6 graph (1), the Secretary, in coordination with the Of-
7 fice for Civil Rights, shall issue guidance to health in-
8 formation exchanges related to best practices to ensure
9 that the electronic health information provided to pa-
10 tients is—

11 “(A) private and secure;

12 “(B) accurate;

13 “(C) verifiable; and

14 “(D) where a patient’s authorization to ex-
15 change information is required by law, easily ex-
16 changed pursuant to such authorization.

17 “(4) *RULE OF CONSTRUCTION.*—Nothing in this
18 subsection shall be construed to preempt State laws
19 applicable to patient consent for the access of infor-
20 mation through a health information exchange (or
21 other relevant platform) that provide protections to
22 patients that are greater than the protections other-
23 wise provided for under applicable Federal law.

24 “(d) *EFFORTS TO PROMOTE ACCESS TO HEALTH IN-*
25 *FORMATION.*—The National Coordinator and the Office for

1 *Civil Rights of the Department of Health and Human Serv-*
2 *ices shall jointly promote patient access to health informa-*
3 *tion in a manner that would ensure that such information*
4 *is available in a form convenient for the patient, in a rea-*
5 *sonable manner, without burdening the health care provider*
6 *involved.*

7 “(e) *ACCESSIBILITY OF PATIENT RECORDS.—*

8 “(1) *ACCESSIBILITY AND UPDATING OF INFORMA-*
9 *TION.—*

10 “(A) *IN GENERAL.—The Secretary, in con-*
11 *sultation with the National Coordinator, shall*
12 *promote policies that ensure that a patient’s elec-*
13 *tronic health information is accessible to that*
14 *patient and the patient’s designees, in a manner*
15 *that facilitates communication with the patient’s*
16 *health care providers and other individuals, in-*
17 *cluding researchers, consistent with such pa-*
18 *tient’s consent.*

19 “(B) *UPDATING EDUCATION ON ACCESSING*
20 *AND EXCHANGING PERSONAL HEALTH INFORMA-*
21 *TION.—To promote awareness that an individual*
22 *has a right of access to inspect, obtain a copy of,*
23 *and transmit to a third party a copy of such in-*
24 *dividual’s protected health information pursuant*
25 *to the Health Information Portability and Ac-*

1 *countability Act, Privacy Rule (subpart E of*
2 *part 164 of title 45, Code of Federal Regula-*
3 *tions), the Director of the Office for Civil Rights,*
4 *in consultation with the National Coordinator,*
5 *shall assist individuals and health care providers*
6 *in understanding a patient’s rights to access and*
7 *protect personal health information under the*
8 *Health Insurance Portability and Accountability*
9 *Act of 1996 (Public Law 104–191), including*
10 *providing best practices for requesting personal*
11 *health information in a computable format, in-*
12 *cluding using patient portals or third-party ap-*
13 *plications and common cases when a provider is*
14 *permitted to exchange and provide access to*
15 *health information.”.*

16 “(2) *CERTIFYING USABILITY FOR PATIENTS.—In*
17 *carrying out certification programs under section*
18 *3001(c)(5), the National Coordinator may require*
19 *that—*

20 “(A) *the certification criteria support—*

21 “(i) *patient access to their electronic*
22 *health information, including in a single*
23 *longitudinal format that is easy to under-*
24 *stand, secure, and may be updated auto-*
25 *matically;*

1 “(ii) the patient’s ability to electroni-
2 cally communicate patient-reported infor-
3 mation (such as family history and medical
4 history); and

5 “(iii) patient access to their personal
6 electronic health information for research at
7 the option of the patient; and

8 “(B) the HIT Advisory Committee develop
9 and prioritize standards, implementation speci-
10 fications, and certification criteria required to
11 help support patient access to electronic health
12 information, patient usability, and support for
13 technologies that offer patients access to their
14 electronic health information in a single, longi-
15 tudinal format that is easy to understand, se-
16 cure, and may be updated automatically.”.

17 (b) ACCESS TO INFORMATION IN AN ELECTRONIC FOR-
18 MAT.—Section 13405(e) of the Health Information Tech-
19 nology for Economic and Clinical Health Act (42 U.S.C.
20 17935) is amended—

21 (1) in paragraph (1), by striking “and” at the
22 end;

23 (2) by redesignating paragraph (2) as para-
24 graph (3); and

1 (3) by inserting after paragraph (1), the fol-
2 lowing:

3 “(2) if the individual makes a request to a busi-
4 ness associate for access to, or a copy of, protected
5 health information about the individual, or if an in-
6 dividual makes a request to a business associate to
7 grant such access to, or transmit such copy directly
8 to, a person or entity designated by the individual, a
9 business associate may provide the individual with
10 such access or copy, which may be in an electronic
11 form, or grant or transmit such access or copy to such
12 person or entity designated by the individual; and”.

13 **SEC. 4007. GAO STUDY ON PATIENT MATCHING.**

14 (a) *IN GENERAL.*—Not later than 1 year after the date
15 of enactment of this Act, the Comptroller General of the
16 United States shall conduct a study to—

17 (1) review the policies and activities of the Office
18 of the National Coordinator for Health Information
19 Technology and other relevant stakeholders, which
20 may include standards development organizations, ex-
21 perts in the technical aspects of health information
22 technology, health information technology developers,
23 providers of health services, health care suppliers,
24 health care payers, health care quality organizations,
25 States, health information technology policy experts,

1 *and other appropriate entities, to ensure appropriate*
2 *patient matching to protect patient privacy and secu-*
3 *rity with respect to electronic health records and the*
4 *exchange of electronic health information; 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 sec-*
8 *tor.*

9 *(b) AREAS OF CONCENTRATION.—In conducting the*
10 *study under subsection (a), the Comptroller General shall—*

11 *(1) evaluate current methods used in certified*
12 *electronic health records for patient matching based*
13 *on performance related to factors such as—*

14 *(A) the privacy of patient information;*

15 *(B) the security of patient information;*

16 *(C) improving matching rates;*

17 *(D) reducing matching errors; and*

18 *(E) reducing duplicate records; and*

19 *(2) determine whether the Office of the National*
20 *Coordinator for Health Information Technology could*
21 *improve patient matching by taking steps includ-*
22 *ing—*

23 *(A) defining additional data elements to as-*
24 *sist in patient data matching;*

1 *Comptroller General shall consider the increase in*
2 *adoption of health information technology and the in-*
3 *creasing prevalence of protected health information*
4 *that is maintained electronically.*

5 (2) *AREAS OF CONCENTRATION.—In conducting*
6 *the review under paragraph (1), the Comptroller Gen-*
7 *eral shall consider—*

8 (A) *instances when covered entities charge*
9 *individuals, including patients, third parties,*
10 *and health care providers, for record requests, in-*
11 *cluding records that are requested in an elec-*
12 *tronic format;*

13 (B) *examples of the amounts and types of*
14 *fees charged to individuals for record requests,*
15 *including instances when the record is requested*
16 *to be transmitted to a third party;*

17 (C) *the extent to which covered entities are*
18 *unable to provide the access requested by individ-*
19 *uals in the form and format requested by the in-*
20 *dividual, including examples of such instances;*

21 (D) *instances in which third parties may*
22 *request protected health information through pa-*
23 *tients' individual right of access, including in-*
24 *stances where such requests may be used to cir-*

1 *cumvent appropriate fees that may be charged to*
2 *third parties;*

3 *(E) opportunities that permit covered enti-*
4 *ties to charge appropriate fees to third parties*
5 *for patient records while providing patients with*
6 *access to their protected health information at*
7 *low or no cost;*

8 *(F) the ability of providers to distinguish*
9 *between requests originating from an individual*
10 *that require limitation to a cost-based fee and re-*
11 *quests originating from third parties that may*
12 *not be limited to cost-based fees; and*

13 *(G) other circumstances that may inhibit*
14 *the ability of providers to provide patients with*
15 *access to their records, and the ability of patients*
16 *to gain access to their records.*

17 *(b) REPORT.—Not later than 18 months after the date*
18 *of enactment of this Act, the Comptroller General shall sub-*
19 *mit a report to Congress on the findings of the study con-*
20 *ducted under subsection (a).*

21 **SEC. 4009. IMPROVING MEDICARE LOCAL COVERAGE DE-**
22 **TERMINATIONS.**

23 *(a) IN GENERAL.—Section 1862(l)(5) of the Social Se-*
24 *curity Act (42 U.S.C. 1395y(l)(5)) is amended by adding*
25 *at the end the following new subparagraph:*

1 “(D) *LOCAL COVERAGE DETERMINATIONS.*—
2 *The Secretary shall require each Medicare ad-*
3 *ministrative contractor that develops a local cov-*
4 *erage determination to make available on the*
5 *Internet website of such contractor and on the*
6 *Medicare Internet website, at least 45 days before*
7 *the effective date of such determination, the fol-*
8 *lowing information:*

9 “(i) *Such determination in its en-*
10 *tirety.*

11 “(ii) *Where and when the proposed de-*
12 *termination was first made public.*

13 “(iii) *Hyperlinks to the proposed deter-*
14 *mination and a response to comments sub-*
15 *mitted to the contractor with respect to such*
16 *proposed determination.*

17 “(iv) *A summary of evidence that was*
18 *considered by the contractor during the de-*
19 *velopment of such determination and a list*
20 *of the sources of such evidence.*

21 “(v) *An explanation of the rationale*
22 *that supports such determination.”.*

23 (b) *EFFECTIVE DATE.*—*The amendment made by sub-*
24 *section (a) shall apply with respect to local coverage deter-*

1 *minations that are proposed or revised on or after the date*
2 *that is 180 days after the date of enactment of this Act.*

3 **SEC. 4010. MEDICARE PHARMACEUTICAL AND TECHNOLOGY**

4 **OMBUDSMAN.**

5 *Section 1808 of the Social Security Act (42 U.S.C.*
6 *1395b–9) is amended by adding at the end the following*
7 *new subsection:*

8 *“(d) PHARMACEUTICAL AND TECHNOLOGY OMBUDS-*
9 *MAN.—*

10 *“(1) IN GENERAL.—Not later than 12 months*
11 *after the date of enactment of this paragraph, the Sec-*
12 *retary shall provide for a pharmaceutical and tech-*
13 *nology ombudsman within the Centers for Medicare &*
14 *Medicaid Services who shall receive and respond to*
15 *complaints, grievances, and requests that—*

16 *“(A) are from entities that manufacture*
17 *pharmaceutical, biotechnology, medical device, or*
18 *diagnostic products that are covered or for which*
19 *coverage is being sought under this title; and*

20 *“(B) are with respect to coverage, coding, or*
21 *payment under this title for such products.*

22 *“(2) APPLICATION.—The second sentence of sub-*
23 *section (c)(2) shall apply to the ombudsman under*
24 *subparagraph (A) in the same manner as such sen-*

1 *timated amount of beneficiary liability, with respect*
2 *to an item or service, is the amount for such item or*
3 *service for which an individual who does not have*
4 *coverage under a Medicare supplemental policy cer-*
5 *tified under section 1882 or any other supplemental*
6 *insurance coverage is responsible.*

7 “(3) *IMPLEMENTATION.*—*In carrying out this*
8 *subsection, the Secretary—*

9 “(A) *shall include in the notice described in*
10 *section 1804(a) a notification of the availability*
11 *of the estimated amounts made available under*
12 *paragraph (1); and*

13 “(B) *may utilize mechanisms in existence*
14 *on the date of enactment of this subsection, such*
15 *as the portion of the Internet website of the Cen-*
16 *ters for Medicare & Medicaid Services on which*
17 *information comparing physician performance is*
18 *posted (commonly referred to as the Physician*
19 *Compare Internet website), to make available*
20 *such estimated amounts under such paragraph.*

21 “(4) *FUNDING.*—*For purposes of implementing*
22 *this subsection, the Secretary shall provide for the*
23 *transfer, from the Federal Supplementary Medical In-*
24 *surance Trust Fund under section 1841 to the Centers*
25 *for Medicare & Medicaid Services Program Manage-*

1 *ment Account, of \$6,000,000 for fiscal year 2017, to*
2 *remain available until expended.”.*

3 **SEC. 4012. TELEHEALTH SERVICES IN MEDICARE.**

4 *(a) PROVISION OF INFORMATION BY CENTERS FOR*
5 *MEDICARE & MEDICAID SERVICES.—Not later than 1 year*
6 *after the date of enactment of this Act, the Administrator*
7 *of the Centers for Medicare & Medicaid Services shall pro-*
8 *vide to the committees of jurisdiction of the House of Rep-*
9 *resentatives and the Senate information on the following:*

10 *(1) The populations of Medicare beneficiaries,*
11 *such as those who are dually eligible for the Medicare*
12 *program under title XVIII of the Social Security Act*
13 *(42 U.S.C. 1395 et seq.) and the Medicaid program*
14 *under title XIX of such Act (42 U.S.C. 1396 et seq.)*
15 *and those with chronic conditions, whose care may be*
16 *improved most in terms of quality and efficiency by*
17 *the expansion, in a manner that meets or exceeds the*
18 *existing in-person standard of care under the Medi-*
19 *care program under such title XVIII, of telehealth*
20 *services under section 1834(m)(4) of such Act (42*
21 *U.S.C. 1395m(m)(4)).*

22 *(2) Activities by the Center for Medicare and*
23 *Medicaid Innovation which examine the use of tele-*
24 *health services in models, projects, or initiatives fund-*

1 *ed through section 1115A of such Act (42 U.S.C.*
2 *1315a).*

3 *(3) The types of high-volume services (and re-*
4 *lated diagnoses) under such title XVIII which might*
5 *be suitable to be furnished using telehealth.*

6 *(4) Barriers that might prevent the expansion of*
7 *telehealth services under section 1834(m)(4) of the So-*
8 *cial Security Act (42 U.S.C. 1395m(m)(4)) beyond*
9 *such services that are in effect as of the date of enact-*
10 *ment of this Act.*

11 *(b) PROVISION OF INFORMATION BY MEDPAC.—Not*
12 *later than March 15, 2018, the Medicare Payment Advisory*
13 *Commission established under section 1805 of the Social Se-*
14 *curity Act (42 U.S.C. 1395b–6) shall, using quantitative*
15 *and qualitative research methods, provide information to*
16 *the committees of jurisdiction of the House of Representa-*
17 *tives and the Senate that identifies—*

18 *(1) the telehealth services for which payment can*
19 *be made, as of the date of enactment of this Act,*
20 *under the fee-for-service program under parts A and*
21 *B of title XVIII of such Act;*

22 *(2) the telehealth services for which payment can*
23 *be made, as of such date, under private health insur-*
24 *ance plans; and*

1 (3) *with respect to services identified under*
2 *paragraph (2) but not under paragraph (1), ways in*
3 *which payment for such services might be incor-*
4 *porated into such fee-for-service program (including*
5 *any recommendations for ways to accomplish this in-*
6 *corporation).*

7 (c) *SENSE OF CONGRESS.—It is the sense of Congress*
8 *that—*

9 (1) *eligible originating sites should be expanded*
10 *beyond those originating sites described in section*
11 *1834(m)(4)(C) of the Social Security Act (42 U.S.C.*
12 *1395m(m)(4)(C)); and*

13 (2) *any expansion of telehealth services under the*
14 *Medicare program under title XVIII of such Act*
15 *should—*

16 (A) *recognize that telemedicine is the deliv-*
17 *ery of safe, effective, quality health care services,*
18 *by a health care provider, using technology as*
19 *the mode of care delivery;*

20 (B) *meet or exceed the conditions of cov-*
21 *erage and payment with respect to the Medicare*
22 *program if the service was furnished in person,*
23 *including standards of care, unless specifically*
24 *addressed in subsequent legislation; and*

1 (C) involve clinically appropriate means to
2 furnish such services.

3 **TITLE V—SAVINGS**

4 **SEC. 5001. SAVINGS IN THE MEDICARE IMPROVEMENT**
5 **FUND.**

6 Section 1898(b)(1) of the Social Security Act (42
7 U.S.C. 1395iii(b)(1)), as amended by section 704(h) of the
8 Comprehensive Addiction and Recovery Act of 2016, is
9 amended by striking “\$140,000,000” and inserting
10 “\$270,000,000”.

11 **SEC. 5002. MEDICAID REIMBURSEMENT TO STATES FOR DU-**
12 **RABLE MEDICAL EQUIPMENT.**

13 Section 1903(i)(27) of the Social Security Act (42
14 U.S.C. 1396b(i)(27)) is amended by striking “January 1,
15 2019” and inserting “January 1, 2018”.

16 **SEC. 5003. PENALTIES FOR VIOLATIONS OF GRANTS, CON-**
17 **TRACTS, AND OTHER AGREEMENTS.**

18 (a) *IN GENERAL.*—Section 1128A of the Social Secu-
19 rity Act (42 U.S.C. 1320a–7a) is amended by adding at
20 the end the following new subsections:

21 “(o) Any person (including an organization, agency,
22 or other entity, but excluding a program beneficiary, as de-
23 fined in subsection (q)(4)) that, with respect to a grant,
24 contract, or other agreement for which the Secretary pro-
25 vides funding—

1 “(1) knowingly presents or causes to be presented
2 a specified claim (as defined in subsection (r)) under
3 such grant, contract, or other agreement that the per-
4 son knows or should know is false or fraudulent;

5 “(2) knowingly makes, uses, or causes to be made
6 or used any false statement, omission, or misrepresen-
7 tation of a material fact in any application, pro-
8 posal, bid, progress report, or other document that is
9 required to be submitted in order to directly or indi-
10 rectly receive or retain funds provided in whole or in
11 part by such Secretary pursuant to such grant, con-
12 tract, or other agreement;

13 “(3) knowingly makes, uses, or causes to be made
14 or used, a false record or statement material to a false
15 or fraudulent specified claim under such grant, con-
16 tract, or other agreement;

17 “(4) knowingly makes, uses, or causes to be made
18 or used, a false record or statement material to an ob-
19 ligation (as defined in subsection (s)) to pay or trans-
20 mit funds or property to such Secretary with respect
21 to such grant, contract, or other agreement, or know-
22 ingly conceals or knowingly and improperly avoids or
23 decreases an obligation to pay or transmit funds or
24 property to such Secretary with respect to such grant,
25 contract, or other agreement; or

1 “(5) fails to grant timely access, upon reasonable
2 request (as defined by such Secretary in regulations),
3 to the Inspector General of the Department, for the
4 purpose of audits, investigations, evaluations, or other
5 statutory functions of such Inspector General in mat-
6 ters involving such grants, contracts, or other agree-
7 ments;
8 shall be subject, in addition to any other penalties that may
9 be prescribed by law, to a civil money penalty in cases
10 under paragraph (1), of not more than \$10,000 for each
11 specified claim; in cases under paragraph (2), not more
12 than \$50,000 for each false statement, omission, or mis-
13 representation of a material fact; in cases under paragraph
14 (3), not more than \$50,000 for each false record or state-
15 ment; in cases under paragraph (4), not more than \$50,000
16 for each false record or statement or \$10,000 for each day
17 that the person knowingly conceals or knowingly and im-
18 properly avoids or decreases an obligation to pay; or in
19 cases under paragraph (5), not more than \$15,000 for each
20 day of the failure described in such paragraph. In addition,
21 in cases under paragraphs (1) and (3), such a person shall
22 be subject to an assessment of not more than 3 times the
23 amount claimed in the specified claim described in such
24 paragraph in lieu of damages sustained by the United
25 States or a specified State agency because of such specified

1 *claim, and in cases under paragraphs (2) and (4), such*
2 *a person shall be subject to an assessment of not more than*
3 *3 times the total amount of the funds described in para-*
4 *graph (2) or (4), respectively (or, in the case of an obliga-*
5 *tion to transmit property to the Secretary described in*
6 *paragraph (4), of the value of the property described in such*
7 *paragraph) in lieu of damages sustained by the United*
8 *States or a specified State agency because of such case. In*
9 *addition, the Secretary may make a determination in the*
10 *same proceeding to exclude the person from participation*
11 *in the Federal health care programs (as defined in section*
12 *1128B(f)(1)) and to direct the appropriate State agency to*
13 *exclude the person from participation in any State health*
14 *care program.*

15 “(p) *The provisions of subsections (c), (d), (g), and (h)*
16 *shall apply to a civil money penalty or assessment under*
17 *subsection (o) in the same manner as such provisions apply*
18 *to a penalty, assessment, or proceeding under subsection*
19 *(a). In applying subsection (d), each reference to a claim*
20 *under such subsection shall be treated as including a ref-*
21 *erence to a specified claim (as defined in subsection (r)).*

22 “(q) *For purposes of this subsection and subsections*
23 *(o) and (p):*

24 “(1) *The term ‘Department’ means the Depart-*
25 *ment of Health and Human Services.*

1 “(2) The term ‘material’ means having a natural
2 tendency to influence, or be capable of influencing, the
3 payment or receipt of money or property.

4 “(3) The term ‘other agreement’ includes a coop-
5 erative agreement, scholarship, fellowship, loan, sub-
6 sidy, payment for a specified use, donation agree-
7 ment, award, or subaward (regardless of whether one
8 or more of the persons entering into the agreement is
9 a contractor or subcontractor).

10 “(4) The term ‘program beneficiary’ means, in
11 the case of a grant, contract, or other agreement de-
12 signed to accomplish the objective of awarding or oth-
13 erwise furnishing benefits or assistance to individuals
14 and for which the Secretary provides funding, an in-
15 dividual who applies for, or who receives, such bene-
16 fits or assistance from such grant, contract, or other
17 agreement. Such term does not include, with respect
18 to such grant, contract, or other agreement, an officer,
19 employee, or agent of a person or entity that receives
20 such grant or that enters into such contract or other
21 agreement.

22 “(5) The term ‘recipient’ includes a subrecipient
23 or subcontractor.

24 “(6) The term ‘specified State agency’ means an
25 agency of a State government established or des-

1 *ignated to administer or supervise the administration*
2 *of a grant, contract, or other agreement funded in*
3 *whole or in part by the Secretary.*

4 *“(r) For purposes of this section, the term ‘specified*
5 *claim’ means any application, request, or demand under*
6 *a grant, contract, or other agreement for money or property,*
7 *whether or not the United States or a specified State agency*
8 *has title to the money or property, that is not a claim (as*
9 *defined in subsection (i)(2)) and that—*

10 *“(1) is presented or caused to be presented to an*
11 *officer, employee, or agent of the Department or agen-*
12 *cy thereof, or of any specified State agency; or*

13 *“(2) is made to a contractor, grantee, or any*
14 *other recipient if the money or property is to be spent*
15 *or used on the Department’s behalf or to advance a*
16 *Department program or interest, and if the Depart-*
17 *ment—*

18 *“(A) provides or has provided any portion*
19 *of the money or property requested or demanded;*
20 *or*

21 *“(B) will reimburse such contractor, grant-*
22 *ee, or other recipient for any portion of the*
23 *money or property which is requested or de-*
24 *manded.*

1 “(s) For purposes of subsection (o), the term ‘obliga-
 2 tion’ means an established duty, whether or not fixed, aris-
 3 ing from an express or implied contractual, grantor-grant-
 4 ee, or licensor-licensee relationship, for a fee-based or simi-
 5 lar relationship, from statute or regulation, or from the re-
 6 tention of any overpayment.”.

7 (b) CONFORMING AMENDMENTS.—Section 1128A of the
 8 Social Security Act (42 U.S.C. 1320a–7a) is amended—

9 (1) in subsection (e), by inserting “or specified
 10 claim” after “claim” in the first sentence; and

11 (2) in subsection (f)—

12 (A) in the matter preceding paragraph

13 (1)—

14 (i) by inserting “or specified claim (as
 15 defined in subsection (r))” after “district
 16 where the claim”; and

17 (ii) by inserting “(or, with respect to a
 18 person described in subsection (o), the per-
 19 son)” after “claimant”; and

20 (B) in the matter following paragraph (4),
 21 by inserting “(or, in the case of a penalty or as-
 22 sessment under subsection (o), by a specified
 23 State agency (as defined in subsection (q)(6)),”
 24 after “or a State agency”.

1 **SEC. 5004. REDUCING OVERPAYMENTS OF INFUSION**
2 **DRUGS.**

3 (a) *TREATMENT OF INFUSION DRUGS FURNISHED*
4 *THROUGH DURABLE MEDICAL EQUIPMENT.*—Section
5 *1842(o)(1) of the Social Security Act (42 U.S.C.*
6 *1395u(o)(1)) is amended—*

7 (1) *in subparagraph (C), by inserting “(and in-*
8 *cluding a drug or biological described in subpara-*
9 *graph (D)(i) furnished on or after January 1, 2017)”*
10 *after “2005”; and*

11 (2) *in subparagraph (D)—*

12 (A) *by striking “infusion drugs” and insert-*
13 *ing “infusion drugs or biologicals” each place it*
14 *appears; and*

15 (B) *in clause (i)—*

16 (i) *by striking “2004” and inserting*
17 *“2004, and before January 1, 2017”; and*

18 (ii) *by striking “for such drug”.*

19 (b) *NONINCLUSION OF DME INFUSION DRUGS UNDER*
20 *DME COMPETITIVE ACQUISITION PROGRAMS.*—

21 (1) *IN GENERAL.*—Section *1847(a)(2)(A) of the*
22 *Social Security Act (42 U.S.C. 1395w-3(a)(2)(A)) is*
23 *amended—*

24 (A) *by striking “and excluding” and insert-*
25 *ing “, excluding”; and*

1 (B) by inserting before the period at the end
2 the following: “, and excluding drugs and
3 biologicals described in section 1842(o)(1)(D)”.

4 (2) CONFORMING AMENDMENT.—Section
5 1842(o)(1)(D)(ii) of the Social Security Act (42
6 U.S.C. 1395u(o)(1)(D)(ii)) is amended by striking
7 “2007” and inserting “2007, and before the date of
8 the enactment of the 21st Century Cures Act.”.

9 **SEC. 5005. INCREASING OVERSIGHT OF TERMINATION OF**
10 **MEDICAID PROVIDERS.**

11 (a) INCREASED OVERSIGHT AND REPORTING.—

12 (1) STATE REPORTING REQUIREMENTS.—Section
13 1902(kk) of the Social Security Act (42 U.S.C.
14 1396a(kk)) is amended—

15 (A) by redesignating paragraph (8) as
16 paragraph (9); and

17 (B) by inserting after paragraph (7) the fol-
18 lowing new paragraph:

19 “(8) PROVIDER TERMINATIONS.—

20 “(A) IN GENERAL.—Beginning on July 1,
21 2018, in the case of a notification under sub-
22 section (a)(41) with respect to a termination for
23 a reason specified in section 455.101 of title 42,
24 Code of Federal Regulations (as in effect on No-
25 vember 1, 2015) or for any other reason specified

1 *by the Secretary, of the participation of a pro-*
2 *vider of services or any other person under the*
3 *State plan (or under a waiver of the plan), the*
4 *State, not later than 30 days after the effective*
5 *date of such termination, submits to the Sec-*
6 *retary with respect to any such provider or per-*
7 *son, as appropriate—*

8 *“(i) the name of such provider or per-*
9 *son;*

10 *“(ii) the provider type of such provider*
11 *or person;*

12 *“(iii) the specialty of such provider’s*
13 *or person’s practice;*

14 *“(iv) the date of birth, Social Security*
15 *number, national provider identifier (if ap-*
16 *plicable), Federal taxpayer identification*
17 *number, and the State license or certifi-*
18 *cation number of such provider or person (if*
19 *applicable);*

20 *“(v) the reason for the termination;*

21 *“(vi) a copy of the notice of termi-*
22 *nation sent to the provider or person;*

23 *“(vii) the date on which such termi-*
24 *nation is effective, as specified in the notice;*

25 *and*

1 “(viii) any other information required
2 by the Secretary.

3 “(B) *EFFECTIVE DATE DEFINED.*—For pur-
4 poses of this paragraph, the term ‘effective date’
5 means, with respect to a termination described
6 in subparagraph (A), the later of—

7 “(i) the date on which such termi-
8 nation is effective, as specified in the notice
9 of such termination; or

10 “(ii) the date on which all appeal
11 rights applicable to such termination have
12 been exhausted or the timeline for any such
13 appeal has expired.”.

14 (2) *CONTRACT REQUIREMENT FOR MANAGED*
15 *CARE ENTITIES.*—Section 1932(d) of the Social Secu-
16 rity Act (42 U.S.C. 1396u–2(d)) is amended by add-
17 ing at the end the following new paragraph:

18 “(5) *CONTRACT REQUIREMENT FOR MANAGED*
19 *CARE ENTITIES.*—With respect to any contract with a
20 managed care entity under section 1903(m) or
21 1905(t)(3) (as applicable), no later than July 1, 2018,
22 such contract shall include a provision that providers
23 of services or persons terminated (as described in sec-
24 tion 1902(kk)(8)) from participation under this title,
25 title XVIII, or title XXI shall be terminated from par-

1 *ticipating under this title as a provider in any net-*
2 *work of such entity that serves individuals eligible to*
3 *receive medical assistance under this title.”.*

4 (3) *TERMINATION NOTIFICATION DATABASE.—*
5 *Section 1902 of the Social Security Act (42 U.S.C.*
6 *1396a) is amended by adding at the end the following*
7 *new subsection:*

8 *“(ll) TERMINATION NOTIFICATION DATABASE.—In the*
9 *case of a provider of services or any other person whose*
10 *participation under this title or title XXI is terminated (as*
11 *described in subsection (kk)(8)), the Secretary shall, not*
12 *later than 30 days after the date on which the Secretary*
13 *is notified of such termination under subsection (a)(41) (as*
14 *applicable), review such termination and, if the Secretary*
15 *determines appropriate, include such termination in any*
16 *database or similar system developed pursuant to section*
17 *6401(b)(2) of the Patient Protection and Affordable Care*
18 *Act (42 U.S.C. 1395cc note; Public Law 111–148).”.*

19 (4) *NO FEDERAL FUNDS FOR ITEMS AND SERV-*
20 *ICES FURNISHED BY TERMINATED PROVIDERS.—Sec-*
21 *tion 1903 of the Social Security Act (42 U.S.C.*
22 *1396b) is amended—*

23 (A) *in subsection (i)(2)—*

1 (i) in subparagraph (A), by striking
2 the comma at the end and inserting a semi-
3 colon;

4 (ii) in subparagraph (B), by striking
5 “or” at the end; and

6 (iii) by adding at the end the following
7 new subparagraph:

8 “(D) beginning on July 1, 2018, under the
9 plan by any provider of services or person whose
10 participation in the State plan is terminated (as
11 described in section 1902(kk)(8)) after the date
12 that is 60 days after the date on which such ter-
13 mination is included in the database or other
14 system under section 1902(ll); or”; and

15 (B) in subsection (m), by inserting after
16 paragraph (2) the following new paragraph:

17 “(3) No payment shall be made under this title to a
18 State with respect to expenditures incurred by the State for
19 payment for services provided by a managed care entity
20 (as defined under section 1932(a)(1)) under the State plan
21 under this title (or under a waiver of the plan) unless the
22 State—

23 “(A) beginning on July 1, 2018, has a contract
24 with such entity that complies with the requirement
25 specified in section 1932(d)(5); and

1 “(B) beginning on January 1, 2018, complies
2 with the requirement specified in section
3 1932(d)(6)(A).”.

4 (5) *DEVELOPMENT OF UNIFORM TERMINOLOGY*
5 *FOR REASONS FOR PROVIDER TERMINATION.*—Not
6 later than July 1, 2017, the Secretary of Health and
7 Human Services shall, in consultation with the heads
8 of State agencies administering State Medicaid plans
9 (or waivers of such plans), issue regulations estab-
10 lishing uniform terminology to be used with respect to
11 specifying reasons under subparagraph (A)(v) of
12 paragraph (8) of section 1902(kk) of the Social Secu-
13 rity Act (42 U.S.C. 1396a(kk)), as added by para-
14 graph (1), for the termination (as described in such
15 paragraph (8)) of the participation of certain pro-
16 viders in the Medicaid program under title XIX of
17 such Act or the Children’s Health Insurance Program
18 under title XXI of such Act.

19 (6) *CONFORMING AMENDMENT.*—Section
20 1902(a)(41) of the Social Security Act (42 U.S.C.
21 1396a(a)(41)) is amended by striking “provide that
22 whenever” and inserting “provide, in accordance with
23 subsection (kk)(8) (as applicable), that whenever”.

24 (b) *INCREASING AVAILABILITY OF MEDICAID PRO-*
25 *VIDER INFORMATION.*—

1 (1) *FFS PROVIDER ENROLLMENT.*—Section
2 1902(a) of the Social Security Act (42 U.S.C.
3 1396a(a)) is amended by inserting after paragraph
4 (77) the following new paragraph:

5 “(78) provide that, not later than January 1,
6 2017, in the case of a State that pursuant to its State
7 plan or waiver of the plan for medical assistance
8 pays for medical assistance on a fee-for-service basis,
9 the State shall require each provider furnishing items
10 and services to, or ordering, prescribing, referring, or
11 certifying eligibility for, services for individuals eligi-
12 ble to receive medical assistance under such plan to
13 enroll with the State agency and provide to the State
14 agency the provider’s identifying information, includ-
15 ing the name, specialty, date of birth, Social Security
16 number, national provider identifier (if applicable),
17 Federal taxpayer identification number, and the
18 State license or certification number of the provider
19 (if applicable);”.

20 (2) *MANAGED CARE PROVIDER ENROLLMENT.*—
21 Section 1932(d) of the Social Security Act (42 U.S.C.
22 1396u–2(d)), as amended by subsection (a)(2), is
23 amended by adding at the end the following new
24 paragraph:

1 “(6) *ENROLLMENT OF PARTICIPATING PRO-*
2 *VIDERS.—*

3 “(A) *IN GENERAL.—Beginning not later*
4 *than January 1, 2018, a State shall require that,*
5 *in order to participate as a provider in the net-*
6 *work of a managed care entity that provides*
7 *services to, or orders, prescribes, refers, or cer-*
8 *tifies eligibility for services for, individuals who*
9 *are eligible for medical assistance under the*
10 *State plan under this title (or under a waiver of*
11 *the plan) and who are enrolled with the entity,*
12 *the provider is enrolled consistent with section*
13 *1902(kk) with the State agency administering*
14 *the State plan under this title. Such enrollment*
15 *shall include providing to the State agency the*
16 *provider’s identifying information, including the*
17 *name, specialty, date of birth, Social Security*
18 *number, national provider identifier, Federal*
19 *taxpayer identification number, and the State li-*
20 *cence or certification number of the provider.*

21 “(B) *RULE OF CONSTRUCTION.—Nothing in*
22 *subparagraph (A) shall be construed as requiring*
23 *a provider described in such subparagraph to*
24 *provide services to individuals who are not en-*

1 *rolled with a managed care entity under this*
2 *title.”.*

3 (c) *COORDINATION WITH CHIP.—*

4 (1) *IN GENERAL.—Section 2107(e)(1) of the So-*
5 *cial Security Act (42 U.S.C. 1397gg(e)(1)) is amend-*
6 *ed—*

7 (A) *by redesignating subparagraphs (B),*
8 *(C), (D), (E), (F), (G), (H), (I), (J), (K), (L),*
9 *(M), (N), and (O) as subparagraphs (D), (E),*
10 *(F), (G), (H), (I), (J), (K), (M), (N), (O), (P),*
11 *(Q), and (R), respectively;*

12 (B) *by inserting after subparagraph (A) the*
13 *following new subparagraphs:*

14 “(B) *Section 1902(a)(39) (relating to termi-*
15 *nation of participation of certain providers).*”

16 “(C) *Section 1902(a)(78) (relating to enroll-*
17 *ment of providers participating in State plans*
18 *providing medical assistance on a fee-for-service*
19 *basis).*”;

20 (C) *by inserting after subparagraph (K) (as*
21 *redesignated by subparagraph (A)) the following*
22 *new subparagraph:*

23 “(L) *Section 1903(m)(3) (relating to limi-*
24 *tation on payment with respect to managed*
25 *care).*”; *and*

1 (D) in subparagraph (P) (as redesignated
2 by subparagraph (A)), by striking “(a)(2)(C)
3 and (h)” and inserting “(a)(2)(C) (relating to
4 Indian enrollment), (d)(5) (relating to contract
5 requirement for managed care entities), (d)(6)
6 (relating to enrollment of providers participating
7 with a managed care entity), and (h) (relating
8 to special rules with respect to Indian enrollees,
9 Indian health care providers, and Indian man-
10 aged care entities)”.

11 (2) *EXCLUDING FROM MEDICAID PROVIDERS EX-*
12 *CLUDED FROM CHIP.*—Section 1902(a)(39) of the So-
13 cial Security Act (42 U.S.C. 1396a(a)(39)) is amend-
14 ed by striking “title XVIII or any other State plan
15 under this title” and inserting “title XVIII, any other
16 State plan under this title (or waiver of the plan), or
17 any State child health plan under title XXI (or waiv-
18 er of the plan) and such termination is included by
19 the Secretary in any database or similar system de-
20 veloped pursuant to section 6401(b)(2) of the Patient
21 Protection and Affordable Care Act”.

22 (d) *RULE OF CONSTRUCTION.*—Nothing in this section
23 shall be construed as changing or limiting the appeal rights
24 of providers or the process for appeals of States under the
25 Social Security Act.

1 (e) *OIG REPORT.*—Not later than March 31, 2020, the
2 *Inspector General of the Department of Health and Human*
3 *Services shall submit to Congress a report on the implemen-*
4 *tation of the amendments made by this section. Such report*
5 *shall include the following:*

6 (1) *An assessment of the extent to which pro-*
7 *viders who are included under subsection (ll) of sec-*
8 *tion 1902 of the Social Security Act (42 U.S.C.*
9 *1396a) (as added by subsection (a)(3)) in the data-*
10 *base or similar system referred to in such subsection*
11 *are terminated (as described in paragraph (8) of sub-*
12 *section (kk) of such section, as added by subsection*
13 *(a)(1)) from participation in all State plans under*
14 *title XIX of such Act (or waivers of such plans).*

15 (2) *Information on the amount of Federal finan-*
16 *cial participation paid to States under section 1903*
17 *of such Act in violation of the limitation on such pay-*
18 *ment specified in subparagraph (D) of subsection*
19 *(i)(2) of such section and paragraph (3) of subsection*
20 *(m) of such section, as added by subsection (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) or*
3 *1932(d)(6)(A) of such Act (42 U.S.C. 1396a(a)(78),*
4 *1396u–2(d)(6)(A)) with State agencies administering*
5 *State plans under title XIX of such Act (or waivers*
6 *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 Secu-*
10 *rity 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-manage-*
21 *ment system described in section 1915(b)(1) (other*
22 *than a primary care case management entity (as de-*
23 *finied by the Secretary)), the State shall publish (and*
24 *update on at least an annual basis) on the public*
25 *website of the State agency administering the State*

1 *plan, a directory of the physicians described in sub-*
2 *section (mm) and, at State option, other providers de-*
3 *scribed 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 services;*
13 *and*

14 *“(IV) the telephone number of the*
15 *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 pro-*
21 *vider is accepting as new patients in-*
22 *dividuals 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 *cluding 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 physi-*
 9 *cian 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 further*
 17 *amended by adding at the end the following new subsection:*

18 *“(mm) DIRECTORY PHYSICIAN OR PROVIDER DE-*
 19 *SCRIBED.—A physician or provider described in this sub-*
 20 *section is—*

21 *“(1) in the case of a physician or provider of a*
 22 *provider type for which the State agency, as a condi-*
 23 *tion on receiving payment for items and services fur-*
 24 *nished by the physician or provider to individuals el-*
 25 *igible to receive medical assistance under the State*

1 *plan, requires the enrollment of the physician or pro-*
2 *vider with the State agency, a physician or a pro-*
3 *vider that—*

4 *“(A) is enrolled with the agency as of the*
5 *date on which the directory is published or up-*
6 *dated (as applicable) under subsection (a)(83);*
7 *and*

8 *“(B) received payment under the State plan*
9 *in the 12-month period preceding such date; and*

10 *“(2) in the case of a physician or provider of a*
11 *provider type for which the State agency does not re-*
12 *quire such enrollment, a physician or provider that*
13 *received payment under the State plan (or a waiver*
14 *of the plan) in the 12-month period preceding the*
15 *date on which the directory is published or updated*
16 *(as applicable) under subsection (a)(83).”.*

17 *(c) RULE OF CONSTRUCTION.—*

18 *(1) IN GENERAL.—The amendment made by sub-*
19 *section (a) shall not be construed to apply in the case*
20 *of a State (as defined for purposes of title XIX of the*
21 *Social Security Act) in which all the individuals en-*
22 *rolled in the State plan under such title (or under a*
23 *waiver of such plan), other than individuals described*
24 *in paragraph (2), are enrolled with a medicaid man-*
25 *aged care organization (as defined in section*

1 *1903(m)(1)(A) of such Act (42 U.S.C.*
2 *1396b(m)(1)(A))), including prepaid inpatient health*
3 *plans and prepaid ambulatory health plans (as de-*
4 *fined by the Secretary of Health and Human Serv-*
5 *ices).*

6 (2) *INDIVIDUALS DESCRIBED.—An individual*
7 *described in this paragraph is an individual who is*
8 *an Indian (as defined in section 4 of the Indian*
9 *Health Care Improvement Act (25 U.S.C. 1603)) or*
10 *an Alaska Native.*

11 (d) *EXCEPTION FOR STATE LEGISLATION.—In the case*
12 *of a State plan under title XIX of the Social Security Act*
13 *(42 U.S.C. 1396 et seq.), which the Secretary of Health and*
14 *Human Services determines requires State legislation in*
15 *order for the respective plan to meet one or more additional*
16 *requirements imposed by amendments made by this section,*
17 *the respective plan shall not be regarded as failing to com-*
18 *ply with the requirements of such title solely on the basis*
19 *of its failure to meet such an additional requirement before*
20 *the first day of the first calendar quarter beginning after*
21 *the close of the first regular session of the State legislature*
22 *that begins after the date of enactment of this Act. For pur-*
23 *poses of the previous sentence, in the case of a State that*
24 *has a 2-year legislative session, each year of the session shall*

1 *be considered to be a separate regular session of the State*
 2 *legislature.*

3 **SEC. 5007. FAIRNESS IN MEDICAID SUPPLEMENTAL NEEDS**
 4 **TRUSTS.**

5 (a) *IN GENERAL.*—Section 1917(d)(4)(A) of the Social
 6 Security Act (42 U.S.C. 1396p(d)(4)(A)) is amended by in-
 7 serting “the individual,” after “for the benefit of such indi-
 8 vidual by”.

9 (b) *EFFECTIVE DATE.*—The amendment made by sub-
 10 section (a) shall apply to trusts established on or after the
 11 date of the enactment of this Act.

12 **SEC. 5008. ELIMINATING FEDERAL FINANCIAL PARTICIPA-**
 13 **TION WITH RESPECT TO EXPENDITURES**
 14 **UNDER MEDICAID FOR AGENTS USED FOR**
 15 **COSMETIC PURPOSES OR HAIR GROWTH.**

16 (a) *IN GENERAL.*—Section 1903(i)(21) of the Social
 17 Security Act (42 U.S.C. 1396b(i)(21)) is amended by in-
 18 serting “section 1927(d)(2)(C) (relating to drugs when used
 19 for cosmetic purposes or hair growth), except where medi-
 20 cally necessary, and” after “drugs described in”.

21 (b) *EFFECTIVE DATE.*—The amendment made by sub-
 22 section (a) shall apply with respect to calendar quarters
 23 beginning on or after the date of the enactment of this Act.

1 **SEC. 5009. AMENDMENT TO THE PREVENTION AND PUBLIC**
2 **HEALTH FUND.**

3 *Section 4002(b) of the Patient Protection and Afford-*
4 *able 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 U.S.C.*
21 *6241), except as provided in subsections (b) and (c),*
22 *the Secretary of Energy shall drawdown and sell from*
23 *the Strategic Petroleum Reserve—*

24 *(A) 10,000,000 barrels of crude oil during*
25 *fiscal year 2017;*

1 *Act (42 U.S.C. 18043(c)(1)), \$464,000,000 is rescinded im-*
2 *mediately upon the date of the enactment of this Act.*

3 **SEC. 5012. MEDICARE COVERAGE OF HOME INFUSION THER-**
4 **APY.**

5 *(a) IN GENERAL.—Section 1861 of the Social Security*
6 *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 sub-*
15 *section (iii)(1));”;* and

16 *(2) by adding at the end the following new sub-*
17 *section:*

18 *“(iii) HOME INFUSION THERAPY.—(1) The term ‘home*
19 *infusion therapy’ means the items and services described*
20 *in paragraph (2) furnished by a qualified home infusion*
21 *therapy supplier (as defined in paragraph (3)(D)) which*
22 *are furnished in the individual’s home (as defined in para-*
23 *graph (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 residence*
2 *used as the home of an individual (as defined for pur-*
3 *poses 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 pe-*
7 *riod of 15 minutes or more, in the home of an indi-*
8 *vidual 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 provision*
24 *and administration of home infusion therapy on*
25 *a 7-day-a-week, 24-hour-a-day basis;*

1 “(III) is accredited by an organization des-
2 ignated by the Secretary pursuant to section
3 1834(u)(5); and

4 “(IV) meets such other requirements as the
5 Secretary determines appropriate, taking into
6 account the standards of care for home infusion
7 therapy established by Medicare Advantage plans
8 under part C and in the private sector.

9 “(ii) A qualified home infusion therapy supplier
10 may subcontract with a pharmacy, physician, pro-
11 vider of services, or supplier to meet the requirements
12 of this subparagraph.”.

13 (b) *PAYMENT AND RELATED REQUIREMENTS FOR*
14 *HOME INFUSION THERAPY.*—Section 1834 of the Social Se-
15 *curity Act (42 U.S.C. 1395m), as amended by section 4011,*
16 *is further amended by adding at the end the following new*
17 *subsection:*

18 “(u) *PAYMENT AND RELATED REQUIREMENTS FOR*
19 *HOME INFUSION THERAPY.*—

20 “(1) *PAYMENT.*—

21 “(A) *SINGLE PAYMENT.*—

22 “(i) *IN GENERAL.*—Subject to clause
23 (iii) and subparagraphs (B) and (C), the
24 Secretary shall implement a payment sys-
25 tem under which a single payment is made

1 *under this title to a qualified home infusion*
2 *therapy supplier for items and services de-*
3 *scribed in subparagraphs (A) and (B) of*
4 *section 1861(iii)(2)) furnished by a quali-*
5 *fied home infusion therapy supplier (as de-*
6 *defined in section 1861(iii)(3)(D)) in coordi-*
7 *nation with the furnishing of home infusion*
8 *drugs (as defined in section 1861(iii)(3)(C))*
9 *under this part.*

10 *“(i) UNIT OF SINGLE PAYMENT.—A*
11 *unit of single payment under the payment*
12 *system implemented under this subpara-*
13 *graph is for each infusion drug administra-*
14 *tion calendar day in the individual’s home.*
15 *The Secretary shall, as appropriate, estab-*
16 *lish single payment amounts for types of in-*
17 *fusion therapy, including to take into ac-*
18 *count variation in utilization of nursing*
19 *services by therapy type.*

20 *“(iii) LIMITATION.—The single pay-*
21 *ment amount determined under this sub-*
22 *paragraph after application of subpara-*
23 *graph (B) and paragraph (3) shall not ex-*
24 *ceed the amount determined under the fee*
25 *schedule under section 1848 for infusion*

1 *therapy services furnished in a calendar*
2 *day if furnished in a physician office set-*
3 *ting, except such single payment shall not*
4 *reflect more than 5 hours of infusion for a*
5 *particular therapy in a calendar day.*

6 “(B) *REQUIRED ADJUSTMENTS.*—*The Sec-*
7 *retary shall adjust the single payment amount*
8 *determined under subparagraph (A) for home in-*
9 *fusion therapy services under section 1861(iii)(1)*
10 *to reflect other factors such as—*

11 “(i) *a geographic wage index and other*
12 *costs that may vary by region; and*

13 “(ii) *patient acuity and complexity of*
14 *drug administration.*

15 “(C) *DISCRETIONARY ADJUSTMENTS.*—

16 “(i) *IN GENERAL.*—*Subject to clause*
17 *(ii), the Secretary may adjust the single*
18 *payment amount determined under sub-*
19 *paragraph (A) (after application of sub-*
20 *paragraph (B)) to reflect outlier situations*
21 *and other factors as the Secretary deter-*
22 *mines appropriate.*

23 “(ii) *REQUIREMENT OF BUDGET NEU-*
24 *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 may*
5 *consider the costs of furnishing infusion therapy in*
6 *the home, consult with home infusion therapy sup-*
7 *pliers, consider payment amounts for similar items*
8 *and services under this part and part A, and consider*
9 *payment amounts established by Medicare Advantage*
10 *plans under part C and in the private insurance*
11 *market for home infusion therapy (including average*
12 *per treatment day payment amounts by type of home*
13 *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 year*
18 *to year beginning in 2022 by increasing the sin-*
19 *gle payment amount from the prior year by the*
20 *percentage increase in the Consumer Price Index*
21 *for all urban consumers (United States city av-*
22 *erage) for the 12-month period ending with June*
23 *of the preceding year.*

24 “(B) *ADJUSTMENT.—For each year, the*
25 *Secretary shall reduce the percentage increase de-*

1 *scribed in subparagraph (A) by the productivity*
2 *adjustment described in section*
3 *1886(b)(3)(B)(xi)(II). The application of the pre-*
4 *ceding sentence may result in a percentage being*
5 *less than 0.0 for a year, and may result in pay-*
6 *ment being less than such payment rates for the*
7 *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 INFU-*
14 *SION 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 designated*
21 *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 suppliers*
3 *located in a rural area (as defined in sec-*
4 *tion 1886(d)(2)(D)).*

5 “(iii) *Whether the organization has es-*
6 *tablished reasonable fees to be charged to*
7 *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 shall*
19 *review the list of accreditation organiza-*
20 *tions 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 LIST*
5 *OF DESIGNATED ACCREDITATION ORGANIZA-*
6 *TIONS.—In the case where the Secretary re-*
7 *moves an organization from the list of ac-*
8 *creditation organizations designated under*
9 *subparagraph (B), any supplier that is ac-*
10 *credited by the organization during the pe-*
11 *riod beginning on the date on which the or-*
12 *ganization is designated as an accreditation*
13 *organization under subparagraph (B) and*
14 *ending on the date on which the organiza-*
15 *tion is removed from such list shall be con-*
16 *sidered to have been accredited by an orga-*
17 *nization designated by the Secretary under*
18 *subparagraph (B) for the remaining period*
19 *such accreditation is in effect.*

20 “(D) *RULE FOR ACCREDITATIONS MADE*
21 *PRIOR TO DESIGNATION.—In the case of a sup-*
22 *plier that is accredited before January 1, 2021,*
23 *by an accreditation organization designated by*
24 *the Secretary under subparagraph (B) as of Jan-*
25 *uary 1, 2019, such supplier shall be considered*

1 to have been accredited by an organization des-
2 ignated by the Secretary under such paragraph
3 as of January 1, 2023, for the remaining period
4 such accreditation is in effect.

5 “(6) NOTIFICATION OF INFUSION THERAPY OP-
6 TIONS AVAILABLE PRIOR TO FURNISHING HOME INFU-
7 SION THERAPY.—Prior to the furnishing of home in-
8 fusion therapy to an individual, the physician who
9 establishes the plan described in section 1861(iii)(1)
10 for the individual shall provide notification (in a
11 form, manner, and frequency determined appropriate
12 by the Secretary) of the options available (such as
13 home, physician’s office, hospital outpatient depart-
14 ment) for the furnishing of infusion therapy under
15 this part.”.

16 (c) CONFORMING AMENDMENTS.—

17 (1) PAYMENT REFERENCE.—Section 1833(a)(1)
18 of the Social Security Act (42 U.S.C. 1395l(a)(1)) is
19 amended—

20 (A) by striking “and” before “(AA)”; and
21 (B) by inserting before the semicolon at the
22 end the following: “, and (BB) with respect to
23 home infusion therapy, the amount paid shall be
24 an amount equal to 80 percent of the lesser of the

1 *actual charge for the services or the amount de-*
2 *termined under section 1834(u)”.*

3 (2) *DIRECT PAYMENT.*—*The first sentence of sec-*
4 *tion 1842(b)(6) of the Social Security Act (42 U.S.C.*
5 *1395u(b)(6)) is amended—*

6 (A) *by striking “and” before “(H)”;* and

7 (B) *by inserting before the period at the end*
8 *the following: “, and (I) in the case of home in-*
9 *fusion therapy, payment shall be made to the*
10 *qualified home infusion therapy supplier”.*

11 (3) *EXCLUSION FROM HOME HEALTH SERV-*
12 *ICES.*—*Section 1861(m) of the Social Security Act*
13 *(42 U.S.C. 1395x(m)) is amended, in the first sen-*
14 *tence, by inserting the following before the period at*
15 *the end: “and home infusion therapy (as defined in*
16 *subsection (iii)(i))”.*

17 (d) *EFFECTIVE DATE.*—*The amendments made by this*
18 *section shall apply to items and services furnished on or*
19 *after January 1, 2021.*

20 ***DIVISION B—HELPING FAMILIES***
21 ***IN MENTAL HEALTH CRISIS***

22 ***SEC. 6000. SHORT TITLE.***

23 *This division may be cited as the “Helping Families*
24 *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 amended
9 to read as follows:

10 “(c) *ASSISTANT SECRETARY AND DEPUTY ASSISTANT*
11 *SECRETARY.*—

12 “(1) *ASSISTANT SECRETARY.*—*The Administra-*
13 *tion shall be headed by an official to be known as the*
14 *Assistant Secretary for Mental Health and Substance*
15 *Use (hereinafter in this title referred to as the ‘Assist-*
16 *ant Secretary’)* who shall be appointed by the Presi-
17 *dent, by and with the advice and consent of the Sen-*
18 *ate.*

19 “(2) *DEPUTY ASSISTANT SECRETARY.*—*The As-*
20 *stant 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 Assistant*
3 *Secretary for Mental Health and Substance Use all duties*
4 *and authorities that—*

5 (1) *as of the day before the date of enactment of*
6 *this Act, were vested in the Administrator of the Sub-*
7 *stance Abuse and Mental Health Services Administra-*
8 *tion; and*

9 (2) *are not terminated by this Act.*

10 (c) *CONFORMING AMENDMENTS.*—*Title V of the Public*
11 *Health Service Act (42 U.S.C. 290aa et seq.), as amended*
12 *by the previous provisions of this section, is further amend-*
13 *ed—*

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 sec-*
24 *tion 501 of such Act (42 U.S.C. 290aa), includ-*

1 *ing the headings of such subsections, within the*
2 *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 term*
13 *“Administrator of the National Highway Traffic*
14 *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–35(a)),*
18 *within the term “Administrator of the Office of*
19 *Juvenile Justice and Delinquency Prevention”.*

20 *(d) REFERENCES.—After executing subsections (a),*
21 *(b), and (c), any reference in statute, regulation, or guid-*
22 *ance to the Administrator of the Substance Abuse and Men-*
23 *tal Health Services Administration shall be construed to be*
24 *a reference to the Assistant Secretary for Mental Health and*
25 *Substance Use.*

1 **SEC. 6002. STRENGTHENING THE LEADERSHIP OF THE SUB-**
2 **STANCE ABUSE AND MENTAL HEALTH SERV-**
3 **ICES ADMINISTRATION.**

4 *Section 501 of the Public Health Service Act (42*
5 *U.S.C. 290aa), as amended by section 6001, is further*
6 *amended—*

7 *(1) in subsection (b)—*

8 *(A) in the subsection heading, by striking*
9 *“AGENCIES” and inserting “CENTERS”; and*

10 *(B) in the matter preceding paragraph (1),*
11 *by striking “entities” and inserting “Centers”;*

12 *(2) in subsection (d)—*

13 *(A) in paragraph (1)—*

14 *(i) by striking “agencies” each place*
15 *the term appears and inserting “Centers”;*
16 *and*

17 *(ii) by striking “such agency” and in-*
18 *serting “such Center”;*

19 *(B) in paragraph (2)—*

20 *(i) by striking “agencies” and insert-*
21 *ing “Centers”;*

22 *(ii) by striking “with respect to sub-*
23 *stance abuse” and inserting “with respect to*
24 *substance use disorders”; and*

1 (iii) by striking “and individuals who
2 are substance abusers” and inserting “and
3 individuals with substance use disorders”;

4 (C) in paragraph (5), by striking “sub-
5 stance abuse” and inserting “substance use dis-
6 order”;

7 (D) in paragraph (6)—

8 (i) by striking “the Centers for Disease
9 Control” and inserting “the Centers for Dis-
10 ease Control and Prevention,”;

11 (ii) by striking “Administration de-
12 velop” and inserting “Administration, de-
13 velop”;

14 (iii) by striking “HIV or tuberculosis
15 among substance abusers and individuals
16 with mental illness” and inserting “HIV,
17 hepatitis, tuberculosis, and other commu-
18 nicable diseases among individuals with
19 mental or substance use disorders,”; and

20 (iv) by striking “illnesses” at the end
21 and inserting “diseases or disorders”;

22 (E) in paragraph (7), by striking “abuse
23 utilizing anti-addiction medications, including
24 methadone” and inserting “use disorders, includ-
25 ing services that utilize drugs or devices ap-

1 *proved or cleared by the Food and Drug Admin-*
2 *istration for the treatment of substance use dis-*
3 *orders”;*

4 *(F) in paragraph (8)—*

5 *(i) by striking “Agency for Health*
6 *Care Policy Research” and inserting “Agen-*
7 *cy for Healthcare Research and Quality”;*
8 *and*

9 *(ii) by striking “treatment and preven-*
10 *tion” and inserting “prevention and treat-*
11 *ment”;*

12 *(G) in paragraph (9)—*

13 *(i) by inserting “and maintenance”*
14 *after “development”;*

15 *(ii) by striking “Agency for Health*
16 *Care Policy Research” and inserting “Agen-*
17 *cy for Healthcare Research and Quality”;*
18 *and*

19 *(iii) by striking “treatment and pre-*
20 *vention services” and inserting “prevention,*
21 *treatment, and recovery support services*
22 *and are appropriately incorporated into*
23 *programs carried out by the Administra-*
24 *tion”;*

1 (H) in paragraph (10), by striking “abuse”
2 and inserting “use disorder”;

3 (I) by striking paragraph (11) and insert-
4 ing the following:

5 “(11) work with relevant agencies of the Depart-
6 ment of Health and Human Services on integrating
7 mental health promotion and substance use disorder
8 prevention with general health promotion and disease
9 prevention and integrating mental and substance use
10 disorders treatment services with physical health
11 treatment services;”;

12 (J) in paragraph (13)—

13 (i) in the matter preceding subpara-
14 graph (A), by striking “this title, assure
15 that” and inserting “this title or part B of
16 title XIX, or grant programs otherwise
17 funded by the Administration”;

18 (ii) in subparagraph (A)—

19 (I) by inserting “require that” be-
20 fore “all grants”; and

21 (II) by striking “and” at the end;

22 (iii) by redesignating subparagraph
23 (B) as subparagraph (C);

24 (iv) by inserting after subparagraph
25 (A) the following:

1 “(B) ensure that the director of each Center
2 of the Administration consistently documents the
3 application of criteria when awarding grants
4 and the ongoing oversight of grantees after such
5 grants are awarded;”;

6 (v) in subparagraph (C), as so redesign-
7 nated—

8 (I) by inserting “require that” be-
9 fore “all grants”; and

10 (II) in clause (ii), by inserting
11 “and” after the semicolon at the end;
12 and

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

14 “(D) inform a State when any funds are
15 awarded through such a grant to any entity
16 within such State;”;

17 (K) in paragraph (16), by striking “abuse
18 and mental health information” and inserting
19 “use disorder information, including evidence-
20 based and promising best practices for preven-
21 tion, treatment, and recovery support services for
22 individuals with mental and substance use dis-
23 orders,”;

24 (L) in paragraph (17)—

1 (i) by striking “substance abuse” and
2 inserting “substance use disorder”; and

3 (ii) by striking “and” at the end;

4 (M) in paragraph (18), by striking the pe-
5 riod and inserting a semicolon; and

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

7 “(19) consult with State, local, and tribal gov-
8 ernments, nongovernmental entities, and individuals
9 with mental illness, particularly adults with a serious
10 mental illness, children with a serious emotional dis-
11 turbance, and the family members of such adults and
12 children, with respect to improving community-based
13 and other mental health services;

14 “(20) collaborate with the Secretary of Defense
15 and the Secretary of Veterans Affairs to improve the
16 provision of mental and substance use disorder serv-
17 ices provided by the Department of Defense and the
18 Department of Veterans Affairs to members of the
19 Armed Forces, veterans, and the family members of
20 such members and veterans, including through the
21 provision of services using the telehealth capabilities
22 of the Department of Defense and the Department of
23 Veterans Affairs;

24 “(21) collaborate with the heads of relevant Fed-
25 eral agencies and departments, States, communities,

1 *and nongovernmental experts to improve mental and*
2 *substance use disorders services for chronically home-*
3 *less individuals, including by designing strategies to*
4 *provide such services in supportive housing;*

5 *“(22) work with States and other stakeholders to*
6 *develop and support activities to recruit and retain*
7 *a workforce addressing mental and substance use dis-*
8 *orders;*

9 *“(23) collaborate with the Attorney General and*
10 *representatives of the criminal justice system to im-*
11 *prove mental and substance use disorders services for*
12 *individuals who have been arrested or incarcerated;*

13 *“(24) after providing an opportunity for public*
14 *input, set standards for grant programs under this*
15 *title for mental and substance use disorders services*
16 *and prevention programs, which standards may ad-*
17 *dress—*

18 *“(A) the capacity of the grantee to imple-*
19 *ment the award;*

20 *“(B) requirements for the description of the*
21 *program implementation approach;*

22 *“(C) the extent to which the grant plan sub-*
23 *mitted by the grantee as part of its application*
24 *must explain how the grantee will reach the pop-*
25 *ulation of focus and provide a statement of need,*

1 *which may include information on how the*
2 *grantee will increase access to services and a de-*
3 *scription of measurable objectives for improving*
4 *outcomes;*

5 *“(D) the extent to which the grantee must*
6 *collect and report on required performance meas-*
7 *ures; and*

8 *“(E) the extent to which the grantee is pro-*
9 *posing to use evidence-based practices; and*

10 *“(25) advance, through existing programs, the*
11 *use of performance metrics, including those based on*
12 *the recommendations on performance metrics from the*
13 *Assistant Secretary for Planning and Evaluation*
14 *under section 6021(d) of the Helping Families in*
15 *Mental Health Crisis Reform Act of 2016.”; and*

16 *(3) in subsection (m), by adding at the end the*
17 *following:*

18 *“(4) EMERGENCY RESPONSE.—Amounts made*
19 *available for carrying out this subsection shall remain*
20 *available through the end of the fiscal year following*
21 *the fiscal year for which such amounts are appro-*
22 *priated.”.*

1 **SEC. 6003. CHIEF MEDICAL OFFICER.**

2 *Section 501 of the Public Health Service Act (42*
3 *U.S.C. 290aa), as amended by sections 6001 and 6002, is*
4 *further amended—*

5 *(1) by redesignating subsections (g) through (j)*
6 *and subsections (k) through (o) as subsections (h)*
7 *through (k) and subsections (m) through (q), respec-*
8 *tively;*

9 *(2) in subsection (e)(3)(C), by striking “sub-*
10 *section (k)” and inserting “subsection (m)”;*

11 *(3) in subsection (f)(2)(C)(iii), by striking “sub-*
12 *section (k)” and inserting “subsection (m)”;* and

13 *(4) by inserting after subsection (f) the following:*
14 *“(g) CHIEF MEDICAL OFFICER.—*

15 *“(1) IN GENERAL.—The Assistant Secretary,*
16 *with the approval of the Secretary, shall appoint a*
17 *Chief Medical Officer to serve within the Administra-*
18 *tion.*

19 *“(2) ELIGIBLE CANDIDATES.—The Assistant Sec-*
20 *retary shall select the Chief Medical Officer from*
21 *among individuals who—*

22 *“(A) have a doctoral degree in medicine or*
23 *osteopathic medicine;*

24 *“(B) have experience in the provision of*
25 *mental or substance use disorder services;*

1 “(C) have experience working with mental
2 or substance use disorder programs;

3 “(D) have an understanding of biological,
4 psychosocial, and pharmaceutical treatments of
5 mental or substance use disorders; and

6 “(E) are licensed to practice medicine in
7 one or more States.

8 “(3) DUTIES.—The Chief Medical Officer shall—

9 “(A) serve as a liaison between the Admin-
10 istration and providers of mental and substance
11 use disorders prevention, treatment, and recovery
12 services;

13 “(B) assist the Assistant Secretary in the
14 evaluation, organization, integration, and co-
15 ordination of programs operated by the Adminis-
16 tration;

17 “(C) promote evidence-based and promising
18 best practices, including culturally and linguis-
19 tically appropriate practices, as appropriate, for
20 the prevention and treatment of, and recovery
21 from, mental and substance use disorders, in-
22 cluding serious mental illness and serious emo-
23 tional disturbances;

24 “(D) participate in regular strategic plan-
25 ning with the Administration;

1 “(E) coordinate with the Assistant Sec-
 2 retary for Planning and Evaluation to assess the
 3 use of performance metrics to evaluate activities
 4 within the Administration related to mental and
 5 substance use disorders; and

6 “(F) coordinate with the Assistant Sec-
 7 retary to ensure mental and substance use dis-
 8 orders grant programs within the Administra-
 9 tion consistently utilize appropriate performance
 10 metrics and evaluation designs.”.

11 **SEC. 6004. IMPROVING THE QUALITY OF BEHAVIORAL**
 12 **HEALTH PROGRAMS.**

13 Section 505 of the Public Health Service Act (42
 14 U.S.C. 290aa-4), as amended by section 6001(c), is amend-
 15 ed—

16 (1) by striking the section designation and head-
 17 ing and inserting the following:

18 **“SEC. 505. CENTER FOR BEHAVIORAL HEALTH STATISTICS**
 19 **AND QUALITY.”;**

20 (2) by redesignating subsections (a) through (d)
 21 as subsections (b) through (e), respectively;

22 (3) before subsection (b), as redesignated by
 23 paragraph (2), by inserting the following:

24 “(a) *IN GENERAL.*—The Assistant Secretary shall
 25 maintain within the Administration a Center for Behav-

1 *ioral Health Statistics and Quality (in this section referred*
2 *to as the ‘Center’). The Center shall be headed by a Director*
3 *(in this section referred to as the ‘Director’) appointed by*
4 *the Secretary from among individuals with extensive expe-*
5 *rience and academic qualifications in research and analysis*
6 *in behavioral health care or related fields.”;*

7 (4) *in subsection (b), as redesignated by para-*
8 *graph (2)—*

9 (A) *by redesignating paragraphs (1) and*
10 (2) *as subparagraphs (A) and (B), respectively;*

11 (B) *by striking “The Secretary, acting” and*
12 *all that follows through “year on—” and insert-*
13 *ing “The Director shall—*

14 *“(1) coordinate the Administration’s integrated*
15 *data strategy, including by collecting data each year*
16 *on—”;*

17 (C) *in the subparagraph (B), as redesign-*
18 *ated by subparagraph (A), by striking “Assist-*
19 *ant Secretary” and inserting “Director”;* and

20 (D) *by adding at the end the following new*
21 *paragraphs:*

22 (2) *provide statistical and analytical support*
23 *for activities of the Administration;*

1 “(3) recommend a core set of performance
2 metrics to evaluate activities supported by the Admin-
3 istration; and

4 “(4) coordinate with the Assistant Secretary, the
5 Assistant Secretary for Planning and Evaluation,
6 and the Chief Medical Officer appointed under section
7 501(g), as appropriate, to improve the quality of serv-
8 ices provided by programs of the Administration and
9 the evaluation of activities carried out by the Admin-
10 istration.”.

11 (5) in subsection (c), as so redesignated—

12 (A) by striking “With respect to the activi-
13 ties” and inserting “MENTAL HEALTH.—With
14 respect to the activities”;

15 (B) by striking “Assistant Secretary” each
16 place it appears and inserting “Director”; and

17 (C) by striking “subsection (a)” and insert-
18 ing “subsection (b)(1)”;

19 (6) in subsection (d), as so redesignated—

20 (A) by striking the subsection designation
21 and all that follows through “With respect to the
22 activities” and inserting the following:

23 “(d) SUBSTANCE ABUSE.—

24 “(1) IN GENERAL.—With respect to the activi-
25 ties”;

- 1 (B) in paragraph (1)—
- 2 (i) in the matter before subparagraph
- 3 (A)—
- 4 (I) by striking “subsection (a)”
- 5 and inserting “subsection (b)(1)”; and
- 6 (II) by striking “Assistant Sec-
- 7 retary” each place it appears and in-
- 8 serting “Director”; and
- 9 (ii) in subparagraph (B), by inserting
- 10 “in coordination with the Centers for Dis-
- 11 ease Control and Prevention” before the
- 12 semicolon at the end; and
- 13 (C) in paragraph (2), by striking “ANNUAL
- 14 SURVEYS” and inserting “ANNUAL SURVEYS;
- 15 PUBLIC AVAILABILITY OF DATA.—Annual sur-
- 16 veys”; and
- 17 (7) in subsection (e), as so redesignated—
- 18 (A) by striking “After consultation” and in-
- 19 serting “CONSULTATION.—After consultation”;
- 20 and
- 21 (B) by striking “Assistant Secretary shall
- 22 develop” and inserting “Assistant Secretary shall
- 23 use existing standards and best practices to de-
- 24 velop”.

1 **SEC. 6005. STRATEGIC PLAN.**

2 *Section 501 of the Public Health Service Act (42*
3 *U.S.C. 290aa), as amended by sections 6001 through 6003,*
4 *is further amended by inserting after subsection (k), as re-*
5 *designated by section 6003, the following:*

6 *“(l) STRATEGIC PLAN.—*

7 *“(1) IN GENERAL.—Not later than September 30,*
8 *2018, and every 4 years thereafter, the Assistant Sec-*
9 *retary shall develop and carry out a strategic plan in*
10 *accordance with this subsection for the planning and*
11 *operation of activities carried out by the Administra-*
12 *tion, including evidence-based programs.*

13 *“(2) COORDINATION.—In developing and car-*
14 *rying out the strategic plan under this subsection, the*
15 *Assistant Secretary shall take into consideration the*
16 *findings and recommendations of the Assistant Sec-*
17 *retary for Planning and Evaluation under section*
18 *6021(d) of the Helping Families in Mental Health*
19 *Crisis Reform Act of 2016 and the report of the Inter-*
20 *departmental Serious Mental Illness Coordinating*
21 *Committee under section 6031 of such Act.*

22 *“(3) PUBLICATION OF PLAN.—Not later than*
23 *September 30, 2018, and every 4 years thereafter, the*
24 *Assistant Secretary shall—*

25 *“(A) submit the strategic plan developed*
26 *under paragraph (1) to the Committee on En-*

1 *ergy and Commerce and the Committee on Ap-*
2 *propriations of the House of Representatives and*
3 *the Committee on Health, Education, Labor, and*
4 *Pensions and the Committee on Appropriations*
5 *of the Senate; and*

6 *“(B) post such plan on the Internet website*
7 *of the Administration.*

8 *“(4) CONTENTS.—The strategic plan developed*
9 *under paragraph (1) shall—*

10 *“(A) identify strategic priorities, goals, and*
11 *measurable objectives for mental and substance*
12 *use disorders activities and programs operated*
13 *and supported by the Administration, including*
14 *priorities to prevent or eliminate the burden of*
15 *mental and substance use disorders;*

16 *“(B) identify ways to improve the quality*
17 *of services for individuals with mental and sub-*
18 *stance use disorders, and to reduce homelessness,*
19 *arrest, incarceration, violence, including self-di-*
20 *rected violence, and unnecessary hospitalization*
21 *of individuals with a mental or substance use*
22 *disorder, including adults with a serious mental*
23 *illness or children with a serious emotional dis-*
24 *turbance;*

1 “(C) ensure that programs provide, as ap-
2 propriate, access to effective and evidence-based
3 prevention, diagnosis, intervention, treatment,
4 and recovery services, including culturally and
5 linguistically appropriate services, as appro-
6 priate, for individuals with a mental or sub-
7 stance use disorder;

8 “(D) identify opportunities to collaborate
9 with the Health Resources and Services Adminis-
10 tration to develop or improve—

11 “(i) initiatives to encourage individ-
12 uals to pursue careers (especially in rural
13 and underserved areas and with rural and
14 underserved populations) as psychiatrists,
15 including child and adolescent psychiatrists,
16 psychologists, psychiatric nurse practi-
17 tioners, physician assistants, clinical social
18 workers, certified peer support specialists,
19 licensed professional counselors, or other li-
20 censed or certified mental health or sub-
21 stance use disorder professionals, including
22 such professionals specializing in the diag-
23 nosis, evaluation, or treatment of adults
24 with a serious mental illness or children
25 with a serious emotional disturbance; and

1 “(i) a strategy to improve the recruit-
2 ment, training, and retention of a workforce
3 for the treatment of individuals with mental
4 or substance use disorders, or co-occurring
5 disorders;

6 “(E) identify opportunities to improve col-
7 laboration with States, local governments, com-
8 munities, and Indian tribes and tribal organiza-
9 tions (as such terms are defined in section 4 of
10 the Indian Self-Determination and Education
11 Assistance Act); and

12 “(F) specify a strategy to disseminate evi-
13 dence-based and promising best practices related
14 to prevention, diagnosis, early intervention,
15 treatment, and recovery services related to men-
16 tal illness, particularly for adults with a serious
17 mental illness and children with a serious emo-
18 tional disturbance, and for individuals with a
19 substance use disorder.”.

20 **SEC. 6006. BIENNIAL REPORT CONCERNING ACTIVITIES**
21 **AND PROGRESS.**

22 (a) *IN GENERAL.*—Section 501 of the Public Health
23 Service Act (42 U.S.C. 290aa), as so amended, is further
24 amended by amending subsection (m), as redesignated by
25 section 6003, to read as follows:

1 “(m) *BIENNIAL REPORT CONCERNING ACTIVITIES AND*
2 *PROGRESS.*—Not later than September 30, 2020, and every
3 2 years thereafter, the Assistant Secretary shall prepare and
4 submit to the Committee on Energy and Commerce and the
5 Committee on Appropriations of the House of Representa-
6 tives and the Committee on Health, Education, Labor, and
7 Pensions and the Committee on Appropriations of the Sen-
8 ate, and post on the Internet website of the Administration,
9 a report containing at a minimum—

10 “(1) a review of activities conducted or sup-
11 ported by the Administration, including progress to-
12 ward strategic priorities, goals, and objectives identi-
13 fied in the strategic plan developed under subsection
14 (l);

15 “(2) an assessment of programs and activities
16 carried out by the Assistant Secretary, including the
17 extent to which programs and activities under this
18 title and part B of title XIX meet identified goals and
19 performance measures developed for the respective
20 programs and activities;

21 “(3) a description of the progress made in ad-
22 dressing gaps in mental and substance use disorders
23 prevention, treatment, and recovery services and im-
24 proving outcomes by the Administration, including

1 *with respect to serious mental illnesses, serious emo-*
2 *tional disturbances, and co-occurring disorders;*

3 *“(4) a description of the manner in which the*
4 *Administration coordinates and partners with other*
5 *Federal agencies and departments related to mental*
6 *and substance use disorders, including activities re-*
7 *lated to—*

8 *“(A) the implementation and dissemination*
9 *of research findings into improved programs, in-*
10 *cluding with respect to how advances in serious*
11 *mental illness and serious emotional disturbance*
12 *research have been incorporated into programs;*

13 *“(B) the recruitment, training, and reten-*
14 *tion of a mental and substance use disorders*
15 *workforce;*

16 *“(C) the integration of mental disorder serv-*
17 *ices, substance use disorder services, and physical*
18 *health services;*

19 *“(D) homelessness; and*

20 *“(E) veterans;*

21 *“(5) a description of the manner in which the*
22 *Administration promotes coordination by grantees*
23 *under this title, and part B of title XIX, with State*
24 *or local agencies; and*

1 “(6) a description of the activities carried out
2 under section 501A(e), with respect to mental and
3 substance use disorders, including—

4 “(A) the number and a description of
5 grants awarded;

6 “(B) the total amount of funding for grants
7 awarded;

8 “(C) a description of the activities sup-
9 ported through such grants, including outcomes
10 of programs supported; and

11 “(D) information on how the National Men-
12 tal Health and Substance Use Policy Laboratory
13 is consulting with the Assistant Secretary for
14 Planning and Evaluation and collaborating with
15 the Center for Substance Abuse Treatment, the
16 Center for Substance Abuse Prevention, the Cen-
17 ter for Behavioral Health Statistics and Quality,
18 and the Center for Mental Health Services to
19 carry out such activities; and

20 “(7) recommendations made by the Assistant
21 Secretary for Planning and Evaluation under section
22 6021 of the Helping Families in Mental Health Crisis
23 Reform Act of 2016 to improve programs within the
24 Administration, and actions taken in response to such

1 (2) by inserting after paragraph (2) the fol-
2 lowing:

3 “(3) collaborate with the Director of the National
4 Institute of Mental Health and the Chief Medical Of-
5 ficer, appointed under section 501(g), to ensure that,
6 as appropriate, programs related to the prevention
7 and treatment of mental illness and the promotion of
8 mental health and recovery support are carried out in
9 a manner that reflects the best available science and
10 evidence-based practices, including culturally and lin-
11 guistically appropriate services, as appropriate;”;

12 (3) in paragraph (5), as so redesignated, by in-
13 serting “, including through programs that reduce
14 risk and promote resiliency” before the semicolon;

15 (4) in paragraph (6), as so redesignated, by in-
16 serting “in collaboration with the Director of the Na-
17 tional Institute of Mental Health,” before “develop”;

18 (5) in paragraph (8), as so redesignated, by in-
19 serting “, increase meaningful participation of indi-
20 viduals with mental illness in programs and activi-
21 ties of the Administration,” before “and protect the
22 legal”;

23 (6) in paragraph (10), as so redesignated, by
24 striking “professional and paraprofessional personnel

1 *pursuant to section 303” and inserting “health para-*
2 *professional personnel and health professionals”;*

3 *(7) in paragraph (11), as so redesignated, by in-*
4 *serting “and tele-mental health” after “rural mental*
5 *health”;*

6 *(8) in paragraph (12), as so redesignated, by*
7 *striking “establish a clearinghouse for mental health*
8 *information to assure the widespread dissemination of*
9 *such information” and inserting “disseminate mental*
10 *health information, including evidence-based prac-*
11 *tices,”;*

12 *(9) in paragraph (15), as so redesignated, by*
13 *striking “and” at the end;*

14 *(10) in paragraph (16), as so redesignated, by*
15 *striking the period and inserting “; and”;* and

16 *(11) by adding at the end the following:*

17 *“(17) ensure the consistent documentation of the*
18 *application of criteria when awarding grants and the*
19 *ongoing oversight of grantees after such grants are*
20 *awarded.”.*

21 **(b) DIRECTOR OF THE CENTER FOR SUBSTANCE**
22 **ABUSE PREVENTION.**—*Section 515 of the Public Health*
23 *Service Act (42 U.S.C. 290bb–21) is amended—*

24 *(1) in the section heading, by striking “OFFICE”*
25 *and inserting “CENTER”;*

1 (2) *in subsection (a)—*

2 (A) *by striking “an Office” and inserting*
3 *“a Center”; and*

4 (B) *by striking “The Office” and inserting*
5 *“The Prevention Center”; and*

6 (3) *in subsection (b)—*

7 (A) *in paragraph (1), by inserting “through*
8 *the reduction of risk and the promotion of resil-*
9 *ency” before the semicolon;*

10 (B) *by redesignating paragraphs (3)*
11 *through (11) as paragraphs (4) through (12), re-*
12 *spectively;*

13 (C) *by inserting after paragraph (2) the fol-*
14 *lowing:*

15 *“(3) collaborate with the Director of the National*
16 *Institute on Drug Abuse, the Director of the National*
17 *Institute on Alcohol Abuse and Alcoholism, and States*
18 *to promote the study of substance abuse prevention*
19 *and the dissemination and implementation of re-*
20 *search findings that will improve the delivery and ef-*
21 *fectiveness of substance abuse prevention activities;”;*

22 (D) *in paragraph (4), as so redesignated, by*
23 *striking “literature on the adverse effects of co-*
24 *caine free base (known as crack)” and inserting*
25 *“educational information on the effects of drugs*

1 *abused by individuals, including drugs that are*
2 *emerging as abused drugs”;*

3 *(E) in paragraph (6), as so redesignated—*

4 *(i) by striking “substance abuse coun-*
5 *selors” and inserting “health professionals*
6 *who provide substance use and misuse pre-*
7 *vention and treatment services”; and*

8 *(ii) by striking “drug abuse education,*
9 *prevention,” and inserting “illicit drug use*
10 *education and prevention”;*

11 *(F) by amending paragraph (7), as so re-*
12 *designated, to read as follows:*

13 *“(7) in cooperation with the Director of the Cen-*
14 *ters for Disease Control and Prevention, develop and*
15 *disseminate educational materials to increase aware-*
16 *ness for individuals at greatest risk for substance use*
17 *disorders to prevent the transmission of commu-*
18 *nicable diseases, such as HIV, hepatitis, tuberculosis,*
19 *and other communicable diseases;”;*

20 *(G) in paragraph (9), as so redesignated—*

21 *(i) by striking “to discourage” and in-*
22 *serting “that reduce the risk of”; and*

23 *(ii) by inserting before the semicolon*
24 *“and promote resiliency”;*

1 (H) in paragraph (11), as so redesignated,
2 by striking “and” after the semicolon;

3 (I) in paragraph (12), as so redesignated,
4 by striking the period and inserting a semicolon;
5 and

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

7 “(13) ensure the consistent documentation of the
8 application of criteria when awarding grants and the
9 ongoing oversight of grantees after such grants are
10 awarded; and

11 “(14) assist and support States in preventing il-
12 licit drug use, including emerging illicit drug use
13 issues.”.

14 (c) *DIRECTOR OF THE CENTER FOR SUBSTANCE*
15 *ABUSE TREATMENT.*—Section 507 of the Public Health
16 *Service Act (42 U.S.C. 290bb) is amended—*

17 (1) in subsection (a)—

18 (A) by striking “treatment of substance
19 abuse” and inserting “treatment of substance use
20 disorders”; and

21 (B) by striking “abuse treatment systems”
22 and inserting “use disorder treatment systems”;
23 and

24 (2) in subsection (b)—

1 (A) in paragraph (1), by striking “abuse”
2 and inserting “use disorder”;

3 (B) in paragraph (3), by striking “abuse”
4 and inserting “use disorder”;

5 (C) in paragraph (4), by striking “individ-
6 uals who abuse drugs” and inserting “individ-
7 uals who illicitly use drugs”;

8 (D) in paragraph (9), by striking “carried
9 out by the Director”;

10 (E) by striking paragraph (10);

11 (F) by redesignating paragraphs (11)
12 through (14) as paragraphs (10) through (13),
13 respectively;

14 (G) in paragraph (12), as so redesignated,
15 by striking “; and” and inserting a semicolon;
16 and

17 (H) by striking paragraph (13), as so redesi-
18 gnated, and inserting the following:

19 “(13) ensure the consistent documentation of the
20 application of criteria when awarding grants and the
21 ongoing oversight of grantees after such grants are
22 awarded; and

23 “(14) work with States, providers, and individ-
24 uals in recovery, and their families, to promote the

1 *expansion of recovery support services and systems of*
2 *care oriented toward recovery.”.*

3 **SEC. 6008. ADVISORY COUNCILS.**

4 *Section 502(b) of the Public Health Service Act (42*
5 *U.S.C. 290aa-1(b)) is amended—*

6 *(1) in paragraph (2)—*

7 *(A) in subparagraph (E), by striking “and”*
8 *after the semicolon;*

9 *(B) by redesignating subparagraph (F) as*
10 *subparagraph (J); and*

11 *(C) by inserting after subparagraph (E),*
12 *the following:*

13 *“(F) the Chief Medical Officer, appointed*
14 *under section 501(g);*

15 *“(G) the Director of the National Institute*
16 *of Mental Health for the advisory councils ap-*
17 *pointed under subsections (a)(1)(A) and*
18 *(a)(1)(D);*

19 *“(H) the Director of the National Institute*
20 *on Drug Abuse for the advisory councils ap-*
21 *pointed under subsections (a)(1)(A), (a)(1)(B),*
22 *and (a)(1)(C);*

23 *“(I) the Director of the National Institute*
24 *on Alcohol Abuse and Alcoholism for the advi-*

1 *sory councils appointed under subsections*
2 *(a)(1)(A), (a)(1)(B), and (a)(1)(C); and”;* and
3 *(2) in paragraph (3), by adding at the end the*
4 *following:*

5 *“(C) Not less than half of the members of*
6 *the advisory council appointed under subsection*
7 *(a)(1)(D)—*

8 *“(i) shall—*

9 *“(I) have a medical degree;*

10 *“(II) have a doctoral degree in*
11 *psychology; or*

12 *“(III) have an advanced degree in*
13 *nursing or social work from an accred-*
14 *ited graduate school or be a certified*
15 *physician assistant; and*

16 *“(ii) shall specialize in the mental*
17 *health field.*

18 *“(D) Not less than half of the members of*
19 *the advisory councils appointed under sub-*
20 *sections (a)(1)(B) and (a)(1)(C)—*

21 *“(i) shall—*

22 *“(I) have a medical degree;*

23 *“(II) have a doctoral degree; or*

24 *“(III) have an advanced degree in*
25 *nursing, public health, behavioral or*

1 *social sciences, or social work from an*
2 *accredited graduate school or be a cer-*
3 *tified physician assistant; and*
4 *“(ii) shall have experience in the provi-*
5 *sion of substance use disorder services or the*
6 *development and implementation of pro-*
7 *grams to prevent substance misuse.”.*

8 **SEC. 6009. PEER REVIEW.**

9 *Section 504(b) of the Public Health Service Act (42*
10 *U.S.C. 290aa–3(b)) is amended by adding at the end the*
11 *following: “In the case of any such peer review group that*
12 *is reviewing a grant, cooperative agreement, or contract re-*
13 *lated to mental illness treatment, not less than half of the*
14 *members of such peer review group shall be licensed and*
15 *experienced professionals in the prevention, diagnosis, or*
16 *treatment of, or recovery from, mental illness or co-occur-*
17 *ring mental illness and substance use disorders and have*
18 *a medical degree, a doctoral degree in psychology, or an*
19 *advanced degree in nursing or social work from an accred-*
20 *ited program, and the Secretary, in consultation with the*
21 *Assistant Secretary, shall, to the extent possible, ensure such*
22 *peer review groups include broad geographic representation,*
23 *including both urban and rural representatives.”.*

1 **Subtitle B—Oversight and**
2 **Accountability**

3 **SEC. 6021. IMPROVING OVERSIGHT OF MENTAL AND SUB-**
4 **STANCE USE DISORDERS PROGRAMS**
5 **THROUGH THE ASSISTANT SECRETARY FOR**
6 **PLANNING AND EVALUATION.**

7 (a) *IN GENERAL.*—*The Secretary of Health and*
8 *Human Services, acting through the Assistant Secretary for*
9 *Planning and Evaluation, shall ensure efficient and effec-*
10 *tive planning and evaluation of mental and substance use*
11 *disorders prevention and treatment programs and related*
12 *activities.*

13 (b) *EVALUATION STRATEGY.*—*In carrying out sub-*
14 *section (a), the Assistant Secretary for Planning and Eval-*
15 *uation shall, not later than 180 days after the date of enact-*
16 *ment of this Act, develop a strategy for conducting ongoing*
17 *evaluations that identifies priority programs to be evalu-*
18 *ated by the Assistant Secretary for Planning and Evalua-*
19 *tion and priority programs to be evaluated by other rel-*
20 *evant offices and agencies within the Department of Health*
21 *and Human Services. The strategy shall—*

22 (1) *include a plan for evaluating programs re-*
23 *lated to mental and substance use disorders, including*
24 *co-occurring disorders, across agencies, as appro-*
25 *priate, including programs related to—*

1 (A) prevention, intervention, treatment, and
2 recovery support services, including such services
3 for adults with a serious mental illness or chil-
4 dren with a serious emotional disturbance;

5 (B) the reduction of homelessness and incar-
6 ceration among individuals with a mental or
7 substance use disorder; and

8 (C) public health and health services; and

9 (2) include a plan for assessing the use of per-
10 formance metrics to evaluate activities carried out by
11 entities receiving grants, contracts, or cooperative
12 agreements related to mental and substance use dis-
13 orders prevention and treatment services under title V
14 or title XIX of the Public Health Service Act (42
15 U.S.C. 290aa et seq.; 42 U.S.C. 300w et seq.).

16 (c) CONSULTATION.—In carrying out this section, the
17 Assistant Secretary for Planning and Evaluation shall con-
18 sult, as appropriate, with the Assistant Secretary for Men-
19 tal Health and Substance Use, the Chief Medical Officer
20 of the Substance Abuse and Mental Health Services Admin-
21 istration appointed under section 501(g) of the Public
22 Health Service Act (42 U.S.C. 290aa(g)), as amended by
23 section 6003, the Behavioral Health Coordinating Council
24 of the Department of Health and Human Services, other
25 agencies within the Department of Health and Human

1 *Services, and other relevant Federal departments and agen-*
2 *cies.*

3 (d) *RECOMMENDATIONS.*—*In carrying out this section,*
4 *the Assistant Secretary for Planning and Evaluation shall*
5 *provide recommendations to the Secretary of Health and*
6 *Human Services, the Assistant Secretary for Mental Health*
7 *and Substance Use, and the Congress on improving the*
8 *quality of prevention and treatment programs and activi-*
9 *ties related to mental and substance use disorders, including*
10 *recommendations for the use of performance metrics. The*
11 *Assistant Secretary for Mental Health and Substance Use*
12 *shall include such recommendations in the biennial report*
13 *required by subsection 501(m) of the Public Health Service*
14 *Act, as redesignated by section 6003 of this Act.*

15 **SEC. 6022. REPORTING FOR PROTECTION AND ADVOCACY**
16 **ORGANIZATIONS.**

17 (a) *PUBLIC AVAILABILITY OF REPORTS.*—*Section*
18 *105(a)(7) of the Protection and Advocacy for Individuals*
19 *with Mental Illness Act (42 U.S.C. 10805(a)(7)) is amended*
20 *by striking “is located a report” and inserting “is located,*
21 *and make publicly available, a report”.*

22 (b) *DETAILED ACCOUNTING.*—*Section 114(a) of the*
23 *Protection and Advocacy for Individuals with Mental Ill-*
24 *ness Act (42 U.S.C. 10824(a)) is amended—*

1 (1) *in paragraph (3), by striking “and” at the*
2 *end;*

3 (2) *in paragraph (4), by striking the period at*
4 *the end and inserting “; and”; and*

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

6 “(5) *using data from the existing required an-*
7 *nual program progress reports submitted by each sys-*
8 *tem funded under this title, a detailed accounting for*
9 *each such system of how funds are spent,*
10 *disaggregated according to whether the funds were re-*
11 *ceived from the Federal Government, the State govern-*
12 *ment, a local government, or a private entity.”.*

13 **SEC. 6023. GAO STUDY.**

14 (a) *IN GENERAL.*—*Not later than 18 months after the*
15 *date of enactment of this Act, the Comptroller General of*
16 *the United States, in consultation with the Secretary of*
17 *Health and Human Services and the Assistant Secretary*
18 *for Mental Health and Substance Use, shall conduct an*
19 *independent evaluation, and submit a report, to the Com-*
20 *mittee on Health, Education, Labor, and Pensions of the*
21 *Senate and the Committee on Energy and Commerce of the*
22 *House of Representatives, on programs funded by allot-*
23 *ments made under title I of the Protection and Advocacy*
24 *for Individuals with Mental Illness Act (42 U.S.C. 10801*
25 *et seq.).*

1 (b) *CONTENTS.*—*The report and evaluation required*
2 *under subsection (a) shall include—*

3 (1) *a review of the programs described in such*
4 *subsection that are carried out by State agencies and*
5 *such programs that are carried out by private, non-*
6 *profit organizations; and*

7 (2) *a review of the compliance of the programs*
8 *described in subsection (a) with statutory and regu-*
9 *latory responsibilities, such as—*

10 (A) *responsibilities relating to family en-*
11 *gagement;*

12 (B) *responsibilities relating to the grievance*
13 *procedure for clients or prospective clients of the*
14 *system to assure that individuals with mental*
15 *illness have full access to the services of the sys-*
16 *tem, for individuals who have received or are re-*
17 *ceiving mental health services, and for family*
18 *members of such individuals with mental illness,*
19 *or representatives of such individuals or family*
20 *members, to assure that the eligible system is op-*
21 *erating in compliance with the provisions of the*
22 *Protection and Advocacy for Individuals with*
23 *Mental Illness Act, as required to be established*
24 *by section 105(a)(9) of such Act (42 U.S.C.*
25 *10805(a)(9));*

1 (C) investigation of alleged abuse and ne-
2 glect of persons with mental illness;

3 (D) availability of adequate medical and
4 behavioral health treatment;

5 (E) denial of rights for persons with mental
6 illness; and

7 (F) compliance with the Federal prohibition
8 on lobbying.

9 **Subtitle C—Interdepartmental Seri-**
10 **ous Mental Illness Coordinating**
11 **Committee**

12 **SEC. 6031. INTERDEPARTMENTAL SERIOUS MENTAL ILL-**
13 **NESS COORDINATING COMMITTEE.**

14 (a) *ESTABLISHMENT.*—

15 (1) *IN GENERAL.*—Not later than 3 months after
16 the date of enactment of this Act, the Secretary of
17 Health and Human Services, or the designee of the
18 Secretary, shall establish a committee to be known as
19 the Interdepartmental Serious Mental Illness Coordi-
20 nating Committee (in this section referred to as the
21 “Committee”).

22 (2) *FEDERAL ADVISORY COMMITTEE ACT.*—*Ex-*
23 *cept as provided in this section, the provisions of the*
24 *Federal Advisory Committee Act (5 U.S.C. App.)*
25 *shall apply to the Committee.*

1 (b) *MEETINGS.*—*The Committee shall meet not fewer*
2 *than 2 times each year.*

3 (c) *RESPONSIBILITIES.*—*Not later than 1 year after*
4 *the date of enactment of this Act, and 5 years after such*
5 *date of enactment, the Committee shall submit to Congress*
6 *and any other relevant Federal department or agency a re-*
7 *port including—*

8 (1) *a summary of advances in serious mental ill-*
9 *ness and serious emotional disturbance research re-*
10 *lated to the prevention of, diagnosis of, intervention*
11 *in, and treatment and recovery of serious mental ill-*
12 *nesses, serious emotional disturbances, and advances*
13 *in access to services and support for adults with a se-*
14 *rious mental illness or children with a serious emo-*
15 *tional disturbance;*

16 (2) *an evaluation of the effect Federal programs*
17 *related to serious mental illness have on public health,*
18 *including public health outcomes such as—*

19 (A) *rates of suicide, suicide attempts, inci-*
20 *dence and prevalence of serious mental illnesses,*
21 *serious emotional disturbances, and substance*
22 *use disorders, overdose, overdose deaths, emer-*
23 *gency hospitalizations, emergency room board-*
24 *ing, preventable emergency room visits, inter-*

1 *action with the criminal justice system, home-*
2 *lessness, and unemployment;*

3 *(B) increased rates of employment and en-*
4 *rollment in educational and vocational pro-*
5 *grams;*

6 *(C) quality of mental and substance use dis-*
7 *orders treatment services; or*

8 *(D) any other criteria as may be deter-*
9 *mined by the Secretary; and*

10 *(3) specific recommendations for actions that*
11 *agencies can take to better coordinate the administra-*
12 *tion of mental health services for adults with a serious*
13 *mental illness or children with a serious emotional*
14 *disturbance.*

15 *(d) COMMITTEE EXTENSION.—Upon the submission of*
16 *the second report under subsection (c), the Secretary shall*
17 *submit a recommendation to Congress on whether to extend*
18 *the operation of the Committee.*

19 *(e) MEMBERSHIP.—*

20 *(1) FEDERAL MEMBERS.—The Committee shall*
21 *be composed of the following Federal representatives,*
22 *or the designees of such representatives—*

23 *(A) the Secretary of Health and Human*
24 *Services, who shall serve as the Chair of the*
25 *Committee;*

1 (B) *the Assistant Secretary for Mental*
2 *Health and Substance Use;*

3 (C) *the Attorney General;*

4 (D) *the Secretary of Veterans Affairs;*

5 (E) *the Secretary of Defense;*

6 (F) *the Secretary of Housing and Urban*
7 *Development;*

8 (G) *the Secretary of Education;*

9 (H) *the Secretary of Labor;*

10 (I) *the Administrator of the Centers for*
11 *Medicare & Medicaid Services; and*

12 (J) *the Commissioner of Social Security.*

13 (2) *NON-FEDERAL MEMBERS.*—*The Committee*
14 *shall also include not less than 14 non-Federal public*
15 *members appointed by the Secretary of Health and*
16 *Human Services, of which—*

17 (A) *at least 2 members shall be an indi-*
18 *vidual who has received treatment for a diag-*
19 *nosis of a serious mental illness;*

20 (B) *at least 1 member shall be a parent or*
21 *legal guardian of an adult with a history of a*
22 *serious mental illness or a child with a history*
23 *of a serious emotional disturbance;*

24 (C) *at least 1 member shall be a representa-*
25 *tive of a leading research, advocacy, or service*

1 *organization for adults with a serious mental ill-*
2 *ness;*

3 *(D) at least 2 members shall be—*

4 *(i) a licensed psychiatrist with experi-*
5 *ence in treating serious mental illnesses;*

6 *(ii) a licensed psychologist with experi-*
7 *ence in treating serious mental illnesses or*
8 *serious emotional disturbances;*

9 *(iii) a licensed clinical social worker*
10 *with experience treating serious mental ill-*
11 *nesses or serious emotional disturbances; or*

12 *(iv) a licensed psychiatric nurse, nurse*
13 *practitioner, or physician assistant with ex-*
14 *perience in treating serious mental illnesses*
15 *or serious emotional disturbances;*

16 *(E) at least 1 member shall be a licensed*
17 *mental health professional with a specialty in*
18 *treating children and adolescents with a serious*
19 *emotional disturbance;*

20 *(F) at least 1 member shall be a mental*
21 *health professional who has research or clinical*
22 *mental health experience in working with mi-*
23 *norities;*

24 *(G) at least 1 member shall be a mental*
25 *health professional who has research or clinical*

1 *mental health experience in working with medi-*
2 *cally underserved populations;*

3 *(H) at least 1 member shall be a State cer-*
4 *tified mental health peer support specialist;*

5 *(I) at least 1 member shall be a judge with*
6 *experience in adjudicating cases related to crimi-*
7 *nal justice or serious mental illness;*

8 *(J) at least 1 member shall be a law en-*
9 *forcement officer or corrections officer with exten-*
10 *sive experience in interfacing with adults with a*
11 *serious mental illness, children with a serious*
12 *emotional disturbance, or individuals in a men-*
13 *tal health crisis; and*

14 *(K) at least 1 member shall have experience*
15 *providing services for homeless individuals and*
16 *working with adults with a serious mental ill-*
17 *ness, children with a serious emotional disturb-*
18 *ance, or individuals in a mental health crisis.*

19 (3) *TERMS.*—*A member of the Committee ap-*
20 *pointed under subsection (e)(2) shall serve for a term*
21 *of 3 years, and may be reappointed for 1 or more ad-*
22 *ditional 3-year terms. Any member appointed to fill*
23 *a vacancy for an unexpired term shall be appointed*
24 *for the remainder of such term. A member may serve*

1 *after the expiration of the member’s term until a suc-*
 2 *cessor has been appointed.*

3 (f) *WORKING GROUPS.*—*In carrying out its functions,*
 4 *the Committee may establish working groups. Such working*
 5 *groups shall be composed of Committee members, or their*
 6 *designees, and may hold such meetings as are necessary.*

7 (g) *SUNSET.*—*The Committee shall terminate on the*
 8 *date that is 6 years after the date on which the Committee*
 9 *is established under subsection (a)(1).*

10 ***TITLE VII—ENSURING MENTAL***
 11 ***AND SUBSTANCE USE DIS-***
 12 ***ORDERS PREVENTION,***
 13 ***TREATMENT, AND RECOVERY***
 14 ***PROGRAMS KEEP PACE WITH***
 15 ***SCIENCE AND TECHNOLOGY***

16 ***SEC. 7001. ENCOURAGING INNOVATION AND EVIDENCE-***
 17 ***BASED PROGRAMS.***

18 *Title V of the Public Health Service Act (42 U.S.C.*
 19 *290aa et seq.) is amended by inserting after section 501*
 20 *(42 U.S.C. 290aa) the following:*

21 ***“SEC. 501A. NATIONAL MENTAL HEALTH AND SUBSTANCE***
 22 ***USE POLICY LABORATORY.***

23 ***“(a) IN GENERAL.***—*There shall be established within*
 24 *the Administration a National Mental Health and Sub-*

1 *stance Use Policy Laboratory (referred to in this section*
2 *as the ‘Laboratory’).*

3 “(b) *RESPONSIBILITIES.—The Laboratory shall—*

4 “(1) *continue to carry out the authorities and*
5 *activities that were in effect for the Office of Policy,*
6 *Planning, and Innovation as such Office existed prior*
7 *to the date of enactment of the Helping Families in*
8 *Mental Health Crisis Reform Act of 2016;*

9 “(2) *identify, coordinate, and facilitate the im-*
10 *plementation of policy changes likely to have a sig-*
11 *nificant effect on mental health, mental illness, recov-*
12 *ery supports, and the prevention and treatment of*
13 *substance use disorder services;*

14 “(3) *work with the Center for Behavioral Health*
15 *Statistics and Quality to collect, as appropriate, in-*
16 *formation from grantees under programs operated by*
17 *the Administration in order to evaluate and dissemi-*
18 *nate information on evidence-based practices, includ-*
19 *ing culturally and linguistically appropriate services,*
20 *as appropriate, and service delivery models;*

21 “(4) *provide leadership in identifying and co-*
22 *ordinating policies and programs, including evidence-*
23 *-based programs, related to mental and substance use*
24 *disorders;*

1 “(5) periodically review programs and activities
2 operated by the Administration relating to the diag-
3 nosis or prevention of, treatment for, and recovery
4 from, mental and substance use disorders to—

5 “(A) identify any such programs or activi-
6 ties that are duplicative;

7 “(B) identify any such programs or activi-
8 ties that are not evidence-based, effective, or effi-
9 cient; and

10 “(C) formulate recommendations for coordi-
11 nating, eliminating, or improving programs or
12 activities identified under subparagraph (A) or
13 (B) and merging such programs or activities
14 into other successful programs or activities; and

15 “(6) carry out other activities as deemed nec-
16 essary to continue to encourage innovation and dis-
17 seminate evidence-based programs and practices.

18 “(c) *EVIDENCE-BASED PRACTICES AND SERVICE DE-*
19 *LIVERY MODELS.—*

20 “(1) *IN GENERAL.—*In carrying out subsection
21 (b)(3), the Laboratory—

22 “(A) may give preference to models that im-
23 prove—

24 “(i) the coordination between mental
25 health and physical health providers;

1 “(ii) the coordination among such pro-
2 viders and the justice and corrections sys-
3 tem; and

4 “(iii) the cost effectiveness, quality, ef-
5 fectiveness, and efficiency of health care
6 services furnished to adults with a serious
7 mental illness, children with a serious emo-
8 tional disturbance, or individuals in a men-
9 tal health crisis; and

10 “(B) may include clinical protocols and
11 practices that address the needs of individuals
12 with early serious mental illness.

13 “(2) CONSULTATION.—In carrying out this sec-
14 tion, the Laboratory shall consult with—

15 “(A) the Chief Medical Officer appointed
16 under section 501(g);

17 “(B) representatives of the National Insti-
18 tute of Mental Health, the National Institute on
19 Drug Abuse, and the National Institute on Alco-
20 hol Abuse and Alcoholism, on an ongoing basis;

21 “(C) other appropriate Federal agencies;

22 “(D) clinical and analytical experts with
23 expertise in psychiatric medical care and clin-
24 ical psychological care, health care management,

1 *education, corrections health care, and mental*
2 *health court systems, as appropriate; and*

3 “(E) *other individuals and agencies as de-*
4 *termined appropriate by the Assistant Secretary.*

5 “(d) *DEADLINE FOR BEGINNING IMPLEMENTATION.—*
6 *The Laboratory shall begin implementation of this section*
7 *not later than January 1, 2018.*

8 “(e) *PROMOTING INNOVATION.—*

9 “(1) *IN GENERAL.—The Assistant Secretary, in*
10 *coordination with the Laboratory, may award grants*
11 *to States, local governments, Indian tribes or tribal*
12 *organizations (as such terms are defined in section 4*
13 *of the Indian Self-Determination and Education As-*
14 *sistance Act), educational institutions, and nonprofit*
15 *organizations to develop evidence-based interventions,*
16 *including culturally and linguistically appropriate*
17 *services, as appropriate, for—*

18 “(A) *evaluating a model that has been sci-*
19 *entifically demonstrated to show promise, but*
20 *would benefit from further applied development,*
21 *for—*

22 “(i) *enhancing the prevention, diag-*
23 *nosis, intervention, and treatment of, and*
24 *recovery from, mental illness, serious emo-*

1 *tional disturbances, substance use disorders,*
2 *and co-occurring illness or disorders; or*

3 *“(ii) integrating or coordinating phys-*
4 *ical health services and mental and sub-*
5 *stance use disorders services; and*

6 *“(B) expanding, replicating, or scaling evi-*
7 *dence-based programs across a wider area to en-*
8 *hance effective screening, early diagnosis, inter-*
9 *vention, and treatment with respect to mental*
10 *illness, serious mental illness, serious emotional*
11 *disturbances, and substance use disorders, pri-*
12 *marily by—*

13 *“(i) applying such evidence-based pro-*
14 *grams to the delivery of care, including by*
15 *training staff in effective evidence-based*
16 *treatments; or*

17 *“(ii) integrating such evidence-based*
18 *programs into models of care across special-*
19 *ties and jurisdictions.*

20 *“(2) CONSULTATION.—In awarding grants under*
21 *this subsection, the Assistant Secretary shall, as ap-*
22 *propriate, consult with the Chief Medical Officer, ap-*
23 *pointed under section 501(g), the advisory councils*
24 *described in section 502, the National Institute of*
25 *Mental Health, the National Institute on Drug Abuse,*

1 *and the National Institute on Alcohol Abuse and Al-*
 2 *coholism, as appropriate.*

3 “(3) *AUTHORIZATION OF APPROPRIATIONS.—*

4 *There are authorized to be appropriated—*

5 “(A) *to carry out paragraph (1)(A),*
 6 *\$7,000,000 for the period of fiscal years 2018*
 7 *through 2020; and*

8 “(B) *to carry out paragraph (1)(B),*
 9 *\$7,000,000 for the period of fiscal years 2018*
 10 *through 2020.”.*

11 **SEC. 7002. PROMOTING ACCESS TO INFORMATION ON EVI-**
 12 **DENCE-BASED PROGRAMS AND PRACTICES.**

13 *Part D of title V of the Public Health Service Act (42*
 14 *U.S.C. 290dd et seq.) is amended by inserting after section*
 15 *543 of such Act (42 U.S.C. 290dd-2) the following:*

16 **“SEC. 543A. PROMOTING ACCESS TO INFORMATION ON EVI-**
 17 **DENCE-BASED PROGRAMS AND PRACTICES.**

18 “(a) *IN GENERAL.—The Assistant Secretary shall, as*
 19 *appropriate, improve access to reliable and valid informa-*
 20 *tion on evidence-based programs and practices, including*
 21 *information on the strength of evidence associated with such*
 22 *programs and practices, related to mental and substance*
 23 *use disorders for States, local communities, nonprofit enti-*
 24 *ties, and other stakeholders, by posting on the Internet*
 25 *website of the Administration information on evidence-*

1 *based programs and practices that have been reviewed by*
2 *the Assistant Secretary in accordance with the requirements*
3 *of this section.*

4 “(b) *APPLICATIONS.—*

5 “(1) *APPLICATION PERIOD.—In carrying out*
6 *subsection (a), the Assistant Secretary may establish*
7 *a period for the submission of applications for evi-*
8 *dence-based programs and practices to be posted pub-*
9 *licly in accordance with subsection (a).*

10 “(2) *NOTICE.—In establishing the application*
11 *period under paragraph (1), the Assistant Secretary*
12 *shall provide for the public notice of such application*
13 *period in the Federal Register. Such notice may so-*
14 *licit applications for evidence-based programs and*
15 *practices to address gaps in information identified by*
16 *the Assistant Secretary, the National Mental Health*
17 *and Substance Use Policy Laboratory established*
18 *under section 501A, or the Assistant Secretary for*
19 *Planning and Evaluation, including pursuant to the*
20 *evaluation and recommendations under section 6021*
21 *of the Helping Families in Mental Health Crisis Re-*
22 *form Act of 2016 or priorities identified in the stra-*
23 *tegic plan under section 501(l).*

24 “(c) *REQUIREMENTS.—The Assistant Secretary may*
25 *establish minimum requirements for the applications sub-*

1 mitted under subsection (b), including applications related
2 to the submission of research and evaluation.

3 “(d) *REVIEW AND RATING.*—

4 “(1) *IN GENERAL.*—The Assistant Secretary
5 shall review applications prior to public posting in
6 accordance with subsection (a), and may prioritize
7 the review of applications for evidence-based pro-
8 grams and practices that are related to topics in-
9 cluded in the notice provided under subsection (b)(2).

10 “(2) *SYSTEM.*—In carrying out paragraph (1),
11 the Assistant Secretary may utilize a rating and re-
12 view system, which may include information on the
13 strength of evidence associated with the evidence-based
14 programs and practices and a rating of the methodo-
15 logical rigor of the research supporting the applica-
16 tions.

17 “(3) *PUBLIC ACCESS TO METRICS AND RATING.*—
18 The Assistant Secretary shall make the metrics used
19 to evaluate applications under this section, and any
20 resulting ratings of such applications, publicly avail-
21 able.”.

22 **SEC. 7003. PRIORITY MENTAL HEALTH NEEDS OF REGIONAL**
23 **AND NATIONAL SIGNIFICANCE.**

24 Section 520A of the Public Health Service Act (42
25 U.S.C. 290bb–32) is amended—

1 (1) *in subsection (a)—*

2 (A) *in paragraph (4), by inserting before*
3 *the period “, which may include technical assist-*
4 *ance centers”;* and

5 (B) *in the flush sentence following para-*
6 *graph (4)—*

7 (i) *by inserting “, contracts,” before*
8 *“or cooperative agreements”;* and

9 (ii) *by striking “Indian tribes and*
10 *tribal organizations” and inserting “Indian*
11 *tribes or tribal organizations (as such terms*
12 *are defined in section 4 of the Indian Self-*
13 *Determination and Education Assistance*
14 *Act), health facilities, or programs operated*
15 *by or in accordance with a contract or*
16 *grant with the Indian Health Service, or”;*
17 *and*

18 (2) *by amending subsection (f) to read as follows:*

19 “(f) *AUTHORIZATION OF APPROPRIATIONS.—There are*
20 *authorized to be appropriated to carry out this section*
21 *\$394,550,000 for each of fiscal years 2018 through 2022.”.*

1 **SEC. 7004. PRIORITY SUBSTANCE USE DISORDER TREAT-**
2 **MENT NEEDS OF REGIONAL AND NATIONAL**
3 **SIGNIFICANCE.**

4 *Section 509 of the Public Health Service Act (42*
5 *U.S.C. 290bb-2) is amended—*

6 *(1) in subsection (a)—*

7 *(A) in the matter preceding paragraph (1),*
8 *by striking “abuse” and inserting “use dis-*
9 *order”;*

10 *(B) in paragraph (3), by inserting before*
11 *the period “that permit States, local govern-*
12 *ments, communities, and Indian tribes and trib-*
13 *al organizations (as the terms ‘Indian tribes’*
14 *and ‘tribal organizations’ are defined in section*
15 *4 of the Indian Self-Determination and Edu-*
16 *cation Assistance Act) to focus on emerging*
17 *trends in substance abuse and co-occurrence of*
18 *substance use disorders with mental illness or*
19 *other conditions”; and*

20 *(C) in the flush sentence following para-*
21 *graph (3)—*

22 *(i) by inserting “, contracts,” before*
23 *“or cooperative agreements”; and*

24 *(ii) by striking “Indian tribes and*
25 *tribal organizations,” and inserting “In-*
26 *Indian tribes or tribal organizations (as such*

1 *terms are defined in section 4 of the Indian*
 2 *Self-Determination and Education Assist-*
 3 *ance Act), health facilities, or programs op-*
 4 *erated by or in accordance with a contract*
 5 *or grant with the Indian Health Service,*
 6 *or”;*

7 (2) *in subsection (b)—*

8 (A) *in paragraph (1), by striking “abuse”*
 9 *and inserting “use disorder”; and*

10 (B) *in paragraph (2), by striking “abuse”*
 11 *and inserting “use disorder”;*

12 (3) *in subsection (e), by striking “abuse” and in-*
 13 *serting “use disorder”; and*

14 (4) *in subsection (f), by striking “\$300,000,000”*
 15 *and all that follows through the period and inserting*
 16 *“\$333,806,000 for each of fiscal years 2018 through*
 17 *2022.”.*

18 **SEC. 7005. PRIORITY SUBSTANCE USE DISORDER PREVEN-**
 19 **TION NEEDS OF REGIONAL AND NATIONAL**
 20 **SIGNIFICANCE.**

21 *Section 516 of the Public Health Service Act (42*
 22 *U.S.C. 290bb–22) is amended—*

23 (1) *in the section heading, by striking “**ABUSE**”*
 24 *and inserting “**USE DISORDER**”;*

25 (2) *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 “, including such programs that focus
6 on emerging drug abuse issues”; and

7 (C) in the flush sentence following para-
8 graph (3)—

9 (i) by inserting “, contracts,” before
10 “or cooperative agreements”; and

11 (ii) by striking “Indian tribes and
12 tribal organizations,” and inserting “In-
13 dian tribes or tribal organizations (as such
14 terms are defined in section 4 of the Indian
15 Self-Determination and Education Assist-
16 ance Act), health facilities, or programs op-
17 erated by or in accordance with a contract
18 or grant with the Indian Health Service,”;

19 (3) in subsection (b)—

20 (A) in paragraph (1), by striking “abuse”
21 and inserting “use disorder”; and

22 (B) in paragraph (2)—

23 (i) in subparagraph (A), by striking “;
24 and” at the end and inserting “;”;

25 (ii) in subparagraph (B)—

1 (I) by striking “abuse” and in-
 2 serting “use disorder”; and

3 (II) by striking the period and in-
 4 serting “; and”; and

5 (iii) by adding at the end the fol-
 6 lowing:

7 “(C) substance use disorder prevention
 8 among high-risk groups.”;

9 (4) in subsection (e), by striking “abuse” and in-
 10 serting “use disorder”; and

11 (5) in subsection (f), by striking “\$300,000,000”
 12 and all that follows through the period and inserting
 13 “\$211,148,000 for each of fiscal years 2018 through
 14 2022.”.

15 **TITLE VIII—SUPPORTING STATE**
 16 **PREVENTION ACTIVITIES AND**
 17 **RESPONSES TO MENTAL**
 18 **HEALTH AND SUBSTANCE USE**
 19 **DISORDER NEEDS**

20 **SEC. 8001. COMMUNITY MENTAL HEALTH SERVICES BLOCK**
 21 **GRANT.**

22 (a) *FORMULA GRANTS.*—Section 1911(b) of the Public
 23 Health Service Act (42 U.S.C. 300x(b)) is amended—

24 (1) by redesignating paragraphs (1) through (3)
 25 as paragraphs (2) through (4), respectively; and

1 (2) *by inserting before paragraph (2) (as so re-*
2 *designated) the following:*

3 “(1) *providing community mental health services*
4 *for adults with a serious mental illness and children*
5 *with a serious emotional disturbance as defined in ac-*
6 *cordance with section 1912(c);”.*

7 (b) *STATE PLAN.—Section 1912(b) of the Public*
8 *Health Service Act (42 U.S.C. 300x–1(b)) is amended—*

9 (1) *in paragraph (3), by redesignating subpara-*
10 *graphs (A) through (C) as clauses (i) through (iii), re-*
11 *spectively, and realigning the margins accordingly;*

12 (2) *by redesignating paragraphs (1) through (5)*
13 *as subparagraphs (A) through (E), respectively, and*
14 *realigning the margins accordingly;*

15 (3) *in the matter preceding subparagraph (A)*
16 *(as so redesignated), by striking “With respect to”*
17 *and all that follows through “are as follows:” and in-*
18 *serting “In accordance with subsection (a), a State*
19 *shall submit to the Secretary a plan every two years*
20 *that, at a minimum, includes each of the following:”;*

21 (4) *by inserting before subparagraph (A) (as so*
22 *redesignated) the following:*

23 “(1) *SYSTEM OF CARE.—A description of the*
24 *State’s system of care that contains the following:”;*

1 (5) *by striking subparagraph (A) (as so redesign-*
2 *ated) and inserting the following:*

3 “(A) *COMPREHENSIVE COMMUNITY-BASED*
4 *HEALTH SYSTEMS.—The plan shall—*

5 “(i) *identify the single State agency to*
6 *be responsible for the administration of the*
7 *program under the grant, including any*
8 *third party who administers mental health*
9 *services and is responsible for complying*
10 *with the requirements of this part with re-*
11 *spect to the grant;*

12 “(ii) *provide for an organized commu-*
13 *nity-based system of care for individuals*
14 *with mental illness, and describe available*
15 *services and resources in a comprehensive*
16 *system of care, including services for indi-*
17 *viduals with co-occurring disorders;*

18 “(iii) *include a description of the man-*
19 *ner in which the State and local entities*
20 *will coordinate services to maximize the ef-*
21 *iciency, effectiveness, quality, and cost-ef-*
22 *fectiveness of services and programs to*
23 *produce the best possible outcomes (includ-*
24 *ing health services, rehabilitation services,*
25 *employment services, housing services, edu-*

1 *cational services, substance use disorder*
2 *services, legal services, law enforcement serv-*
3 *ices, social services, child welfare services,*
4 *medical and dental care services, and other*
5 *support services to be provided with Fed-*
6 *eral, State, and local public and private re-*
7 *sources) with other agencies to enable indi-*
8 *viduals receiving services to function outside*
9 *of inpatient or residential institutions, to*
10 *the maximum extent of their capabilities,*
11 *including services to be provided by local*
12 *school systems under the Individuals with*
13 *Disabilities Education Act;*

14 *“(iv) include a description of how the*
15 *State promotes evidence-based practices, in-*
16 *cluding those evidence-based programs that*
17 *address the needs of individuals with early*
18 *serious mental illness regardless of the age*
19 *of the individual at onset, provide com-*
20 *prehensive individualized treatment, or in-*
21 *tegrate mental and physical health services;*

22 *“(v) include a description of case man-*
23 *agement 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 block*
10 *grant funds, include—*

11 *“(I) a description of the activities*
12 *intended to reduce hospitalizations and*
13 *hospital stays using the block grant*
14 *funds;*

15 *“(II) a description of the activi-*
16 *ties intended to reduce incidents of sui-*
17 *cide using the block grant funds;*

18 *“(III) a description of how the*
19 *State integrates mental health and pri-*
20 *mary care using the block grant funds,*
21 *which may include providing, in the*
22 *case of individuals with co-occurring*
23 *mental and substance use disorders,*
24 *both mental and substance use dis-*
25 *orders services in primary care settings*

1 or arrangements to provide primary
2 and specialty care services in commu-
3 nity-based mental and substance use
4 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 reded-
24 ignated) 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 substance*
5 *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), by*
11 *striking “plan describes” and inserting “plan shall*
12 *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 pro-*
18 *vides for” and inserting “plan shall describe the*
19 *financial resources available, the existing mental*
20 *health workforce, and the workforce trained in*
21 *treating individuals with co-occurring mental*
22 *and substance use disorders, and shall provide*
23 *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; and

9 (11) by adding at the end the following:

10 “(2) GOALS AND OBJECTIVES.—The establish-
11 ment of goals and objectives for the period of the plan,
12 including targets and milestones that are intended to
13 be met, and the activities that will be undertaken to
14 achieve those targets.”.

15 (c) EARLY SERIOUS MENTAL ILLNESS.—Section 1920
16 of the Public Health Service Act (42 U.S.C. 300x–9) is
17 amended by adding at the end the following:

18 “(c) EARLY SERIOUS MENTAL ILLNESS.—

19 “(1) IN GENERAL.—Except as provided in para-
20 graph (2), a State shall expend not less than 10 per-
21 cent of the amount the State receives for carrying out
22 this section for each fiscal year to support evidence-
23 based programs that address the needs of individuals
24 with early serious mental illness, including psychotic

1 *disorders, regardless of the age of the individual at*
2 *onset.*

3 “(2) *STATE FLEXIBILITY.*—*In lieu of expending*
4 *10 percent of the amount the State receives under this*
5 *section for a fiscal year as required under paragraph*
6 *(1), a State may elect to expend not less than 20 per-*
7 *cent of such amount by the end of such succeeding fis-*
8 *cal year.”.*

9 *(d) ADDITIONAL PROVISIONS.*—*Section 1915(b) of the*
10 *Public Health Service Act (42 U.S.C. 300x-4(b)) is amend-*
11 *ed—*

12 *(1) in paragraph (3)—*

13 *(A) by striking “The Secretary” and insert-*
14 *ing 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 waiver”;*
21 *and*

22 *(D) by adding at the end the following:*

23 *“(B) DATE CERTAIN FOR ACTION UPON RE-*
24 *QUEST.—The Secretary shall approve or deny a*
25 *request for a waiver under this paragraph not*

1 later than 120 days after the date on which the
2 request is made.

3 “(C) *APPLICABILITY OF WAIVER.*—A waiver
4 provided by the Secretary under this paragraph
5 shall be applicable only to the fiscal year in-
6 volved.”; and

7 (2) in paragraph (4)—

8 (A) in subparagraph (A)—

9 (i) by inserting after the subparagraph
10 designation the following: “*IN GENERAL.*—
11 ”;

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 has
19 failed to comply with paragraph (1) and
20 would otherwise be subject to a reduction in
21 the State’s allotment under section 1911
22 may, upon request by the State, in lieu of
23 having the amount of the allotment under
24 section 1911 for the State reduced for the
25 fiscal year of the grant, agree to comply

1 with a negotiated agreement that is ap-
2 proved by the Secretary and carried out in
3 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 subparagraph
11 designation the following: “SUBMISSION OF
12 INFORMATION TO THE SECRETARY.—”; and

13 (ii) by striking “subparagraph (A)”
14 and inserting “subparagraph (A)(i)”.

15 (e) APPLICATION FOR GRANT.—Section 1917(a) of the
16 Public Health Service Act (42 U.S.C. 300x-6(a)) is amend-
17 ed—

18 (1) in paragraph (1), by striking “1941” and in-
19 serting “1942(a)”; and

20 (2) in paragraph (5), by striking
21 “1915(b)(3)(B)” and inserting “1915(b)”.

22 (f) FUNDING.—Section 1920 of the Public Health Serv-
23 ice Act (42 U.S.C. 300x-9) is amended—

24 (1) in subsection (a)—

1 (A) by striking “section 505” and inserting
2 “section 505(c)”; and

3 (B) by striking “\$450,000,000” and all that
4 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 505
8 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 Public
12 Health Service Act (42 U.S.C. 300x–21(b)) is amended—

13 (1) by inserting “carrying out the plan developed
14 in accordance with section 1932(b) and for” after “for
15 the purpose of”; and

16 (2) by striking “abuse” and inserting “use dis-
17 orders”.

18 (b) *OUTREACH TO PERSONS WHO INJECT DRUGS.*—
19 Section 1923(b) of the Public Health Service Act (42 U.S.C.
20 300x–23(b)) is amended—

21 (1) in the subsection heading, by striking “RE-
22 GARDING INTRAVENOUS SUBSTANCE ABUSE” and in-
23 serting “TO PERSONS WHO INJECT DRUGS”; and

24 (2) by striking “for intravenous drug abuse” and
25 inserting “for persons who inject drugs”.

1 (c) *REQUIREMENTS REGARDING TUBERCULOSIS AND*
2 *HUMAN IMMUNODEFICIENCY VIRUS.*—Section 1924 of the
3 *Public Health Service Act (42 U.S.C. 300x–24)* is amend-
4 *ed—*

5 (1) *in subsection (a)(1)—*

6 (A) *in the matter preceding subparagraph*
7 *(A), by striking “substance abuse” and inserting*
8 *“substance use disorders”; and*

9 (B) *in subparagraph (A), by striking “such*
10 *abuse” and inserting “such disorders”;*

11 (2) *in subsection (b)—*

12 (A) *in paragraph (1)(A), by striking “sub-*
13 *stance abuse” and inserting “substance use dis-*
14 *orders”;*

15 (B) *in paragraph (2), by inserting “and*
16 *Prevention” after “Disease Control”;*

17 (C) *in paragraph (3)—*

18 (i) *in the paragraph heading, by strik-*
19 *ing “ABUSE” and inserting “USE DIS-*
20 *ORDERS”;* and

21 (ii) *by striking “substance abuse” and*
22 *inserting “substance use disorders”; and*

23 (D) *in paragraph (6)(B), by striking “sub-*
24 *stance abuse” and inserting “substance use dis-*
25 *orders”;*

1 (3) by striking subsection (d); and

2 (4) by redesignating subsection (e) as subsection
3 (d).

4 (d) *GROUP HOMES*.—Section 1925 of the Public
5 *Health Service Act (42 U.S.C. 300x–25) is amended—*

6 (1) in the section heading, by striking “**RECOV-**
7 **ERING SUBSTANCE ABUSERS**” and inserting
8 “**PERSONS IN RECOVERY FROM SUBSTANCE**
9 **USE DISORDERS**”; and

10 (2) in subsection (a), in the matter preceding
11 paragraph (1), by striking “recovering substance
12 abusers” and inserting “persons in recovery from sub-
13 stance use disorders”.

14 (e) *ADDITIONAL AGREEMENTS*.—Section 1928 of the
15 *Public Health Service Act (42 U.S.C. 300x–28) is amend-*
16 *ed—*

17 (1) in subsection (a), by striking “(relative to
18 fiscal year 1992)”;

19 (2) by striking subsection (b) and inserting the
20 following:

21 “(b) *PROFESSIONAL DEVELOPMENT*.—A funding
22 agreement for a grant under section 1921 is that the State
23 involved will ensure that prevention, treatment, and recov-
24 ery personnel operating in the State’s substance use dis-
25 order prevention, treatment, and recovery systems have an

1 opportunity to receive training, on an ongoing basis, con-
2 cerning—

3 “(1) recent trends in substance use disorders in
4 the State;

5 “(2) improved methods and evidence-based prac-
6 tices for providing substance use disorder prevention
7 and treatment services;

8 “(3) performance-based accountability;

9 “(4) data collection and reporting requirements;
10 and

11 “(5) any other matters that would serve to fur-
12 ther improve the delivery of substance use disorder
13 prevention and treatment services within the State.”;
14 and

15 (3) in subsection (d)(1), by striking “substance
16 abuse” and inserting “substance use disorders”.

17 (f) *REPEAL*.—Section 1929 of the Public Health Serv-
18 ice Act (42 U.S.C. 300x–29) is repealed.

19 (g) *MAINTENANCE OF EFFORT*.—Section 1930 of the
20 Public Health Service Act (42 U.S.C. 300x–30) is amend-
21 ed—

22 (1) in subsection (c)(1), by striking “in the State
23 justify the waiver” and inserting “exist in the State,
24 or any part of the State, to justify the waiver”; and

1 (2) *in subsection (d), by inserting at the end the*
2 *following:*

3 “(3) *ALTERNATIVE.—A State that has failed to*
4 *comply with this section and would otherwise be sub-*
5 *ject to a reduction in the State’s allotment under sec-*
6 *tion 1921, may, upon request by the State, in lieu of*
7 *having the State’s allotment under section 1921 re-*
8 *duced, agree to comply with a negotiated agreement*
9 *that is approved by the Secretary and carried out in*
10 *accordance with guidelines issued by the Secretary. If*
11 *a State fails to enter into or comply with a negotiated*
12 *agreement, the Secretary may take action under this*
13 *paragraph or the terms of the negotiated agreement.”.*

14 (h) *RESTRICTIONS ON EXPENDITURES.—Section*
15 *1931(b)(1) of the Public Health Service Act (42 U.S.C.*
16 *300x–31(b)(1)) is amended by striking “substance abuse”*
17 *and inserting “substance use disorders”.*

18 (i) *APPLICATION.—Section 1932 of the Public Health*
19 *Service Act (42 U.S.C. 300x–32) is amended—*

20 (1) *in subsection (a)—*

21 (A) *in the matter preceding paragraph (1),*
22 *by striking “subsections (c) and (d)(2)” and in-*
23 *serting “subsection (c)”;* and

1 (B) in paragraph (5), by striking “the in-
2 formation required in section 1929, the informa-
3 tion required in section 1930(c)(2), and”;

4 (2) in subsection (b)—

5 (A) by striking paragraph (1) and inserting
6 the following:

7 “(1) *IN GENERAL.*—In order for a State to be in
8 compliance with subsection (a)(6), the State shall sub-
9 mit to the Secretary a plan that, at a minimum, in-
10 cludes the following:

11 “(A) A description of the State’s system of
12 care that—

13 “(i) identifies the single State agency
14 responsible for the administration of the
15 program, including any third party who
16 administers substance use disorder services
17 and is responsible for complying with the
18 requirements of the grant;

19 “(ii) provides information on the need
20 for substance use disorder prevention and
21 treatment services in the State, including
22 estimates on the number of individuals who
23 need treatment, who are pregnant women,
24 women with dependent children, individuals
25 with a co-occurring mental health and sub-

1 *stance use disorder, persons who inject*
2 *drugs, and persons who are experiencing*
3 *homelessness;*

4 “(iii) provides aggregate information
5 on the number of individuals in treatment
6 within the State, including the number of
7 such individuals who are pregnant women,
8 women with dependent children, individuals
9 with a co-occurring mental health and sub-
10 stance use disorder, persons who inject
11 drugs, and persons who are experiencing
12 homelessness;

13 “(iv) provides a description of the sys-
14 tem that is available to provide services by
15 modality, including the provision of recov-
16 ery support services;

17 “(v) provides a description of the
18 State’s comprehensive statewide prevention
19 efforts, including the number of individuals
20 being served in the system, target popu-
21 lations, and priority needs, and provides a
22 description of the amount of funds from the
23 prevention set-aside expended on primary
24 prevention;

1 “(vi) provides a description of the fi-
2 nancial resources available;

3 “(vii) describes the existing substance
4 use disorders workforce and workforce
5 trained in treating co-occurring substance
6 use and mental disorders;

7 “(viii) includes a description of how
8 the State promotes evidence-based practices;
9 and

10 “(ix) describes how the State integrates
11 substance use disorder services and primary
12 health care, which in the case of those indi-
13 viduals with co-occurring mental health and
14 substance use disorders may include pro-
15 viding both mental health and substance use
16 disorder services in primary care settings or
17 providing primary and specialty care serv-
18 ices in community-based mental health and
19 substance use disorder service settings.

20 “(B) The establishment of goals and objec-
21 tives for the period of the plan, including targets
22 and milestones that are intended to be met, and
23 the activities that will be undertaken to achieve
24 those targets.

1 “(C) A description of how the State will
2 comply with each funding agreement for a grant
3 under section 1921 that is applicable to the
4 State, including a description of the manner in
5 which the State intends to expend grant funds.”;
6 and

7 (B) in paragraph (2)—

8 (i) in the paragraph heading, by strik-
9 ing “AUTHORITY OF SECRETARY REGARDING
10 MODIFICATIONS” and inserting “MODIFICA-
11 TIONS”;

12 (ii) by striking “As a condition” and
13 inserting the following:

14 “(A) AUTHORITY OF SECRETARY.—As a
15 condition;” and

16 (iii) by adding at the end the fol-
17 lowing:

18 “(B) STATE REQUEST FOR MODIFICA-
19 TION.—If the State determines that a modifica-
20 tion to such plan is necessary, the State may re-
21 quest the Secretary to approve the modification.
22 Any such modification shall be in accordance
23 with paragraph (1) and section 1941.”; and

1 (C) in paragraph (3), by inserting, “, in-
2 cluding any modification under paragraph (2)”
3 after “subsection (a)(6)”; and

4 (3) in subsection (e)(2), by striking “section
5 1922(c)” and inserting “section 1922(b)”.

6 (j) *DEFINITIONS.*—Section 1934 of the Public Health
7 Service Act (42 U.S.C. 300x–34) is amended—

8 (1) in paragraph (3), by striking “substance
9 abuse” and inserting “substance use disorders”; and

10 (2) in paragraph (7), by striking “substance
11 abuse” and inserting “substance use disorders”.

12 (k) *FUNDING.*—Section 1935 of the Public Health
13 Service Act (42 U.S.C. 300x–35) is amended—

14 (1) in subsection (a)—

15 (A) by striking “section 505” and inserting
16 “section 505(d)”; and

17 (B) by striking “\$2,000,000,000 for fiscal
18 year 2001, and such sums as may be necessary
19 for each of the fiscal years 2002 and 2003” and
20 inserting “\$1,858,079,000 for each of fiscal years
21 2018 through 2022.”; and

22 (2) in subsection (b)(1)(B) by striking “sections
23 505 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 Health*
4 *Service Act (42 U.S.C. 300x–51 et seq.) is amended—*

5 *(1) in section 1943(a)(3) (42 U.S.C. 300x–*
6 *53(a)(3)), by striking “section 505” and inserting*
7 *“subsections (c) and (d) of section 505”;*

8 *(2) in section 1953(b) (42 U.S.C. 300x–63(b)),*
9 *by striking “substance abuse” and inserting “sub-*
10 *stance use disorder”;* and

11 *(3) by adding at the end the following:*

12 **“SEC. 1957. PUBLIC HEALTH EMERGENCIES.**

13 *“In the case of a public health emergency (as deter-*
14 *mined under section 319), the Secretary, on a State by*
15 *State basis, may, as the circumstances of the emergency rea-*
16 *sonably require and for the period of the emergency, grant*
17 *an extension, or waive application deadlines or compliance*
18 *with any other requirement, of a grant authorized under*
19 *section 521, 1911, or 1921 or an allotment authorized under*
20 *Public Law 99–319 (42 U.S.C. 10801 et seq.).*

21 **“SEC. 1958. JOINT APPLICATIONS.**

22 *“The Secretary, acting through the Assistant Secretary*
23 *for Mental Health and Substance Use, shall permit a joint*
24 *application to be submitted for grants under subpart I and*
25 *subpart II upon the request of a State. Such application*
26 *may be jointly reviewed and approved by the Secretary*

1 *with respect to such subparts, consistent with the purposes*
2 *and authorized activities of each such grant program. A*
3 *State submitting such a joint application shall otherwise*
4 *meet the requirements with respect to each such subpart.”.*

5 **SEC. 8004. STUDY OF DISTRIBUTION OF FUNDS UNDER THE**
6 **SUBSTANCE ABUSE PREVENTION AND TREAT-**
7 **MENT BLOCK GRANT AND THE COMMUNITY**
8 **MENTAL HEALTH SERVICES BLOCK GRANT.**

9 (a) *IN GENERAL.*—*The Secretary of Health and*
10 *Human Services, acting through the Assistant Secretary for*
11 *Mental Health and Substance Use, shall through a grant*
12 *or contract, or through an agreement with a third party,*
13 *conduct a study on the formulas for distribution of funds*
14 *under the substance abuse prevention and treatment block*
15 *grant, and the community mental health services block*
16 *grant, under part B of title XIX of the Public Health Serv-*
17 *ice Act (42 U.S.C. 300x et seq.) and recommend changes*
18 *if necessary. Such study shall include—*

19 (1) *an analysis of whether the distributions*
20 *under such block grants accurately reflect the need for*
21 *the services under the grants in the States;*

22 (2) *an examination of whether the indices used*
23 *under the formulas for distribution of funds under*
24 *such block grants are appropriate, and if not, alter-*
25 *natives recommended by the Secretary;*

1 (3) *where recommendations are included under*
2 *paragraph (2) for the use of different indices, a de-*
3 *scription of the variables and data sources that should*
4 *be used to determine the indices;*

5 (4) *an evaluation of the variables and data*
6 *sources that are being used for each of the indices in-*
7 *volved, and whether such variables and data sources*
8 *accurately represent the need for services, the cost of*
9 *providing services, and the ability of the States to*
10 *pay for such services;*

11 (5) *the effect that the minimum allotment re-*
12 *quirements for each such block grant have on each*
13 *State's final allotment and the effect of such require-*
14 *ments, if any, on each State's formula-based allot-*
15 *ment;*

16 (6) *recommendations for modifications to the*
17 *minimum allotment provisions to ensure an appro-*
18 *priate distribution of funds; and*

19 (7) *any other information that the Secretary de-*
20 *termines appropriate.*

21 (b) *REPORT.*—*Not later than 2 years after the date*
22 *of enactment of this Act, the Secretary of Health and*
23 *Human Services shall submit to the Committee on Health,*
24 *Education, Labor, and Pensions of the Senate and the Com-*
25 *mittee on Energy and Commerce of the House of Represent-*

1 *atives, a report containing the findings and recommenda-*
 2 *tions of the study conducted under subsection (a) and the*
 3 *study conducted under section 9004(g).*

4 ***TITLE IX—PROMOTING ACCESS***
 5 ***TO MENTAL HEALTH AND***
 6 ***SUBSTANCE USE DISORDER***
 7 ***CARE***

8 ***Subtitle A—Helping Individuals***
 9 ***and Families***

10 ***SEC. 9001. GRANTS FOR TREATMENT AND RECOVERY FOR***
 11 ***HOMELESS INDIVIDUALS.***

12 *Section 506 of the Public Health Service Act (42*
 13 *U.S.C. 290aa–5) is amended—*

14 *(1) in subsection (a), by striking “substance*
 15 *abuse” and inserting “substance use disorder”;*

16 *(2) in subsection (b)—*

17 *(A) in paragraphs (1) and (3), by striking*
 18 *“substance abuse” each place the term appears*
 19 *and inserting “substance use disorder”; and*

20 *(B) in paragraph (4), by striking “sub-*
 21 *stance abuse” and inserting “a substance use*
 22 *disorder”;*

23 *(3) in subsection (c)—*

1 (A) in paragraph (1), by striking “sub-
2 stance abuse disorder” and inserting “substance
3 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 “substance
10 use disorder”; and

11 (4) in subsection (e), by striking “, \$50,000,000
12 for fiscal year 2001, and such sums as may be nec-
13 essary for each of the fiscal years 2002 and 2003”
14 and inserting “\$41,304,000 for each of fiscal years
15 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 such
20 term appears and inserting “substance use disorder”;

21 (2) in subsection (a)—

22 (A) by striking “Indian tribes, and tribal
23 organizations” and inserting “and Indian tribes
24 and tribal organizations (as the terms ‘Indian
25 tribes’ and ‘tribal organizations’ are defined in

1 *section 4 of the Indian Self-Determination and*
2 *Education Assistance Act)”; and*

3 *(B) by inserting “or a health facility or*
4 *program operated by or in accordance with a*
5 *contract or grant with the Indian Health Serv-*
6 *ice,” after “entities,”;*

7 *(3) in subsection (c)(2)(A)(i), by striking “the*
8 *best known” and inserting “evidence-based”;*

9 *(4) by redesignating subsections (d) through (i)*
10 *as subsections (e) through (j), respectively;*

11 *(5) by inserting after subsection (c) the fol-*
12 *lowing:*

13 *“(d) SPECIAL CONSIDERATION REGARDING VET-*
14 *ERANS.—In awarding grants under subsection (a), the Sec-*
15 *retary shall, as appropriate, give special consideration to*
16 *entities proposing to use grant funding to support jail di-*
17 *version services for veterans.”;*

18 *(6) in subsection (e), as so redesignated—*

19 *(A) in paragraph (3), by striking “; and”*
20 *and inserting a semicolon;*

21 *(B) in paragraph (4), by striking the period*
22 *and inserting “; and”; and*

23 *(C) by adding at the end the following:*

24 *“(5) develop programs to divert individuals*
25 *prior to booking or arrest.”; and*

1 (7) in subsection (j), as so redesignated, by strik-
 2 ing “\$10,000,000 for fiscal year 2001, and such sums
 3 as may be necessary for fiscal years 2002 through
 4 2003” and inserting “\$4,269,000 for each of fiscal
 5 years 2018 through 2022”.

6 **SEC. 9003. PROMOTING INTEGRATION OF PRIMARY AND BE-**
 7 **HAVIORAL HEALTH CARE.**

8 Section 520K of the Public Health Service Act (42
 9 U.S.C. 290bb–42) is amended to read as follows:

10 **“SEC. 520K. INTEGRATION INCENTIVE GRANTS AND COOP-**
 11 **ERATIVE AGREEMENTS.**

12 “(a) *DEFINITIONS.*—In this section:

13 “(1) *ELIGIBLE ENTITY.*—The term ‘eligible enti-
 14 ty’ means a State, or other appropriate State agency,
 15 in collaboration with 1 or more qualified community
 16 programs as described in section 1913(b)(1) or 1 or
 17 more community health centers as described in section
 18 330.

19 “(2) *INTEGRATED CARE.*—The term ‘integrated
 20 care’ means collaborative models or practices offering
 21 mental and physical health services, which may in-
 22 clude practices that share the same space in the same
 23 facility.

24 “(3) *SPECIAL POPULATION.*—The term ‘special
 25 population’ means—

1 “(A) adults with a mental illness who have
2 co-occurring physical health conditions or chron-
3 ic diseases;

4 “(B) adults with a serious mental illness
5 who have co-occurring physical health conditions
6 or chronic diseases;

7 “(C) children and adolescents with a serious
8 emotional disturbance with co-occurring physical
9 health conditions or chronic diseases; or

10 “(D) individuals with a substance use dis-
11 order.

12 “(b) GRANTS AND COOPERATIVE AGREEMENTS.—

13 “(1) IN GENERAL.—The Secretary may award
14 grants and cooperative agreements to eligible entities
15 to support the improvement of integrated care for pri-
16 mary care and behavioral health care in accordance
17 with paragraph (2).

18 “(2) PURPOSES.—A grant or cooperative agree-
19 ment awarded under this section shall be designed
20 to—

21 “(A) promote full integration and collabora-
22 tion in clinical practices between primary and
23 behavioral health care;

24 “(B) support the improvement of integrated
25 care models for primary care and behavioral

1 *health care to improve the overall wellness and*
2 *physical health status of adults with a serious*
3 *mental illness or children with a serious emo-*
4 *tional disturbance; and*

5 “(C) *promote integrated care services re-*
6 *lated to screening, diagnosis, prevention, and*
7 *treatment of mental and substance use disorders,*
8 *and co-occurring physical health conditions and*
9 *chronic diseases.*

10 “(c) *APPLICATIONS.—*

11 “(1) *IN GENERAL.—An eligible entity seeking a*
12 *grant or cooperative agreement under this section*
13 *shall submit an application to the Secretary at such*
14 *time, in such manner, and accompanied by such in-*
15 *formation as the Secretary may require, including the*
16 *contents described in paragraph (2).*

17 “(2) *CONTENTS.—The contents described in this*
18 *paragraph are—*

19 “(A) *a description of a plan to achieve fully*
20 *collaborative agreements to provide services to*
21 *special populations;*

22 “(B) *a document that summarizes the poli-*
23 *cies, if any, that serve as barriers to the provi-*
24 *sion of integrated care, and the specific steps, if*

1 applicable, that will be taken to address such
2 barriers;

3 “(C) a description of partnerships or other
4 arrangements with local health care providers to
5 provide services to special populations;

6 “(D) an agreement and plan to report to
7 the Secretary performance measures necessary to
8 evaluate patient outcomes and facilitate evalua-
9 tions across participating projects; and

10 “(E) a plan for sustainability beyond the
11 grant or cooperative agreement period under sub-
12 section (e).

13 “(d) GRANT AND COOPERATIVE AGREEMENT
14 AMOUNTS.—

15 “(1) TARGET AMOUNT.—The target amount that
16 an eligible entity may receive for a year through a
17 grant or cooperative agreement under this section
18 shall be \$2,000,000.

19 “(2) ADJUSTMENT PERMITTED.—The Secretary,
20 taking into consideration the quality of the applica-
21 tion and the number of eligible entities that received
22 grants under this section prior to the date of enact-
23 ment of the Helping Families in Mental Health Cri-
24 sis Reform Act of 2016, may adjust the target amount

1 *that an eligible entity may receive for a year through*
2 *a grant or cooperative agreement under this section.*

3 “(3) *LIMITATION.*—*An eligible entity receiving*
4 *funding under this section may not allocate more*
5 *than 10 percent of funds awarded under this section*
6 *to administrative functions, and the remaining*
7 *amounts shall be allocated to health facilities that*
8 *provide integrated care.*

9 “(e) *DURATION.*—*A grant or cooperative agreement*
10 *under this section shall be for a period not to exceed 5 years.*

11 “(f) *REPORT ON PROGRAM OUTCOMES.*—*An eligible*
12 *entity receiving a grant or cooperative agreement under this*
13 *section shall submit an annual report to the Secretary that*
14 *includes—*

15 “(1) *the progress made to reduce barriers to inte-*
16 *grated care as described in the entity’s application*
17 *under subsection (c); and*

18 “(2) *a description of functional outcomes of spe-*
19 *cial populations, including—*

20 “(A) *with respect to adults with a serious*
21 *mental illness, participation in supportive hous-*
22 *ing or independent living programs, attendance*
23 *in social and rehabilitative programs, participa-*
24 *tion in job training opportunities, satisfactory*
25 *performance in work settings, attendance at*

1 *scheduled medical and mental health appoint-*
2 *ments, and compliance with prescribed medica-*
3 *tion regimes;*

4 “(B) *with respect to individuals with co-oc-*
5 *curing mental illness and physical health condi-*
6 *tions and chronic diseases, attendance at sched-*
7 *uled medical and mental health appointments,*
8 *compliance with prescribed medication regimes,*
9 *and participation in learning opportunities re-*
10 *lated to improved health and lifestyle practices;*
11 *and*

12 “(C) *with respect to children and adoles-*
13 *cents with a serious emotional disturbance who*
14 *have co-occurring physical health conditions and*
15 *chronic diseases, attendance at scheduled medical*
16 *and mental health appointments, compliance*
17 *with prescribed medication regimes, and partici-*
18 *pation in learning opportunities at school and*
19 *extracurricular activities.*

20 “(g) *TECHNICAL ASSISTANCE FOR PRIMARY-BEHAV-*
21 *IORAL HEALTH CARE INTEGRATION.—*

22 “(1) *IN GENERAL.—The Secretary may provide*
23 *appropriate information, training, and technical as-*
24 *sistance to eligible entities that receive a grant or co-*
25 *operative agreement under this section, in order to*

1 *help such entities meet the requirements of this sec-*
2 *tion, including assistance with—*

3 *“(A) development and selection of integrated*
4 *care models;*

5 *“(B) dissemination of evidence-based inter-*
6 *ventions in integrated care;*

7 *“(C) establishment of organizational prac-*
8 *tices to support operational and administrative*
9 *success; and*

10 *“(D) other activities, as the Secretary deter-*
11 *mines appropriate.*

12 *“(2) ADDITIONAL DISSEMINATION OF TECHNICAL*
13 *INFORMATION.—The information and resources pro-*
14 *vided by the Secretary under paragraph (1) shall, as*
15 *appropriate, be made available to States, political*
16 *subdivisions of States, Indian tribes or tribal organi-*
17 *zations (as defined in section 4 of the Indian Self-De-*
18 *termination and Education Assistance Act), out-*
19 *patient mental health and addiction treatment cen-*
20 *ters, community mental health centers that meet the*
21 *criteria under section 1913(c), certified community*
22 *behavioral health clinics described in section 223 of*
23 *the Protecting Access to Medicare Act of 2014, pri-*
24 *mary care organizations such as Federally qualified*
25 *health centers or rural health clinics as defined in sec-*

1 (A) in paragraph (1), by striking “sub-
2 stance abuse” and inserting “a substance use
3 disorder”; and

4 (B) in paragraph (2), by striking “sub-
5 stance abuse” and inserting “substance use dis-
6 order”;

7 (5) by striking subsection (g) and redesignating
8 subsections (h) and (i) as (g) and (h), accordingly;
9 and

10 (6) in subsection (g), as redesignated by para-
11 graph (5), by striking “substance abuse” each place
12 such term appears and inserting “substance use dis-
13 order”.

14 (c) *DESCRIPTION OF INTENDED EXPENDITURES OF*
15 *GRANT.*—Section 527 of the Public Health Service Act (42
16 U.S.C. 290cc–27) is amended by striking “substance abuse”
17 each place such term appears and inserting “substance use
18 disorder”.

19 (d) *TECHNICAL ASSISTANCE.*—Section 530 of the Pub-
20 lic Health Service Act (42 U.S.C. 290cc–30) is amended
21 by striking “through the National Institute of Mental
22 Health, the National Institute of Alcohol Abuse and Alco-
23 holism, and the National Institute on Drug Abuse” and in-
24 serting “acting through the Assistant Secretary”.

1 (e) *DEFINITIONS.*—Section 534(4) of the Public Health
2 Service Act (42 U.S.C. 290cc–34(4)) is amended to read as
3 follows:

4 “(4) *SUBSTANCE USE DISORDER SERVICES.*—The
5 term ‘substance use disorder services’ has the meaning
6 given the term ‘substance abuse services’ in section
7 330(h)(5)(C).”.

8 (f) *FUNDING.*—Section 535(a) of the Public Health
9 Service Act (42 U.S.C. 290cc–35(a)) is amended by striking
10 “\$75,000,000 for each of the fiscal years 2001 through
11 2003” and inserting “\$64,635,000 for each of fiscal years
12 2018 through 2022”.

13 (g) *STUDY CONCERNING FORMULA.*—

14 (1) *IN GENERAL.*—Not later than 2 years after
15 the date of enactment of this Act, the Assistant Sec-
16 retary for Mental Health and Substance Use (referred
17 to in this section as the “Assistant Secretary”) shall
18 conduct a study concerning the formula used under
19 section 524 of the Public Health Service Act (42
20 U.S.C. 290cc–24) for making allotments to States
21 under section 521 of such Act (42 U.S.C. 290cc–21).
22 Such study shall include an evaluation of quality in-
23 dicators of need for purposes of revising the formula
24 for determining the amount of each allotment for the
25 fiscal years following the submission of the study.

1 (2) *REPORT.*—*In accordance with section*
2 *8004(b), the Assistant Secretary shall submit to the*
3 *committees of Congress described in such section a re-*
4 *port concerning the results of the study conducted*
5 *under paragraph (1).*

6 **SEC. 9005. NATIONAL SUICIDE PREVENTION LIFELINE PRO-**
7 **GRAM.**

8 *Subpart 3 of part B of title V of the Public Health*
9 *Service Act (42 U.S.C. 290bb–31 et seq.) is amended by in-*
10 *serting after section 520E–2 (42 U.S.C. 290bb–36b) the fol-*
11 *lowing:*

12 **“SEC. 520E–3. NATIONAL SUICIDE PREVENTION LIFELINE**
13 **PROGRAM.**

14 “(a) *IN GENERAL.*—*The Secretary, acting through the*
15 *Assistant Secretary, shall maintain the National Suicide*
16 *Prevention Lifeline program (referred to in this section as*
17 *the ‘program’), authorized under section 520A and in effect*
18 *prior to the date of enactment of the Helping Families in*
19 *Mental Health Crisis Reform Act of 2016.*

20 “(b) *ACTIVITIES.*—*In maintaining the program, the*
21 *activities of the Secretary shall include—*

22 “(1) *coordinating a network of crisis centers*
23 *across the United States for providing suicide preven-*
24 *tion and crisis intervention services to individuals*
25 *seeking help at any time, day or night;*

1 “(b) *ACTIVITIES OF THE SECRETARY.*—*To maintain*
2 *the Routing Service, the activities of the Assistant Secretary*
3 *shall include administering—*

4 “(1) *a nationwide, telephone number providing*
5 *year-round access to information that is updated on*
6 *a regular basis regarding local behavioral health pro-*
7 *viders and community-based organizations in a man-*
8 *ner that is confidential, without requiring individuals*
9 *to identify themselves, is in languages that include at*
10 *least English and Spanish, and is at no cost to the*
11 *individual using the Routing Service; and*

12 “(2) *an Internet website to provide a searchable,*
13 *online treatment services locator of behavioral health*
14 *treatment providers and community-based organiza-*
15 *tions, which shall include information on the name,*
16 *location, contact information, and basic services pro-*
17 *vided by such providers and organizations.*

18 “(c) *REMOVING PRACTITIONER CONTACT INFORMA-*
19 *TION.*—*In the event that the Internet website described in*
20 *subsection (b)(2) contains information on any qualified*
21 *practitioner that is certified to prescribe medication for*
22 *opioid dependency under section 303(g)(2)(B) of the Con-*
23 *trolled Substances Act, the Assistant Secretary—*

24 “(1) *shall provide an opportunity to such practi-*
25 *tioner to have the contact information of the practi-*

1 *tioner removed from the website at the request of the*
2 *practitioner; and*

3 *“(2) may evaluate other methods to periodically*
4 *update the information displayed on such website.*

5 *“(d) RULE OF CONSTRUCTION.—Nothing in this sec-*
6 *tion shall be construed to prevent the Assistant Secretary*
7 *from using any unobligated amounts otherwise made avail-*
8 *able to the Administration to maintain the Routing Serv-*
9 *ice.”.*

10 **SEC. 9007. STRENGTHENING COMMUNITY CRISIS RESPONSE**
11 **SYSTEMS.**

12 *Section 520F of the Public Health Service Act (42*
13 *U.S.C. 290bb–37) is amended to read as follows:*

14 **“SEC. 520F. STRENGTHENING COMMUNITY CRISIS RE-**
15 **SPONSE SYSTEMS.**

16 *“(a) IN GENERAL.—The Secretary shall award com-*
17 *petitive grants to—*

18 *“(1) State and local governments and Indian*
19 *tribes and tribal organizations, to enhance commu-*
20 *nity-based crisis response systems; or*

21 *“(2) States to develop, maintain, or enhance a*
22 *database of beds at inpatient psychiatric facilities,*
23 *crisis stabilization units, and residential community*
24 *mental health and residential substance use disorder*
25 *treatment facilities, for adults with a serious mental*

1 *illness, children with a serious emotional disturbance,*
2 *or individuals with a substance use disorder.*

3 “(b) *APPLICATIONS.*—

4 “(1) *IN GENERAL.*—*To receive a grant under*
5 *subsection (a), an entity shall submit to the Secretary*
6 *an application, at such time, in such manner, and*
7 *containing such information as the Secretary may re-*
8 *quire.*

9 “(2) *COMMUNITY-BASED CRISIS RESPONSE*
10 *PLAN.*—*An application for a grant under subsection*
11 *(a)(1) shall include a plan for—*

12 “(A) *promoting integration and coordina-*
13 *tion between local public and private entities en-*
14 *gaged in crisis response, including first respond-*
15 *ers, emergency health care providers, primary*
16 *care providers, law enforcement, court systems,*
17 *health care payers, social service providers, and*
18 *behavioral health providers;*

19 “(B) *developing memoranda of under-*
20 *standing with public and private entities to im-*
21 *plement crisis response services;*

22 “(C) *addressing gaps in community re-*
23 *sources for crisis intervention and prevention;*
24 *and*

1 “(D) developing models for minimizing hos-
2 pital readmissions, including through appro-
3 priate discharge planning.

4 “(3) *BEDS DATABASE PLAN*.—An application for
5 a grant under subsection (a)(2) shall include a plan
6 for developing, maintaining, or enhancing a real-
7 time, Internet-based bed database to collect, aggregate,
8 and display information about beds in inpatient psy-
9 chiatric facilities and crisis stabilization units, and
10 residential community mental health and residential
11 substance use disorder treatment facilities to facilitate
12 the identification and designation of facilities for the
13 temporary treatment of individuals in mental or sub-
14 stance use disorder crisis.

15 “(c) *DATABASE REQUIREMENTS*.—A bed database de-
16 scribed in this section is a database that—

17 “(1) includes information on inpatient psy-
18 chiatric facilities, crisis stabilization units, and resi-
19 dential community mental health and residential sub-
20 stance use disorder facilities in the State involved, in-
21 cluding contact information for the facility or unit;

22 “(2) provides real-time information about the
23 number of beds available at each facility or unit and,
24 for each available bed, the type of patient that may
25 be admitted, the level of security provided, and any

1 *other information that may be necessary to allow for*
2 *the proper identification of appropriate facilities for*
3 *treatment of individuals in mental or substance use*
4 *disorder crisis; and*

5 *“(3) enables searches of the database to identify*
6 *available beds that are appropriate for the treatment*
7 *of individuals in mental or substance use disorder*
8 *crisis.*

9 *“(d) EVALUATION.—An entity receiving a grant under*
10 *subsection (a)(1) shall submit to the Secretary, at such time,*
11 *in such manner, and containing such information as the*
12 *Secretary may reasonably require, a report, including an*
13 *evaluation of the effect of such grant on—*

14 *“(1) local crisis response services and measures*
15 *for individuals receiving crisis planning and early*
16 *intervention supports;*

17 *“(2) individuals reporting improved functional*
18 *outcomes; and*

19 *“(3) individuals receiving regular followup care*
20 *following a crisis.*

21 *“(e) AUTHORIZATION OF APPROPRIATIONS.—There are*
22 *authorized to be appropriated to carry out this section,*
23 *\$12,500,000 for the period of fiscal years 2018 through*
24 *2022.”.*

1 **SEC. 9008. GARRETT LEE SMITH MEMORIAL ACT REAUTHOR-**
2 **IZATION.**

3 (a) *SUICIDE PREVENTION TECHNICAL ASSISTANCE*
4 *CENTER.*—Section 520C of the Public Health Service Act
5 (42 U.S.C. 290bb–34), as amended by section 6001, is fur-
6 ther amended—

7 (1) in the section heading, by striking “**YOUTH**
8 **INTERAGENCY RESEARCH, TRAINING, AND**
9 **TECHNICAL ASSISTANCE CENTERS**” and insert-
10 ing “**SUICIDE PREVENTION TECHNICAL ASSIST-**
11 **ANCE CENTER**”;

12 (2) in subsection (a), by striking “acting through
13 the Assistant Secretary for Mental Health and Sub-
14 stance Use” and all that follows through the period at
15 the end of paragraph (2) and inserting “acting
16 through the Assistant Secretary, shall establish a re-
17 search, training, and technical assistance resource
18 center to provide appropriate information, training,
19 and technical assistance to States, political subdivi-
20 sions of States, federally recognized Indian tribes,
21 tribal organizations, institutions of higher education,
22 public organizations, or private nonprofit organiza-
23 tions regarding the prevention of suicide among all
24 ages, particularly among groups that are at a high
25 risk for suicide.”;

26 (3) by striking subsections (b) and (c);

1 (4) by redesignating subsection (d) as subsection
2 (b);

3 (5) in subsection (b), as so redesignated—

4 (A) in the subsection heading, by striking
5 “ADDITIONAL CENTER” and inserting “RESPON-
6 SIBILITIES OF THE CENTER”;

7 (B) in the matter preceding paragraph (1),
8 by striking “The additional research” and all
9 that follows through “nonprofit organizations
10 for” and inserting “The center established under
11 subsection (a) shall conduct activities for the
12 purpose of”;

13 (C) by striking “youth suicide” each place
14 such term appears and inserting “suicide”;

15 (D) in paragraph (1)—

16 (i) by striking “the development or
17 continuation of” and inserting “developing
18 and continuing”; and

19 (ii) by inserting “for all ages, particu-
20 larly among groups that are at a high risk
21 for suicide” before the semicolon at the end;

22 (E) in paragraph (2), by inserting “for all
23 ages, particularly among groups that are at a
24 high risk for suicide” before the semicolon at the
25 end;

1 (F) in paragraph (3), by inserting “and
2 tribal” after “statewide”;

3 (G) in paragraph (5), by inserting “and
4 prevention” after “intervention”;

5 (H) in paragraph (8), by striking “in
6 youth”;

7 (I) in paragraph (9), by striking “and be-
8 havioral health” and inserting “health and sub-
9 stance use disorder”; and

10 (J) in paragraph (10), by inserting “con-
11 ducting” before “other”; and

12 (6) by striking subsection (e) and inserting the
13 following:

14 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—For the
15 purpose of carrying out this section, there are authorized
16 to be appropriated \$5,988,000 for each of fiscal years 2018
17 through 2022.

18 “(d) *ANNUAL REPORT.*—Not later than 2 years after
19 the date of enactment of this subsection, the Secretary shall
20 submit to Congress a report on the activities carried out
21 by the center established under subsection (a) during the
22 year involved, including the potential effects of such activi-
23 ties, and the States, organizations, and institutions that
24 have worked with the center.”.

1 (b) *YOUTH SUICIDE EARLY INTERVENTION AND PRE-*
2 *VENTION STRATEGIES.*—Section 520E of the Public Health
3 *Service Act (42 U.S.C. 290bb–36) is amended—*

4 (1) *in paragraph (1) of subsection (a) and in*
5 *subsection (c), by striking “substance abuse” each*
6 *place such term appears and inserting “substance use*
7 *disorder”;*

8 (2) *in subsection (b)—*

9 (A) *in paragraph (2)—*

10 (i) *by striking “ensure that each State*
11 *is awarded only 1 grant or cooperative*
12 *agreement under this section” and inserting*
13 *“ensure that a State does not receive more*
14 *than 1 grant or cooperative agreement*
15 *under this section at any 1 time”; and*

16 (ii) *by striking “been awarded” and*
17 *inserting “received”; and*

18 (B) *by adding after paragraph (2) the fol-*
19 *lowing:*

20 “(3) *CONSIDERATION.*—*In awarding grants*
21 *under this section, the Secretary shall take into con-*
22 *sideration the extent of the need of the applicant, in-*
23 *cluding the incidence and prevalence of suicide in the*
24 *State and among the populations of focus, including*
25 *rates of suicide determined by the Centers for Disease*

1 *Control and Prevention for the State or population of*
2 *focus.”;*

3 (3) *in subsection (g)(2), by striking “2 years*
4 *after the date of enactment of this section,” and insert*
5 *“2 years after the date of enactment of Helping Fam-*
6 *ilies in Mental Health Crisis Reform Act of 2016,”;*
7 *and*

8 (4) *by striking subsection (m) and inserting the*
9 *following:*

10 *“(m) AUTHORIZATION OF APPROPRIATIONS.—For the*
11 *purpose of carrying out this section, there are authorized*
12 *to be appropriated \$30,000,000 for each of fiscal years 2018*
13 *through 2022.”.*

14 **SEC. 9009. ADULT SUICIDE PREVENTION.**

15 *Subpart 3 of part B of title V of the Public Health*
16 *Service Act (42 U.S.C. 290bb–31 et seq.) is amended by*
17 *adding at the end the following:*

18 **“SEC. 520L. ADULT SUICIDE PREVENTION.**

19 *“(a) GRANTS.—*

20 *“(1) IN GENERAL.—The Assistant Secretary*
21 *shall award grants to eligible entities described in*
22 *paragraph (2) to implement suicide prevention and*
23 *intervention programs, for individuals who are 25*
24 *years of age or older, that are designed to raise*
25 *awareness of suicide, establish referral processes, and*

1 *improve care and outcomes for such individuals who*
2 *are at risk of suicide.*

3 “(2) *ELIGIBLE ENTITIES.*—*To be eligible to re-*
4 *ceive a grant under this section, an entity shall be a*
5 *community-based primary care or behavioral health*
6 *care setting, an emergency department, a State men-*
7 *tal health agency (or State health agency with mental*
8 *or behavioral health functions), public health agency,*
9 *a territory of the United States, or an Indian tribe*
10 *or tribal organization (as the terms ‘Indian tribe’ and*
11 *‘tribal organization’ are defined in section 4 of the*
12 *Indian Self-Determination and Education Assistance*
13 *Act).*

14 “(3) *USE OF FUNDS.*—*The grants awarded*
15 *under paragraph (1) shall be used to implement pro-*
16 *grams, in accordance with such paragraph, that in-*
17 *clude one or more of the following components:*

18 “(A) *Screening for suicide risk, suicide*
19 *intervention services, and services for referral for*
20 *treatment for individuals at risk for suicide.*

21 “(B) *Implementing evidence-based practices*
22 *to provide treatment for individuals at risk for*
23 *suicide, including appropriate followup services.*

24 “(C) *Raising awareness and reducing stig-*
25 *ma of suicide.*

1 “(b) *EVALUATIONS AND TECHNICAL ASSISTANCE.*—

2 *The Assistant Secretary shall—*

3 “(1) *evaluate the activities supported by grants*
4 *awarded under subsection (a), and disseminate, as*
5 *appropriate, the findings from the evaluation; and*

6 “(2) *provide appropriate information, training,*
7 *and technical assistance, as appropriate, to eligible*
8 *entities that receive a grant under this section, in*
9 *order to help such entities to meet the requirements of*
10 *this section, including assistance with selection and*
11 *implementation of evidence-based interventions and*
12 *frameworks to prevent suicide.*

13 “(c) *DURATION.*—*A grant under this section shall be*
14 *for a period of not more than 5 years.*

15 “(d) *AUTHORIZATION OF APPROPRIATIONS.*—*There*
16 *are authorized to be appropriated to carry out this section*
17 *\$30,000,000 for the period of fiscal years 2018 through*
18 *2022.”.*

19 **SEC. 9010. MENTAL HEALTH AWARENESS TRAINING**
20 **GRANTS.**

21 *Section 520J of the Public Health Service Act (42*
22 *U.S.C. 290bb-41) is amended—*

23 (1) *in the section heading, by inserting “***MENT-**
24 **TAL HEALTH AWARENESS***” before “***TRAINING***”;*
25 *and*

1 (2) *in subsection (b)—*

2 (A) *in the subsection heading, by striking*
3 “*ILLNESS*” *and inserting “HEALTH”;*

4 (B) *in paragraph (1), by inserting “vet-*
5 *erans, law enforcement, and other categories of*
6 *individuals, as determined by the Secretary,”*
7 *after “emergency services personnel”;*

8 (C) *in paragraph (5)—*

9 (i) *in the matter preceding subpara-*
10 *graph (A), by striking “to” and inserting*
11 *“for evidence-based programs that provide*
12 *training and education in accordance with*
13 *paragraph (1) on matters including”;* *and*

14 (ii) *by striking subparagraphs (A)*
15 *through (C) and inserting the following:*

16 “*(A) recognizing the signs and symptoms of*
17 *mental illness; and*

18 “*(B)(i) resources available in the commu-*
19 *nity for individuals with a mental illness and*
20 *other relevant resources; or*

21 “*(ii) safely de-escalating crisis situations*
22 *involving individuals with a mental illness.”;*
23 *and*

24 (D) *in paragraph (7), by striking “,*
25 *\$25,000,000” and all that follows through the pe-*

1 riod at the end and inserting “\$14,693,000 for
2 each of fiscal years 2018 through 2022.”.

3 **SEC. 9011. SENSE OF CONGRESS ON PRIORITIZING AMER-**
4 **ICAN INDIANS AND ALASKA NATIVE YOUTH**
5 **WITHIN SUICIDE PREVENTION PROGRAMS.**

6 (a) *FINDINGS.*—*The Congress finds as follows:*

7 (1) *Suicide is the eighth leading cause of death*
8 *among American Indians and Alaska Natives across*
9 *all ages.*

10 (2) *Among American Indians and Alaska Na-*
11 *tives who are 10 to 34 years of age, suicide is the sec-*
12 *ond leading cause of death.*

13 (3) *The suicide rate among American Indian*
14 *and Alaska Native adolescents and young adults ages*
15 *15 to 34 (17.9 per 100,000) is approximately 1.3*
16 *times higher than the national average for that age*
17 *group (13.3 per 100,000).*

18 (b) *SENSE OF CONGRESS.*—*It is the sense of Congress*
19 *that the Secretary of Health and Human Services, in car-*
20 *rying out suicide prevention and intervention programs,*
21 *should prioritize programs and activities for populations*
22 *with disproportionately high rates of suicide, such as Amer-*
23 *ican Indians and Alaska Natives.*

1 **SEC. 9012. EVIDENCE-BASED PRACTICES FOR OLDER**
2 **ADULTS.**

3 *Section 520A(e) of the Public Health Service Act (42*
4 *U.S.C. 290bb–32(e)) is amended by adding at the end the*
5 *following:*

6 *“(3) GERIATRIC MENTAL DISORDERS.—The Sec-*
7 *retary shall, as appropriate, provide technical assist-*
8 *ance to grantees regarding evidence-based practices*
9 *for the prevention and treatment of geriatric mental*
10 *disorders and co-occurring mental health and sub-*
11 *stance use disorders among geriatric populations, as*
12 *well as disseminate information about such evidence-*
13 *based practices to States and nongrantees throughout*
14 *the United States.”.*

15 **SEC. 9013. NATIONAL VIOLENT DEATH REPORTING SYSTEM.**

16 *The Secretary of Health and Human Services, acting*
17 *through the Director of the Centers for Disease Control and*
18 *Prevention, is encouraged to improve, particularly through*
19 *the inclusion of additional States, the National Violent*
20 *Death Reporting System as authorized by title III of the*
21 *Public Health Service Act (42 U.S.C. 241 et seq.). Partici-*
22 *pation in the system by the States shall be voluntary.*

23 **SEC. 9014. ASSISTED OUTPATIENT TREATMENT.**

24 *Section 224 of the Protecting Access to Medicare Act*
25 *of 2014 (42 U.S.C. 290aa note) is amended—*

1 (1) *in subsection (e), by striking “and 2018,”*
2 *and inserting “2018, 2019, 2020, 2021, and 2022,”;*
3 *and*

4 (2) *in subsection (g)—*

5 (A) *in paragraph (1), by striking “2018”*
6 *and inserting “2022”; and*

7 (B) *in paragraph (2), by striking “is au-*
8 *thorized to be appropriated to carry out this sec-*
9 *tion \$15,000,000 for each of fiscal years 2015*
10 *through 2018” and inserting “are authorized to*
11 *be appropriated to carry out this section*
12 *\$15,000,000 for each of fiscal years 2015 through*
13 *2017, \$20,000,000 for fiscal year 2018,*
14 *\$19,000,000 for each of fiscal years 2019 and*
15 *2020, and \$18,000,000 for each of fiscal years*
16 *2021 and 2022”.*

17 **SEC. 9015. ASSERTIVE COMMUNITY TREATMENT GRANT**
18 **PROGRAM.**

19 *Part B of title V of the Public Health Service Act (42*
20 *U.S.C. 290bb et seq.), as amended by section 9009, is further*
21 *amended by adding at the end the following:*

22 **“SEC. 520M. ASSERTIVE COMMUNITY TREATMENT GRANT**
23 **PROGRAM.**

24 “(a) *IN GENERAL.—The Assistant Secretary shall*
25 *award grants to eligible entities—*

1 “(1) to establish assertive community treatment
2 programs for adults with a serious mental illness; or

3 “(2) to maintain or expand such programs.

4 “(b) *ELIGIBLE ENTITIES*.—To be eligible to receive a
5 grant under this section, an entity shall be a State, political
6 subdivision of a State, Indian tribe or tribal organization
7 (as such terms are defined in section 4 of the Indian Self-
8 Determination and Education Assistance Act), mental
9 health system, health care facility, or any other entity the
10 Assistant Secretary deems appropriate.

11 “(c) *SPECIAL CONSIDERATION*.—In selecting among
12 applicants for a grant under this section, the Assistant Sec-
13 retary may give special consideration to the potential of
14 the applicant’s program to reduce hospitalization, homeless-
15 ness, and involvement with the criminal justice system
16 while improving the health and social outcomes of the pa-
17 tient.

18 “(d) *ADDITIONAL ACTIVITIES*.—The Assistant Sec-
19 retary shall—

20 “(1) not later than the end of fiscal year 2021,
21 submit a report to the appropriate congressional com-
22 mittees on the grant program under this section, in-
23 cluding an evaluation of—

1 “(A) any cost savings and public health
2 outcomes such as mortality, suicide, substance
3 use disorders, hospitalization, and use of services;

4 “(B) rates of involvement with the criminal
5 justice system of patients;

6 “(C) rates of homelessness among patients;
7 and

8 “(D) patient and family satisfaction with
9 program participation; and

10 “(2) provide appropriate information, training,
11 and technical assistance to grant recipients under this
12 section to help such recipients to establish, maintain,
13 or expand their assertive community treatment pro-
14 grams.

15 “(e) *AUTHORIZATION OF APPROPRIATIONS.*—

16 “(1) *IN GENERAL.*—To carry out this section,
17 there is authorized to be appropriated \$5,000,000 for
18 the period of fiscal years 2018 through 2022.

19 “(2) *USE OF CERTAIN FUNDS.*—Of the funds ap-
20 propriated to carry out this section in any fiscal
21 year, not more than 5 percent shall be available to the
22 Assistant Secretary for carrying out subsection (d).”.

1 **SEC. 9016. SOBER TRUTH ON PREVENTING UNDERAGE**
2 **DRINKING REAUTHORIZATION.**

3 *Section 519B of the Public Health Service Act (42*
4 *U.S.C. 290bb–25b) is amended—*

5 *(1) in subsection (c)(3), by striking “fiscal year*
6 *2007” and all that follows through the period at the*
7 *end and inserting “each of the fiscal years 2018*
8 *through 2022.”;*

9 *(2) in subsection (d)(4), by striking “fiscal year*
10 *2007” and all that follows through the period at the*
11 *end and inserting “each of the fiscal years 2018*
12 *through 2022.”;*

13 *(3) in subsection (e)(1)(I), by striking “fiscal*
14 *year 2007” and all that follows through the period at*
15 *the end and inserting “each of the fiscal years 2018*
16 *through 2022.”;*

17 *(4) in subsection (f)(2), by striking “\$6,000,000*
18 *for fiscal year 2007” and all that follows through the*
19 *period at the end and inserting “\$3,000,000 for each*
20 *of the fiscal years 2018 through 2022”; and*

21 *(5) by adding at the end the following new sub-*
22 *section:*

23 *“(g) REDUCING UNDERAGE DRINKING THROUGH*
24 *SCREENING AND BRIEF INTERVENTION.—*

25 *“(1) GRANTS TO PEDIATRIC HEALTH CARE PRO-*
26 *VIDERS TO REDUCE UNDERAGE DRINKING.—The As-*

1 *sistant Secretary may make grants to eligible entities*
2 *to increase implementation of practices for reducing*
3 *the prevalence of alcohol use among individuals under*
4 *the age of 21, including college students.*

5 *“(2) PURPOSES.—Grants under this subsection*
6 *shall be made to improve—*

7 *“(A) screening children and adolescents for*
8 *alcohol use;*

9 *“(B) offering brief interventions to children*
10 *and adolescents to discourage such use;*

11 *“(C) educating parents about the dangers*
12 *of, and methods of discouraging, such use;*

13 *“(D) diagnosing and treating alcohol use*
14 *disorders; and*

15 *“(E) referring patients, when necessary, to*
16 *other appropriate care.*

17 *“(3) USE OF FUNDS.—An entity receiving a*
18 *grant under this subsection may use such funding for*
19 *the purposes identified in paragraph (2) by—*

20 *“(A) providing training to health care pro-*
21 *viders;*

22 *“(B) disseminating best practices, including*
23 *culturally and linguistically appropriate best*
24 *practices, as appropriate, and developing and*
25 *distributing materials; and*

1 “(C) supporting other activities, as deter-
2 mined appropriate by the Assistant Secretary.

3 “(4) APPLICATION.—To be eligible to receive a
4 grant under this subsection, an entity shall submit an
5 application to the Assistant Secretary at such time,
6 and in such manner, and accompanied by such infor-
7 mation as the Assistant Secretary may require. Each
8 application shall include—

9 “(A) a description of the entity;

10 “(B) a description of activities to be com-
11 pleted;

12 “(C) a description of how the services speci-
13 fied in paragraphs (2) and (3) will be carried
14 out and the qualifications for providing such
15 services; and

16 “(D) a timeline for the completion of such
17 activities.

18 “(5) DEFINITIONS.—For the purpose of this sub-
19 section:

20 “(A) BRIEF INTERVENTION.—The term
21 ‘brief intervention’ means, after screening a pa-
22 tient, providing the patient with brief advice
23 and other brief motivational enhancement tech-
24 niques designed to increase the insight of the pa-
25 tient regarding the patient’s alcohol use, and any

1 *realized or potential consequences of such use, to*
2 *effect the desired related behavioral change.*

3 “(B) *CHILDREN AND ADOLESCENTS.*—*The*
4 *term ‘children and adolescents’ means any per-*
5 *son under 21 years of age.*

6 “(C) *ELIGIBLE ENTITY.*—*The term ‘eligible*
7 *entity’ means an entity consisting of pediatric*
8 *health care providers and that is qualified to*
9 *support or provide the activities identified in*
10 *paragraph (2).*

11 “(D) *PEDIATRIC HEALTH CARE PRO-*
12 *VIDER.*—*The term ‘pediatric health care pro-*
13 *vider’ means a provider of primary health care*
14 *to individuals under the age of 21 years.*

15 “(E) *SCREENING.*—*The term ‘screening’*
16 *means using validated patient interview tech-*
17 *niques to identify and assess the existence and*
18 *extent of alcohol use in a patient.”.*

19 **SEC. 9017. CENTER AND PROGRAM REPEALS.**

20 *Part B of title V of the Public Health Service Act (42*
21 *U.S.C. 290bb et seq.) is amended by striking section 506B*
22 *(42 U.S.C. 290aa–5b), the second section 514 (42 U.S.C.*
23 *290bb–9) relating to methamphetamine and amphetamine*
24 *treatment initiatives, and each of sections 514A, 517, 519A,*
25 *519C, 519E, 520B, 520D, and 520H (42 U.S.C. 290bb–8,*

1 290bb–23, 290bb–25a, 290bb–25c, 290bb–25e, 290bb–33,
2 290bb–35, and 290bb–39).

3 ***Subtitle B—Strengthening the***
4 ***Health Care Workforce***

5 ***SEC. 9021. MENTAL AND BEHAVIORAL HEALTH EDUCATION***
6 ***AND TRAINING GRANTS.***

7 *Section 756 of the Public Health Service Act (42*
8 *U.S.C. 294e–1) is amended—*

9 *(1) in subsection (a)—*

10 *(A) in the matter preceding paragraph (1),*
11 *by striking “of higher education”; and*

12 *(B) by striking paragraphs (1) through (4)*
13 *and inserting the following:*

14 *“(1) accredited institutions of higher education*
15 *or accredited professional training programs that are*
16 *establishing or expanding internships or other field*
17 *placement programs in mental health in psychiatry,*
18 *psychology, school psychology, behavioral pediatrics,*
19 *psychiatric nursing (which may include master’s and*
20 *doctoral level programs), social work, school social*
21 *work, substance use disorder prevention and treat-*
22 *ment, marriage and family therapy, occupational*
23 *therapy, school counseling, or professional counseling,*
24 *including such programs with a focus on child and*
25 *adolescent mental health and transitional-age youth;*

1 “(2) accredited doctoral, internship, and post-
2 doctoral residency programs of health service psy-
3 chology (including clinical psychology, counseling,
4 and school psychology) for the development and im-
5 plementation of interdisciplinary training of psy-
6 chology graduate students for providing behavioral
7 health services, including substance use disorder pre-
8 vention and treatment services, as well as the develop-
9 ment of faculty in health service psychology;

10 “(3) accredited master’s and doctoral degree pro-
11 grams of social work for the development and imple-
12 mentation of interdisciplinary training of social work
13 graduate students for providing behavioral health
14 services, including substance use disorder prevention
15 and treatment services, and the development of faculty
16 in social work; and

17 “(4) State-licensed mental health nonprofit and
18 for-profit organizations to enable such organizations
19 to pay for programs for preservice or in-service train-
20 ing in a behavioral health-related paraprofessional
21 field with preference for preservice or in-service train-
22 ing of paraprofessional child and adolescent mental
23 health workers.”;

24 (2) in subsection (b)—

25 (A) by striking paragraph (5);

1 (B) by redesignating paragraphs (1)
2 through (4) as paragraphs (2) through (5), re-
3 spectively;

4 (C) by inserting before paragraph (2), as so
5 redesignated, the following:

6 “(1) an ability to recruit and place the students
7 described in subsection (a) in areas with a high need
8 and high demand population;”;

9 (D) in paragraph (3), as so redesignated, by
10 striking “subsection (a)” and inserting “para-
11 graph (2), especially individuals with mental
12 disorder symptoms or diagnoses, particularly
13 children and adolescents, and transitional-age
14 youth”;

15 (E) in paragraph (4), as so redesignated, by
16 striking “;” and inserting “; and”; and

17 (F) in paragraph (5), as so redesignated, by
18 striking “; and” and inserting a period;

19 (3) in subsection (c), by striking “authorized
20 under subsection (a)(1)” and inserting “awarded
21 under paragraphs (2) and (3) of subsection (a)”;

22 (4) by amending subsection (d) to read as fol-
23 lows:

24 “(d) *PRIORITY*.—In selecting grant recipients under
25 this section, the Secretary shall give priority to—

1 “(1) programs that have demonstrated the abil-
2 ity to train psychology, psychiatry, and social work
3 professionals to work in integrated care settings for
4 purposes of recipients under paragraphs (1), (2), and
5 (3) of subsection (a); and

6 “(2) programs for paraprofessionals that empha-
7 size the role of the family and the lived experience of
8 the consumer and family-paraprofessional partner-
9 ships for purposes of recipients under subsection
10 (a)(4).”; and

11 (5) by striking subsection (e) and inserting the
12 following:

13 “(e) *REPORT TO CONGRESS.*—Not later than 4 years
14 after the date of enactment of the *Helping Families in Men-*
15 *tal Health Crisis Reform Act of 2016*, the Secretary shall
16 include in the biennial report submitted to Congress under
17 section 501(m) an assessment on the effectiveness of the
18 grants under this section in—

19 “(1) providing graduate students support for ex-
20 periential training (internship or field placement);

21 “(2) recruiting students interested in behavioral
22 health practice;

23 “(3) recruiting students in accordance with sub-
24 section (b)(1);

1 **“SEC. 760. TRAINING DEMONSTRATION PROGRAM.**

2 “(a) *IN GENERAL.*—*The Secretary shall establish a*
3 *training demonstration program to award grants to eligible*
4 *entities to support—*

5 “(1) *training for medical residents and fellows to*
6 *practice psychiatry and addiction medicine in under-*
7 *served, community-based settings that integrate pri-*
8 *mary care with mental and substance use disorders*
9 *prevention and treatment services;*

10 “(2) *training for nurse practitioners, physician*
11 *assistants, health service psychologists, and social*
12 *workers to provide mental and substance use disorders*
13 *services in underserved community-based settings that*
14 *integrate primary care and mental and substance use*
15 *disorders services; and*

16 “(3) *establishing, maintaining, or improving*
17 *academic units or programs that—*

18 “(A) *provide training for students or fac-*
19 *ulty, including through clinical experiences and*
20 *research, to improve the ability to be able to rec-*
21 *ognize, diagnose, and treat mental and substance*
22 *use disorders, with a special focus on addiction;*
23 *or*

24 “(B) *develop evidence-based practices or rec-*
25 *ommendations for the design of the units or pro-*

1 *grams described in subparagraph (A), including*
2 *curriculum content standards.*

3 “(b) *ACTIVITIES.*—

4 “(1) *TRAINING FOR RESIDENTS AND FELLOWS.*—

5 *A recipient of a grant under subsection (a)(1)—*

6 “(A) *shall use the grant funds—*

7 “(i)(I) *to plan, develop, and operate a*
8 *training program for medical psychiatry*
9 *residents and fellows in addiction medicine*
10 *practicing in eligible entities described in*
11 *subsection (c)(1); or*

12 “(II) *to train new psychiatric residents*
13 *and fellows in addiction medicine to pro-*
14 *vide and expand access to integrated mental*
15 *and substance use disorders services; and*

16 “(ii) *to provide at least 1 training*
17 *track that is—*

18 “(I) *a virtual training track that*
19 *includes an in-person rotation at a*
20 *teaching health center or in a commu-*
21 *nity-based setting, followed by a vir-*
22 *tual rotation in which the resident or*
23 *fellow continues to support the care of*
24 *patients at the teaching health center*
25 *or in the community-based setting*

1 *through the use of health information*
2 *technology and, as appropriate, tele-*
3 *health services;*

4 “(II) *an in-person training track*
5 *that includes a rotation, during which*
6 *the resident or fellow practices at a*
7 *teaching health center or in a commu-*
8 *nity-based setting; or*

9 “(III) *an in-person training track*
10 *that includes a rotation during which*
11 *the resident practices in a community-*
12 *based setting that specializes in the*
13 *treatment of infants, children, adoles-*
14 *cents, or pregnant or postpartum*
15 *women; and*

16 “(B) *may use the grant funds to provide*
17 *additional support for the administration of the*
18 *program or to meet the costs of projects to estab-*
19 *lish, maintain, or improve faculty development,*
20 *or departments, divisions, or other units nec-*
21 *essary to implement such training.*

22 “(2) *TRAINING FOR OTHER PROVIDERS.—A re-*
23 *cipient of a grant under subsection (a)(2)—*

24 “(A) *shall use the grant funds to plan, de-*
25 *velop, or operate a training program to provide*

1 *mental and substance use disorders services in*
2 *underserved, community-based settings, as ap-*
3 *propriate, that integrate primary care and men-*
4 *tal and substance use disorders prevention and*
5 *treatment services; and*

6 “(B) *may use the grant funds to provide*
7 *additional support for the administration of the*
8 *program or to meet the costs of projects to estab-*
9 *lish, maintain, or improve faculty development,*
10 *or departments, divisions, or other units nec-*
11 *essary to implement such program.*

12 “(3) *ACADEMIC UNITS OR PROGRAMS.—A recipi-*
13 *ent of a grant under subsection (a)(3) shall enter into*
14 *a partnership with organizations such as an edu-*
15 *cation accrediting organization (such as the Liaison*
16 *Committee on Medical Education, the Accreditation*
17 *Council for Graduate Medical Education, the Com-*
18 *mission on Osteopathic College Accreditation, the Ac-*
19 *creditation Commission for Education in Nursing,*
20 *the Commission on Collegiate Nursing Education, the*
21 *Accreditation Council for Pharmacy Education, the*
22 *Council on Social Work Education, American Psycho-*
23 *logical Association Commission on Accreditation, or*
24 *the Accreditation Review Commission on Education*

1 *for the Physician Assistant) to carry out activities*
2 *under subsection (a)(3).*

3 “(c) *ELIGIBLE ENTITIES.*—

4 “(1) *TRAINING FOR RESIDENTS AND FELLOWS.*—
5 *To be eligible to receive a grant under subsection*
6 *(a)(1), an entity shall—*

7 “(A) *be a consortium consisting of—*

8 “(i) *at least one teaching health center;*

9 *and*

10 “(ii) *the sponsoring institution (or*
11 *parent institution of the sponsoring institu-*
12 *tion) of—*

13 “(I) *a psychiatry residency pro-*
14 *gram that is accredited by the Accredi-*
15 *tation Council of Graduate Medical*
16 *Education (or the parent institution of*
17 *such a program); or*

18 “(II) *a fellowship in addiction*
19 *medicine, as determined appropriate*
20 *by the Secretary; or*

21 “(B) *be an entity described in subpara-*
22 *graph (A)(ii) that provides opportunities for*
23 *residents or fellows to train in community-based*
24 *settings that integrate primary care with mental*

1 *and substance use disorders prevention and*
2 *treatment services.*

3 “(2) *TRAINING FOR OTHER PROVIDERS.—To be*
4 *eligible to receive a grant under subsection (a)(2), an*
5 *entity shall be—*

6 “(A) *a teaching health center (as defined in*
7 *section 749A(f));*

8 “(B) *a Federally qualified health center (as*
9 *defined in section 1905(l)(2)(B) of the Social Se-*
10 *curity Act);*

11 “(C) *a community mental health center (as*
12 *defined in section 1861(ff)(3)(B) of the Social*
13 *Security Act);*

14 “(D) *a rural health clinic (as defined in*
15 *section 1861(aa) of the Social Security Act);*

16 “(E) *a health center operated by the Indian*
17 *Health Service, an Indian tribe, a tribal organi-*
18 *zation, or an urban Indian organization (as de-*
19 *fined in section 4 of the Indian Health Care Im-*
20 *provement Act); or*

21 “(F) *an entity with a demonstrated record*
22 *of success in providing training for nurse practi-*
23 *tioners, physician assistants, health service psy-*
24 *chologists, and social workers.*

1 “(3) *ACADEMIC UNITS OR PROGRAMS.*—*To be eli-*
2 *gible to receive a grant under subsection (a)(3), an*
3 *entity shall be a school of medicine or osteopathic*
4 *medicine, a nursing school, a physician assistant*
5 *training program, a school of pharmacy, a school of*
6 *social work, an accredited public or nonprofit private*
7 *hospital, an accredited medical residency program, or*
8 *a public or private nonprofit entity which the Sec-*
9 *retary has determined is capable of carrying out such*
10 *grant.*

11 “(d) *PRIORITY.*—

12 “(1) *IN GENERAL.*—*In awarding grants under*
13 *subsection (a)(1) or (a)(2), the Secretary shall give*
14 *priority to eligible entities that—*

15 “(A) *demonstrate sufficient size, scope, and*
16 *capacity to undertake the requisite training of*
17 *an appropriate number of psychiatric residents,*
18 *fellows, nurse practitioners, physician assistants,*
19 *or social workers in addiction medicine per year*
20 *to meet the needs of the area served;*

21 “(B) *demonstrate experience in training*
22 *providers to practice team-based care that inte-*
23 *grates mental and substance use disorder preven-*
24 *tion and treatment services with primary care*
25 *in community-based settings;*

1 “(C) demonstrate experience in using health
2 information technology and, as appropriate, tele-
3 health to support—

4 “(i) the delivery of mental and sub-
5 stance use disorders services at the eligible
6 entities described in subsections (c)(1) and
7 (c)(2); and

8 “(ii) community health centers in inte-
9 grating primary care and mental and sub-
10 stance use disorders treatment; or

11 “(D) have the capacity to expand access to
12 mental and substance use disorders services in
13 areas with demonstrated need, as determined by
14 the Secretary, such as tribal, rural, or other un-
15 derserved communities.

16 “(2) *ACADEMIC UNITS OR PROGRAMS.*—In
17 awarding grants under subsection (a)(3), the Sec-
18 retary shall give priority to eligible entities that—

19 “(A) have a record of training the greatest
20 percentage of mental and substance use disorders
21 providers who enter and remain in these fields or
22 who enter and remain in settings with inte-
23 grated primary care and mental and substance
24 use disorder prevention and treatment services;

1 “(B) have a record of training individuals
2 who are from underrepresented minority groups,
3 including native populations, or from a rural or
4 disadvantaged background;

5 “(C) provide training in the care of vulner-
6 able populations such as infants, children, ado-
7 lescents, pregnant and postpartum women, older
8 adults, homeless individuals, victims of abuse or
9 trauma, individuals with disabilities, and other
10 groups as defined by the Secretary;

11 “(D) teach trainees the skills to provide
12 interprofessional, integrated care through col-
13 laboration among health professionals; or

14 “(E) provide training in cultural com-
15 petency and health literacy.

16 “(e) DURATION.—Grants awarded under this section
17 shall be for a minimum of 5 years.

18 “(f) STUDY AND REPORT.—

19 “(1) STUDY.—

20 “(A) IN GENERAL.—The Secretary, acting
21 through the Administrator of the Health Re-
22 sources and Services Administration, shall con-
23 duct a study on the results of the demonstration
24 program under this section.

1 “(B) *DATA SUBMISSION.*—Not later than 90
2 *days after the completion of the first year of the*
3 *training program and each subsequent year that*
4 *the program is in effect, each recipient of a grant*
5 *under subsection (a) shall submit to the Sec-*
6 *retary such data as the Secretary may require*
7 *for analysis for the report described in para-*
8 *graph (2).*

9 “(2) *REPORT TO CONGRESS.*—Not later than 1
10 *year after receipt of the data described in paragraph*
11 *(1)(B), the Secretary shall submit to Congress a re-*
12 *port that includes—*

13 “(A) *an analysis of the effect of the dem-*
14 *onstration program under this section on the*
15 *quality, quantity, and distribution of mental*
16 *and substance use disorders services;*

17 “(B) *an analysis of the effect of the dem-*
18 *onstration program on the prevalence of un-*
19 *treated mental and substance use disorders in the*
20 *surrounding communities of health centers par-*
21 *ticipating in the demonstration; and*

22 “(C) *recommendations on whether the dem-*
23 *onstration program should be expanded.*

1 “(g) *AUTHORIZATION OF APPROPRIATIONS.*—There
2 are authorized to be appropriated to carry out this section
3 \$10,000,000 for each of fiscal years 2018 through 2022.”.

4 **SEC. 9023. CLARIFICATION ON CURRENT ELIGIBILITY FOR**
5 **LOAN REPAYMENT PROGRAMS.**

6 *The Administrator of the Health Resources and Serv-*
7 *ices Administration shall clarify the eligibility pursuant to*
8 *section 338B(b)(1)(B) of the Public Health Service Act (42*
9 *U.S.C. 254l–1(b)(1)(B)) of child and adolescent psychia-*
10 *trists for the National Health Service Corps Loan Repay-*
11 *ment Program under subpart III of part D of title III of*
12 *such Act (42 U.S.C. 254l et seq.).*

13 **SEC. 9024. MINORITY FELLOWSHIP PROGRAM.**

14 *Title V of the Public Health Service Act (42 U.S.C.*
15 *290aa et seq.) is amended by adding at the end the fol-*
16 *lowing:*

17 **“PART K—MINORITY FELLOWSHIP PROGRAM**

18 **“SEC. 597. FELLOWSHIPS.**

19 “(a) *IN GENERAL.*—The Secretary shall maintain a
20 program, to be known as the Minority Fellowship Program,
21 under which the Secretary shall award fellowships, which
22 may include stipends, for the purposes of—

23 “(1) *increasing the knowledge of mental and sub-*
24 *stance use disorders practitioners on issues related to*
25 *prevention, treatment, and recovery support for indi-*

1 *viduals who are from racial and ethnic minority pop-*
2 *ulations and who have a mental or substance use dis-*
3 *order;*

4 *“(2) improving the quality of mental and sub-*
5 *stance use disorder prevention and treatment services*
6 *delivered to racial and ethnic minority populations;*
7 *and*

8 *“(3) increasing the number of culturally com-*
9 *petent mental and substance use disorders profes-*
10 *sionals who teach, administer services, conduct re-*
11 *search, and provide direct mental or substance use*
12 *disorder services to racial and ethnic minority popu-*
13 *lations.*

14 *“(b) TRAINING COVERED.—The fellowships awarded*
15 *under subsection (a) shall be for postbaccalaureate training*
16 *(including for master’s and doctoral degrees) for mental*
17 *and substance use disorder treatment professionals, includ-*
18 *ing in the fields of psychiatry, nursing, social work, psy-*
19 *chology, marriage and family therapy, mental health coun-*
20 *seling, and substance use disorder and addiction counseling.*

21 *“(c) AUTHORIZATION OF APPROPRIATIONS.—To carry*
22 *out this section, there are authorized to be appropriated*
23 *\$12,669,000 for each of fiscal years 2018 through 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 following:*

6 *“(q)(1) For purposes of this section, a health profes-*
7 *sional volunteer at a deemed entity described in subsection*
8 *(g)(4) shall, in providing a health professional service eligi-*
9 *ble for funding under section 330 to an individual, be*
10 *deemed to be an employee of the Public Health Service for*
11 *a calendar year that begins during a fiscal year for which*
12 *a transfer was made under paragraph (4)(C). The pre-*
13 *ceding sentence is subject to the provisions of this sub-*
14 *section.*

15 *“(2) In providing a health service to an individual,*
16 *a health care practitioner shall for purposes of this sub-*
17 *section be considered to be a health professional volunteer*
18 *at an entity described in subsection (g)(4) if the following*
19 *conditions are met:*

20 *“(A) The service is provided to the individual at*
21 *the facilities of an entity described in subsection*
22 *(g)(4), or through offsite programs or events carried*
23 *out by the entity.*

24 *“(B) The entity is sponsoring the health care*
25 *practitioner pursuant to paragraph (3)(B).*

1 “(C) *The health care practitioner does not receive*
2 *any compensation for the service from the individual,*
3 *the entity described in subsection (g)(4), or any third-*
4 *party payer (including reimbursement under any in-*
5 *surance policy or health plan, or under any Federal*
6 *or State health benefits program), except that the*
7 *health care practitioner may receive repayment from*
8 *the entity described in subsection (g)(4) for reasonable*
9 *expenses incurred by the health care practitioner in*
10 *the provision of the service to the individual, which*
11 *may include travel expenses to or from the site of*
12 *services.*

13 “(D) *Before the service is provided, the health*
14 *care practitioner or the entity described in subsection*
15 *(g)(4) posts a clear and conspicuous notice at the site*
16 *where the service is provided of the extent to which the*
17 *legal liability of the health care practitioner is lim-*
18 *ited 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 enti-*
24 *ty 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 ex-
6 tent and in the same manner as such subsections apply to
7 an officer, governing board member, employee, or contractor
8 of an entity described in subsection (g)(4), subject to para-
9 graph (4), and subject to the following:

10 “(A) The first sentence of paragraph (1) applies
11 *in lieu of the first sentence of subsection (g)(1)(A).*

12 “(B) With respect to an entity described in sub-
13 *section (g)(4), a health care practitioner is not a*
14 *health professional volunteer at such entity unless the*
15 *entity sponsors the health care practitioner. For pur-*
16 *poses of this subsection, the entity shall be considered*
17 *to be sponsoring the health care practitioner if—*

18 “(i) with respect to the health care practi-
19 *tioner, the entity submits to the Secretary an ap-*
20 *plication meeting the requirements of subsection*
21 *(g)(1)(D); and*

22 “(ii) the Secretary, pursuant to subsection
23 *(g)(1)(E), determines that the health care practi-*
24 *tioner is deemed to be an employee of the Public*
25 *Health Service.*

1 “(C) *In the case of a health care practitioner*
2 *who is determined by the Secretary pursuant to sub-*
3 *section (g)(1)(E) to be a health professional volunteer*
4 *at such entity, this subsection applies to the health*
5 *care practitioner (with respect to services performed*
6 *on behalf of the entity sponsoring the health care*
7 *practitioner pursuant to subparagraph (B)) for any*
8 *cause of action arising from an act or omission of the*
9 *health care practitioner occurring on or after the date*
10 *on which the Secretary makes such determination.*

11 “(D) *Subsection (g)(1)(F) applies to a health*
12 *care practitioner for purposes of this subsection only*
13 *to the extent that, in providing health services to an*
14 *individual, each of the conditions specified in para-*
15 *graph (2) is met.*

16 “(4)(A) *Amounts in the fund established under sub-*
17 *section (k)(2) shall be available for transfer under subpara-*
18 *graph (C) for purposes of carrying out this subsection.*

19 “(B)(i) *Not later than May 1 of each fiscal year, the*
20 *Attorney General, in consultation with the Secretary, shall*
21 *submit to the Congress a report providing an estimate of*
22 *the amount of claims (together with related fees and ex-*
23 *penses of witnesses) that, by reason of the acts or omissions*
24 *of health professional volunteers, will be paid pursuant to*

1 *this section during the calendar year that begins in the fol-*
2 *lowing fiscal year.*

3 “(ii) *Subsection (k)(1)(B) applies to the estimate*
4 *under clause (i) regarding health professional volunteers to*
5 *the same extent and in the same manner as such subsection*
6 *applies to the estimate under such subsection regarding offi-*
7 *cers, governing board members, employees, and contractors*
8 *of entities described in subsection (g)(4).*

9 “(iii) *The report shall include a summary of the data*
10 *relied upon for the estimate in clause (i), including the*
11 *number of claims filed and paid from the previous calendar*
12 *year.*

13 “(C) *Not later than December 31 of each fiscal year,*
14 *the Secretary shall transfer from the fund under subsection*
15 *(k)(2) to the appropriate accounts in the Treasury an*
16 *amount equal to the estimate made under subparagraph (B)*
17 *for the calendar year beginning in such fiscal year, subject*
18 *to the extent of amounts in the fund.*

19 “(5)(A) *This subsection shall take effect on October 1,*
20 *2017, except as provided in subparagraph (B) and para-*
21 *graph (6).*

22 “(B) *Effective on the date of the enactment of this sub-*
23 *section—*

24 “(i) *the Secretary may issue regulations for car-*
25 *rying out this subsection, and the Secretary may ac-*

1 *cept and consider applications submitted pursuant to*
2 *paragraph (3)(B); and*

3 *“(i) reports under paragraph (4)(B) may be*
4 *submitted to Congress.*

5 *“(6) Beginning on October 1, 2022, this subsection*
6 *shall cease to have any force or effect.”.*

7 **SEC. 9026. REPORTS.**

8 *(a) WORKFORCE DEVELOPMENT REPORT.—*

9 *(1) IN GENERAL.—Not later than 2 years after*
10 *the date of enactment of this Act, the Administrator*
11 *of the Health Resources and Services Administration,*
12 *in consultation with the Assistant Secretary for Men-*
13 *tal Health and Substance Use, shall conduct a study*
14 *and publicly post on the appropriate Internet website*
15 *of the Department of Health and Human Services a*
16 *report on the adult and pediatric mental health and*
17 *substance use disorder workforce in order to inform*
18 *Federal, State, and local efforts related to workforce*
19 *enhancement.*

20 *(2) CONTENTS.—The report under this subsection*
21 *shall contain—*

22 *(A) national and State-level projections of*
23 *the supply and demand of the mental health and*
24 *substance use disorder health workforce,*
25 *disaggregated by profession;*

1 (B) an assessment of the mental health and
2 substance use disorder workforce capacity,
3 strengths, and weaknesses as of the date of the re-
4 port, including the extent to which primary care
5 providers are preventing, screening, or referring
6 for mental and substance use disorder services;

7 (C) information on trends within the men-
8 tal health and substance use disorder provider
9 workforce, including the number of individuals
10 expected to enter the mental health workforce
11 over the next 5 years; and

12 (D) any additional information determined
13 by the Administrator of the Health Resources
14 and Services Administration, in consultation
15 with the Assistant Secretary for Mental Health
16 and Substance Use, to be relevant to the mental
17 health and substance use disorder provider work-
18 force.

19 (b) *PEER-SUPPORT SPECIALIST PROGRAMS.*—

20 (1) *IN GENERAL.*—The Comptroller General of
21 the United States shall conduct a study on peer-sup-
22 port specialist programs in up to 10 States that re-
23 ceive funding from the Substance Abuse and Mental
24 Health Services Administration.

1 (2) *CONTENTS OF STUDY.*—*In conducting the*
2 *study under paragraph (1), the Comptroller General*
3 *of the United States shall examine and identify best*
4 *practices, in the States selected pursuant to such*
5 *paragraph, related to training and credential require-*
6 *ments for peer-support specialist programs, such as—*

7 (A) *hours of formal work or volunteer expe-*
8 *rience related to mental and substance use dis-*
9 *orders conducted through such programs;*

10 (B) *types of peer-support specialist exams*
11 *required for such programs in the selected States;*

12 (C) *codes of ethics used by such programs in*
13 *the selected States;*

14 (D) *required or recommended skill sets for*
15 *such programs in the selected States; and*

16 (E) *requirements for continuing education.*

17 (3) *REPORT.*—*Not later than 2 years after the*
18 *date of enactment of this Act, the Comptroller General*
19 *of the United States shall submit to the Committee on*
20 *Health, Education, Labor, and Pensions of the Senate*
21 *and the Committee on Energy and Commerce of the*
22 *House of Representatives a report on the study con-*
23 *ducted under paragraph (1).*

1 **Subtitle C—Mental Health on**
2 **Campus Improvement**

3 **SEC. 9031. MENTAL HEALTH AND SUBSTANCE USE DIS-**
4 **ORDER SERVICES ON CAMPUS.**

5 *Section 520E–2 of the Public Health Service Act (42*
6 *U.S.C. 290bb–36b) is amended—*

7 (1) *in the section heading, by striking “AND BE-*
8 *HAVIORAL HEALTH” and inserting “HEALTH AND*
9 ***SUBSTANCE USE DISORDER*”;**

10 (2) *in subsection (a)—*

11 (A) *by striking “Services,” and inserting*
12 *“Services and”;*

13 (B) *by striking “and behavioral health*
14 *problems” and inserting “health or substance use*
15 *disorders”;*

16 (C) *by striking “substance abuse” and in-*
17 *serting “substance use disorders”; and*

18 (D) *by adding after, “suicide attempts,” the*
19 *following: “prevent mental and substance use*
20 *disorders, reduce stigma, and improve the identi-*
21 *fication and treatment for students at risk.”;*

22 (3) *in subsection (b)—*

23 (A) *in the matter preceding paragraph (1),*
24 *by striking “for—” and inserting “for one or*
25 *more of the following.”; and*

1 (B) by striking paragraphs (1) through (6)
2 and inserting the following:

3 “(1) Educating students, families, faculty, and
4 staff to increase awareness of mental and substance
5 use disorders.

6 “(2) The operation of hotlines.

7 “(3) Preparing informational material.

8 “(4) Providing outreach services to notify stu-
9 dents about available mental and substance use dis-
10 order services.

11 “(5) Administering voluntary mental and sub-
12 stance use disorder screenings and assessments.

13 “(6) Supporting the training of students, faculty,
14 and staff to respond effectively to students with men-
15 tal and substance use disorders.

16 “(7) Creating a network infrastructure to link
17 institutions of higher education with health care pro-
18 viders who treat mental and substance use disorders.

19 “(8) Providing mental and substance use dis-
20 orders prevention and treatment services to students,
21 which may include recovery support services and pro-
22 gramming and early intervention, treatment, and
23 management, including through the use of telehealth
24 services.

1 “(9) *Conducting research through a counseling*
2 *or health center at the institution of higher education*
3 *involved regarding improving the behavioral health of*
4 *students through clinical services, outreach, preven-*
5 *tion, or academic success, in a manner that is in*
6 *compliance with all applicable personal privacy laws.*

7 “(10) *Supporting student groups on campus, in-*
8 *cluding athletic teams, that engage in activities to*
9 *educate students, including activities to reduce stigma*
10 *surrounding mental and behavioral disorders, and*
11 *promote mental health.*

12 “(11) *Employing appropriately trained staff.*

13 “(12) *Developing and supporting evidence-based*
14 *and emerging best practices, including a focus on cul-*
15 *turally and linguistically appropriate best prac-*
16 *tices.”;*

17 (4) *in subsection (c)(5), by striking “substance*
18 *abuse” and inserting “substance use disorder”;*

19 (5) *in subsection (d)—*

20 (A) *in the matter preceding paragraph (1),*
21 *by striking “An institution of higher education*
22 *desiring a grant under this section” and insert-*
23 *ing “To be eligible to receive a grant under this*
24 *section, an institution of higher education”;*

1 (B) by striking paragraph (1) and insert-
2 ing—

3 “(1) A description of the population to be tar-
4 geted by the program carried out under the grant, in-
5 cluding veterans whenever possible and appropriate,
6 and of identified mental and substance use disorder
7 needs of students at the institution of higher edu-
8 cation.”;

9 (C) in paragraph (2), by inserting “, which
10 may include, as appropriate and in accordance
11 with subsection (b)(7), a plan to seek input from
12 relevant stakeholders in the community, includ-
13 ing appropriate public and private entities, in
14 order to carry out the program under the grant”
15 before the period at the end; and

16 (D) by adding after paragraph (5) the fol-
17 lowing new paragraphs:

18 “(6) An outline of the objectives of the program
19 carried out under the grant.

20 “(7) For an institution of higher education pro-
21 posing to use the grant for an activity described in
22 paragraph (8) or (9) of subsection (b), a description
23 of the policies and procedures of the institution of
24 higher education that are related to applicable laws
25 regarding access to, and sharing of, treatment records

1 of students at any campus-based mental health center
2 or partner organization, including the policies and
3 State laws governing when such records can be
4 accessed and shared for non-treatment purposes and
5 a description of the process used by the institution of
6 higher education to notify students of these policies
7 and procedures, including the extent to which written
8 consent is required.

9 “(8) An assurance that grant funds will be used
10 to supplement and not supplant any other Federal,
11 State, or local funds available to carry out activities
12 of the type carried out under the grant.”;

13 (6) in subsection (e)(1), by striking “and behav-
14 ioral health problems” and inserting “health and sub-
15 stance use disorders”;

16 (7) in subsection (f)(2)—

17 (A) by striking “and behavioral health” and
18 inserting “health and substance use disorder”;
19 and

20 (B) by striking “suicide and substance
21 abuse” and inserting “suicide and substance use
22 disorders”;

23 (8) by redesignating subsection (h) as subsection
24 (i);

1 *is affected by, mental health and education policies and*
2 *projects, including—*

3 *(1) the Department of Education;*

4 *(2) the Department of Health and Human Serv-*
5 *ices;*

6 *(3) the Department of Veterans Affairs; and*

7 *(4) such other Federal agencies as the Assistant*
8 *Secretary for Mental Health and Substance Use, in*
9 *consultation with the Secretary, determines to be ap-*
10 *propriate.*

11 *(d) DUTIES.—The Task Force shall—*

12 *(1) serve as a centralized mechanism to coordi-*
13 *nate a national effort to—*

14 *(A) discuss and evaluate evidence and*
15 *knowledge on mental and behavioral health serv-*
16 *ices available to, and the prevalence of mental*
17 *illness among, the age population of students at-*
18 *tending institutions of higher education in the*
19 *United States;*

20 *(B) determine the range of effective, feasible,*
21 *and comprehensive actions to improve mental*
22 *and behavioral health on campuses of institu-*
23 *tions of higher education;*

24 *(C) examine and better address the needs of*
25 *the age population of students attending institu-*

1 *tions of higher education dealing with mental ill-*
2 *ness;*

3 *(D) survey Federal agencies to determine*
4 *which policies are effective in encouraging, and*
5 *how best to facilitate outreach without dupli-*
6 *cating, efforts relating to mental and behavioral*
7 *health promotion;*

8 *(E) establish specific goals within and*
9 *across Federal agencies for mental health pro-*
10 *motion, including determinations of account-*
11 *ability for reaching those goals;*

12 *(F) develop a strategy for allocating respon-*
13 *sibilities and ensuring participation in mental*
14 *and behavioral health promotion, particularly in*
15 *the case of competing agency priorities;*

16 *(G) coordinate plans to communicate re-*
17 *search results relating to mental and behavioral*
18 *health amongst the age population of students at-*
19 *tending institutions of higher education to enable*
20 *reporting and outreach activities to produce*
21 *more useful and timely information;*

22 *(H) provide a description of evidence-based*
23 *practices, model programs, effective guidelines,*
24 *and other strategies for promoting mental and*

1 *behavioral health on campuses of institutions of*
2 *higher education;*

3 *(I) make recommendations to improve Fed-*
4 *eral efforts relating to mental and behavioral*
5 *health promotion on campuses of institutions of*
6 *higher education and to ensure Federal efforts*
7 *are consistent with available standards, evidence,*
8 *and other programs in existence as of the date of*
9 *enactment of this Act;*

10 *(J) monitor Federal progress in meeting*
11 *specific mental and behavioral health promotion*
12 *goals as they relate to settings of institutions of*
13 *higher education; and*

14 *(K) examine and disseminate best practices*
15 *related to intracampus sharing of treatment*
16 *records;*

17 *(2) consult with national organizations with ex-*
18 *pertise in mental and behavioral health, especially*
19 *those organizations working with the age population*
20 *of students attending institutions of higher education;*
21 *and*

22 *(3) consult with and seek input from mental*
23 *health professionals working on campuses of institu-*
24 *tions of higher education as appropriate.*

25 *(e) MEETINGS.—*

1 *mental health services to ensure that students at institutions*
2 *of higher education have the support necessary to success-*
3 *fully complete their studies.*

4 “(b) *NATIONAL PUBLIC EDUCATION CAMPAIGN.—The*
5 *Secretary, acting through the Assistant Secretary and in*
6 *collaboration with the Director of the Centers for Disease*
7 *Control and Prevention, shall convene an interagency, pub-*
8 *lic-private sector working group to plan, establish, and*
9 *begin coordinating and evaluating a targeted public edu-*
10 *cation campaign that is designed to focus on mental and*
11 *behavioral health on the campuses of institutions of higher*
12 *education. Such campaign shall be designed to—*

13 “(1) *improve the general understanding of men-*
14 *tal health and mental disorders;*

15 “(2) *encourage help-seeking behaviors relating to*
16 *the promotion of mental health, prevention of mental*
17 *disorders, and treatment of such disorders;*

18 “(3) *make the connection between mental and be-*
19 *havioral health and academic success; and*

20 “(4) *assist the general public in identifying the*
21 *early warning signs and reducing the stigma of men-*
22 *tal illness.*

23 “(c) *COMPOSITION.—The working group convened*
24 *under subsection (b) shall include—*

1 “(1) mental health consumers, including students
2 and family members;

3 “(2) representatives of institutions of higher edu-
4 cation;

5 “(3) representatives of national mental and be-
6 havioral health associations and associations of insti-
7 tutions of higher education;

8 “(4) representatives of health promotion and pre-
9 vention organizations at institutions of higher edu-
10 cation;

11 “(5) representatives of mental health providers,
12 including community mental health centers; and

13 “(6) representatives of private-sector and public-
14 sector groups with experience in the development of ef-
15 fective public health education campaigns.

16 “(d) *PLAN*.—The working group under subsection (b)
17 shall develop a plan that—

18 “(1) targets promotional and educational efforts
19 to the age population of students at institutions of
20 higher education and individuals who are employed
21 in settings of institutions of higher education, includ-
22 ing through the use of roundtables;

23 “(2) develops and proposes the implementation of
24 research-based public health messages and activities;

1 “(3) provides support for local efforts to reduce
2 stigma by using the National Health Information
3 Center as a primary point of contact for information,
4 publications, and service program referrals; and

5 “(4) develops and proposes the implementation of
6 a social marketing campaign that is targeted at the
7 population of students attending institutions of higher
8 education and individuals who are employed in set-
9 tings of institutions of higher education.

10 “(e) DEFINITION.—In this section, the term ‘institu-
11 tion of higher education’ has the meaning given such term
12 in section 101 of the Higher Education Act of 1965 (20
13 U.S.C. 1001).

14 “(f) AUTHORIZATION OF APPROPRIATIONS.—To carry
15 out this section, there are authorized to be appropriated
16 \$1,000,000 for the period of fiscal years 2018 through
17 2022.”.

18 **TITLE X—STRENGTHENING MEN-**
19 **TAL AND SUBSTANCE USE**
20 **DISORDER CARE FOR CHIL-**
21 **DREN AND ADOLESCENTS**

22 **SEC. 10001. PROGRAMS FOR CHILDREN WITH A SERIOUS**
23 **EMOTIONAL DISTURBANCE.**

24 (a) **COMPREHENSIVE COMMUNITY MENTAL HEALTH**
25 **SERVICES FOR CHILDREN WITH A SERIOUS EMOTIONAL**

1 *DISTURBANCE.*—Section 561(a)(1) of the Public Health
2 Service Act (42 U.S.C. 290ff(a)(1)) is amended by inserting
3 “, which may include efforts to identify and serve children
4 at risk” before the period.

5 (b) *REQUIREMENTS WITH RESPECT TO CARRYING*
6 *OUT PURPOSE OF GRANTS.*—Section 562(b) of the Public
7 Health Service Act (42 U.S.C. 290ff–1(b)) is amended by
8 striking “will not provide an individual with access to the
9 system if the individual is more than 21 years of age” and
10 inserting “will provide an individual with access to the sys-
11 tem through the age of 21 years”.

12 (c) *ADDITIONAL PROVISIONS.*—Section 564(f) of the
13 Public Health Service Act (42 U.S.C. 290ff–3(f)) is amend-
14 ed by inserting “(and provide a copy to the State involved)”
15 after “to the Secretary”.

16 (d) *GENERAL PROVISIONS.*—Section 565 of the Public
17 Health Service Act (42 U.S.C. 290ff–4) is amended—

18 (1) in subsection (b)(1)—

19 (A) in the matter preceding subparagraph
20 (A), by striking “receiving a grant under section
21 561(a)” and inserting “, regardless of whether
22 such public entity is receiving a grant under sec-
23 tion 561(a)”; and

24 (B) in subparagraph (B), by striking “pur-
25 suant to” and inserting “described in”;

1 (2) *in subsection (d)(1), by striking “not more*
2 *than 21 years of age” and inserting “through the age*
3 *of 21 years”;* and

4 (3) *in subsection (f)(1), by striking*
5 *“\$100,000,000 for fiscal year 2001, and such sums as*
6 *may be necessary for each of the fiscal years 2002 and*
7 *2003” and inserting “\$119,026,000 for each of fiscal*
8 *years 2018 through 2022”.*

9 **SEC. 10002. INCREASING ACCESS TO PEDIATRIC MENTAL**
10 **HEALTH CARE.**

11 *Title III of the Public Health Service Act is amended*
12 *by inserting after section 330L of such Act (42 U.S.C. 254c-*
13 *18) the following new section:*

14 **“SEC. 330M PEDIATRIC MENTAL HEALTH CARE ACCESS**
15 **GRANTS.**

16 “(a) *IN GENERAL.—The Secretary, acting through the*
17 *Administrator of the Health Resources and Services Admin-*
18 *istration and in coordination with other relevant Federal*
19 *agencies, shall award grants to States, political subdivi-*
20 *sions of States, and Indian tribes and tribal organizations*
21 *(for purposes of this section, as such terms are defined in*
22 *section 4 of the Indian Self-Determination and Education*
23 *Assistance Act (25 U.S.C. 450b)) to promote behavioral*
24 *health integration in pediatric primary care by—*

1 “(1) supporting the development of statewide or
2 regional pediatric mental health care telehealth access
3 programs; and

4 “(2) supporting the improvement of existing
5 statewide or regional pediatric mental health care
6 telehealth access programs.

7 “(b) PROGRAM REQUIREMENTS.—

8 “(1) IN GENERAL.—A pediatric mental health
9 care telehealth access program referred to in sub-
10 section (a), with respect to which a grant under such
11 subsection may be used, shall—

12 “(A) be a statewide or regional network of
13 pediatric mental health teams that provide sup-
14 port to pediatric primary care sites as an inte-
15 grated team;

16 “(B) support and further develop organized
17 State or regional networks of pediatric mental
18 health teams to provide consultative support to
19 pediatric primary care sites;

20 “(C) conduct an assessment of critical be-
21 havioral consultation needs among pediatric pro-
22 viders and such providers’ preferred mechanisms
23 for receiving consultation, training, and tech-
24 nical assistance;

1 “(D) develop an online database and com-
2 munication mechanisms, including telehealth, to
3 facilitate consultation support to pediatric prac-
4 tices;

5 “(E) provide rapid statewide or regional
6 clinical telephone or telehealth consultations
7 when requested between the pediatric mental
8 health teams and pediatric primary care pro-
9 viders;

10 “(F) conduct training and provide technical
11 assistance to pediatric primary care providers to
12 support the early identification, diagnosis, treat-
13 ment, and referral of children with behavioral
14 health conditions;

15 “(G) provide information to pediatric pro-
16 viders about, and assist pediatric providers in
17 accessing, pediatric mental health care providers,
18 including child and adolescent psychiatrists, and
19 licensed mental health professionals, such as psy-
20 chologists, social workers, or mental health coun-
21 selors and in scheduling and conducting tech-
22 nical assistance;

23 “(H) assist with referrals to specialty care
24 and community or behavioral health resources;
25 and

1 “(I) *establish mechanisms for measuring*
2 *and monitoring increased access to pediatric*
3 *mental health care services by pediatric primary*
4 *care providers and expanded capacity of pedi-*
5 *atric primary care providers to identify, treat,*
6 *and refer children with mental health problems.*

7 “(2) *PEDIATRIC MENTAL HEALTH TEAMS.—In*
8 *this subsection, the term ‘pediatric mental health*
9 *team’ means a team consisting of at least one case co-*
10 *ordinator, at least one child and adolescent psychia-*
11 *trist, and at least one licensed clinical mental health*
12 *professional, such as a psychologist, social worker, or*
13 *mental health counselor. Such a team may be region-*
14 *ally based.*

15 “(c) *APPLICATION.—A State, political subdivision of*
16 *a State, Indian tribe, or tribal organization seeking a grant*
17 *under this section shall submit an application to the Sec-*
18 *retary at such time, in such manner, and containing such*
19 *information as the Secretary may require, including a plan*
20 *for the comprehensive evaluation of activities that are car-*
21 *ried out with funds received under such grant.*

22 “(d) *EVALUATION.—A State, political subdivision of*
23 *a State, Indian tribe, or tribal organization that receives*
24 *a grant under this section shall prepare and submit an*
25 *evaluation of activities that are carried out with funds re-*

1 *ceived under such grant to the Secretary at such time, in*
2 *such manner, and containing such information as the Sec-*
3 *retary may reasonably require, including a process and*
4 *outcome evaluation.*

5 “(e) *ACCESS TO BROADBAND.*—*In administering*
6 *grants under this section, the Secretary may coordinate*
7 *with other agencies to ensure that funding opportunities are*
8 *available to support access to reliable, high-speed Internet*
9 *for providers.*

10 “(f) *MATCHING REQUIREMENT.*—*The Secretary may*
11 *not award a grant under this section unless the State, polit-*
12 *ical subdivision of a State, Indian tribe, or tribal organiza-*
13 *tion involved agrees, with respect to the costs to be incurred*
14 *by the State, political subdivision of a State, Indian tribe,*
15 *or tribal organization in carrying out the purpose described*
16 *in this section, to make available non-Federal contributions*
17 *(in cash or in kind) toward such costs in an amount that*
18 *is not less than 20 percent of Federal funds provided in*
19 *the grant.*

20 “(g) *AUTHORIZATION OF APPROPRIATIONS.*—*To carry*
21 *out this section, there are authorized to be appropriated,*
22 *\$9,000,000 for the period of fiscal years 2018 through*
23 *2022.”.*

1 **SEC. 10003. SUBSTANCE USE DISORDER TREATMENT AND**
2 **EARLY INTERVENTION SERVICES FOR CHIL-**
3 **DREN AND ADOLESCENTS.**

4 *The first section 514 of the Public Health Service Act*
5 *(42 U.S.C. 290bb-7), relating to substance abuse treatment*
6 *services for children and adolescents, is amended—*

7 *(1) in the section heading, by striking “**ABUSE***
8 ***TREATMENT**” and inserting “**USE DISORDER***
9 ***TREATMENT AND EARLY INTERVENTION**”;*

10 *(2) by striking subsection (a) and inserting the*
11 *following:*

12 *“(a) IN GENERAL.—The Secretary shall award grants,*
13 *contracts, or cooperative agreements to public and private*
14 *nonprofit entities, including Indian tribes or tribal organi-*
15 *zations (as such terms are defined in section 4 of the Indian*
16 *Self-Determination and Education Assistance Act), or*
17 *health facilities or programs operated by or in accordance*
18 *with a contract or grant with the Indian Health Service,*
19 *for the purpose of—*

20 *“(1) providing early identification and services*
21 *to meet the needs of children and adolescents who are*
22 *at risk of substance use disorders;*

23 *“(2) providing substance use disorder treatment*
24 *services for children, including children and adoles-*
25 *cents with co-occurring mental illness and substance*
26 *use disorders; and*

1 “(3) providing assistance to pregnant women,
2 and parenting women, with substance use disorders,
3 in obtaining treatment services, linking mothers to
4 community resources to support independent family
5 lives, and staying in recovery so that children are in
6 safe, stable home environments and receive appro-
7 priate health care services.”;

8 (3) in subsection (b)—

9 (A) by striking paragraph (1) and inserting
10 the following:

11 “(1) apply evidence-based and cost-effective
12 methods;”;

13 (B) in paragraph (2)—

14 (i) by striking “treatment”; and

15 (ii) by inserting “substance abuse,”
16 after “child welfare,”;

17 (C) in paragraph (3), by striking “sub-
18 stance abuse disorders” and inserting “substance
19 use disorders, including children and adolescents
20 with co-occurring mental illness and substance
21 use disorders,”;

22 (D) in paragraph (5), by striking “treat-
23 ment;” and inserting “services; and”;

1 (E) in paragraph (6), by striking “sub-
2 stance abuse treatment; and” and inserting
3 “treatment.”; and

4 (F) by striking paragraph (7); and
5 (4) in subsection (f), by striking “\$40,000,000”
6 and all that follows through the period and inserting
7 “\$29,605,000 for each of fiscal years 2018 through
8 2022.”.

9 **SEC. 10004. CHILDREN’S RECOVERY FROM TRAUMA.**

10 *The first section 582 of the Public Health Service Act*
11 *(42 U.S.C. 290hh–1; relating to grants to address the prob-*
12 *lems of persons who experience violence related stress) is*
13 *amended—*

14 (1) in subsection (a), by striking “developing
15 programs” and all that follows through the period at
16 the end and inserting the following: “developing and
17 maintaining programs that provide for—

18 “(1) the continued operation of the National
19 Child Traumatic Stress Initiative (referred to in this
20 section as the ‘NCTSI’), which includes a cooperative
21 agreement with a coordinating center, that focuses on
22 the mental, behavioral, and biological aspects of psy-
23 chological trauma response, prevention of the long-
24 term consequences of child trauma, and early inter-

1 *vention services and treatment to address the long-*
2 *term consequences of child trauma; and*

3 *“(2) the development of knowledge with regard to*
4 *evidence-based practices for identifying and treating*
5 *mental, behavioral, and biological disorders of chil-*
6 *dren and youth resulting from witnessing or experi-*
7 *encing a traumatic event.”;*

8 *(2) in subsection (b)—*

9 *(A) by striking “subsection (a) related” and*
10 *inserting “subsection (a)(2) (related”;*

11 *(B) by striking “treating disorders associ-*
12 *ated with psychological trauma” and inserting*
13 *“treating mental, behavioral, and biological dis-*
14 *orders associated with psychological trauma”;*
15 *and*

16 *(C) by striking “mental health agencies and*
17 *programs that have established clinical and basic*
18 *research” and inserting “universities, hospitals,*
19 *mental health agencies, and other programs that*
20 *have established clinical expertise and research”;*

21 *(3) by redesignating subsections (c) through (g)*
22 *as subsections (g) through (k), respectively;*

23 *(4) by inserting after subsection (b), the fol-*
24 *lowing:*

1 “(c) *CHILD OUTCOME DATA.*—The NCTSI coordi-
2 nating center described in subsection (a)(1) shall collect,
3 analyze, report, and make publicly available, as appro-
4 priate, NCTSI-wide child treatment process and outcome
5 data regarding the early identification and delivery of evi-
6 dence-based treatment and services for children and families
7 served by the NCTSI grantees.

8 “(d) *TRAINING.*—The NCTSI coordinating center shall
9 facilitate the coordination of training initiatives in evi-
10 dence-based and trauma-informed treatments, interven-
11 tions, and practices offered to NCTSI grantees, providers,
12 and partners.

13 “(e) *DISSEMINATION AND COLLABORATION.*—The
14 NCTSI coordinating center shall, as appropriate, collabo-
15 rate with—

16 “(1) the Secretary, in the dissemination of evi-
17 dence-based and trauma-informed interventions,
18 treatments, products, and other resources to appro-
19 priate stakeholders; and

20 “(2) appropriate agencies that conduct or fund
21 research within the Department of Health and
22 Human Services, for purposes of sharing NCTSI ex-
23 pertise, evaluation data, and other activities, as ap-
24 propriate.

1 “(f) *REVIEW.*—*The Secretary shall, consistent with the*
2 *peer-review process, ensure that NCTSI applications are re-*
3 *viewed by appropriate experts in the field as part of a con-*
4 *sensus-review process. The Secretary shall include review*
5 *criteria related to expertise and experience in child trauma*
6 *and evidence-based practices.”;*

7 (5) *in subsection (g) (as so redesignated), by*
8 *striking “with respect to centers of excellence are dis-*
9 *tributed equitably among the regions of the country”*
10 *and inserting “are distributed equitably among the*
11 *regions of the United States”;*

12 (6) *in subsection (i) (as so redesignated), by*
13 *striking “recipient may not exceed 5 years” and in-*
14 *serting “recipient shall not be less than 4 years, but*
15 *shall not exceed 5 years”;* and

16 (7) *in subsection (j) (as so redesignated), by*
17 *striking “\$50,000,000” and all that follows through*
18 *“2006” and inserting “\$46,887,000 for each of fiscal*
19 *years 2018 through 2022”.*

20 **SEC. 10005. SCREENING AND TREATMENT FOR MATERNAL**
21 **DEPRESSION.**

22 *Part B of title III of the Public Health Service Act*
23 *(42 U.S.C. 243 et seq.) is amended by inserting after section*
24 *317L (42 U.S.C. 247b–13) the following:*

1 **“SEC. 317L–1. SCREENING AND TREATMENT FOR MATERNAL**
2 **DEPRESSION.**

3 “(a) *GRANTS.*—*The Secretary shall make grants to*
4 *States to establish, improve, or maintain programs for*
5 *screening, assessment, and treatment services, including*
6 *culturally and linguistically appropriate services, as appro-*
7 *priate, for women who are pregnant, or who have given*
8 *birth within the preceding 12 months, for maternal depres-*
9 *sion.*

10 “(b) *APPLICATION.*—*To seek a grant under this sec-*
11 *tion, a State shall submit an application to the Secretary*
12 *at such time, in such manner, and containing such infor-*
13 *mation as the Secretary may require. At a minimum, any*
14 *such application shall include explanations of—*

15 “(1) *how a program, or programs, will increase*
16 *the percentage of women screened and treated, as ap-*
17 *propriate, for maternal depression in 1 or more com-*
18 *munities; and*

19 “(2) *how a program, or programs, if expanded,*
20 *would increase access to screening and treatment serv-*
21 *ices for maternal depression.*

22 “(c) *PRIORITY.*—*In awarding grants under this sec-*
23 *tion, the Secretary may give priority to States proposing*
24 *to improve or enhance access to screening services for mater-*
25 *nal depression in primary care settings.*

1 “(d) *USE OF FUNDS.*—*The activities eligible for fund-*
2 *ing through a grant under subsection (a)—*

3 “(1) *shall include—*

4 “(A) *providing appropriate training to*
5 *health care providers; and*

6 “(B) *providing information to health care*
7 *providers, including information on maternal*
8 *depression screening, treatment, and followup*
9 *support services, and linkages to community-*
10 *based resources; and*

11 “(2) *may include—*

12 “(A) *enabling health care providers (includ-*
13 *ing obstetrician-gynecologists, pediatricians, psy-*
14 *chiatrists, mental health care providers, and*
15 *adult primary care clinicians) to provide or re-*
16 *ceive real-time psychiatric consultation (in-per-*
17 *son or remotely) to aid in the treatment of preg-*
18 *nant and parenting women;*

19 “(B) *establishing linkages with and among*
20 *community-based resources, including mental*
21 *health resources, primary care resources, and*
22 *support groups; and*

23 “(C) *utilizing telehealth services for rural*
24 *areas and medically underserved areas (as de-*
25 *fin ed in section 330I(a)).*

1 “(e) *AUTHORIZATION OF APPROPRIATIONS.—To carry*
2 *out this section, there are authorized to be appropriated*
3 *\$5,000,000 for each of fiscal years 2018 through 2022.”.*

4 **SEC. 10006. INFANT AND EARLY CHILDHOOD MENTAL**
5 **HEALTH PROMOTION, INTERVENTION, AND**
6 **TREATMENT.**

7 *Part Q of title III of the Public Health Service Act*
8 *(42 U.S.C. 280h et seq.) is amended by adding at the end*
9 *the following:*

10 **“SEC. 399Z–2. INFANT AND EARLY CHILDHOOD MENTAL**
11 **HEALTH PROMOTION, INTERVENTION, AND**
12 **TREATMENT.**

13 “(a) *GRANTS.—The Secretary shall—*

14 “(1) *award grants to eligible entities to develop,*
15 *maintain, or enhance infant and early childhood*
16 *mental health promotion, intervention, and treatment*
17 *programs, including—*

18 “(A) *programs for infants and children at*
19 *significant risk of developing, showing early*
20 *signs of, or having been diagnosed with mental*
21 *illness, including a serious emotional disturb-*
22 *ance; and*

23 “(B) *multigenerational therapy and other*
24 *services that support the caregiving relationship;*
25 *and*

1 “(2) ensure that programs funded through grants
2 under this section are evidence-informed or evidence-
3 based models, practices, and methods that are, as ap-
4 propriate, culturally and linguistically appropriate,
5 and can be replicated in other appropriate settings.

6 “(b) *ELIGIBLE CHILDREN AND ENTITIES.*—In this sec-
7 tion:

8 “(1) *ELIGIBLE CHILD.*—The term ‘eligible child’
9 means a child from birth to not more than 12 years
10 of age who—

11 “(A) is at risk for, shows early signs of, or
12 has been diagnosed with a mental illness, includ-
13 ing a serious emotional disturbance; and

14 “(B) may benefit from infant and early
15 childhood intervention or treatment programs or
16 specialized preschool or elementary school pro-
17 grams that are evidence-based or that have been
18 scientifically demonstrated to show promise but
19 would benefit from further applied development.

20 “(2) *ELIGIBLE ENTITY.*—The term ‘eligible enti-
21 ty’ means a human services agency or nonprofit insti-
22 tution that—

23 “(A) employs licensed mental health profes-
24 sionals who have specialized training and expe-
25 rience in infant and early childhood mental

1 *health assessment, diagnosis, and treatment, or*
2 *is accredited or approved by the appropriate*
3 *State agency, as applicable, to provide for chil-*
4 *dren from infancy to 12 years of age mental*
5 *health promotion, intervention, or treatment*
6 *services; and*

7 “(B) *provides services or programs de-*
8 *scribed in subsection (a) that are evidence-based*
9 *or that have been scientifically demonstrated to*
10 *show promise but would benefit from further ap-*
11 *plied development.*

12 “(c) *APPLICATION.—An eligible entity seeking a grant*
13 *under subsection (a) shall submit to the Secretary an appli-*
14 *cation at such time, in such manner, and containing such*
15 *information as the Secretary may require.*

16 “(d) *USE OF FUNDS FOR EARLY INTERVENTION AND*
17 *TREATMENT PROGRAMS.—An eligible entity may use*
18 *amounts awarded under a grant under subsection (a)(1) to*
19 *carry out the following:*

20 “(1) *Provide age-appropriate mental health pro-*
21 *motion and early intervention services or mental ill-*
22 *ness treatment services, which may include specialized*
23 *programs, for eligible children at significant risk of*
24 *developing, showing early signs of, or having been di-*
25 *agnosed with a mental illness, including a serious*

1 *emotional disturbance. Such services may include so-*
2 *cial and behavioral services as well as*
3 *multigenerational therapy and other services that*
4 *support the caregiving relationship.*

5 *“(2) Provide training for health care profes-*
6 *sionals with expertise in infant and early childhood*
7 *mental health care with respect to appropriate and*
8 *relevant integration with other disciplines such as*
9 *primary care clinicians, early intervention special-*
10 *ists, child welfare staff, home visitors, early care and*
11 *education providers, and others who work with young*
12 *children and families.*

13 *“(3) Provide mental health consultation to per-*
14 *sonnel of early care and education programs (includ-*
15 *ing licensed or regulated center-based and home-based*
16 *child care, home visiting, preschool special education,*
17 *and early intervention programs) who work with chil-*
18 *dren and families.*

19 *“(4) Provide training for mental health clini-*
20 *cians in infant and early childhood in promising and*
21 *evidence-based practices and models for infant and*
22 *early childhood mental health treatment and early*
23 *intervention, including with regard to practices for*
24 *identifying and treating mental illness and behav-*
25 *ioral disorders of infants and children resulting from*

1 *exposure or repeated exposure to adverse childhood ex-*
2 *periences or childhood trauma.*

3 *“(5) Provide age-appropriate assessment, diag-*
4 *nostic, and intervention services for eligible children,*
5 *including early mental health promotion, interven-*
6 *tion, and treatment services.*

7 *“(e) MATCHING FUNDS.—The Secretary may not*
8 *award a grant under this section to an eligible entity unless*
9 *the eligible entity agrees, with respect to the costs to be in-*
10 *curred by the eligible entity in carrying out the activities*
11 *described in subsection (d), to make available non-Federal*
12 *contributions (in cash or in kind) toward such costs in an*
13 *amount that is not less than 10 percent of the total amount*
14 *of Federal funds provided in the grant.*

15 *“(f) AUTHORIZATION OF APPROPRIATIONS.—To carry*
16 *out this section, there are authorized to be appropriated*
17 *\$20,000,000 for the period of fiscal years 2018 through*
18 *2022.”.*

19 ***TITLE XI—COMPASSIONATE***
20 ***COMMUNICATION ON HIPAA***

21 ***SEC. 11001. SENSE OF CONGRESS.***

22 *(a) FINDINGS.—Congress finds the following:*

23 *(1) According to the National Survey on Drug*
24 *Use and Health, in 2015, there were approximately*

1 9,800,000 adults in the United States with serious
2 mental illness.

3 (2) *The Substance Abuse and Mental Health*
4 *Services Administration defines the term “serious*
5 *mental illness” as an illness affecting individuals 18*
6 *years of age or older as having, at any time in the*
7 *past year, a diagnosable mental, behavioral, or emo-*
8 *tional disorder that results in serious functional im-*
9 *pairment and substantially interferes with or limits*
10 *one or more major life activities.*

11 (3) *In reporting on the incidence of serious men-*
12 *tal illness, the Substance Abuse and Mental Health*
13 *Services Administration includes major depression,*
14 *schizophrenia, bipolar disorder, and other mental dis-*
15 *orders that cause serious impairment.*

16 (4) *Adults with a serious mental illness are at*
17 *a higher risk for chronic physical illnesses and pre-*
18 *mature death.*

19 (5) *According to the World Health Organization,*
20 *adults with a serious mental illness have lifespans*
21 *that are 10 to 25 years shorter than those without se-*
22 *rious mental illness. The vast majority of these deaths*
23 *are due to chronic physical medical conditions, such*
24 *as cardiovascular, respiratory, and infectious dis-*
25 *eases, as well as diabetes and hypertension.*

1 (6) *According to the World Health Organization,*
2 *the majority of deaths of adults with a serious mental*
3 *illness that are due to physical medical conditions are*
4 *preventable.*

5 (7) *Supported decision making can facilitate*
6 *care decisions in areas where serious mental illness*
7 *may impact the capacity of an individual to deter-*
8 *mine a course of treatment while still allowing the in-*
9 *dividual to make decisions independently.*

10 (8) *Help should be provided to adults with a se-*
11 *rious mental illness to address their acute or chronic*
12 *physical illnesses, make informed choices about treat-*
13 *ment, and understand and follow through with appro-*
14 *priate treatment.*

15 (9) *There is confusion in the health care commu-*
16 *nity regarding permissible practices under the regula-*
17 *tions promulgated under the Health Insurance Port-*
18 *ability and Accountability Act of 1996 (commonly*
19 *known as “HIPAA”). This confusion may hinder ap-*
20 *propriate communication of health care information*
21 *or treatment preferences with appropriate caregivers.*

22 (b) *SENSE OF CONGRESS.—It is the sense of Congress*
23 *that clarification is needed regarding the privacy rule pro-*
24 *mulgated under section 264(c) of the Health Insurance*
25 *Portability and Accountability Act of 1996 (42 U.S.C.*

1 1320d–2 note) regarding existing permitted uses and disclo-
2 sures of health information by health care professionals to
3 communicate with caregivers of adults with a serious men-
4 tal illness to facilitate treatment.

5 **SEC. 11002. CONFIDENTIALITY OF RECORDS.**

6 Not later than 1 year after the date on which the Sec-
7 retary of Health and Human Services (in this title referred
8 to as the “Secretary”) first finalizes regulations updating
9 part 2 of title 42, Code of Federal Regulations, relating to
10 confidentiality of alcohol and drug abuse patient records,
11 after the date of enactment of this Act, the Secretary shall
12 convene relevant stakeholders to determine the effect of such
13 regulations on patient care, health outcomes, and patient
14 privacy.

15 **SEC. 11003. CLARIFICATION ON PERMITTED USES AND DIS-**
16 **CLOSURES OF PROTECTED HEALTH INFOR-**
17 **MATION.**

18 (a) *IN GENERAL.*—The Secretary, acting through the
19 Director of the Office for Civil Rights, shall ensure that
20 health care providers, professionals, patients and their fam-
21 ilies, and others involved in mental or substance use dis-
22 order treatment have adequate, accessible, and easily com-
23 prehensible resources relating to appropriate uses and dis-
24 closures of protected health information under the regula-
25 tions promulgated under section 264(c) of the Health Insur-

1 *ance Portability and Accountability Act of 1996 (42 U.S.C.*
2 *1320d–2 note).*

3 *(b) GUIDANCE.—*

4 *(1) ISSUANCE.—In carrying out subsection (a),*
5 *not later than 1 year after the date of enactment of*
6 *this section, the Secretary shall issue guidance clari-*
7 *fying the circumstances under which, consistent with*
8 *regulations promulgated under section 264(c) of the*
9 *Health Insurance Portability and Accountability Act*
10 *of 1996, a health care provider or covered entity may*
11 *use or disclose protected health information.*

12 *(2) CIRCUMSTANCES ADDRESSED.—The guidance*
13 *issued under this section shall address circumstances*
14 *including those that—*

15 *(A) require the consent of the patient;*

16 *(B) require providing the patient with an*
17 *opportunity to object;*

18 *(C) are based on the exercise of professional*
19 *judgment regarding whether the patient would*
20 *object when the opportunity to object cannot*
21 *practicably be provided because of the incapacity*
22 *of the patient or an emergency treatment cir-*
23 *cumstance; and*

24 *(D) are determined, based on the exercise of*
25 *professional judgment, to be in the best interest*

1 *of the patient when the patient is not present or*
2 *otherwise incapacitated.*

3 (3) *COMMUNICATION WITH FAMILY MEMBERS*
4 *AND CAREGIVERS.—In addressing the circumstances*
5 *described in paragraph (2), the guidance issued under*
6 *this section shall clarify permitted uses or disclosures*
7 *of protected health information for purposes of—*

8 (A) *communicating with a family member*
9 *of the patient, caregiver of the patient, or other*
10 *individual, to the extent that such family mem-*
11 *ber, caregiver, or individual is involved in the*
12 *care of the patient;*

13 (B) *in the case that the patient is an adult,*
14 *communicating with a family member of the pa-*
15 *tient, caregiver of the patient, or other indi-*
16 *vidual involved in the care of the patient;*

17 (C) *in the case that the patient is a minor,*
18 *communicating with the parent or caregiver of*
19 *the patient;*

20 (D) *involving the family members or care-*
21 *givers of the patient, or others involved in the*
22 *patient's care or care plan, including facilitating*
23 *treatment and medication adherence;*

1 (E) listening to the patient, or receiving in-
2 formation with respect to the patient from the
3 family or caregiver of the patient;

4 (F) communicating with family members of
5 the patient, caregivers of the patient, law en-
6 forcement, or others when the patient presents a
7 serious and imminent threat of harm to self or
8 others; and

9 (G) communicating to law enforcement and
10 family members or caregivers of the patient
11 about the admission of the patient to receive care
12 at, or the release of a patient from, a facility for
13 an emergency psychiatric hold or involuntary
14 treatment.

15 **SEC. 11004. DEVELOPMENT AND DISSEMINATION OF MODEL**
16 **TRAINING PROGRAMS.**

17 (a) *INITIAL PROGRAMS AND MATERIALS.*—Not later
18 than 1 year after the date of the enactment of this Act, the
19 Secretary, in consultation with appropriate experts, shall
20 identify the following model programs and materials, or (in
21 the case that no such programs or materials exist) recognize
22 private or public entities to develop and disseminate each
23 of the following:

24 (1) Model programs and materials for training
25 health care providers (including physicians, emer-

1 *gency medical personnel, psychiatrists, including*
2 *child and adolescent psychiatrists, psychologists,*
3 *counselors, therapists, nurse practitioners, physician*
4 *assistants, behavioral health facilities and clinics,*
5 *care managers, and hospitals, including individuals*
6 *such as general counsels or regulatory compliance*
7 *staff who are responsible for establishing provider pri-*
8 *vacy policies) regarding the permitted uses and dis-*
9 *closures, consistent with the standards governing the*
10 *privacy and security of individually identifiable*
11 *health information promulgated by the Secretary*
12 *under part C of title XI of the Social Security Act*
13 *(42 U.S.C. 1320d et seq.) and regulations promul-*
14 *gated under section 264(c) of the Health Insurance*
15 *Portability and Accountability Act of 1996 (42*
16 *U.S.C. 1320d–2 note) and such part C, of the pro-*
17 *TECTED health information of patients seeking or un-*
18 *dergoing mental or substance use disorder treatment.*

19 *(2) A model program and materials for training*
20 *patients and their families regarding their rights to*
21 *protect and obtain information under the standards*
22 *and regulations specified in paragraph (1).*

23 *(b) PERIODIC UPDATES.—The Secretary shall—*

1 (1) *periodically review and update the model*
2 *programs and materials identified or developed under*
3 *subsection (a); and*

4 (2) *disseminate the updated model programs and*
5 *materials to the individuals described in subsection*
6 *(a).*

7 (c) *COORDINATION.*—*The Secretary shall carry out*
8 *this section in coordination with the Director of the Office*
9 *for Civil Rights within the Department of Health and*
10 *Human Services, the Assistant Secretary for Mental Health*
11 *and Substance Use, the Administrator of the Health Re-*
12 *sources and Services Administration, and the heads of other*
13 *relevant agencies within the Department of Health and*
14 *Human Services.*

15 (d) *INPUT OF CERTAIN ENTITIES.*—*In identifying, re-*
16 *viewing, or updating the model programs and materials*
17 *under subsections (a) and (b), the Secretary shall solicit the*
18 *input of relevant national, State, and local associations;*
19 *medical societies; licensing boards; providers of mental and*
20 *substance use disorder treatment; organizations with exper-*
21 *tise on domestic violence, sexual assault, elder abuse, and*
22 *child abuse; and organizations representing patients and*
23 *consumers and the families of patients and consumers.*

24 (e) *FUNDING.*—*There are authorized to be appro-*
25 *priated to carry out this section—*

- 1 (1) \$4,000,000 for fiscal year 2018;
2 (2) \$2,000,000 for each of fiscal years 2019 and
3 2020; and
4 (3) \$1,000,000 for each of fiscal years 2021 and
5 2022.

6 **TITLE XII—MEDICAID MENTAL**
7 **HEALTH COVERAGE**

8 **SEC. 12001. RULE OF CONSTRUCTION RELATED TO MED-**
9 **ICAID COVERAGE OF MENTAL HEALTH SERV-**
10 **ICES AND PRIMARY CARE SERVICES FUR-**
11 **NISHED ON THE SAME DAY.**

12 *Nothing in title XIX of the Social Security Act (42*
13 *U.S.C. 1396 et seq.) shall be construed as prohibiting sepa-*
14 *rate payment under the State plan under such title (or*
15 *under a waiver of the plan) for the provision of a mental*
16 *health service or primary care service under such plan, with*
17 *respect to an individual, because such service is—*

18 (1) *a primary care service furnished to the indi-*
19 *vidual by a provider at a facility on the same day*
20 *a mental health service is furnished to such indi-*
21 *vidual by such provider (or another provider) at the*
22 *facility; or*

23 (2) *a mental health service furnished to the indi-*
24 *vidual by a provider at a facility on the same day*

1 (2) *The number of individuals receiving medical*
2 *assistance under a State plan under such title XIX,*
3 *or a waiver of such plan, who receive services in in-*
4 *stitutions for mental diseases through such organiza-*
5 *tions and plans.*

6 (3) *The range of and average number of months,*
7 *and the length of stay during such months, that such*
8 *individuals are receiving such services in such insti-*
9 *tutions.*

10 (4) *How such organizations or plans determine*
11 *when to provide for the furnishing of such services*
12 *through an institution for mental diseases in lieu of*
13 *other benefits (including the full range of community-*
14 *based services) under their contract with the State*
15 *agency administering the State plan under such title*
16 *XIX, or a waiver of such plan, to address psychiatric*
17 *or substance use disorder treatment.*

18 (5) *The extent to which the provision of services*
19 *within such institutions has affected the capitated*
20 *payments for such organizations or plans.*

21 (b) *REPORT.*—*Not later than 3 years after the date*
22 *of the enactment of this Act, the Secretary shall submit to*
23 *Congress a report on the study conducted under subsection*
24 *(a).*

1 **SEC. 12003. GUIDANCE ON OPPORTUNITIES FOR INNOVA-**
2 **TION.**

3 *Not later than 1 year after the date of the enactment*
4 *of this Act, the Administrator of the Centers for Medicare*
5 *& Medicaid Services shall issue a State Medicaid Director*
6 *letter regarding opportunities to design innovative service*
7 *delivery systems, including systems for providing commu-*
8 *nity-based services, for adults with a serious mental illness*
9 *or children with a serious emotional disturbance who are*
10 *receiving medical assistance under title XIX of the Social*
11 *Security Act (42 U.S.C. 1396 et seq.). The letter shall in-*
12 *clude opportunities for demonstration projects under section*
13 *1115 of such Act (42 U.S.C. 1315) to improve care for such*
14 *adults and children.*

15 **SEC. 12004. STUDY AND REPORT ON MEDICAID EMERGENCY**
16 **PSYCHIATRIC DEMONSTRATION PROJECT.**

17 (a) *COLLECTION OF INFORMATION.—The Secretary of*
18 *Health and Human Services, acting through the Adminis-*
19 *trator of the Centers for Medicare & Medicaid Services,*
20 *shall, to the extent practical and data is available, with*
21 *respect to each State that has participated in the dem-*
22 *onstration project established under section 2707 of the Pa-*
23 *tient Protection and Affordable Care Act (42 U.S.C. 1396a*
24 *note), collect from each such State information on the fol-*
25 *lowing:*

1 (1) *The number of institutions for mental dis-*
2 *eases (as defined in section 1905(i) of the Social Secu-*
3 *rity Act (42 U.S.C. 1396d(i))) and beds in such insti-*
4 *tutions that received payment for the provision of*
5 *services to individuals who receive medical assistance*
6 *under a State plan under the Medicaid program*
7 *under title XIX of the Social Security Act (42 U.S.C.*
8 *1396 et seq.) (or under a waiver of such plan)*
9 *through the demonstration project in each such State*
10 *as compared to the total number of institutions for*
11 *mental diseases and beds in the State.*

12 (2) *The extent to which there is a reduction in*
13 *expenditures under the Medicaid program under title*
14 *XIX of the Social Security Act (42 U.S.C. 1396 et*
15 *seq.) or other spending on the full continuum of phys-*
16 *ical or mental health care for individuals who receive*
17 *treatment in an institution for mental diseases under*
18 *the demonstration project, including outpatient, inpa-*
19 *tient, emergency, and ambulatory care, that is attrib-*
20 *utable to such individuals receiving treatment in in-*
21 *stitutions for mental diseases under the demonstration*
22 *project.*

23 (3) *The number of forensic psychiatric hospitals,*
24 *the number of beds in such hospitals, and the number*
25 *of forensic psychiatric beds in other hospitals in such*

1 *State, based on the most recent data available, to the*
2 *extent practical, as determined by such Adminis-*
3 *trator.*

4 (4) *The amount of any disproportionate share*
5 *hospital payments under section 1923 of the Social*
6 *Security Act (42 U.S.C. 1396r-4) that institutions*
7 *for mental diseases in the State received during the*
8 *period beginning on July 1, 2012, and ending on*
9 *June 30, 2015, and the extent to which the dem-*
10 *onstration project reduced the amount of such pay-*
11 *ments.*

12 (5) *The most recent data regarding all facilities*
13 *or sites in the State in which any adults with a seri-*
14 *ous mental illness who are receiving medical assist-*
15 *ance under a State plan under the Medicaid program*
16 *under title XIX of the Social Security Act (42 U.S.C.*
17 *1396 et seq.) (or under a waiver of such plan) are*
18 *treated during the period referred to in paragraph*
19 *(4), to the extent practical, as determined by the Ad-*
20 *ministrator, including—*

21 (A) *the types of such facilities or sites (such*
22 *as an institution for mental diseases, a hospital*
23 *emergency department, or other inpatient hos-*
24 *pital);*

1 (B) the average length of stay in such a fa-
2 cility or site by such an individual,
3 disaggregated by facility type; and

4 (C) the payment rate under the State plan
5 (or a waivers of such plan) for services furnished
6 to such an individual for that treatment,
7 disaggregated by facility type, during the period
8 in which the demonstration project is in oper-
9 ation.

10 (6) The extent to which the utilization of hos-
11 pital emergency departments during the period in
12 which the demonstration project was is in operation
13 differed, with respect to individuals who are receiving
14 medical assistance under a State plan under the Med-
15 icaid program under title XIX of the Social Security
16 Act (42 U.S.C. 1396 et seq.) (or under a waiver of
17 such plan), between—

18 (A) those individuals who received treat-
19 ment in an institution for mental diseases under
20 the demonstration project;

21 (B) those individuals who met the eligibility
22 requirements for the demonstration project but
23 who did not receive treatment in an institution
24 for mental diseases under the demonstration
25 project; and

1 (C) those adults with a serious mental ill-
2 ness who did not meet such eligibility require-
3 ments and did not receive treatment for such ill-
4 ness in an institution for mental diseases.

5 (b) *REPORT.*—Not later than 2 years after the date
6 of the enactment of this Act, the Secretary of Health and
7 Human Services shall submit to Congress a report that
8 summarizes and analyzes the information collected under
9 subsection (a). Such report may be submitted as part of
10 the report required under section 2707(f) of the Patient Pro-
11 tection and Affordable Care Act (42 U.S.C. 1396a note) or
12 separately.

13 **SEC. 12005. PROVIDING EPSDT SERVICES TO CHILDREN IN**
14 **IMDS.**

15 (a) *IN GENERAL.*—Section 1905(a)(16) of the Social
16 Security Act (42 U.S.C. 1396d(a)(16)) is amended—

17 (1) by striking “effective January 1, 1973” and
18 inserting “(A) effective January 1, 1973”; and

19 (2) by inserting before the semicolon at the end
20 the following: “, and, (B) for individuals receiving
21 services described in subparagraph (A), early and
22 periodic screening, diagnostic, and treatment services
23 (as defined in subsection (r)), whether or not such
24 screening, diagnostic, and treatment services are fur-

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 pro-
22 vide personal care services, home health care services,
23 or both under the State plan (or under a waiver of
24 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 that
9 includes input from beneficiaries, family caregivers,
10 individuals who furnish personal care services or
11 home health care services, and other stakeholders, as
12 determined by the State in accordance with guidance
13 from the Secretary; and

14 “(C) ensure that individuals who furnish per-
15 sonal care services, home health care services, or both
16 under the State plan (or under a waiver of the plan)
17 are provided the opportunity for training on the use
18 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 this
21 subsection, requires the use of any system for the electronic
22 verification of visits conducted as part of both personal care
23 services and home health care services, so long as the State
24 continues to require the use of such system with respect to
25 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 cal-*
5 *endar quarters in 2019; and*

6 “(ii) *in the case of home health care services, for*
7 *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 with*
12 *the requirements of paragraphs (1) and (2) (includ-*
13 *ing by taking steps to adopt the technology used for*
14 *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 visits*
21 *conducted as part of such services are electronically*
22 *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’ means
6 services described in section 1905(a)(7) provided
7 under a State plan under this title (or under a waiv-
8 er 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(c), 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 utilize
17 an electronic visit verification system operated by the State
18 or a contractor on behalf of the State, the Secretary shall
19 pay to the State, for each quarter, an amount equal to 90
20 per centum of so much of the sums expended during such
21 quarter as are attributable to the design, development, or
22 installation of such system, and 75 per centum of so much
23 of the sums for the operation and maintenance of such sys-
24 tem.

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 a
5 contractor on behalf of the State.”.

6 (b) *COLLECTION AND DISSEMINATION OF BEST PRAC-*
7 *TICES.*—Not later than January 1, 2018, the Secretary of
8 *Health and Human Services shall, with respect to electronic*
9 *visit verification systems (as defined in subsection (l)(5) of*
10 *section 1903 of the Social Security Act (42 U.S.C. 1396b),*
11 *as inserted by subsection (a)), collect and disseminate best*
12 *practices to State Medicaid Directors with respect to—*

13 (1) *training individuals who furnish personal*
14 *care services, home health care services, or both under*
15 *the State plan under title XIX of such Act (or under*
16 *a waiver of the plan) on such systems and the oper-*
17 *ation of such systems and the prevention of fraud*
18 *with respect to the provision of personal care services*
19 *or home health care services (as defined in such sub-*
20 *section (l)(5)); and*

21 (2) *the provision of notice and educational mate-*
22 *rials to family caregivers and beneficiaries with re-*
23 *spect to the use of such electronic visit verification*
24 *systems and other means to prevent such fraud.*

25 (c) *RULES OF CONSTRUCTION.*—

1 (1) *NO EMPLOYER-EMPLOYEE RELATIONSHIP ES-*
2 *TABLISHED.—Nothing in the amendment made by*
3 *this section may be construed as establishing an em-*
4 *ployer-employee relationship between the agency or*
5 *entity that provides for personal care services or home*
6 *health care services and the individuals who, under a*
7 *contract with such an agency or entity, furnish such*
8 *services for purposes of part 552 of title 29, Code of*
9 *Federal Regulations (or any successor regulations).*

10 (2) *NO PARTICULAR OR UNIFORM ELECTRONIC*
11 *VISIT VERIFICATION SYSTEM REQUIRED.—Nothing in*
12 *the amendment made by this section shall be con-*
13 *strued to require the use of a particular or uniform*
14 *electronic visit verification system (as defined in sub-*
15 *section (l)(5) of section 1903 of the Social Security*
16 *Act (42 U.S.C. 1396b), as inserted by subsection (a))*
17 *by all agencies or entities that provide personal care*
18 *services or home health care under a State plan under*
19 *title XIX of the Social Security Act (or under a waiv-*
20 *er of the plan) (42 U.S.C. 1396 et seq.).*

21 (3) *NO LIMITS ON PROVISION OF CARE.—Nothing*
22 *in the amendment made by this section may be con-*
23 *strued to limit, with respect to personal care services*
24 *or home health care services provided under a State*
25 *plan under title XIX of the Social Security Act (or*

1 “(A) *IN GENERAL.*—Not later than 12
2 months after the date of enactment of the *Help-*
3 *ing Families in Mental Health Crisis Reform*
4 *Act of 2016*, the Secretary, the Secretary of
5 Labor, and the Secretary of the Treasury, in
6 consultation with the Inspector General of the
7 Department of Health and Human Services, the
8 Inspector General of the Department of Labor,
9 and the Inspector General of the Department of
10 the Treasury, shall issue a compliance program
11 guidance document to help improve compliance
12 with this section, section 712 of the *Employee*
13 *Retirement Income Security Act of 1974*, and
14 section 9812 of the *Internal Revenue Code of*
15 1986, as applicable. In carrying out this para-
16 graph, the Secretaries may take into consider-
17 ation the 2016 publication of the Department of
18 Health and Human Services and the Depart-
19 ment of Labor, entitled ‘Warning Signs - Plan
20 or Policy Non-Quantitative Treatment Limita-
21 tions (NQTLs) that Require Additional Analysis
22 to Determine Mental Health Parity Compliance’.

23 “(B) *EXAMPLES ILLUSTRATING COMPLIANCE*
24 *AND NONCOMPLIANCE.*—

1 “(i) *IN GENERAL.*—*The compliance*
2 *program guidance document required under*
3 *this paragraph shall provide illustrative,*
4 *de-identified examples (that do not disclose*
5 *any protected health information or indi-*
6 *vidually identifiable information) of pre-*
7 *vious findings of compliance and non-*
8 *compliance with this section, section 712 of*
9 *the Employee Retirement Income Security*
10 *Act of 1974, or section 9812 of the Internal*
11 *Revenue Code of 1986, as applicable, based*
12 *on investigations of violations of such sec-*
13 *tions, including—*

14 “(I) *examples illustrating require-*
15 *ments for information disclosures and*
16 *nonquantitative treatment limitations;*
17 *and*

18 “(II) *descriptions of the violations*
19 *uncovered during the course of such in-*
20 *vestigations.*

21 “(ii) *NONQUANTITATIVE TREATMENT*
22 *LIMITATIONS.*—*To the extent that any ex-*
23 *ample described in clause (i) involves a*
24 *finding of compliance or noncompliance*
25 *with regard to any requirement for non-*

1 *quantitative treatment limitations, the ex-*
2 *ample shall provide sufficient detail to fully*
3 *explain such finding, including a full de-*
4 *scription of the criteria involved for approv-*
5 *ing medical and surgical benefits and the*
6 *criteria involved for approving mental*
7 *health and substance use disorder benefits.*

8 “(iii) *ACCESS TO ADDITIONAL INFOR-*
9 *MATION REGARDING COMPLIANCE.—In de-*
10 *veloping and issuing the compliance pro-*
11 *gram guidance document required under*
12 *this paragraph, the Secretaries specified in*
13 *subparagraph (A)—*

14 “(I) *shall enter into interagency*
15 *agreements with the Inspector General*
16 *of the Department of Health and*
17 *Human Services, the Inspector General*
18 *of the Department of Labor, and the*
19 *Inspector General of the Department of*
20 *the Treasury to share findings of com-*
21 *pliance and noncompliance with this*
22 *section, section 712 of the Employee*
23 *Retirement Income Security Act of*
24 *1974, or section 9812 of the Internal*

1 *Revenue Code of 1986, as applicable;*
2 *and*

3 *“(II) shall seek to enter into an*
4 *agreement with a State to share infor-*
5 *mation on findings of compliance and*
6 *noncompliance with this section, sec-*
7 *tion 712 of the Employee Retirement*
8 *Income Security Act of 1974, or section*
9 *9812 of the Internal Revenue Code of*
10 *1986, as applicable.*

11 *“(C) RECOMMENDATIONS.—The compliance*
12 *program guidance document shall include rec-*
13 *ommendations to advance compliance with this*
14 *section, section 712 of the Employee Retirement*
15 *Income Security Act of 1974, or section 9812 of*
16 *the Internal Revenue Code of 1986, as applica-*
17 *ble, and encourage the development and use of*
18 *internal controls to monitor adherence to appli-*
19 *cable statutes, regulations, and program require-*
20 *ments. Such internal controls may include illus-*
21 *trative examples of nonquantitative treatment*
22 *limitations on mental health and substance use*
23 *disorder benefits, which may fail to comply with*
24 *this section, section 712 of the Employee Retire-*
25 *ment Income Security Act of 1974, or section*

1 9812 of the Internal Revenue Code of 1986, as
2 applicable, in relation to nonquantitative treat-
3 ment limitations on medical and surgical bene-
4 fits.

5 “(D) *UPDATING THE COMPLIANCE PROGRAM*
6 *GUIDANCE DOCUMENT.*—The Secretary, the Sec-
7 retary of Labor, and the Secretary of the Treas-
8 ury, in consultation with the Inspector General
9 of the Department of Health and Human Serv-
10 ices, the Inspector General of the Department of
11 Labor, and the Inspector General of the Depart-
12 ment of the Treasury, shall update the compli-
13 ance program guidance document every 2 years
14 to include illustrative, de-identified examples
15 (that do not disclose any protected health infor-
16 mation or individually identifiable information)
17 of previous findings of compliance and non-
18 compliance with this section, section 712 of the
19 Employee Retirement Income Security Act of
20 1974, or section 9812 of the Internal Revenue
21 Code of 1986, as applicable.”.

22 (b) *ADDITIONAL GUIDANCE.*—Section 2726(a) of the
23 Public Health Service Act (42 U.S.C. 300gg–26(a)), as
24 amended by subsection (a), is further amended by adding
25 at the end the following:

1 “(7) *ADDITIONAL GUIDANCE.*—

2 “(A) *IN GENERAL.*—*Not later than 12*
3 *months after the date of enactment of the Help-*
4 *ing Families in Mental Health Crisis Reform*
5 *Act of 2016, the Secretary, the Secretary of*
6 *Labor, and the Secretary of the Treasury shall*
7 *issue guidance to group health plans and health*
8 *insurance issuers offering group or individual*
9 *health insurance coverage to assist such plans*
10 *and issuers in satisfying the requirements of this*
11 *section, section 712 of the Employee Retirement*
12 *Income Security Act of 1974, or section 9812 of*
13 *the Internal Revenue Code of 1986, as applica-*
14 *ble.*

15 “(B) *DISCLOSURE.*—

16 “(i) *GUIDANCE FOR PLANS AND*
17 *ISSUERS.*—*The guidance issued under this*
18 *paragraph shall include clarifying informa-*
19 *tion and illustrative examples of methods*
20 *that group health plans and health insur-*
21 *ance issuers offering group or individual*
22 *health insurance coverage may use for dis-*
23 *closing information to ensure compliance*
24 *with the requirements under this section,*
25 *section 712 of the Employee Retirement In-*

1 *come Security Act of 1974, or section 9812*
2 *of the Internal Revenue Code of 1986, as*
3 *applicable, (and any regulations promul-*
4 *gated pursuant to such sections, as applica-*
5 *ble).*

6 “(ii) *DOCUMENTS FOR PARTICIPANTS,*
7 *BENEFICIARIES, CONTRACTING PROVIDERS,*
8 *OR AUTHORIZED REPRESENTATIVES.—The*
9 *guidance issued under this paragraph shall*
10 *include clarifying information and illus-*
11 *trative examples of methods that group*
12 *health plans and health insurance issuers*
13 *offering group or individual health insur-*
14 *ance coverage may use to provide any par-*
15 *ticipant, beneficiary, contracting provider,*
16 *or authorized representative, as applicable,*
17 *with documents containing information*
18 *that the health plans or issuers are required*
19 *to disclose to participants, beneficiaries,*
20 *contracting providers, or authorized rep-*
21 *resentatives to ensure compliance with this*
22 *section, section 712 of the Employee Retire-*
23 *ment Income Security Act of 1974, or sec-*
24 *tion 9812 of the Internal Revenue Code of*
25 *1986, as applicable, compliance with any*

1 regulation issued pursuant to such respec-
2 tive section, or compliance with any other
3 applicable law or regulation. Such guidance
4 shall include information that is compara-
5 tive in nature with respect to—

6 “(I) nonquantitative treatment
7 limitations for both medical and sur-
8 gical benefits and mental health and
9 substance use disorder benefits;

10 “(II) the processes, strategies, evi-
11 dentiary standards, and other factors
12 used to apply the limitations described
13 in subclause (I); and

14 “(III) the application of the limi-
15 tations described in subclause (I) to en-
16 sure that such limitations are applied
17 in parity with respect to both medical
18 and surgical benefits and mental
19 health and substance use disorder bene-
20 fits.

21 “(C) NONQUANTITATIVE TREATMENT LIM-
22 TATIONS.—The guidance issued under this para-
23 graph shall include clarifying information and
24 illustrative examples of methods, processes, strat-
25 egies, evidentiary standards, and other factors

1 that group health plans and health insurance
2 issuers offering group or individual health insur-
3 ance coverage may use regarding the develop-
4 ment and application of nonquantitative treat-
5 ment limitations to ensure compliance with this
6 section, section 712 of the Employee Retirement
7 Income Security Act of 1974, or section 9812 of
8 the Internal Revenue Code of 1986, as applica-
9 ble, (and any regulations promulgated pursuant
10 to such respective section), including—

11 “(i) examples of methods of deter-
12 mining appropriate types of nonquantita-
13 tive treatment limitations with respect to
14 both medical and surgical benefits and men-
15 tal health and substance use disorder bene-
16 fits, including nonquantitative treatment
17 limitations pertaining to—

18 “(I) medical management stand-
19 ards based on medical necessity or ap-
20 propriateness, or whether a treatment
21 is experimental or investigative;

22 “(II) limitations with respect to
23 prescription drug formulary design;
24 and

1 “(III) use of fail-first or step ther-
2 apy protocols;

3 “(ii) examples of methods of deter-
4 mining—

5 “(I) network admission standards
6 (such as credentialing); and

7 “(II) factors used in provider re-
8 imbursement methodologies (such as
9 service type, geographic market, de-
10 mand for services, and provider sup-
11 ply, practice size, training, experience,
12 and licensure) as such factors apply to
13 network adequacy;

14 “(iii) examples of sources of informa-
15 tion that may serve as evidentiary stand-
16 ards for the purposes of making determina-
17 tions regarding the development and appli-
18 cation of nonquantitative treatment limita-
19 tions;

20 “(iv) examples of specific factors, and
21 the evidentiary standards used to evaluate
22 such factors, used by such plans or issuers
23 in performing a nonquantitative treatment
24 limitation analysis;

1 “(v) examples of how specific evi-
2 dentiary standards may be used to deter-
3 mine whether treatments are considered ex-
4 perimental or investigative;

5 “(vi) examples of how specific evi-
6 dentiary standards may be applied to each
7 service category or classification of benefits;

8 “(vii) examples of methods of reaching
9 appropriate coverage determinations for
10 new mental health or substance use disorder
11 treatments, such as evidence-based early
12 intervention programs for individuals with
13 a serious mental illness and types of med-
14 ical management techniques;

15 “(viii) examples of methods of reaching
16 appropriate coverage determinations for
17 which there is an indirect relationship be-
18 tween the covered mental health or sub-
19 stance use disorder benefit and a traditional
20 covered medical and surgical benefit, such
21 as residential treatment or hospitalizations
22 involving voluntary or involuntary commit-
23 ment; and

24 “(ix) additional illustrative examples
25 of methods, processes, strategies, evidentiary

1 standards, and other factors for which the
2 Secretary determines that additional guid-
3 ance is necessary to improve compliance
4 with this section, section 712 of the Em-
5 ployee Retirement Income Security Act of
6 1974, or section 9812 of the Internal Rev-
7 enue Code of 1986, as applicable.

8 “(D) *PUBLIC COMMENT.*—Prior to issuing
9 any final guidance under this paragraph, the
10 Secretary shall provide a public comment period
11 of not less than 60 days during which any mem-
12 ber of the public may provide comments on a
13 draft of the guidance.”.

14 (c) *AVAILABILITY OF PLAN INFORMATION.*—

15 (1) *SOLICITATION OF PUBLIC FEEDBACK.*—Not
16 later than 6 months after the date of enactment of this
17 Act, the Secretary of Health and Human Services, the
18 Secretary of Labor, and the Secretary of the Treasury
19 shall solicit feedback from the public on how the dis-
20 closure request process for documents containing in-
21 formation that health plans or health insurance
22 issuers are required under Federal or State law to
23 disclose to participants, beneficiaries, contracting pro-
24 viders, or authorized representatives to ensure compli-
25 ance with existing mental health parity and addic-

1 *tion equity requirements can be improved while con-*
2 *tinuing to ensure consumers' rights to access all infor-*
3 *mation required by Federal or State law to be dis-*
4 *closed.*

5 (2) *PUBLIC AVAILABILITY.*—*Not later than 12*
6 *months after the date of the enactment of this Act, the*
7 *Secretary of Health and Human Services, the Sec-*
8 *retary of Labor, and the Secretary of the Treasury*
9 *shall make such feedback publicly available.*

10 (3) *NAIC.*—*The Secretary of Health and*
11 *Human Services, the Secretary of Labor, and the Sec-*
12 *retary of the Treasury shall share feedback obtained*
13 *pursuant to paragraph (1) directly with the National*
14 *Association of Insurance Commissioners to the extent*
15 *such feedback includes recommendations for the devel-*
16 *opment of simplified information disclosure tools to*
17 *provide consistent information for consumers. Such*
18 *feedback may be taken into consideration by the Na-*
19 *tional Association of Insurance Commissioners and*
20 *other appropriate entities for the voluntary develop-*
21 *ment and voluntary use of common templates and*
22 *other sample standardized forms to improve consumer*
23 *access to plan information.*

24 (d) *IMPROVING COMPLIANCE.*—

1 (1) *IN GENERAL.*—*In the case that the Secretary*
2 *of Health and Human Services, the Secretary of*
3 *Labor, or the Secretary of the Treasury determines*
4 *that a group health plan or health insurance issuer*
5 *offering group or individual health insurance cov-*
6 *erage has violated, at least 5 times, section 2726 of*
7 *the Public Health Service Act (42 U.S.C. 300gg–26),*
8 *section 712 of the Employee Retirement Income Secu-*
9 *rity Act of 1974 (29 U.S.C. 1185a), or section 9812*
10 *of the Internal Revenue Code of 1986, respectively, the*
11 *appropriate Secretary shall audit plan documents for*
12 *such health plan or issuer in the plan year following*
13 *the Secretary’s determination in order to help im-*
14 *prove compliance with such section.*

15 (2) *RULE OF CONSTRUCTION.*—*Nothing in this*
16 *subsection shall be construed to limit the authority, as*
17 *in effect on the day before the date of enactment of*
18 *this Act, of the Secretary of Health and Human Serv-*
19 *ices, the Secretary of Labor, or the Secretary of the*
20 *Treasury to audit documents of health plans or health*
21 *insurance issuers.*

22 **SEC. 13002. ACTION PLAN FOR ENHANCED ENFORCEMENT**
23 **OF MENTAL HEALTH AND SUBSTANCE USE**
24 **DISORDER COVERAGE.**

25 (a) *PUBLIC MEETING.*—

1 (1) *IN GENERAL.*—Not later than 6 months after
2 the date of enactment of this Act, the Secretary of
3 Health and Human Services shall convene a public
4 meeting of stakeholders described in paragraph (2) to
5 produce an action plan for improved Federal and
6 State coordination related to the enforcement of sec-
7 tion 2726 of the Public Health Service Act (42 U.S.C.
8 300gg–26), section 712 of the Employee Retirement
9 Income Security Act of 1974 (29 U.S.C. 1185a), and
10 section 9812 of the Internal Revenue Code of 1986,
11 and any comparable provisions of State law (in this
12 section such sections and provisions are collectively
13 referred to as “mental health parity and addiction eq-
14 uity requirements”).

15 (2) *STAKEHOLDERS.*—The stakeholders described
16 in this paragraph shall include each of the following:

17 (A) *The Federal Government, including rep-*
18 *resentatives from—*

19 (i) *the Department of Health and*
20 *Human Services;*

21 (ii) *the Department of the Treasury;*

22 (iii) *the Department of Labor; and*

23 (iv) *the Department of Justice.*

24 (B) *State governments, including—*

1 (i) *State health insurance commis-*
2 *sioners;*

3 (ii) *appropriate State agencies, includ-*
4 *ing agencies on public health or mental*
5 *health; and*

6 (iii) *State attorneys general or other*
7 *representatives of State entities involved in*
8 *the enforcement of mental health parity and*
9 *addiction equity requirements.*

10 (C) *Representatives from key stakeholder*
11 *groups, including—*

12 (i) *the National Association of Insur-*
13 *ance Commissioners;*

14 (ii) *health insurance issuers;*

15 (iii) *providers of mental health and*
16 *substance use disorder treatment;*

17 (iv) *employers; and*

18 (v) *patients or their advocates.*

19 (b) *ACTION PLAN.—Not later than 6 months after the*
20 *conclusion of the public meeting under subsection (a), the*
21 *Secretary of Health and Human Services shall finalize the*
22 *action plan described in such subsection and make it plain-*
23 *ly available on the Internet website of the Department of*
24 *Health and Human Services.*

1 (c) *CONTENT.*—*The action plan under this section*
2 *shall—*

3 (1) *take into consideration the recommendations*
4 *of the Mental Health and Substance Use Disorder*
5 *Parity Task Force in its final report issued in Octo-*
6 *ber of 2016, and any subsequent Federal and State*
7 *actions in relation to such recommendations;*

8 (2) *reflect the input of the stakeholders partici-*
9 *pating in the public meeting under subsection (a);*

10 (3) *identify specific strategic objectives regarding*
11 *how the various Federal and State agencies charged*
12 *with enforcement of mental health parity and addic-*
13 *tion equity requirements will collaborate to improve*
14 *enforcement of such requirements;*

15 (4) *provide a timeline for implementing the ac-*
16 *tion plan; and*

17 (5) *provide specific examples of how such objec-*
18 *tives may be met, which may include—*

19 (A) *providing common educational infor-*
20 *mation and documents, such as the Consumer*
21 *Guide to Disclosure Rights, to patients about*
22 *their rights under mental health parity and ad-*
23 *dition equity requirements;*

24 (B) *facilitating the centralized collection of,*
25 *monitoring of, and response to patient com-*

1 *plaints or inquiries relating to mental health*
2 *parity and addiction equity requirements, which*
3 *may be through the development and adminis-*
4 *tration of—*

5 *(i) a single, toll-free telephone number;*

6 *and*

7 *(ii) a new parity website—*

8 *(I) to help consumers find the ap-*
9 *propriate Federal or State agency to*
10 *assist with their parity complaints,*
11 *appeals, and other actions; and*

12 *(II) that takes into consideration,*
13 *but is not duplicative of, the parity*
14 *beta site being tested, and released for*
15 *public comment, by the Department of*
16 *Health and Human Services as of the*
17 *date of the enactment of this Act;*

18 *(C) Federal and State law enforcement*
19 *agencies entering into memoranda of under-*
20 *standing to better coordinate enforcement respon-*
21 *sibilities and information sharing—*

22 *(i) including whether such agencies*
23 *should make the results of enforcement ac-*
24 *tions related to mental health parity and*

1 *addiction equity requirements publicly*
2 *available; and*

3 *(ii) which may include State Policy*
4 *Academies on Parity Implementation for*
5 *State Officials and other forums to bring to-*
6 *gether national experts to provide technical*
7 *assistance to teams of State officials on*
8 *strategies to advance compliance with men-*
9 *tal health parity and addiction equity re-*
10 *quirements in both the commercial market,*
11 *and in the Medicaid program under title*
12 *XIX of the Social Security Act and the*
13 *State Children’s Health Insurance Program*
14 *under title XXI of such Act; and*

15 *(D) recommendations to the Congress re-*
16 *garding the need for additional legal authority*
17 *to improve enforcement of mental health parity*
18 *and addiction equity requirements, including the*
19 *need for additional legal authority to ensure that*
20 *nonquantitative treatment limitations are ap-*
21 *plied, and the extent and frequency of the appli-*
22 *cations of such limitations, both to medical and*
23 *surgical benefits and to mental health and sub-*
24 *stance use disorder benefits in a comparable*
25 *manner.*

1 **SEC. 13003. REPORT ON INVESTIGATIONS REGARDING PAR-**
2 **ITY IN MENTAL HEALTH AND SUBSTANCE USE**
3 **DISORDER BENEFITS.**

4 (a) *IN GENERAL.*—Not later than 1 year after the date
5 of enactment of this Act, and annually thereafter for the
6 subsequent 5 years, the Assistant Secretary of Labor of the
7 Employee Benefits Security Administration, in collabora-
8 tion with the Administrator of the Centers for Medicare &
9 Medicaid Services and the Secretary of the Treasury, shall
10 submit to the Committee on Energy and Commerce of the
11 House of Representatives and the Committee on Health,
12 Education, Labor, and Pensions of the Senate a report sum-
13 marizing the results of all closed Federal investigations
14 completed during the preceding 12-month period with find-
15 ings of any serious violation regarding compliance with
16 mental health and substance use disorder coverage require-
17 ments under section 2726 of the Public Health Service Act
18 (42 U.S.C. 300gg–26), section 712 of the Employee Retirement
19 Income Security Act of 1974 (29 U.S.C. 1185a), and
20 section 9812 of the Internal Revenue Code of 1986.

21 (b) *CONTENTS.*—Subject to subsection (c), a report
22 under subsection (a) shall, with respect to investigations de-
23 scribed in such subsection, include each of the following:

24 (1) *The number of closed Federal investigations*
25 *conducted during the covered reporting period.*

1 *mittee on Health, Education, Labor, and Pensions of the*
2 *Senate a report detailing the extent to which group health*
3 *plans or health insurance issuers offering group or indi-*
4 *vidual health insurance coverage that provides both medical*
5 *and surgical benefits and mental health or substance use*
6 *disorder benefits, medicaid managed care organizations*
7 *with a contract under section 1903(m) of the Social Secu-*
8 *rity Act (42 U.S.C. 1396b(m)), and health plans provided*
9 *under the State Children’s Health Insurance Program*
10 *under title XXI of the Social Security Act (42 U.S.C.*
11 *1397aa et seq.) comply with section 2726 of the Public*
12 *Health Service Act (42 U.S.C. 300gg–26), section 712 of*
13 *the Employee Retirement Income Security Act of 1974 (29*
14 *U.S.C. 1185a), and section 9812 of the Internal Revenue*
15 *Code of 1986, including—*

16 (1) *how nonquantitative treatment limitations,*
17 *including medical necessity criteria, of such plans or*
18 *issuers comply with such sections;*

19 (2) *how the responsible Federal departments and*
20 *agencies ensure that such plans or issuers comply*
21 *with such sections, including an assessment of how*
22 *the Secretary of Health and Human Services has used*
23 *its authority to conduct audits of such plans to ensure*
24 *compliance;*

1 (3) a review of how the various Federal and
2 State agencies responsible for enforcing mental health
3 parity requirements have improved enforcement of
4 such requirements in accordance with the objectives
5 and timeline described in the action plan under sec-
6 tion 13002; and

7 (4) recommendations for how additional enforce-
8 ment, education, and coordination activities by re-
9 sponsible Federal and State departments and agencies
10 could better ensure compliance with such sections, in-
11 cluding recommendations regarding the need for addi-
12 tional legal authority.

13 **SEC. 13005. INFORMATION AND AWARENESS ON EATING**
14 **DISORDERS.**

15 (a) *INFORMATION.*—The Secretary of Health and
16 Human Services, acting through the Director of the Office
17 on Women’s Health, may—

18 (1) update information, related fact sheets, and
19 resource lists related to eating disorders that are
20 available on the public Internet website of the Na-
21 tional Women’s Health Information Center sponsored
22 by the Office on Women’s Health, to include—

23 (A) updated findings and current research
24 related to eating disorders, as appropriate; and

1 (B) *information about eating disorders, in-*
2 *cluding information related to males and fe-*
3 *males;*

4 (2) *incorporate, as appropriate, and in coordi-*
5 *nation with the Secretary of Education, information*
6 *from publicly available resources into appropriate*
7 *obesity prevention programs developed by the Office*
8 *on Women's Health; and*

9 (3) *make publicly available (through a public*
10 *Internet website or other method) information, related*
11 *fact sheets, and resource lists, as updated under para-*
12 *graph (1), and the information incorporated into ap-*
13 *propriate obesity prevention programs under para-*
14 *graph (2).*

15 (b) *AWARENESS.—The Secretary of Health and*
16 *Human Services may advance public awareness on—*

17 (1) *the types of eating disorders;*

18 (2) *the seriousness of eating disorders, including*
19 *prevalence, comorbidities, and physical and mental*
20 *health consequences;*

21 (3) *methods to identify, intervene, refer for treat-*
22 *ment, and prevent behaviors that may lead to the de-*
23 *velopment of eating disorders;*

24 (4) *discrimination and bullying based on body*
25 *size;*

1 (5) *the effects of media on self-esteem and body*
2 *image; and*

3 (6) *the signs and symptoms of eating disorders.*

4 **SEC. 13006. EDUCATION AND TRAINING ON EATING DIS-**
5 **ORDERS.**

6 *The Secretary of Health and Human Services may fa-*
7 *cilitate the identification of model programs and materials*
8 *for educating and training health professionals in effective*
9 *strategies to—*

10 (1) *identify individuals with eating disorders;*

11 (2) *provide early intervention services for indi-*
12 *viduals with eating disorders;*

13 (3) *refer patients with eating disorders for ap-*
14 *propriate treatment;*

15 (4) *prevent the development of eating disorders;*

16 *and*

17 (5) *provide appropriate treatment services for*
18 *individuals with eating disorders.*

19 **SEC. 13007. CLARIFICATION OF EXISTING PARITY RULES.**

20 *If a group health plan or a health insurance issuer*
21 *offering group or individual health insurance coverage pro-*
22 *vides coverage for eating disorder benefits, including resi-*
23 *dential treatment, such group health plan or health insur-*
24 *ance issuer shall provide such benefits consistent with the*
25 *requirements of section 2726 of the Public Health Service*

1 *Act (42 U.S.C. 300gg–26), section 712 of the Employee Re-*
2 *tirement Income Security Act of 1974 (29 U.S.C. 1185a),*
3 *and section 9812 of the Internal Revenue Code of 1986.*

4 **TITLE XIV—MENTAL HEALTH**
5 **AND SAFE COMMUNITIES**
6 **Subtitle A—Mental Health and Safe**
7 **Communities**

8 **SEC. 14001. LAW ENFORCEMENT GRANTS FOR CRISIS**
9 **INTERVENTION TEAMS, MENTAL HEALTH**
10 **PURPOSES.**

11 (a) *EDWARD BYRNE MEMORIAL JUSTICE ASSISTANCE*
12 *GRANT PROGRAM.*—Section 501(a)(1) of title I of the Om-
13 *nibus Crime Control and Safe Streets Act of 1968 (42*
14 *U.S.C. 3751(a)(1)) is amended by adding at the end the*
15 *following:*

16 *“(H) Mental health programs and related*
17 *law enforcement and corrections programs, in-*
18 *cluding behavioral programs and crisis interven-*
19 *tion teams.”.*

20 (b) *COMMUNITY ORIENTED POLICING SERVICES PRO-*
21 *GRAM.*—Section 1701(b) of title I of the Omnibus Crime
22 *Control and Safe Streets Act of 1968 (42 U.S.C. 3796dd(b))*
23 *is amended—*

24 *(1) in paragraph (17), by striking “and” at the*
25 *end;*

1 (2) by redesignating paragraph (18) as para-
2 graph (22);

3 (3) by inserting after paragraph (17) the fol-
4 lowing:

5 “(18) to provide specialized training to law en-
6 forcement officers to—

7 “(A) recognize individuals who have a men-
8 tal illness; and

9 “(B) properly interact with individuals who
10 have a mental illness, including strategies for
11 verbal de-escalation of crises;

12 “(19) to establish collaborative programs that en-
13 hance the ability of law enforcement agencies to ad-
14 dress the mental health, behavioral, and substance
15 abuse problems of individuals encountered by law en-
16 forcement officers in the line of duty;

17 “(20) to provide specialized training to correc-
18 tions officers to recognize individuals who have a
19 mental illness;

20 “(21) to enhance the ability of corrections officers
21 to address the mental health of individuals under the
22 care and custody of jails and prisons, including spe-
23 cialized training and strategies for verbal de-esca-
24 lation of crises; and”;

1 (4) in paragraph (22), as redesignated, by strik-
2 ing “through (17)” and inserting “through (21)”.

3 (c) *MODIFICATIONS TO THE STAFFING FOR ADEQUATE*
4 *FIRE AND EMERGENCY RESPONSE GRANTS.*—Section
5 *34(a)(1)(B) of the Federal Fire Prevention and Control Act*
6 *of 1974 (15 U.S.C. 2229a(a)(1)(B)) is amended by inserting*
7 *before the period at the end the following: “and to provide*
8 *specialized training to paramedics, emergency medical serv-*
9 *ices workers, and other first responders to recognize individ-*
10 *uals who have mental illness and how to properly intervene*
11 *with individuals with mental illness, including strategies*
12 *for verbal de-escalation of crises”.*

13 **SEC. 14002. ASSISTED OUTPATIENT TREATMENT PRO-**
14 **GRAMS.**

15 (a) *IN GENERAL.*—Section 2201 of title I of the *Omni-*
16 *bus Crime Control and Safe Streets Act of 1968 (42 U.S.C.*
17 *3796ii) is amended in paragraph (2)(B), by inserting be-*
18 *fore the semicolon the following: “, or court-ordered assisted*
19 *outpatient treatment when the court has determined such*
20 *treatment to be necessary”.*

21 (b) *DEFINITIONS.*—Section 2202 of title I of the *Omni-*
22 *bus Crime Control and Safe Streets Act of 1968 (42 U.S.C.*
23 *3796ii—1) is amended—*

24 (1) in paragraph (1), by striking “and” at the
25 end;

1 (2) *in paragraph (2), by striking the period at*
2 *the end and inserting a semicolon; and*

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

4 “(3) *the term ‘court-ordered assisted outpatient*
5 *treatment’ means a program through which a court*
6 *may order a treatment plan for an eligible patient*
7 *that—*

8 “(A) *requires such patient to obtain out-*
9 *patient mental health treatment while the pa-*
10 *tient is not currently residing in a correctional*
11 *facility or inpatient treatment facility; and*

12 “(B) *is designed to improve access and ad-*
13 *herence by such patient to intensive behavioral*
14 *health services in order to—*

15 “(i) *avert relapse, repeated hospitaliza-*
16 *tions, arrest, incarceration, suicide, prop-*
17 *erty destruction, and violent behavior; and*

18 “(ii) *provide such patient with the op-*
19 *portunity to live in a less restrictive alter-*
20 *native to incarceration or involuntary hos-*
21 *pitalization; and*

22 “(4) *the term ‘eligible patient’ means an adult,*
23 *mentally ill person who, as determined by a court—*

24 “(A) *has a history of violence, incarcer-*
25 *ation, or medically unnecessary hospitalizations;*

1 “(B) without supervision and treatment,
2 may be a danger to self or others in the commu-
3 nity;

4 “(C) is substantially unlikely to voluntarily
5 participate in treatment;

6 “(D) may be unable, for reasons other than
7 indigence, to provide for any of his or her basic
8 needs, such as food, clothing, shelter, health, or
9 safety;

10 “(E) has a history of mental illness or a
11 condition that is likely to substantially deterio-
12 rate if the person is not provided with timely
13 treatment; or

14 “(F) due to mental illness, lacks capacity to
15 fully understand or lacks judgment to make in-
16 formed decisions regarding his or her need for
17 treatment, care, or supervision.”.

18 **SEC. 14003. FEDERAL DRUG AND MENTAL HEALTH COURTS.**

19 (a) *DEFINITIONS.*—*In this section—*

20 (1) the term “eligible offender” means a person
21 who—

22 (A)(i) previously or currently has been di-
23 agnosed by a qualified mental health professional
24 as having a mental illness, mental retardation,

1 or co-occurring mental illness and substance
2 abuse disorders; or

3 (ii) manifests obvious signs of mental ill-
4 ness, mental retardation, or co-occurring mental
5 illness and substance abuse disorders during ar-
6 rest or confinement or before any court;

7 (B) comes into contact with the criminal
8 justice system or is arrested or charged with an
9 offense that is not—

10 (i) a crime of violence, as defined
11 under applicable State law or in section
12 3156 of title 18, United States Code; or

13 (ii) a serious drug offense, as defined
14 in section 924(e)(2)(A) of title 18, United
15 States Code; and

16 (C) is determined by a judge to be eligible;
17 and

18 (2) the term “mental illness” means a
19 diagnosable mental, behavioral, or emotional dis-
20 order—

21 (A) of sufficient duration to meet diagnostic
22 criteria within the most recent edition of the Di-
23 agnostic and Statistical Manual of Mental Dis-
24 orders published by the American Psychiatric
25 Association; and

1 (B) that has resulted in functional impair-
2 ment that substantially interferes with or limits
3 1 or more major life activities.

4 (b) *ESTABLISHMENT OF PROGRAM.*—Not later than 1
5 year after the date of enactment of this Act, the Attorney
6 General shall establish a pilot program to determine the ef-
7 fectiveness of diverting eligible offenders from Federal pros-
8 ecution, Federal probation, or a Bureau of Prisons facility,
9 and placing such eligible offenders in drug or mental health
10 courts.

11 (c) *PROGRAM SPECIFICATIONS.*—The pilot program
12 established under subsection (b) shall involve—

13 (1) continuing judicial supervision, including
14 periodic review, of program participants who have a
15 substance abuse problem or mental illness; and

16 (2) the integrated administration of services and
17 sanctions, which shall include—

18 (A) mandatory periodic testing, as appro-
19 priate, for the use of controlled substances or
20 other addictive substances during any period of
21 supervised release or probation for each program
22 participant;

23 (B) substance abuse treatment for each pro-
24 gram participant who requires such services;

1 (C) diversion, probation, or other supervised
2 release with the possibility of prosecution, con-
3 finement, or incarceration based on noncompli-
4 ance with program requirements or failure to
5 show satisfactory progress toward completing
6 program requirements;

7 (D) programmatic offender management,
8 including case management, and aftercare serv-
9 ices, such as relapse prevention, health care, edu-
10 cation, vocational training, job placement, hous-
11 ing placement, and child care or other family
12 support services for each program participant
13 who requires such services;

14 (E) outpatient or inpatient mental health
15 treatment, as ordered by the court, that carries
16 with it the possibility of dismissal of charges or
17 reduced sentencing upon successful completion of
18 such treatment;

19 (F) centralized case management, includ-
20 ing—

21 (i) the consolidation of all cases, in-
22 cluding violations of probations, of the pro-
23 gram participant; and

24 (ii) coordination of all mental health
25 treatment plans and social services, includ-

1 *ing life skills and vocational training, hous-*
2 *ing and job placement, education, health*
3 *care, and relapse prevention for each pro-*
4 *gram participant who requires such serv-*
5 *ices; and*

6 *(G) continuing supervision of treatment*
7 *plan compliance by the program participant for*
8 *a term not to exceed the maximum allowable sen-*
9 *tence or probation period for the charged or rel-*
10 *evant offense and, to the extent practicable, con-*
11 *tinuity of psychiatric care at the end of the su-*
12 *pervised period.*

13 *(d) IMPLEMENTATION; DURATION.—The pilot program*
14 *established under subsection (b) shall be conducted—*

15 *(1) in not less than 1 United States judicial dis-*
16 *trict, designated by the Attorney General in consulta-*
17 *tion with the Director of the Administrative Office of*
18 *the United States Courts, as appropriate for the pilot*
19 *program; and*

20 *(2) during fiscal year 2017 through fiscal year*
21 *2021.*

22 *(e) CRITERIA FOR DESIGNATION.—Before making a*
23 *designation under subsection (d)(1), the Attorney General*
24 *shall—*

1 (1) obtain the approval, in writing, of the
2 United States Attorney for the United States judicial
3 district being designated;

4 (2) obtain the approval, in writing, of the chief
5 judge for the United States judicial district being des-
6 ignated; and

7 (3) determine that the United States judicial dis-
8 trict being designated has adequate behavioral health
9 systems for treatment, including substance abuse and
10 mental health treatment.

11 (f) ASSISTANCE FROM OTHER FEDERAL ENTITIES.—
12 The Administrative Office of the United States Courts and
13 the United States Probation Offices shall provide such as-
14 sistance and carry out such functions as the Attorney Gen-
15 eral may request in monitoring, supervising, providing
16 services to, and evaluating eligible offenders placed in a
17 drug or mental health court under this section.

18 (g) REPORTS.—The Attorney General, in consultation
19 with the Director of the Administrative Office of the United
20 States Courts, shall monitor the drug and mental health
21 courts under this section, and shall submit a report to Con-
22 gress on the outcomes of the program at the end of the period
23 described in subsection (d)(2).

1 **SEC. 14004. MENTAL HEALTH IN THE JUDICIAL SYSTEM.**

2 *Part V of title I of the Omnibus Crime Control and*
3 *Safe Streets Act of 1968 (42 U.S.C. 3796ii et seq.) is*
4 *amended by inserting at the end the following:*

5 **“SEC. 2209. MENTAL HEALTH RESPONSES IN THE JUDICIAL**
6 **SYSTEM.**

7 *“(a) PRETRIAL SCREENING AND SUPERVISION.—*

8 *“(1) IN GENERAL.—The Attorney General may*
9 *award grants to States, units of local government, ter-*
10 *ritories, Indian Tribes, nonprofit agencies, or any*
11 *combination thereof, to develop, implement, or expand*
12 *pretrial services programs to improve the identifica-*
13 *tion and outcomes of individuals with mental illness.*

14 *“(2) ALLOWABLE USES.—Grants awarded under*
15 *this subsection may be may be used for—*

16 *“(A) behavioral health needs and risk*
17 *screening of defendants, including verification of*
18 *interview information, mental health evaluation,*
19 *and criminal history screening;*

20 *“(B) assessment of risk of pretrial mis-*
21 *conduct through objective, statistically validated*
22 *means, and presentation to the court of rec-*
23 *ommendations based on such assessment, includ-*
24 *ing services that will reduce the risk of pre-trial*
25 *misconduct;*

1 “(C) *followup review of defendants unable*
2 *to meet the conditions of pretrial release;*

3 “(D) *evaluation of process and results of*
4 *pre-trial service programs;*

5 “(E) *supervision of defendants who are on*
6 *pretrial release, including reminders to defend-*
7 *ants of scheduled court dates;*

8 “(F) *reporting on process and results of pre-*
9 *trial services programs to relevant public and*
10 *private mental health stakeholders; and*

11 “(G) *data collection and analysis necessary*
12 *to make available information required for as-*
13 *essment of risk.*

14 “(b) *BEHAVIORAL HEALTH ASSESSMENTS AND INTER-*
15 *VENTION.—*

16 “(1) *IN GENERAL.—The Attorney General may*
17 *award grants to States, units of local government, ter-*
18 *ritories, Indian Tribes, nonprofit agencies, or any*
19 *combination thereof, to develop, implement, or expand*
20 *a behavioral health screening and assessment program*
21 *framework for State or local criminal justice systems.*

22 “(2) *ALLOWABLE USES.—Grants awarded under*
23 *this subsection may be used for—*

24 “(A) *promotion of the use of validated as-*
25 *essment tools to gauge the criminogenic risk,*

1 *substance abuse needs, and mental health needs*
2 *of individuals;*

3 “(B) *initiatives to match the risk factors*
4 *and needs of individuals to programs and prac-*
5 *tices associated with research-based, positive out-*
6 *comes;*

7 “(C) *implementing methods for identifying*
8 *and treating individuals who are most likely to*
9 *benefit from coordinated supervision and treat-*
10 *ment strategies, and identifying individuals who*
11 *can do well with fewer interventions; and*

12 “(D) *collaborative decision-making among*
13 *the heads of criminal justice agencies, mental*
14 *health systems, judicial systems, substance abuse*
15 *systems, and other relevant systems or agencies*
16 *for determining how treatment and intensive su-*
17 *pervision services should be allocated in order to*
18 *maximize benefits, and developing and utilizing*
19 *capacity accordingly.*

20 “(c) *USE OF GRANT FUNDS.—A State, unit of local*
21 *government, territory, Indian Tribe, or nonprofit agency*
22 *that receives a grant under this section shall, in accordance*
23 *with subsection (b)(2), use grant funds for the expenses of*
24 *a treatment program, including—*

1 “(1) salaries, personnel costs, equipment costs,
2 and other costs directly related to the operation of the
3 program, including costs relating to enforcement;

4 “(2) payments for treatment providers that are
5 approved by the State or Indian Tribe and licensed,
6 if necessary, to provide needed treatment to program
7 participants, including aftercare supervision, voca-
8 tional training, education, and job placement; and

9 “(3) payments to public and nonprofit private
10 entities that are approved by the State or Indian
11 Tribe and licensed, if necessary, to provide alcohol
12 and drug addiction treatment to offenders partici-
13 pating in the program.

14 “(d) SUPPLEMENT OF NON-FEDERAL FUNDS.—

15 “(1) IN GENERAL.—Grants awarded under this
16 section shall be used to supplement, and not supplant,
17 non-Federal funds that would otherwise be available
18 for programs described in this section.

19 “(2) FEDERAL SHARE.—The Federal share of a
20 grant made under this section may not exceed 50 per-
21 cent of the total costs of the program described in an
22 application under subsection (e).

23 “(e) APPLICATIONS.—To request a grant under this
24 section, a State, unit of local government, territory, Indian
25 Tribe, or nonprofit agency shall submit an application to

1 *the Attorney General in such form and containing such in-*
2 *formation as the Attorney General may reasonably require.*

3 “(f) *GEOGRAPHIC DISTRIBUTION.—The Attorney Gen-*
4 *eral shall ensure that, to the extent practicable, the distribu-*
5 *tion of grants under this section is equitable and includes—*

6 “(1) *each State; and*

7 “(2) *a unit of local government, territory, In-*
8 *dian Tribe, or nonprofit agency—*

9 “(A) *in each State; and*

10 “(B) *in rural, suburban, Tribal, and urban*
11 *jurisdictions.*

12 “(g) *REPORTS AND EVALUATIONS.—For each fiscal*
13 *year, each grantee under this section during that fiscal year*
14 *shall submit to the Attorney General a report on the effec-*
15 *tiveness of activities carried out using such grant. Each re-*
16 *port shall include an evaluation in such form and con-*
17 *taining such information as the Attorney General may rea-*
18 *sonably require. The Attorney General shall specify the*
19 *dates on which such reports shall be submitted.*

20 “(h) *ACCOUNTABILITY.—Grants awarded under this*
21 *section shall be subject to the following accountability provi-*
22 *sions:*

23 “(1) *AUDIT REQUIREMENT.—*

24 “(A) *DEFINITION.—In this paragraph, the*
25 *term ‘unresolved audit finding’ means a finding*

1 *in the final audit report of the Inspector General*
2 *of the Department of Justice under subpara-*
3 *graph (C) that the audited grantee has used*
4 *grant funds for an unauthorized expenditure or*
5 *otherwise unallowable cost that is not closed or*
6 *resolved within 1 year after the date on which*
7 *final audit report is issued.*

8 “(B) *AUDITS.*—*Beginning in the first fiscal*
9 *year beginning after the date of enactment of*
10 *this section, and in each fiscal year thereafter,*
11 *the Inspector General of the Department of Jus-*
12 *tice shall conduct audits of grantees under this*
13 *section to prevent waste, fraud, and abuse of*
14 *funds by grantees. The Inspector General shall*
15 *determine the appropriate number of grantees to*
16 *be audited each year.*

17 “(C) *FINAL AUDIT REPORT.*—*The Inspector*
18 *General of the Department of Justice shall sub-*
19 *mit to the Attorney General a final report on*
20 *each audit conducted under subparagraph (B).*

21 “(D) *MANDATORY EXCLUSION.*—*Grantees*
22 *under this section about which there is an unre-*
23 *solved audit finding shall not be eligible to re-*
24 *ceive a grant under this section during the 2 fis-*

1 *cal years beginning after the end of the 1-year*
2 *period described in subparagraph (A).*

3 “(E) *PRIORITY.*—*In making grants under*
4 *this section, the Attorney General shall give pri-*
5 *ority to applicants that did not have an unre-*
6 *solved audit finding during the 3 fiscal years be-*
7 *fore submitting an application for a grant under*
8 *this section.*

9 “(F) *REIMBURSEMENT.*—*If an entity re-*
10 *ceives a grant under this section during the 2-*
11 *fiscal-year period during which the entity is pro-*
12 *hibited from receiving grants under subpara-*
13 *graph (D), the Attorney General shall—*

14 “(i) *deposit an amount equal to the*
15 *amount of the grant that was improperly*
16 *awarded to the grantee into the General*
17 *Fund of the Treasury; and*

18 “(ii) *seek to recoup the costs of the re-*
19 *payment under clause (i) from the grantee*
20 *that was erroneously awarded grant funds.*

21 “(2) *NONPROFIT AGENCY REQUIREMENTS.*—

22 “(A) *DEFINITION.*—*For purposes of this*
23 *paragraph and the grant program under this*
24 *section, the term ‘nonprofit agency’ means an or-*
25 *ganization that is described in section 501(c)(3)*

1 *of the Internal Revenue Code of 1986 (26 U.S.C.*
2 *501(c)(3)) and is exempt from taxation under*
3 *section 501(a) of the Internal Revenue Code of*
4 *1986 (26 U.S.C. 501(a)).*

5 “(B) *PROHIBITION.*—*The Attorney General*
6 *may not award a grant under this section to a*
7 *nonprofit agency that holds money in an offshore*
8 *account for the purpose of avoiding paying the*
9 *tax described in section 511(a) of the Internal*
10 *Revenue Code of 1986 (26 U.S.C. 511(a)).*

11 “(C) *DISCLOSURE.*—*Each nonprofit agency*
12 *that is awarded a grant under this section and*
13 *uses the procedures prescribed in regulations to*
14 *create a rebuttable presumption of reasonableness*
15 *for the compensation of its officers, directors,*
16 *trustees, and key employees, shall disclose to the*
17 *Attorney General, in the application for the*
18 *grant, the process for determining such com-*
19 *pen-sation, including the independent persons in-*
20 *volved in reviewing and approving such com-*
21 *pen-sation, the comparability data used, and con-*
22 *tem-poraneous substantiation of the deliberation*
23 *and decision. Upon request, the Attorney General*
24 *shall make the information disclosed under this*
25 *subparagraph available for public inspection.*

1 “(3) *CONFERENCE EXPENDITURES.*—

2 “(A) *LIMITATION.*—Not more than \$20,000
3 of the amounts made available to the Depart-
4 ment of Justice to carry out this section may be
5 used by the Attorney General, or by any indi-
6 vidual or entity awarded a grant under this sec-
7 tion to host, or make any expenditures relating
8 to, a conference unless the Deputy Attorney Gen-
9 eral provides prior written authorization that
10 the funds may be expended to host the conference
11 or make such expenditure.

12 “(B) *WRITTEN APPROVAL.*—Written ap-
13 proval under subparagraph (A) shall include a
14 written estimate of all costs associated with the
15 conference, including the cost of all food, bev-
16 erages, audio-visual equipment, honoraria for
17 speakers, and entertainment.

18 “(C) *REPORT.*—The Deputy Attorney Gen-
19 eral shall submit an annual report to the Com-
20 mittee on the Judiciary of the Senate and the
21 Committee on the Judiciary of the House of Rep-
22 resentatives on all conference expenditures ap-
23 proved under this paragraph.

24 “(4) *ANNUAL CERTIFICATION.*—Beginning in the
25 first fiscal year beginning after the date of enactment

1 of this subsection, the Attorney General shall submit
2 to the Committee on the Judiciary and the Committee
3 on Appropriations of the Senate and the Committee
4 on the Judiciary and the Committee on Appropria-
5 tions of the House of Representatives an annual cer-
6 tification—

7 “(A) indicating whether—

8 “(i) all final audit reports issued by
9 the Office of the Inspector General under
10 paragraph (1) have been completed and re-
11 viewed by the appropriate Assistant Attor-
12 ney General or Director;

13 “(ii) all mandatory exclusions required
14 under paragraph (1)(D) have been issued;
15 and

16 “(iii) any reimbursements required
17 under paragraph (1)(F) have been made;
18 and

19 “(B) that includes a list of any grantees ex-
20 cluded under paragraph (1)(D) from the pre-
21 vious year.

22 “(i) PREVENTING DUPLICATIVE GRANTS.—

23 “(1) IN GENERAL.—Before the Attorney General
24 awards a grant to an applicant under this section,
25 the Attorney General shall compare the possible grant

1 *with any other grants awarded to the applicant*
 2 *under this Act to determine whether the grants are for*
 3 *the same purpose.*

4 “(2) *REPORT.—If the Attorney General awards*
 5 *multiple grants to the same applicant for the same*
 6 *purpose, the Attorney General shall submit to the*
 7 *Committee on the Judiciary of the Senate and the*
 8 *Committee on the Judiciary of the House of Rep-*
 9 *resentatives a report that includes—*

10 “(A) *a list of all duplicate grants awarded,*
 11 *including the total dollar amount of any such*
 12 *grants awarded; and*

13 “(B) *the reason the Attorney General*
 14 *awarded the duplicate grants.”*

15 **SEC. 14005. FORENSIC ASSERTIVE COMMUNITY TREATMENT**
 16 **INITIATIVES.**

17 *Section 2991 of the Omnibus Crime Control and Safe*
 18 *Streets Act of 1968 (42 U.S.C. 3797aa) is amended by—*

19 (1) *redesignating subsection (j) as subsection (o);*

20 *and*

21 (2) *inserting after subsection (i) the following:*

22 “(j) **FORENSIC ASSERTIVE COMMUNITY TREATMENT**
 23 **(FACT) INITIATIVE PROGRAM.—**

24 “(1) **IN GENERAL.—The Attorney General may**
 25 **make grants to States, units of local government, ter-**

1 *ritories, Indian Tribes, nonprofit agencies, or any*
2 *combination thereof, to develop, implement, or expand*
3 *Assertive Community Treatment initiatives to develop*
4 *forensic assertive community treatment (referred to in*
5 *this subsection as ‘FACT’) programs that provide*
6 *high intensity services in the community for individ-*
7 *uals with mental illness with involvement in the*
8 *criminal justice system to prevent future incarcer-*
9 *ations.*

10 *“(2) ALLOWABLE USES.—Grant funds awarded*
11 *under this subsection may be used for—*

12 *“(A) multidisciplinary team initiatives for*
13 *individuals with mental illnesses with criminal*
14 *justice involvement that address criminal justice*
15 *involvement as part of treatment protocols;*

16 *“(B) FACT programs that involve mental*
17 *health professionals, criminal justice agencies,*
18 *chemical dependency specialists, nurses, psychia-*
19 *trists, vocational specialists, forensic peer spe-*
20 *cialists, forensic specialists, and dedicated ad-*
21 *ministrative support staff who work together to*
22 *provide recovery oriented, 24/7 wraparound serv-*
23 *ices;*

24 *“(C) services such as integrated evidence-*
25 *based practices for the treatment of co-occurring*

1 *mental health and substance-related disorders,*
2 *assertive outreach and engagement, community-*
3 *based service provision at participants' residence*
4 *or in the community, psychiatric rehabilitation,*
5 *recovery oriented services, services to address*
6 *criminogenic risk factors, and community ten-*
7 *ure;*

8 “(D) *payments for treatment providers that*
9 *are approved by the State or Indian Tribe and*
10 *licensed, if necessary, to provide needed treat-*
11 *ment to eligible offenders participating in the*
12 *program, including behavioral health services*
13 *and aftercare supervision; and*

14 “(E) *training for all FACT teams to pro-*
15 *mote high-fidelity practice principles and tech-*
16 *nical assistance to support effective and con-*
17 *tinuing integration with criminal justice agency*
18 *partners.*

19 “(3) *SUPPLEMENT AND NOT SUPPLANT.—Grants*
20 *made under this subsection shall be used to supple-*
21 *ment, and not supplant, non-Federal funds that*
22 *would otherwise be available for programs described*
23 *in this subsection.*

24 “(4) *APPLICATIONS.—To request a grant under*
25 *this subsection, a State, unit of local government, ter-*

1 *substance abuse and mental health problems,” after*
2 *“problems”; and*

3 (2) *in section 2959(a) (42 U.S.C. 3797u–8(a)),*
4 *by inserting “, including training for drug court per-*
5 *sonnel and officials on identifying and addressing co-*
6 *occurring substance abuse and mental health prob-*
7 *lems” after “part”.*

8 **SEC. 14008. MENTAL HEALTH TRAINING FOR FEDERAL UNI-**
9 **FORMED SERVICES.**

10 (a) *IN GENERAL.*—*Not later than 180 days after the*
11 *date of enactment of this Act, the Secretary of Defense, the*
12 *Secretary of Homeland Security, the Secretary of Health*
13 *and Human Services, and the Secretary of Commerce shall*
14 *provide the following to each of the uniformed services (as*
15 *that term is defined in section 101 of title 10, United States*
16 *Code) under their direction:*

17 (1) *TRAINING PROGRAMS.*—*Programs that offer*
18 *specialized and comprehensive training in procedures*
19 *to identify and respond appropriately to incidents in*
20 *which the unique needs of individuals with mental ill-*
21 *nesses are involved.*

22 (2) *IMPROVED TECHNOLOGY.*—*Computerized in-*
23 *formation systems or technological improvements to*
24 *provide timely information to Federal law enforce-*
25 *ment personnel, other branches of the uniformed serv-*

1 *ices, and criminal justice system personnel to improve*
2 *the Federal response to mentally ill individuals.*

3 (3) *COOPERATIVE PROGRAMS.—The establish-*
4 *ment and expansion of cooperative efforts to promote*
5 *public safety through the use of effective intervention*
6 *with respect to mentally ill individuals encountered*
7 *by members of the uniformed services.*

8 **SEC. 14009. ADVANCING MENTAL HEALTH AS PART OF OF-**
9 **FENDER REENTRY.**

10 (a) *REENTRY DEMONSTRATION PROJECTS.—Section*
11 *2976(f) of title I of the Omnibus Crime Control and Safe*
12 *Streets Act of 1968 (42 U.S.C. 3797w(f)), as amended by*
13 *section 14006, is amended—*

14 (1) *in paragraph (3)(C), by inserting “mental*
15 *health services,” before “drug treatment”; and*

16 (2) *by adding at the end the following:*

17 *“(8) target offenders with histories of homeless-*
18 *ness, substance abuse, or mental illness, including a*
19 *prerelease assessment of the housing status of the of-*
20 *fender and behavioral health needs of the offender*
21 *with clear coordination with mental health, substance*
22 *abuse, and homelessness services systems to achieve*
23 *stable and permanent housing outcomes with appro-*
24 *priate support service.”.*

1 (b) *MENTORING GRANTS.*—Section 211(b)(2) of the
2 *Second Chance Act of 2007 (42 U.S.C. 17531(b)(2))* is
3 *amended by inserting “, including mental health care”* after
4 *“community”*.

5 **SEC. 14010. SCHOOL MENTAL HEALTH CRISIS INTERVEN-**
6 **TION TEAMS.**

7 Section 2701(b) of title I of the *Omnibus Crime Con-*
8 *trol and Safe Streets Act of 1968 (42 U.S.C. 3797a(b))* is
9 *amended—*

10 (1) *by redesignating paragraphs (4) and (5) as*
11 *paragraphs (5) and (6), respectively; and*

12 (2) *by inserting after paragraph (3) the fol-*
13 *lowing:*

14 “(4) *The development and operation of crisis*
15 *intervention teams that may include coordination*
16 *with law enforcement agencies and specialized train-*
17 *ing for school officials in responding to mental health*
18 *crises.”*.

19 **SEC. 14011. ACTIVE-SHOOTER TRAINING FOR LAW EN-**
20 **FORCEMENT.**

21 *The Attorney General, as part of the Preventing Vio-*
22 *lence Against Law Enforcement and Ensuring Officer Re-*
23 *silience and Survivability Initiative (VALOR) of the De-*
24 *partment of Justice, may provide safety training and tech-*

1 nical assistance to local law enforcement agencies, including
 2 active-shooter response training.

3 **SEC. 14012. CO-OCCURRING SUBSTANCE ABUSE AND MEN-**
 4 **TAL HEALTH CHALLENGES IN RESIDENTIAL**
 5 **SUBSTANCE ABUSE TREATMENT PROGRAMS.**

6 Section 1901(a) of title I of the Omnibus Crime Con-
 7 trol and Safe Streets Act of 1968 (42 U.S.C. 3796ff(a)) is
 8 amended—

9 (1) in paragraph (1), by striking “and” at the
 10 end;

11 (2) in paragraph (2), by striking the period at
 12 the end and inserting “; and”; and

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

14 “(3) developing and implementing specialized
 15 residential substance abuse treatment programs that
 16 identify and provide appropriate treatment to in-
 17 mates with co-occurring mental health and substance
 18 abuse disorders or challenges.”.

19 **SEC. 14013. MENTAL HEALTH AND DRUG TREATMENT AL-**
 20 **TERNATIVES TO INCARCERATION PROGRAMS.**

21 Title I of the Omnibus Crime Control and Safe Streets
 22 Act of 1968 (42 U.S.C. 3711 et seq.) is amended by striking
 23 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 PROGRAMS.**

6 *“(a) DEFINITIONS.—In this section—*

7 *“(1) the term ‘eligible entity’ means a State,*
8 *unit of local government, Indian tribe, or nonprofit*
9 *organization; and*

10 *“(2) the term ‘eligible participant’ means an in-*
11 *dividual who—*

12 *“(A) comes into contact with the criminal*
13 *justice system or is arrested or charged with an*
14 *offense that is not—*

15 *“(i) a crime of violence, as defined*
16 *under applicable State law or in section*
17 *3156 of title 18, United States Code; or*

18 *“(ii) a serious drug offense, as defined*
19 *in section 924(e)(2)(A) of title 18, United*
20 *States Code;*

21 *“(B) has a history of, or a current—*

22 *“(i) substance use disorder;*

23 *“(ii) mental illness; or*

24 *“(iii) co-occurring mental illness and*
25 *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 attor-
4 ney, defense attorney, probation official, correc-
5 tions official, judge, representative of a mental
6 health agency, or representative of a substance
7 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 program
11 for eligible participants, including—

12 “(1) pre-booking treatment alternative to incar-
13 ceration programs, including—

14 “(A) law enforcement training on substance
15 use disorders, mental illness, and co-occurring
16 mental illness and substance use disorders;

17 “(B) receiving centers as alternatives to in-
18 carceration of eligible participants;

19 “(C) specialized response units for calls re-
20 lated to substance use disorders, mental illness,
21 or co-occurring mental illness and substance use
22 disorders; and

23 “(D) other arrest and pre-booking treatment
24 alternatives to incarceration models; or

1 “(2) *post-booking treatment alternative to incar-*
2 *ceration programs, including—*

3 “(A) *specialized clinical case management;*

4 “(B) *pre-trial services related to substances*
5 *use disorders, mental illness, and co-occurring*
6 *mental illness and substance use disorders;*

7 “(C) *prosecutor and defender based pro-*
8 *grams;*

9 “(D) *specialized probation;*

10 “(E) *treatment and rehabilitation pro-*
11 *grams; and*

12 “(F) *problem-solving courts, including men-*
13 *tal health courts, drug courts, co-occurring men-*
14 *tal health and substance abuse courts, DWI*
15 *courts, and veterans treatment courts.*

16 “(c) *APPLICATION.—*

17 “(1) *IN GENERAL.—An eligible entity desiring a*
18 *grant under this section shall submit an application*
19 *to the Attorney General—*

20 “(A) *that meets the criteria under para-*
21 *graph (2); and*

22 “(B) *at such time, in such manner, and ac-*
23 *companied by such information as the Attorney*
24 *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 collabora-*
4 *tion with State and local government agencies*
5 *overseeing health, community corrections, courts,*
6 *prosecution, substance abuse, mental health, vic-*
7 *tims services, and employment services, and with*
8 *local law enforcement agencies;*

9 “(B) *demonstrate consultation with the Sin-*
10 *gle State Authority for Substance Abuse of the*
11 *State (as that term is defined in section 201(e)*
12 *of the Second Chance Act of 2007);*

13 “(C) *demonstrate that evidence-based treat-*
14 *ment 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 a*
20 *grant for a treatment alternative to incarceration program*
21 *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 men-
2 tal health treatment component is licensed and quali-
3 fied by the relevant jurisdiction;

4 “(3) for programs described in subsection (b)(2),
5 organize an enforcement unit comprised of appro-
6 priately trained law enforcement professionals under
7 the supervision of the State, Tribal, or local criminal
8 justice agency involved, the duties of which shall in-
9 clude—

10 “(A) the verification of addresses and other
11 contact information of each eligible participant
12 who participates or desires to participate in the
13 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 program,

1 *consistent with Federal and State confidentiality re-*
2 *quirements;*

3 “(5) *submit periodic reports on the progress of*
4 *treatment or other measured outcomes from participa-*
5 *tion in the program of each eligible participant in the*
6 *program to the relevant State, Tribal, or local crimi-*
7 *nal justice agency, including mental health courts,*
8 *drug courts, co-occurring mental health and substance*
9 *abuse courts, DWI courts, and veterans treatment*
10 *courts;*

11 “(6) *describe the evidence-based methodology and*
12 *outcome measurements that will be used to evaluate*
13 *the program, and specifically explain how such meas-*
14 *urements will provide valid measures of the impact of*
15 *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 treatment*
20 *alternative to incarceration program, including—*

21 “(1) *salaries, personnel costs, equipment costs,*
22 *and other costs directly related to the operation of the*
23 *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 treatment*
2 *to eligible offenders participating in the program, in-*
3 *cluding aftercare supervision, vocational training,*
4 *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 offenders*
9 *participating in the program.*

10 *“(f) SUPPLEMENT NOT SUPPLANT.—An eligible entity*
11 *shall use Federal funds received under this section only to*
12 *supplement the funds that would, in the absence of those*
13 *Federal funds, be made available from other Federal and*
14 *non-Federal sources for the activities described in this sec-*
15 *tion, and not to supplant those funds. The Federal share*
16 *of a grant made under this section may not exceed 50 per-*
17 *cent of the total costs of the program described in an appli-*
18 *cation under subsection (d).*

19 *“(g) GEOGRAPHIC DISTRIBUTION.—The Attorney Gen-*
20 *eral shall ensure that, to the extent practicable, the geo-*
21 *graphical distribution of grants under this section is equi-*
22 *table 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 year,
2 each recipient of a grant under this section during that fis-
3 cal year shall submit to the Attorney General a report on
4 the outcomes of activities carried out using that grant in
5 such form, containing such information, and on such dates
6 as the Attorney General shall specify.

7 “(i) *ACCOUNTABILITY.*—All grants awarded by the At-
8 torney General under this section shall be subject to the fol-
9 lowing 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 General
14 of the Department of Justice that the audited
15 grantee has utilized grant funds for an unau-
16 thorized expenditure or otherwise unallowable
17 cost that is not closed or resolved within 12
18 months from the date on which the final audit
19 report is issued.

20 “(B) *AUDITS.*—Beginning in the first fiscal
21 year beginning after the date of enactment of
22 this subsection, and in each fiscal year there-
23 after, the Inspector General of the Department of
24 Justice shall conduct audits of recipients of
25 grants under this section to prevent waste, fraud,

1 *and abuse of funds by grantees. The Inspector*
2 *General shall determine the appropriate number*
3 *of grantees to be audited each year.*

4 “(C) *MANDATORY EXCLUSION.*—*A recipient*
5 *of grant funds under this section that is found*
6 *to have an unresolved audit finding shall not be*
7 *eligible to receive grant funds under this section*
8 *during the first 2 fiscal years beginning after the*
9 *end of the 12-month period described in subpara-*
10 *graph (A).*

11 “(D) *PRIORITY.*—*In awarding grants under*
12 *this section, the Attorney General shall give pri-*
13 *ority to eligible applicants that did not have an*
14 *unresolved audit finding during the 3 fiscal*
15 *years before submitting an application for a*
16 *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 re-
2 payment to the fund from the grant recipi-
3 ent 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 an
10 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 General
15 may not award a grant under this part to a
16 nonprofit organization that holds money in off-
17 shore accounts for the purpose of avoiding pay-
18 ing the tax described in section 511(a) of the In-
19 ternal Revenue Code of 1986.

20 “(C) *DISCLOSURE.—*Each nonprofit organi-
21 zation that is awarded a grant under this section
22 and uses the procedures prescribed in regulations
23 to create a rebuttable presumption of reasonable-
24 ness for the compensation of its officers, direc-
25 tors, trustees, and key employees, shall disclose to

1 *the Attorney General, in the application for the*
2 *grant, the process for determining such com-*
3 *ensation, including the independent persons in-*
4 *olved in reviewing and approving such com-*
5 *ensation, the comparability data used, and con-*
6 *temporaneous substantiation of the deliberation*
7 *and decision. Upon request, the Attorney General*
8 *shall make the information disclosed under this*
9 *subparagraph available for public inspection.*

10 “(3) *CONFERENCE EXPENDITURES.—*

11 “(A) *LIMITATION.—No amounts made*
12 *available to the Department of Justice under this*
13 *section may be used by the Attorney General, or*
14 *by any individual or entity awarded discre-*
15 *tionary funds through a cooperative agreement*
16 *under this section, to host or support any ex-*
17 *penditure for conferences that uses more than*
18 *\$20,000 in funds made available by the Depart-*
19 *ment of Justice, unless the head of the relevant*
20 *agency or department, provides prior written*
21 *authorization that the funds may be expended to*
22 *host the conference.*

23 “(B) *WRITTEN APPROVAL.—Written ap-*
24 *proval under subparagraph (A) shall include a*
25 *written estimate of all costs associated with the*

1 conference, including the cost of all food, bev-
2 erages, audio-visual equipment, honoraria for
3 speakers, and entertainment.

4 “(C) *REPORT.*—The Deputy Attorney Gen-
5 eral shall submit an annual report to the Com-
6 mittee on the Judiciary of the Senate and the
7 Committee on the Judiciary of the House of Rep-
8 resentatives on all conference expenditures ap-
9 proved under this paragraph.

10 “(4) *ANNUAL CERTIFICATION.*—Beginning in the
11 first fiscal year beginning after the date of enactment
12 of this subsection, the Attorney General shall submit,
13 to the Committee on the Judiciary and the Committee
14 on Appropriations of the Senate and the Committee
15 on the Judiciary and the Committee on Appropria-
16 tions of the House of Representatives, an annual cer-
17 tification—

18 “(A) indicating whether—

19 “(i) all audits issued by the Office of
20 the Inspector General under paragraph (1)
21 have been completed and reviewed by the
22 appropriate Assistant Attorney General or
23 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 award-
15 ed under this Act to determine if duplicate grant
16 awards are awarded for the same purpose.

17 “(B) REPORT.—If the Attorney General
18 awards duplicate grants to the same applicant
19 for the same purpose the Attorney General shall
20 submit to the Committee on the Judiciary of the
21 Senate and the Committee on the Judiciary of
22 the House of Representatives a report that in-
23 cludes—

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 establish-*
17 *ment of a National Criminal Justice and Mental Health*
18 *Training and Technical Assistance Center.*

19 “(b) *ELIGIBLE ORGANIZATION.*—*For purposes of sub-*
20 *section (a), the term ‘eligible organization’ means a na-*
21 *tional nonprofit organization that provides technical assist-*
22 *ance and training to, and has special expertise and broad,*
23 *national-level experience in, mental health, crisis interven-*
24 *tion, criminal justice systems, law enforcement, translating*
25 *evidence into practice, training, and research, and edu-*

1 cation and support of people with mental illness and the
2 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 re-
9 garding mental health and working with individuals
10 with mental illnesses, with an emphasis on de-escala-
11 tion of encounters between law enforcement officers
12 and those with mental disorders or in crisis, which
13 shall include support the development of in-person
14 and technical information exchanges between systems
15 and the individuals working in those systems in sup-
16 port of the concepts identified in the training;

17 “(2) provide education, training, and technical
18 assistance for States, Indian tribes, territories, units
19 of local government, service providers, nonprofit orga-
20 nizations, probation or parole officers, prosecutors,
21 defense attorneys, emergency response providers, and
22 corrections institutions to advance practice and
23 knowledge relating to mental health crisis and ap-
24 proaches to mental health and criminal justice across
25 systems;

1 “(3) provide training and best practices to men-
2 tal health providers and criminal justice agencies re-
3 lating to diversion initiatives, jail and prison strate-
4 gies, reentry of individuals with mental illnesses into
5 the community, and dispatch protocols and triage ca-
6 pabilities, including the establishment of learning
7 sites;

8 “(4) develop suicide prevention and crisis inter-
9 vention training and technical assistance for criminal
10 justice agencies;

11 “(5) develop a receiving center system and pilot
12 strategy that provides, for a jurisdiction, a single
13 point of entry into the mental health and substance
14 abuse system for assessments and appropriate place-
15 ment of individuals experiencing a crisis;

16 “(6) collect data and best practices in mental
17 health and criminal health and criminal justice ini-
18 tiatives and policies from grantees under this part,
19 other recipients of grants under this section, Federal,
20 State, and local agencies involved in the provision of
21 mental health services, and nongovernmental organi-
22 zations involved in the provision of mental health
23 services;

24 “(7) develop and disseminate to mental health
25 providers and criminal justice agencies evaluation

1 *tools, mechanisms, and measures to better assess and*
2 *document performance measures and outcomes relat-*
3 *ing to the provision of mental health services;*

4 *“(8) disseminate information to States, units of*
5 *local government, criminal justice agencies, law en-*
6 *forcement agencies, and other relevant entities about*
7 *best practices, policy standards, and research findings*
8 *relating to the provision of mental health services;*
9 *and*

10 *“(9) provide education and support to individ-*
11 *uals with mental illness involved with, or at risk of*
12 *involvement with, the criminal justice system, includ-*
13 *ing the families of such individuals.*

14 *“(d) ACCOUNTABILITY.—Grants awarded under this*
15 *section shall be subject to the following accountability provi-*
16 *sions:*

17 *“(1) AUDIT REQUIREMENT.—*

18 *“(A) DEFINITION.—In this paragraph, the*
19 *term ‘unresolved audit finding’ means a finding*
20 *in the final audit report of the Inspector General*
21 *of the Department of Justice under subpara-*
22 *graph (C) that the audited grantee has used*
23 *grant funds for an unauthorized expenditure or*
24 *otherwise unallowable cost that is not closed or*

1 *resolved within 1 year after the date on which*
2 *the final audit report is issued.*

3 “(B) *AUDITS.*—*Beginning in the first fiscal*
4 *year beginning after the date of enactment of*
5 *this section, and in each fiscal year thereafter,*
6 *the Inspector General of the Department of Jus-*
7 *tice shall conduct audits of grantees under this*
8 *section to prevent waste, fraud, and abuse of*
9 *funds by grantees. The Inspector General shall*
10 *determine the appropriate number of grantees to*
11 *be audited each year.*

12 “(C) *FINAL AUDIT REPORT.*—*The Inspector*
13 *General of the Department of Justice shall sub-*
14 *mit to the Attorney General a final report on*
15 *each audit conducted under subparagraph (B).*

16 “(D) *MANDATORY EXCLUSION.*—*Grantees*
17 *under this section about which there is an unre-*
18 *solved audit finding shall not be eligible to re-*
19 *ceive a grant under this section during the 2 fis-*
20 *cal years beginning after the end of the 1-year*
21 *period described in subparagraph (A).*

22 “(E) *PRIORITY.*—*In making grants under*
23 *this section, the Attorney General shall give pri-*
24 *ority to applicants that did not have an unre-*
25 *solved audit finding during the 3 fiscal years be-*

1 *fore submitting an application for a grant under*
2 *this section.*

3 “(F) *REIMBURSEMENT.*—*If an entity re-*
4 *ceives a grant under this section during the 2-*
5 *fiscal-year period during which the entity is pro-*
6 *hibited from receiving grants under subpara-*
7 *graph (D), the Attorney General shall—*

8 “(i) *deposit an amount equal to the*
9 *amount of the grant that was improperly*
10 *awarded to the grantee into the General*
11 *Fund of the Treasury; and*

12 “(ii) *seek to recoup the costs of the re-*
13 *payment under clause (i) from the grantee*
14 *that was erroneously awarded grant funds.*

15 “(2) *NONPROFIT AGENCY REQUIREMENTS.*—

16 “(A) *DEFINITION.*—*For purposes of this*
17 *paragraph and the grant program under this*
18 *section, the term ‘nonprofit agency’ means an or-*
19 *ganization that is described in section 501(c)(3)*
20 *of the Internal Revenue Code of 1986 (26 U.S.C.*
21 *501(c)(3)) and is exempt from taxation under*
22 *section 501(a) of the Internal Revenue Code of*
23 *1986 (26 U.S.C. 501(a)).*

24 “(B) *PROHIBITION.*—*The Attorney General*
25 *may not award a grant under this section to a*

1 *nonprofit agency that holds money in an offshore*
2 *account for the purpose of avoiding paying the*
3 *tax described in section 511(a) of the Internal*
4 *Revenue Code of 1986 (26 U.S.C. 511(a)).*

5 “(C) *DISCLOSURE.*—*Each nonprofit agency*
6 *that is awarded a grant under this section and*
7 *uses the procedures prescribed in regulations to*
8 *create a rebuttable presumption of reasonableness*
9 *for the compensation of its officers, directors,*
10 *trustees, and key employees, shall disclose to the*
11 *Attorney General, in the application for the*
12 *grant, the process for determining such com-*
13 *penensation, including the independent persons in-*
14 *olved in reviewing and approving such com-*
15 *penensation, the comparability data used, and con-*
16 *temporaneous substantiation of the deliberation*
17 *and decision. Upon request, the Attorney General*
18 *shall make the information disclosed under this*
19 *subparagraph available for public inspection.*

20 “(3) *CONFERENCE EXPENDITURES.*—

21 “(A) *LIMITATION.*—*No amounts made*
22 *available to the Department of Justice under this*
23 *section may be used by the Attorney General, or*
24 *by any individual or entity awarded discre-*
25 *tionary funds through a cooperative agreement*

1 *under this section, to host or support any ex-*
2 *penditure for conferences that uses more than*
3 *\$20,000 in funds made available by the Depart-*
4 *ment of Justice, unless the head of the relevant*
5 *agency or department, provides prior written*
6 *authorization that the funds may be expended to*
7 *host the conference.*

8 “(B) *WRITTEN APPROVAL.*—*Written ap-*
9 *proval under subparagraph (A) shall include a*
10 *written estimate of all costs associated with the*
11 *conference, including the cost of all food, bev-*
12 *erages, audio-visual equipment, honoraria for*
13 *speakers, and entertainment.*

14 “(C) *REPORT.*—*The Deputy Attorney Gen-*
15 *eral shall submit an annual report to the Com-*
16 *mittee on the Judiciary of the Senate and the*
17 *Committee on the Judiciary of the House of Rep-*
18 *resentatives on all conference expenditures ap-*
19 *proved under this paragraph.*

20 “(4) *ANNUAL CERTIFICATION.*—*Beginning in the*
21 *first fiscal year beginning after the date of enactment*
22 *of this subsection, the Attorney General shall submit*
23 *to the Committee on the Judiciary and the Committee*
24 *on Appropriations of the Senate and the Committee*
25 *on the Judiciary and the Committee on Appropria-*

1 *tions of the House of Representatives an annual cer-*
2 *tification—*

3 *“(A) indicating whether—*

4 *“(i) all final audit reports issued by*
5 *the Office of the Inspector General under*
6 *paragraph (1) have been completed and re-*
7 *viewed by the appropriate Assistant Attor-*
8 *ney General or Director;*

9 *“(ii) all mandatory exclusions required*
10 *under paragraph (1)(D) have been issued;*
11 *and*

12 *“(iii) any reimbursements required*
13 *under paragraph (1)(F) have been made;*
14 *and*

15 *“(B) that includes a list of any grantees ex-*
16 *cluded under paragraph (1)(D) from the pre-*
17 *vious year.*

18 *“(5) PREVENTING DUPLICATIVE GRANTS.—*

19 *“(A) IN GENERAL.—Before the Attorney*
20 *General awards a grant to an applicant under*
21 *this section, the Attorney General shall compare*
22 *potential grant awards with other grants award-*
23 *ed under this Act to determine if duplicate grant*
24 *awards are awarded for the same purpose.*

1 “(B) *REPORT.*—*If the Attorney General*
2 *awards duplicate grants to the same applicant*
3 *for the same purpose the Attorney General shall*
4 *submit to the Committee on the Judiciary of the*
5 *Senate and the Committee on the Judiciary of*
6 *the House of Representatives a report that in-*
7 *cludes—*

8 “(i) *a list of all duplicate grants*
9 *awarded, including the total dollar amount*
10 *of any duplicate grants awarded; and*

11 “(ii) *the reason the Attorney General*
12 *awarded the duplicate grants.”.*

13 **SEC. 14015. IMPROVING DEPARTMENT OF JUSTICE DATA**
14 **COLLECTION ON MENTAL ILLNESS INVOLVED**
15 **IN CRIME.**

16 (a) *IN GENERAL.*—*Notwithstanding any other provi-*
17 *sion of law, on or after the date that is 90 days after the*
18 *date on which the Attorney General promulgates regulations*
19 *under subsection (b), any data prepared by, or submitted*
20 *to, the Attorney General or the Director of the Federal Bu-*
21 *reau of Investigation with respect to the incidences of homi-*
22 *cides, law enforcement officers killed, seriously injured, and*
23 *assaulted, or individuals killed or seriously injured by law*
24 *enforcement officers shall include data with respect to the*
25 *involvement of mental illness in such incidences, if any.*

1 (b) *REGULATIONS.*—Not later than 90 days after the
2 date of the enactment of this Act, the Attorney General shall
3 promulgate or revise regulations as necessary to carry out
4 subsection (a).

5 **SEC. 14016. REPORTS ON THE NUMBER OF MENTALLY ILL**
6 **OFFENDERS IN PRISON.**

7 (a) *REPORT ON THE COST OF TREATING THE MEN-*
8 *TALLY ILL IN THE CRIMINAL JUSTICE SYSTEM.*—Not later
9 than 12 months after the date of enactment of this Act, the
10 Comptroller General of the United States shall submit to
11 Congress a report detailing the cost of imprisonment for
12 individuals who have serious mental illness by the Federal
13 Government or a State or unit of local government, which
14 shall include—

15 (1) *the number and type of crimes committed by*
16 *individuals with serious mental illness each year; and*

17 (2) *detail strategies or ideas for preventing*
18 *crimes by those individuals with serious mental ill-*
19 *ness from occurring.*

20 (b) *DEFINITION.*—For purposes of this section, the At-
21 torney General, in consultation with the Assistant Sec-
22 retary of Mental Health and Substance Use Disorders, shall
23 define “serious mental illness” based on the “Health Care
24 Reform for Americans with Severe Mental Illnesses: Report”

1 *of the National Advisory Mental Health Council, American*
2 *Journal of Psychiatry* 1993; 150:1447–1465.

3 **SEC. 14017. CODIFICATION OF DUE PROCESS FOR DETER-**
4 **MINATIONS BY SECRETARY OF VETERANS AF-**
5 **FAIRS OF MENTAL CAPACITY OF BENE-**
6 **FICIARIES.**

7 (a) *IN GENERAL.*—Chapter 55 of title 38, United
8 States Code, is amended by inserting after section 5501 the
9 following new section:

10 **“§5501A. Beneficiaries’ rights in mental competence**
11 **determinations**

12 “The Secretary may not make an adverse determina-
13 tion concerning the mental capacity of a beneficiary to
14 manage monetary benefits paid to or for the beneficiary by
15 the Secretary under this title unless such beneficiary has
16 been provided all of the following, subject to the procedures
17 and timelines prescribed by the Secretary for determina-
18 tions of incompetency:

19 “(1) Notice of the proposed adverse determina-
20 tion and the supporting evidence.

21 “(2) An opportunity to request a hearing.

22 “(3) An opportunity to present evidence, includ-
23 ing an opinion from a medical professional or other
24 person, on the capacity of the beneficiary to manage

1 *monetary benefits paid to or for the beneficiary by the*
2 *Secretary under this title.*

3 “(4) *An opportunity to be represented at no ex-*
4 *penditure to the Government (including by counsel) at*
5 *any such hearing and to bring a medical professional*
6 *or other person to provide relevant testimony at any*
7 *such hearing.”.*

8 (b) *CLERICAL AMENDMENT.*—*The table of sections at*
9 *the beginning of such chapter 55 is amended by inserting*
10 *after the item relating to section 5501 the following new*
11 *item:*

 “5501A. *Beneficiaries’ rights in mental competence determinations*”.

12 (c) *EFFECTIVE DATE.*—*Section 5501A of title 38,*
13 *United States Code, as added by subsection (a), shall apply*
14 *to determinations made by the Secretary of Veterans Affairs*
15 *on or after the date of the enactment of this Act.*

16 **SEC. 14018. REAUTHORIZATION OF APPROPRIATIONS.**

17 *Subsection (o) of section 2991 of the Omnibus Crime*
18 *Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa),*
19 *as redesignated by section 14006, is amended—*

20 (1) *in paragraph (1)(C), by striking “2009*
21 *through 2014” and inserting “2017 through 2021”;*
22 *and*

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

24 “(3) *LIMITATION.*—*Not more than 20 percent of the*
25 *funds authorized to be appropriated under this section may*

1 *be used for purposes described in subsection (i) (relating*
 2 *to veterans).’.*

3 ***Subtitle B—Comprehensive Justice***
 4 ***and Mental Health***

5 ***SEC. 14021. SEQUENTIAL INTERCEPT MODEL.***

6 *Section 2991 of title I of the Omnibus Crime Control*
 7 *and Safe Streets Act of 1968 (42 U.S.C. 3797aa), as amend-*
 8 *ed by section 14005, is amended by inserting after sub-*
 9 *section (j), the following:*

10 *“(k) SEQUENTIAL INTERCEPT GRANTS.—*

11 *“(1) DEFINITION.—In this subsection, the term*
 12 *‘eligible entity’ means a State, unit of local govern-*
 13 *ment, Indian tribe, or tribal organization.*

14 *“(2) AUTHORIZATION.—The Attorney General*
 15 *may make grants under this subsection to an eligible*
 16 *entity for sequential intercept mapping and imple-*
 17 *mentation in accordance with paragraph (3).*

18 *“(3) SEQUENTIAL INTERCEPT MAPPING; IMPLE-*
 19 *MENTATION.—An eligible entity that receives a grant*
 20 *under this subsection may use funds for—*

21 *“(A) sequential intercept mapping, which—*

22 *“(i) shall consist of—*

23 *“(I) convening mental health and*
 24 *criminal justice stakeholders to—*

1 “(aa) develop a shared un-
2 derstanding of the flow of justice-
3 involved individuals with mental
4 illnesses through the criminal jus-
5 tice system; and

6 “(bb) identify opportunities
7 for improved collaborative re-
8 sponses to the risks and needs of
9 individuals described in item
10 (aa); and

11 “(II) developing strategies to ad-
12 dress gaps in services and bring inno-
13 vative and effective programs to scale
14 along multiple intercepts, including—

15 “(aa) emergency and crisis
16 services;

17 “(bb) specialized police-based
18 responses;

19 “(cc) court hearings and dis-
20 position alternatives;

21 “(dd) reentry from jails and
22 prisons; and

23 “(ee) community supervision,
24 treatment and support services;
25 and

1 “(i) may serve as a starting point for
2 the development of strategic plans to achieve
3 positive public health and safety outcomes;
4 and

5 “(B) implementation, which shall—

6 “(i) be derived from the strategic plans
7 described in subparagraph (A)(i); and

8 “(ii) consist of—

9 “(I) hiring and training per-
10 sonnel;

11 “(II) identifying the eligible enti-
12 ty’s target population;

13 “(III) providing services and sup-
14 ports to reduce unnecessary penetra-
15 tion into the criminal justice system;

16 “(IV) reducing recidivism;

17 “(V) evaluating the impact of the
18 eligible entity’s approach; and

19 “(VI) planning for the sustain-
20 ability of effective interventions.”.

21 **SEC. 14022. PRISON AND JAILS.**

22 Section 2991 of title I of the Omnibus Crime Control
23 and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amend-
24 ed by inserting after subsection (k), as added by section
25 14021, the following:

1 “(l) *CORRECTIONAL FACILITIES.*—

2 “(1) *DEFINITIONS.*—

3 “(A) *CORRECTIONAL FACILITY.*—*The term*
4 *‘correctional facility’ means a jail, prison, or*
5 *other detention facility used to house people who*
6 *have been arrested, detained, held, or convicted*
7 *by a criminal justice agency or a court.*

8 “(B) *ELIGIBLE INMATE.*—*The term ‘eligible*
9 *inmate’ means an individual who—*

10 “(i) *is being held, detained, or incar-*
11 *cerated in a correctional facility; and*

12 “(ii) *manifests obvious signs of a men-*
13 *tal illness or has been diagnosed by a quali-*
14 *fied mental health professional as having a*
15 *mental illness.*

16 “(2) *CORRECTIONAL FACILITY GRANTS.*—*The At-*
17 *torney General may award grants to applicants to*
18 *enhance the capabilities of a correctional facility—*

19 “(A) *to identify and screen for eligible in-*
20 *mates;*

21 “(B) *to plan and provide—*

22 “(i) *initial and periodic assessments of*
23 *the clinical, medical, and social needs of in-*
24 *mates; and*

1 “(ii) appropriate treatment and serv-
2 ices that address the mental health and sub-
3 stance abuse needs of inmates;

4 “(C) to develop, implement, and enhance—

5 “(i) post-release transition plans for el-
6 igible 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 treatment
12 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 segregated
17 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 sub-
22 stance 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 crisis*
13 *services for public service personnel,*
14 *including criminal justice, mental*
15 *health, substance abuse, emergency*
16 *room, healthcare, law enforcement, cor-*
17 *rections, and housing personnel;*

18 “(III) *develop or support alter-*
19 *natives to hospital and jail admissions*
20 *for frequent users of crisis services that*
21 *provide treatment, stabilization, and*
22 *other appropriate supports in the least*
23 *restrictive, yet appropriate, environ-*
24 *ment; 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 sup-
15 port for academy curricula, law enforcement offi-
16 cer orientation programs, continuing education
17 training, and other programs that teach law en-
18 forcement personnel how to identify and respond
19 to incidents involving persons with mental
20 health disorders or co-occurring mental health
21 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 sub-*
2 *stance abuse professions develop and administer coop-*
3 *eratively.”.*

4 **SEC. 14025. FEDERAL LAW ENFORCEMENT TRAINING.**

5 *Not later than 1 year after the date of enactment of*
6 *this Act, the Attorney General shall provide direction and*
7 *guidance for the following:*

8 (1) *TRAINING PROGRAMS.—Programs that offer*
9 *specialized and comprehensive training, in procedures*
10 *to identify and appropriately respond to incidents in*
11 *which the unique needs of individuals who have a*
12 *mental illness are involved, to first responders and*
13 *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 other*
18 *agencies that the Attorney General determines*
19 *appropriate.*

20 (2) *IMPROVED TECHNOLOGY.—The establishment*
21 *of, or improvement of existing, computerized informa-*
22 *tion systems to provide timely information to employ-*
23 *ees of Federal law enforcement agencies, and Federal*
24 *criminal justice agencies to improve the response of*

1 *such employees to situations involving individuals*
2 *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, in*
6 *coordination with the Attorney General, shall submit to*
7 *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 in*
16 *criminal justice settings to better address individuals*
17 *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(c))*
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 shown*
8 *by empirical evidence to reduce recidivism;*

9 “*(5) when appropriate, use validated assessment*
10 *tools to target preliminarily qualified offenders with*
11 *a moderate or high risk of recidivism and a need for*
12 *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 been*
8 *diagnosed by a qualified mental health pro-*
9 *fessional as having a mental illness or co-*
10 *occurring mental illness and substance*
11 *abuse disorders;*

12 “(II) *manifests obvious signs of mental*
13 *illness or co-occurring mental illness and*
14 *substance abuse disorders during arrest or*
15 *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 obvi-*
19 *ous signs of, mental illness or a substance*
20 *abuse disorder or co-occurring mental ill-*
21 *ness 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 corrections
4 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 vio-
14 lence to any person in the program, or the
15 public, if selected to participate in the pro-
16 gram; and
17 “(iv) has not been charged with or con-
18 victed of—
19 “(I) any sex offense (as defined in
20 section 111 of the Sex Offender Reg-
21 istration and Notification Act (42
22 U.S.C. 16911)) or any offense relating
23 to the sexual exploitation of children;
24 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 take
9 into account—

10 “(i) whether the participation of the
11 defendant in the program would pose a sub-
12 stantial risk of violence to the community;

13 “(ii) the criminal history of the defend-
14 ant and the nature and severity of the of-
15 fense for which the defendant is charged;

16 “(iii) the views of any relevant victims
17 to the offense;

18 “(iv) the extent to which the defendant
19 would benefit from participation in the pro-
20 gram;

21 “(v) the extent to which the community
22 would realize cost savings because of the de-
23 fendant’s participation in the program; and

24 “(vi) whether the defendant satisfies
25 the eligibility criteria for program partici-

1 *pation unanimously established by the rel-*
2 *evant prosecuting attorney, defense attor-*
3 *ney, probation or corrections official, judge*
4 *and mental health or substance abuse agen-*
5 *cy representative.”.*

6 *(b) TECHNICAL AND CONFORMING AMENDMENT.—Sec-*
7 *tion 2927(2) of title I of the Omnibus Crime Control and*
8 *Safe Streets Act of 1968 (42 U.S.C. 3797s–6(2)) is amended*
9 *by striking “has the meaning given that term in section*
10 *2991(a).” and inserting “means an offense that—*

11 *“(A) does not have as an element the use,*
12 *attempted use, or threatened use of physical force*
13 *against the person or property of another; or*

14 *“(B) is not a felony that by its nature in-*
15 *volves a substantial risk that physical force*
16 *against the person or property of another may be*
17 *used in the course of committing the offense.”.*

18 **SEC. 14029. GRANT ACCOUNTABILITY.**

19 *Section 2991 of title I of the Omnibus Crime Control*
20 *and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amend-*
21 *ed by inserting after subsection (l), as added by section*
22 *14022, the following:*

23 *“(m) ACCOUNTABILITY.—All grants awarded by the*
24 *Attorney General under this section shall be subject to the*
25 *following accountability provisions:*

1 “(1) *AUDIT REQUIREMENT.*—

2 “(A) *DEFINITION.*—*In this paragraph, the*
3 *term ‘unresolved audit finding’ means a finding*
4 *in the final audit report of the Inspector General*
5 *of the Department of Justice that the audited*
6 *grantee has utilized grant funds for an unau-*
7 *thorized expenditure or otherwise unallowable*
8 *cost that is not closed or resolved within 12*
9 *months from the date when the final audit report*
10 *is issued.*

11 “(B) *AUDITS.*—*Beginning in the first fiscal*
12 *year beginning after the date of enactment of*
13 *this subsection, and in each fiscal year there-*
14 *after, the Inspector General of the Department of*
15 *Justice shall conduct audits of recipients of*
16 *grants under this section to prevent waste, fraud,*
17 *and abuse of funds by grantees. The Inspector*
18 *General shall determine the appropriate number*
19 *of grantees to be audited each year.*

20 “(C) *MANDATORY EXCLUSION.*—*A recipient*
21 *of grant funds under this section that is found*
22 *to have an unresolved audit finding shall not be*
23 *eligible to receive grant funds under this section*
24 *during the first 2 fiscal years beginning after the*

1 *end of the 12-month period described in subpara-*
2 *graph (A).*

3 “(D) *PRIORITY.*—*In awarding grants under*
4 *this section, the Attorney General shall give pri-*
5 *ority to eligible applicants that did not have an*
6 *unresolved audit finding during the 3 fiscal*
7 *years before submitting an application for a*
8 *grant under this section.*

9 “(E) *REIMBURSEMENT.*—*If an entity is*
10 *awarded grant funds under this section during*
11 *the 2-fiscal-year period during which the entity*
12 *is barred from receiving grants under subpara-*
13 *graph (C), the Attorney General shall—*

14 “(i) *deposit an amount equal to the*
15 *amount of the grant funds that were im-*
16 *properly awarded to the grantee into the*
17 *General Fund of the Treasury; and*

18 “(ii) *seek to recoup the costs of the re-*
19 *payment to the fund from the grant recipi-*
20 *ent that was erroneously awarded grant*
21 *funds.*

22 “(2) *NONPROFIT ORGANIZATION REQUIRE-*
23 *MENTS.*—

24 “(A) *DEFINITION.*—*For purposes of this*
25 *paragraph and the grant programs under this*

1 *part, the term ‘nonprofit organization’ means an*
2 *organization that is described in section*
3 *501(c)(3) of the Internal Revenue Code of 1986*
4 *and is exempt from taxation under section*
5 *501(a) of such Code.*

6 “(B) *PROHIBITION.*—*The Attorney General*
7 *may not award a grant under this part to a*
8 *nonprofit organization that holds money in off-*
9 *shore accounts for the purpose of avoiding pay-*
10 *ing the tax described in section 511(a) of the In-*
11 *ternal Revenue Code of 1986.*

12 “(C) *DISCLOSURE.*—*Each nonprofit organi-*
13 *zation that is awarded a grant under this section*
14 *and uses the procedures prescribed in regulations*
15 *to create a rebuttable presumption of reasonable-*
16 *ness for the compensation of its officers, direc-*
17 *tors, trustees, and key employees, shall disclose to*
18 *the Attorney General, in the application for the*
19 *grant, the process for determining such com-*
20 *penetration, including the independent persons in-*
21 *involved in reviewing and approving such com-*
22 *penetration, the comparability data used, and con-*
23 *temporaneous substantiation of the deliberation*
24 *and decision. Upon request, the Attorney General*

1 *shall make the information disclosed under this*
2 *subparagraph available for public inspection.*

3 “(3) *CONFERENCE EXPENDITURES.*—

4 “(A) *LIMITATION.*—*No amounts made*
5 *available to the Department of Justice under this*
6 *section may be used by the Attorney General, or*
7 *by any individual or entity awarded discre-*
8 *tionary funds through a cooperative agreement*
9 *under this section, to host or support any ex-*
10 *penditure for conferences that uses more than*
11 *\$20,000 in funds made available by the Depart-*
12 *ment of Justice, unless the head of the relevant*
13 *agency or department, provides prior written*
14 *authorization that the funds may be expended to*
15 *host the conference.*

16 “(B) *WRITTEN APPROVAL.*—*Written ap-*
17 *proval under subparagraph (A) shall include a*
18 *written estimate of all costs associated with the*
19 *conference, including the cost of all food, bev-*
20 *erages, audio-visual equipment, honoraria for*
21 *speakers, and entertainment.*

22 “(C) *REPORT.*—*The Deputy Attorney Gen-*
23 *eral shall submit an annual report to the Com-*
24 *mittee on the Judiciary of the Senate and the*
25 *Committee on the Judiciary of the House of Rep-*

1 representatives on all conference expenditures ap-
2 proved under this paragraph.

3 “(4) ANNUAL CERTIFICATION.—Beginning in the
4 first fiscal year beginning after the date of enactment
5 of this subsection, the Attorney General shall submit,
6 to the Committee on the Judiciary and the Committee
7 on Appropriations of the Senate and the Committee
8 on the Judiciary and the Committee on Appropria-
9 tions of the House of Representatives, an annual cer-
10 tification—

11 “(A) indicating whether—

12 “(i) all audits issued by the Office of
13 the Inspector General under paragraph (1)
14 have been completed and reviewed by the
15 appropriate Assistant Attorney General or
16 Director;

17 “(ii) all mandatory exclusions required
18 under paragraph (1)(C) have been issued;
19 and

20 “(iii) all reimbursements required
21 under paragraph (1)(E) have been made;
22 and

23 “(B) that includes a list of any grant re-
24 cipients excluded under paragraph (1) from the
25 previous year.

1 “(n) *PREVENTING DUPLICATIVE GRANTS.*—

2 “(1) *IN GENERAL.*—*Before the Attorney General*
 3 *awards a grant to an applicant under this section,*
 4 *the Attorney General shall compare potential grant*
 5 *awards with other grants awarded under this Act to*
 6 *determine if duplicate grant awards are awarded for*
 7 *the same purpose.*

8 “(2) *REPORT.*—*If the Attorney General awards*
 9 *duplicate grants to the same applicant for the same*
 10 *purpose the Attorney General shall submit to the*
 11 *Committee on the Judiciary of the Senate and the*
 12 *Committee on the Judiciary of the House of Rep-*
 13 *resentatives a report that includes—*

14 “(A) *a list of all duplicate grants awarded,*
 15 *including the total dollar amount of any dupli-*
 16 *cate grants awarded; and*

17 “(B) *the reason the Attorney General*
 18 *awarded the duplicate grants.”.*

19 ***DIVISION C—INCREASING***
 20 ***CHOICE, ACCESS, AND QUAL-***
 21 ***ITY IN HEALTH CARE FOR***
 22 ***AMERICANS***

23 ***SEC. 15000. SHORT TITLE.***

24 *This division may be cited as the “Increasing Choice,*
 25 *Access, and Quality in Health Care for Americans Act”.*

1 **TITLE XV—PROVISIONS**
2 **RELATING TO MEDICARE PART A**

3 **SEC. 15001. DEVELOPMENT OF MEDICARE HCPCS VERSION**
4 **OF MS-DRG CODES FOR SIMILAR HOSPITAL**
5 **SERVICES.**

6 *Section 1886 of the Social Security Act (42 U.S.C.*
7 *1395ww) is amended by adding at the end the following*
8 *new subsection:*

9 “(t) *RELATING SIMILAR INPATIENT AND OUTPATIENT*
10 *HOSPITAL SERVICES.—*

11 “(1) *DEVELOPMENT OF HCPCS VERSION OF MS-*
12 *DRG CODES.—Not later than January 1, 2018, the*
13 *Secretary shall develop HCPCS versions for MS-*
14 *DRGs that are similar to the ICD-10-PCS for such*
15 *MS-DRGs such that, to the extent possible, the MS-*
16 *DRG assignment shall be similar for a claim coded*
17 *with the HCPCS version as an identical claim coded*
18 *with a ICD-10-PCS code.*

19 “(2) *COVERAGE OF SURGICAL MS-DRGS.—In*
20 *carrying out paragraph (1), the Secretary shall de-*
21 *velop HCPCS versions of MS-DRG codes for not*
22 *fewer than 10 surgical MS-DRGs.*

23 “(3) *PUBLICATION AND DISSEMINATION OF THE*
24 *HCPCS VERSIONS OF MS-DRGS.—*

1 “(A) *IN GENERAL.*—*The Secretary shall de-*
2 *velop a HCPCS MS–DRG definitions manual*
3 *and software that is similar to the definitions*
4 *manual and software for ICD–10–PCS codes for*
5 *such MS–DRGs. The Secretary shall post the*
6 *HCPCS MS–DRG definitions manual and soft-*
7 *ware on the Internet website of the Centers for*
8 *Medicare & Medicaid Services. The HCPCS*
9 *MS–DRG definitions manual and software shall*
10 *be in the public domain and available for use*
11 *and redistribution without charge.*

12 “(B) *USE OF PREVIOUS ANALYSIS DONE BY*
13 *MEDPAC.*—*In developing the HCPCS MS–DRG*
14 *definitions manual and software under subpara-*
15 *graph (A), the Secretary shall consult with the*
16 *Medicare Payment Advisory Commission and*
17 *shall consider the analysis done by such Commis-*
18 *sion in translating outpatient surgical claims*
19 *into inpatient surgical MS–DRGs in preparing*
20 *chapter 7 (relating to hospital short-stay policy*
21 *issues) of its ‘Medicare and the Health Care De-*
22 *livery System’ report submitted to Congress in*
23 *June 2015.*

24 “(4) *DEFINITION AND REFERENCE.*—*In this sub-*
25 *section:*

1 “(A) HCPCS.—The term ‘HCPCS’ means,
2 with respect to hospital items and services, the
3 code under the Healthcare Common Procedure
4 Coding System (HCPCS) (or a successor code)
5 for such items and services.

6 “(B) ICD–10–PCS.—The term ‘ICD–10–
7 PCS’ means the International Classification of
8 Diseases, 10th Revision, Procedure Coding Sys-
9 tem, and includes any subsequent revision of
10 such International Classification of Diseases,
11 Procedure Coding System.”.

12 **SEC. 15002. ESTABLISHING BENEFICIARY EQUITY IN THE**
13 **MEDICARE HOSPITAL READMISSION PRO-**
14 **GRAM.**

15 (a) *TRANSITIONAL ADJUSTMENT FOR DUAL ELIGIBLE*
16 *POPULATION.*—Section 1886(q)(3) of the Social Security
17 Act (42 U.S.C. 1395ww(q)(3)) is amended—

18 (1) in subparagraph (A), by inserting “subject to
19 subparagraph (D),” after “purposes of paragraph
20 (1),”; and

21 (2) by adding at the end the following new sub-
22 paragraph:

23 “(D) *TRANSITIONAL ADJUSTMENT FOR*
24 *DUAL ELIGIBLES.*—

1 “(i) *IN GENERAL.*—*In determining a*
2 *hospital’s adjustment factor under this*
3 *paragraph for purposes of making pay-*
4 *ments for discharges occurring during and*
5 *after fiscal year 2019, and before the appli-*
6 *cation of clause (i) of subparagraph (E), the*
7 *Secretary shall assign hospitals to groups*
8 *(as defined by the Secretary under clause*
9 *(ii)) and apply the applicable provisions of*
10 *this subsection using a methodology in a*
11 *manner that allows for separate comparison*
12 *of hospitals within each such group, as de-*
13 *termined by the Secretary.*

14 “(ii) *DEFINING GROUPS.*—*For pur-*
15 *poses of this subparagraph, the Secretary*
16 *shall define groups of hospitals, based on*
17 *their overall proportion, of the inpatients*
18 *who are entitled to, or enrolled for, benefits*
19 *under part A, and who are full-benefit dual*
20 *eligible individuals (as defined in section*
21 *1935(c)(6)). In defining groups, the Sec-*
22 *retary shall consult the Medicare Payment*
23 *Advisory Commission and may consider the*
24 *analysis done by such Commission in pre-*
25 *paring the portion of its report submitted to*

1 Congress in June 2013 relating to readmis-
2 sions.

3 “(iii) *MINIMIZING REPORTING BURDEN*
4 *ON HOSPITALS.*—In carrying out this sub-
5 paragraph, the Secretary shall not impose
6 any additional reporting requirements on
7 hospitals.

8 “(iv) *BUDGET NEUTRAL DESIGN METH-*
9 *ODOLOGY.*—The Secretary shall design the
10 methodology to implement this subpara-
11 graph so that the estimated total amount of
12 reductions in payments under this sub-
13 section equals the estimated total amount of
14 reductions in payments that would other-
15 wise occur under this subsection if this sub-
16 paragraph did not apply.”

17 (b) *CHANGES IN RISK ADJUSTMENT.*—Section
18 1886(q)(3) of the Social Security Act (42 U.S.C.
19 1395ww(q)(3)), as amended by subsection (a), is further
20 amended by adding at the end the following new subpara-
21 graph:

22 “(E) *CHANGES IN RISK ADJUSTMENT.*—

23 “(i) *CONSIDERATION OF RECOMMENDA-*
24 *TIONS IN IMPACT REPORTS.*—The Secretary
25 may take into account the studies conducted

1 and the recommendations made by the Sec-
2 retary under section 2(d)(1) of the *IMPACT*
3 Act of 2014 (Public Law 113–185; 42
4 U.S.C. 1395lll note) with respect to the ap-
5 plication under this subsection of risk ad-
6 justment methodologies. Nothing in this
7 clause shall be construed as precluding con-
8 sideration of the use of groupings of hos-
9 pitals.

10 “(ii) *CONSIDERATION OF EXCLUSION*
11 *OF PATIENT CASES BASED ON V OR OTHER*
12 *APPROPRIATE CODES.—In promulgating*
13 *regulations to carry out this subsection with*
14 *respect to discharges occurring after fiscal*
15 *year 2018, the Secretary may consider the*
16 *use of V or other ICD-related codes for re-*
17 *moval of a readmission. The Secretary may*
18 *consider modifying measures under this*
19 *subsection to incorporate V or other ICD-re-*
20 *lated codes at the same time as other*
21 *changes are being made under this subpara-*
22 *graph.*

23 “(iii) *REMOVAL OF CERTAIN READMIS-*
24 *SIONS.—In promulgating regulations to*
25 *carry out this subsection, with respect to*

1 (1) in subsection (a)(5), by striking “5-year ex-
2 tension period” and inserting “10-year extension pe-
3 riod”; and

4 (2) in subsection (g)—

5 (A) in the subsection heading, by striking
6 “FIVE-YEAR” and inserting “TEN-YEAR”;

7 (B) in paragraph (1), by striking “addi-
8 tional 5-year” and inserting “additional 10-
9 year”;

10 (C) by striking “5-year extension period”
11 and inserting “10-year extension period” each
12 place it appears;

13 (D) in paragraph (4)(B)—

14 (i) in the matter preceding clause (i),
15 by inserting “each 5-year period in” after
16 “hospital during”; and

17 (ii) in clause (i), by inserting “each
18 applicable 5-year period in” after “the first
19 day of”; and

20 (E) by adding at the end the following new
21 paragraphs:

22 “(5) OTHER HOSPITALS IN DEMONSTRATION
23 PROGRAM.—During the second 5 years of the 10-year
24 extension period, the Secretary shall apply the provi-
25 sions of paragraph (4) to rural community hospitals

1 *that are not described in paragraph (4) but are par-*
2 *ticipating in the demonstration program under this*
3 *section as of December 30, 2014, in a similar manner*
4 *as such provisions apply to rural community hos-*
5 *pitals described in paragraph (4).*

6 “(6) *EXPANSION OF DEMONSTRATION PROGRAM*
7 *TO RURAL AREAS IN ANY STATE.—*

8 “(A) *IN GENERAL.—The Secretary shall,*
9 *notwithstanding subsection (a)(2) or paragraph*
10 *(2) of this subsection, not later than 120 days*
11 *after the date of the enactment of this paragraph,*
12 *issue a solicitation for applications to select up*
13 *to the maximum number of additional rural*
14 *community hospitals located in any State to*
15 *participate in the demonstration program under*
16 *this section for the second 5 years of the 10-year*
17 *extension period without exceeding the limitation*
18 *under paragraph (3) of this subsection.*

19 “(B) *PRIORITY.—In determining which*
20 *rural community hospitals that submitted an*
21 *application pursuant to the solicitation under*
22 *subparagraph (A) to select for participation in*
23 *the demonstration program, the Secretary—*

24 “(i) *shall give priority to rural com-*
25 *munity hospitals located in one of the 20*

1 *States with the lowest population densities*
2 *(as determined by the Secretary using the*
3 *2015 Statistical Abstract of the United*
4 *States); and*

5 “(ii) may consider—

6 “(I) closures of hospitals located
7 *in rural areas in the State in which*
8 *the rural community hospital is lo-*
9 *cated during the 5-year period imme-*
10 *diately preceding the date of the enact-*
11 *ment of this paragraph; and*

12 “(II) the population density of the
13 *State in which the rural community*
14 *hospital is located.”.*

15 (b) *CHANGE IN TIMING FOR REPORT.*—Subsection (e)
16 *of such section 410A is amended—*

17 (1) *by striking “Not later than 6 months after*
18 *the completion of the demonstration program under*
19 *this section” and inserting “Not later than August 1,*
20 *2018”; and*

21 (2) *by striking “such program” and inserting*
22 *“the demonstration program under this section”.*

23 **SEC. 15004. REGULATORY RELIEF FOR LTCHS.**

24 (a) *TECHNICAL CHANGE TO THE MEDICARE LONG-*
25 *TERM CARE HOSPITAL MORATORIUM EXCEPTION.*—

1 (1) *IN GENERAL.*—Section 114(d)(7) of the Medi-
2 *care, Medicaid, and SCHIP Extension Act of 2007*
3 *(42 U.S.C. 1395ww note), as amended by sections*
4 *3106(b) and 10312(b) of Public Law 111–148, section*
5 *1206(b)(2) of the Pathway for SGR Reform Act of*
6 *2013 (division B of Public Law 113–67), and section*
7 *112 of the Protecting Access to Medicare Act of 2014*
8 *(Public Law 113–93), is amended by striking “The*
9 *moratorium under paragraph (1)(A)” and inserting*
10 *“Any moratorium under paragraph (1)”.*

11 (2) *EFFECTIVE DATE.*—The amendment made by
12 *paragraph (1) shall take effect as if included in the*
13 *enactment of section 112 of the Protecting Access to*
14 *Medicare Act of 2014.*

15 (b) *MODIFICATION TO MEDICARE LONG-TERM CARE*
16 *HOSPITAL HIGH COST OUTLIER PAYMENTS.*—Section
17 *1886(m) of the Social Security Act (42 U.S.C. 1395ww(m))*
18 *is amended by adding at the end the following new para-*
19 *graph:*

20 “(7) *TREATMENT OF HIGH COST OUTLIER PAY-*
21 *MENTS.*—

22 “(A) *ADJUSTMENT TO THE STANDARD FED-*
23 *ERAL PAYMENT RATE FOR ESTIMATED HIGH*
24 *COST OUTLIER PAYMENTS.*—Under the system
25 *described in paragraph (1), for fiscal years be-*

1 *ginning on or after October 1, 2017, the Sec-*
2 *retary shall reduce the standard Federal pay-*
3 *ment rate as if the estimated aggregate amount*
4 *of high cost outlier payments for standard Fed-*
5 *eral payment rate discharges for each such fiscal*
6 *year would be equal to 8 percent of estimated ag-*
7 *gregate payments for standard Federal payment*
8 *rate discharges for each such fiscal year.*

9 *“(B) LIMITATION ON HIGH COST OUTLIER*
10 *PAYMENT AMOUNTS.—Notwithstanding subpara-*
11 *graph (A), the Secretary shall set the fixed loss*
12 *amount for high cost outlier payments such that*
13 *the estimated aggregate amount of high cost*
14 *outlier payments made for standard Federal*
15 *payment rate discharges for fiscal years begin-*
16 *ning on or after October 1, 2017, shall be equal*
17 *to 99.6875 percent of 8 percent of estimated ag-*
18 *gregate payments for standard Federal payment*
19 *rate discharges for each such fiscal year.*

20 *“(C) WAIVER OF BUDGET NEUTRALITY.—*
21 *Any reduction in payments resulting from the*
22 *application of subparagraph (B) shall not be*
23 *taken into account in applying any budget neu-*
24 *trality provision under such system.*

1 “(D) NO EFFECT ON SITE NEUTRAL HIGH
2 COST OUTLIER PAYMENT RATE.—This paragraph
3 shall not apply with respect to the computation
4 of the applicable site neutral payment rate under
5 paragraph (6).”.

6 **SEC. 15005. SAVINGS FROM IPPS MACRA PAY-FOR THROUGH**
7 **NOT APPLYING DOCUMENTATION AND COD-**
8 **ING ADJUSTMENTS.**

9 Section 7(b)(1)(B) of the TMA, Abstinence Education,
10 and QI Programs Extension Act of 2007 (Public Law 110–
11 90), as amended by section 631(b) of the American Tax-
12 payer Relief Act of 2012 (Public Law 112–240) and section
13 414(1)(B)(iii) of the Medicare Access and CHIP Reauthor-
14 ization Act of 2015 (Public Law 114–10), is amended in
15 clause (iii) by striking “an increase of 0.5 percentage points
16 for discharges occurring during each of fiscal years 2018
17 through 2023” and inserting “an increase of 0.4588 per-
18 centage points for discharges occurring during fiscal year
19 2018 and 0.5 percentage points for discharges occurring
20 during each of fiscal years 2019 through 2023”.

21 **SEC. 15006. EXTENSION OF CERTAIN LTCH MEDICARE PAY-**
22 **MENT RULES.**

23 (a) 25–PERCENT PATIENT THRESHOLD PAYMENT AD-
24 JUSTMENT.—Section 114(c)(1)(A) of the Medicare, Med-
25 icaid, and SCHIP Extension Act of 2007 (42 U.S.C.

1 1395ww note), as amended by section 4302(a) of division
2 B of the American Recovery and Reinvestment Act (Public
3 Law 111–5), sections 3106(a) and 10312(a) of Public Law
4 111–148, and section 1206(b)(1)(B) of the Pathway for
5 SGR Reform Act of 2013 (division B of Public Law 113–
6 67), is amended by striking “for a 9-year period” and in-
7 serting “through June 30, 2016, and for discharges occur-
8 ring on or after October 1, 2016, and before October 1,
9 2017”.

10 (b) *PAYMENT FOR HOSPITALS-WITHIN-HOSPITALS.*—
11 Section 114(c)(2) of the Medicare, Medicaid, and SCHIP
12 Extension Act of 2007 (42 U.S.C. 1395ww note), as amend-
13 ed by section 4302(a) of division B of the American Recov-
14 ery and Reinvestment Act (Public Law 111–5), sections
15 3106(a) and 10312(a) of Public Law 111–148, and section
16 1206(b)(1)(A) of the Pathway for SGR Reform Act of 2013
17 (division B of Public Law 113–67), is amended—

18 (1) in subparagraph (A), by inserting “or any
19 similar provision,” after “Regulations,”;

20 (2) in subparagraph (B)—

21 (A) in clause (i), by inserting “or any simi-
22 lar provision,” after “Regulations,”; and

23 (B) in clause (ii), by inserting “, or any
24 similar provision,” after “Regulations,”; and

1 (3) *in subparagraph (C), by striking “for a 9-*
 2 *year period” and inserting “through June 30, 2016,*
 3 *and for discharges occurring on or after October 1,*
 4 *2016, and before October 1, 2017”.*

5 **SEC. 15007. APPLICATION OF RULES ON THE CALCULATION**
 6 **OF HOSPITAL LENGTH OF STAY TO ALL**
 7 **LTCHS.**

8 (a) *IN GENERAL.*—*Section 1206(a)(3) of the Pathway*
 9 *for SGR Reform Act of 2013 (division B of Public Law*
 10 *113–67; 42 U.S.C. 1395ww note) is amended—*

11 (1) *by striking subparagraph (B);*

12 (2) *by striking “SITE NEUTRAL BASIS.—” and*
 13 *all that follows through “For discharges occurring”*
 14 *and inserting “SITE NEUTRAL BASIS.—For discharges*
 15 *occurring”;*

16 (3) *by striking “subject to subparagraph (B),”;*
 17 *and*

18 (4) *by redesignating clauses (i) and (ii) as sub-*
 19 *paragraphs (A) and (B), respectively, and moving*
 20 *each of such subparagraphs (as so redesignated) 2 ems*
 21 *to the left.*

22 (b) *EFFECTIVE DATE.*—*The amendments made by sub-*
 23 *section (a) shall be effective as if included in the enactment*
 24 *of section 1206(a)(3) of the Pathway for SGR Reform Act*

1 of 2013 (division B of Public Law 113–67; 42 U.S.C.
2 1395ww note).

3 **SEC. 15008. CHANGE IN MEDICARE CLASSIFICATION FOR**
4 **CERTAIN HOSPITALS.**

5 (a) *IN GENERAL.*—Subsection (d)(1)(B)(iv) of section
6 1886 of the Social Security Act (42 U.S.C. 1395ww) is
7 amended—

8 (1) in subclause (I), by striking “or” at the end;

9 (2) in subclause (II)—

10 (A) by striking “, or” at the end and insert-
11 ing a semicolon;

12 (B) by redesignating such subclause as
13 clause (vi) and by moving it to immediately fol-
14 low clause (v); and

15 (C) in clause (v), by striking the semicolon
16 at the end and inserting “, or”; and

17 (3) by striking “(iv)(I) a hospital” and inserting
18 “(iv) a hospital”.

19 (b) *CONFORMING PAYMENT REFERENCES.*—The second
20 sentence of subsection (d)(1)(B) of such section is amend-
21 ed—

22 (1) by inserting “(as in effect as of such date)”
23 after “clause (iv)”; and

24 (2) by inserting “(or, in the case of a hospital
25 described in clause (iv)(II), as so in effect, shall be

1 *classified under clause (vi) on and after the effective*
2 *date of such clause (vi) and for cost reporting periods*
3 *beginning on or after January 1, 2015, shall not be*
4 *subject to subsection (m) as of the date of such classi-*
5 *fication)” after “so classified”.*

6 *(c) APPLICATION.—*

7 *(1) IN GENERAL.—For cost reporting periods be-*
8 *ginning on or after January 1, 2015, in the case of*
9 *an applicable hospital (as defined in paragraph (3)),*
10 *the following shall apply:*

11 *(A) Payment for inpatient operating costs*
12 *shall be made on a reasonable cost basis in the*
13 *manner provided in section 412.526(c)(3) of title*
14 *42, Code of Federal Regulations (as in effect on*
15 *January 1, 2015) and in any subsequent modi-*
16 *fications.*

17 *(B) Payment for capital costs shall be made*
18 *in the manner provided by section 412.526(c)(4)*
19 *of title 42, Code of Federal Regulations (as in ef-*
20 *fect on such date).*

21 *(C) Claims for payment for Medicare bene-*
22 *ficiaries who are discharged on or after January*
23 *1, 2017, shall be processed as claims which are*
24 *paid on a reasonable cost basis as described in*

1 *section 412.526(c) of title 42, Code of Federal*
2 *Regulations (as in effect on such date).*

3 (2) *APPLICABLE HOSPITAL DEFINED.*—*In this*
4 *subsection, the term “applicable hospital” means a*
5 *hospital that is classified under clause (iv)(II) of sec-*
6 *tion 1886(d)(1)(B) of the Social Security Act (42*
7 *U.S.C. 1395ww(d)(1)(B)) on the day before the date*
8 *of the enactment of this Act and which is classified*
9 *under clause (vi) of such section, as redesignated and*
10 *moved by subsection (a), on or after such date of en-*
11 *actment.*

12 (d) *CONFORMING TECHNICAL AMENDMENTS.*—

13 (1) *Section 1899B(a)(2)(A)(iv) of the Social Se-*
14 *curity Act (42 U.S.C. 1395lll(a)(2)(A)(iv)) is amend-*
15 *ed by striking “1886(d)(1)(B)(iv)(II)” and inserting*
16 *“1886(d)(1)(B)(vi)”.*

17 (2) *Section 1886(m)(5)(F) of such Act (42*
18 *U.S.C. 1395ww(m)(5)(F)) is amended in each of*
19 *clauses (i) and (ii) by striking “(d)(1)(B)(iv)(II)”*
20 *and inserting “(d)(1)(B)(vi)”.*

1 **SEC. 15009. TEMPORARY EXCEPTION TO THE APPLICATION**
2 **OF THE MEDICARE LTCH SITE NEUTRAL PRO-**
3 **VISIONS FOR CERTAIN SPINAL CORD SPE-**
4 **CIALTY HOSPITALS.**

5 (a) *EXCEPTION.*—Section 1886(m)(6) of the Social Se-
6 curity Act (42 U.S.C. 1395ww(m)(6)) is amended—

7 (1) in subparagraph (A)(i), by striking “and
8 (E)” and inserting “, (E), and (F)”; and

9 (2) by adding at the end the following new sub-
10 paragraph:

11 “(F) *TEMPORARY EXCEPTION FOR CERTAIN*
12 *SPINAL CORD SPECIALTY HOSPITALS.*—For dis-
13 charges in cost reporting periods beginning dur-
14 ing fiscal years 2018 and 2019, subparagraph
15 (A)(i) shall not apply (and payment shall be
16 made to a long-term care hospital without regard
17 to this paragraph) if such discharge is from a
18 long-term care hospital that meets each of the fol-
19 lowing requirements:

20 “(i) *NOT-FOR-PROFIT.*—The long-term
21 care hospital was a not-for-profit long-term
22 care hospital on June 1, 2014, as deter-
23 mined by cost report data.

24 “(ii) *PRIMARILY PROVIDING TREAT-*
25 *MENT FOR CATASTROPHIC SPINAL CORD OR*
26 *ACQUIRED BRAIN INJURIES OR OTHER*

1 *PARALYZING NEUROMUSCULAR CONDI-*
2 *TIONS.—Of the discharges in calendar year*
3 *2013 from the long-term care hospital for*
4 *which payment was made under this sec-*
5 *tion, at least 50 percent were classified*
6 *under MS-LTCH-DRGs 28, 29, 52, 57,*
7 *551, 573, and 963.*

8 *“(iii) SIGNIFICANT OUT-OF-STATE AD-*
9 *MISSIONS.—*

10 *“(I) IN GENERAL.—The long-term*
11 *care hospital discharged inpatients (in-*
12 *cluding both individuals entitled to, or*
13 *enrolled for, benefits under this title*
14 *and individuals not so entitled or en-*
15 *rolled) during fiscal year 2014 who*
16 *had been admitted from at least 20 of*
17 *the 50 States, determined by the States*
18 *of residency of such inpatients and*
19 *based on such data submitted by the*
20 *hospital to the Secretary as the Sec-*
21 *retary may require.*

22 *“(II) IMPLEMENTATION.—Not-*
23 *withstanding any other provision of*
24 *law, the Secretary may implement sub-*

1 *clause (I) by program instruction or*
2 *otherwise.*

3 *“(III) NON-APPLICATION OF PA-*
4 *PERWORK REDUCTION ACT.—Chapter*
5 *35 of title 44, United States Code, shall*
6 *not apply to data collected under this*
7 *clause.”.*

8 *(b) STUDY AND REPORT ON THE STATUS AND VIABIL-*
9 *ITY OF CERTAIN SPINAL CORD SPECIALTY LONG-TERM*
10 *CARE HOSPITALS.—*

11 *(1) STUDY.—The Comptroller General of the*
12 *United States shall conduct a study on long-term care*
13 *hospitals described in section 1886(m)(6)(F) of the*
14 *Social Security Act, as added by subsection (a). Such*
15 *report shall include an analysis of the following:*

16 *(A) The impact on such hospitals of the*
17 *classification and facility licensure by State*
18 *agencies of such hospitals.*

19 *(B) The Medicare payment rates for such*
20 *hospitals.*

21 *(C) Data on the number and health care*
22 *needs of Medicare beneficiaries who have been di-*
23 *agnosed with catastrophic spinal cord or ac-*
24 *quired brain injuries or other paralyzing neuro-*
25 *muscular conditions (as described within the dis-*

1 charge classifications specified in clause (ii) of
2 such section) who are receiving services from
3 such hospitals.

4 (2) *REPORT.*—Not later than October 1, 2018,
5 the Comptroller General shall submit to Congress a
6 report on the study conducted under paragraph (1),
7 including recommendations for such legislation and
8 administrative action as the Comptroller General de-
9 termines appropriate.

10 **SEC. 15010. TEMPORARY EXTENSION TO THE APPLICATION**
11 **OF THE MEDICARE LTCH SITE NEUTRAL PRO-**
12 **VISIONS FOR CERTAIN DISCHARGES WITH SE-**
13 **VERE WOUNDS.**

14 (a) *IN GENERAL.*—Section 1886(m)(6) of the Social
15 Security Act (42 U.S.C. 1395ww(m)(6)), as amended by
16 section 15009, is further amended—

17 (1) in subparagraph (A)(i) by striking “and
18 (F)” and inserting “(F), and (G)”;

19 (2) in subparagraph (E)(i)(I)(aa), by striking
20 “the amendment made” and all that follows before the
21 semicolon and inserting “the last sentence of sub-
22 section (d)(1)(B)”;

23 (3) by adding at the end the following new sub-
24 paragraph:

1 “(G) *ADDITIONAL TEMPORARY EXCEPTION*
2 *FOR CERTAIN SEVERE WOUND DISCHARGES FROM*
3 *CERTAIN LONG-TERM CARE HOSPITALS.—*

4 “(i) *IN GENERAL.—For a discharge oc-*
5 *curring in a cost reporting period begin-*
6 *ning during fiscal year 2018, subparagraph*
7 *(A)(i) shall not apply (and payment shall*
8 *be made to a long-term care hospital with-*
9 *out regard to this paragraph) if such dis-*
10 *charge—*

11 “(I) *is from a long-term care hos-*
12 *pital identified by the last sentence of*
13 *subsection (d)(1)(B);*

14 “(II) *is classified under MS-*
15 *LTCH-DRG 602, 603, 539, or 540;*
16 *and*

17 “(III) *is with respect to an indi-*
18 *vidual treated by a long-term care hos-*
19 *pital for a severe wound.*

20 “(ii) *SEVERE WOUND DEFINED.—In*
21 *this subparagraph, the term ‘severe wound’*
22 *means a wound which is a stage 3 wound,*
23 *stage 4 wound, unstageable wound, non-*
24 *healing surgical wound, or fistula as identi-*

1 *fied in the claim from the long-term care*
2 *hospital.*

3 “(iii) *WOUND DEFINED.*—*In this sub-*
4 *paragraph, the term ‘wound’ means an in-*
5 *jury involving division of tissue or rupture*
6 *of the integument or mucous membrane*
7 *with exposure to the external environment.”.*

8 *(c) STUDY AND REPORT TO CONGRESS.—*

9 *(1) STUDY.—The Comptroller General of the*
10 *United States shall, in consultation with relevant*
11 *stakeholders, conduct a study on the treatment needs*
12 *of individuals entitled to benefits under part A of title*
13 *XVIII of the Social Security Act or enrolled under*
14 *part B of such title who require specialized wound*
15 *care, and the cost, for such individuals and the Medi-*
16 *care program under such title, of treating severe*
17 *wounds in rural and urban areas. Such study shall*
18 *include an assessment of—*

19 *(A) access of such individuals to appro-*
20 *priate levels of care for such cases;*

21 *(B) the potential impact that section*
22 *1886(m)(6)(A)(i) of such Act (42 U.S.C.*
23 *1395ww(m)(6)(A)(i)) will have on the access,*
24 *quality, and cost of care for such individuals;*
25 *and*

1 (C) how to appropriately pay for such care
2 under the Medicare program under such title.

3 (2) *REPORT.*—Not later than October 1, 2020,
4 the Comptroller General shall submit to Congress a
5 report on the study conducted under paragraph (1),
6 including recommendations for such legislation and
7 administrative action as the Comptroller General de-
8 termines appropriate.

9 **TITLE XVI—PROVISIONS**
10 **RELATING TO MEDICARE PART B**

11 **SEC. 16001. CONTINUING MEDICARE PAYMENT UNDER**
12 **HOPD PROSPECTIVE PAYMENT SYSTEM FOR**
13 **SERVICES FURNISHED BY MID-BUILD OFF-**
14 **CAMPUS OUTPATIENT DEPARTMENTS OF**
15 **PROVIDERS.**

16 (a) *IN GENERAL.*—Section 1833(t)(21) of the Social
17 Security Act (42 U.S.C. 1395l(t)(21)) is amended—

18 (1) in subparagraph (B)—

19 (A) in clause (i), by striking “clause (ii)”
20 and inserting “the subsequent provisions of this
21 subparagraph”; and

22 (B) by adding at the end the following new
23 clauses:

24 “(iii) *DEEMED TREATMENT FOR*
25 *2017.*—For purposes of applying clause (ii)

1 with respect to applicable items and services
2 furnished during 2017, a department of a
3 provider (as so defined) not described in
4 such clause is deemed to be billing under
5 this subsection with respect to covered OPD
6 services furnished prior to November 2,
7 2015, if the Secretary received from the pro-
8 vider prior to December 2, 2015, an attesta-
9 tion (pursuant to section 413.65(b)(3) of
10 title 42 of the Code of Federal Regulations)
11 that such department was a department of
12 a provider (as so defined).

13 “(iv) *ALTERNATIVE EXCEPTION BEGIN-*
14 *NING WITH 2018.*—For purposes of para-
15 graph (1)(B)(v) and this paragraph with
16 respect to applicable items and services fur-
17 nished during 2018 or a subsequent year,
18 the term ‘off-campus outpatient department
19 of a provider’ also shall not include a de-
20 partment of a provider (as so defined) that
21 is not described in clause (ii) 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 enactment
2 of this clause), that such department
3 met the requirements of a department
4 of a provider specified in section
5 413.65 of title 42 of the Code of Fed-
6 eral 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 offi-
18 cer 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, 2015,
25 the provider had a binding written agree-

1 *ment with an outside unrelated party for*
2 *the actual construction of such department.*

3 “(vii) *AUDIT.*—*Not later than Decem-*
4 *ber 31, 2018, the Secretary shall audit the*
5 *compliance with requirements of clause (iv)*
6 *with respect to each department of a pro-*
7 *vider to which such clause applies. If the*
8 *Secretary finds as a result of an audit*
9 *under this clause that the applicable re-*
10 *quirements were not met with respect to*
11 *such department, the department shall not*
12 *be excluded from the term ‘off-campus out-*
13 *patient department of a provider’ under*
14 *such clause.*

15 “(viii) *IMPLEMENTATION.*—*For pur-*
16 *poses of implementing clauses (iii) through*
17 *(vi):*

18 “(I) *Notwithstanding any other*
19 *provision of law, the Secretary may*
20 *implement such clauses by program in-*
21 *struction or otherwise.*

22 “(II) *Subchapter I of chapter 35*
23 *of title 44, United States Code, shall*
24 *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 the
6 Federal Supplementary Medical Insur-
7 ance Trust Fund under section 1841,
8 to remain available until December 31,
9 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 this
15 section shall be effective as if included in the enactment of
16 section 603 of the Bipartisan Budget Act of 2015 (Public
17 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 CANCER*
2 *HOSPITALS.*—For purposes of paragraph
3 (1)(B)(v) and this paragraph with respect
4 to applicable items and services furnished
5 during 2017 or a subsequent year, the term
6 ‘off-campus outpatient department of a pro-
7 vider’ also shall not include a department of
8 a provider (as so defined) that is not de-
9 scribed in clause (ii) if the provider is a
10 hospital described in section
11 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 enact-
17 ment of this clause, the Secretary re-
18 ceives from the provider an attestation
19 that such department met such require-
20 ments not later than 60 days after
21 such date of enactment; or

22 “(II) in the case of a department
23 that meets such requirements after such
24 date of enactment, the Secretary re-
25 ceives from the provider an attestation

1 that such department meets such re-
2 quirements 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 the
15 following: “For purposes of carrying out this sub-
16 paragraph 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, to
20 remain available until expended.”.

21 (b) *OFFSETTING SAVINGS*.—Section 1833(t)(18) of the
22 Social Security Act (42 U.S.C. 1395l(t)(18)) is amended—

23 (1) in subparagraph (B), by inserting “, subject
24 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 apply-*
4 *ing section 419.43(i) of title 42 of the Code of*
5 *Federal Regulations to implement the appro-*
6 *priate adjustment under this paragraph for serv-*
7 *ices furnished on or after January 1, 2018, the*
8 *Secretary shall use a target PCR that is 1.0 per-*
9 *centage 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 ad-*
13 *ditional percentage point reduction to such tar-*
14 *get PCR that takes into account payment rates*
15 *for applicable items and services described in*
16 *paragraph (21)(C) other than for services fur-*
17 *nished 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 this*
25 *section shall be effective as if included in the enactment of*

1 *section 603 of the Bipartisan Budget Act of 2015 (Public*
2 *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 PRO-*
9 *FESSIONALS” and all that follows through “No pay-*
10 *ment” and inserting the following: “HOSPITAL-BASED*
11 *AND AMBULATORY SURGICAL CENTER-BASED ELIGI-*
12 *BLE PROFESSIONALS.—*

13 *“(i) HOSPITAL-BASED.—No payment”;*

14 *and*

15 *(2) by adding at the end the following new*
16 *clauses:*

17 *“(ii) AMBULATORY SURGICAL CENTER-*
18 *BASED.—Subject to clause (iv), no payment*
19 *adjustment may be made under subpara-*
20 *graph (A) for 2017 and 2018 in the case of*
21 *an eligible professional with respect to*
22 *whom substantially all of the covered profes-*
23 *sional services furnished by such profes-*
24 *sional are furnished in an ambulatory sur-*
25 *gical center.*

1 “(iii) *DETERMINATION.*—*The deter-*
2 *mination of whether an eligible professional*
3 *is an eligible professional described in*
4 *clause (ii) may be made on the basis of—*

5 “(I) *the site of service (as defined*
6 *by the Secretary); or*

7 “(II) *an attestation submitted by*
8 *the eligible professional.*

9 *Determinations made under subclauses (I)*
10 *and (II) shall be made without regard to*
11 *any employment or billing arrangement be-*
12 *tween the eligible professional and any other*
13 *supplier or provider of services.*

14 “(iv) *SUNSET.*—*Clause (ii) shall no*
15 *longer apply as of the first year that begins*
16 *more than 3 years after the date on which*
17 *the Secretary determines, through notice*
18 *and comment rulemaking, that certified*
19 *EHR technology applicable to the ambula-*
20 *tory surgical center setting is available.”.*

21 **SEC. 16004. CONTINUING ACCESS TO HOSPITALS ACT OF**
22 **2016.**

23 (a) *EXTENSION OF ENFORCEMENT INSTRUCTION ON*
24 *SUPERVISION REQUIREMENTS FOR OUTPATIENT THERA-*
25 *PEUTIC SERVICES IN CRITICAL ACCESS AND SMALL RURAL*

1 *HOSPITALS THROUGH 2016*.—Section 1 of Public Law
2 113–198, as amended by section 1 of Public Law 114–112,
3 is amended—

4 (1) in the heading, by striking “**2014 AND 2015**”
5 and inserting “**2016**”; and

6 (2) by striking “and 2015” and inserting “,
7 2015, and 2016”.

8 (b) *REPORT*.—Not later than 1 year after the date of
9 the enactment of this Act, the Medicare Payment Advisory
10 Commission (established under section 1805 of the Social
11 Security Act (42 U.S.C. 1395b–6)) shall submit to Congress
12 a report analyzing the effect of the extension of the enforce-
13 ment instruction under section 1 of Public Law 113–198,
14 as amended by section 1 of Public Law 114–112 and sub-
15 section (a) of this section, on the access to health care by
16 Medicare beneficiaries, on the economic impact and the im-
17 pact upon hospital staffing needs, and on the quality of
18 health care furnished to such beneficiaries.

1 **SEC. 16005. DELAY OF IMPLEMENTATION OF MEDICARE FEE**
2 **SCHEDULE ADJUSTMENTS FOR WHEELCHAIR**
3 **ACCESSORIES AND SEATING SYSTEMS WHEN**
4 **USED IN CONJUNCTION WITH COMPLEX RE-**
5 **HABILITATION TECHNOLOGY (CRT) WHEEL-**
6 **CHAIRS.**

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)), sub-*
26 *paragraph (D) of this sentence shall apply to such*

1 (A) *IN GENERAL.*—*The Secretary of Health*
2 *and Human Services shall conduct a study that*
3 *examines the impact of applicable payment ad-*
4 *justments upon—*

5 (i) *the number of suppliers of durable*
6 *medical equipment that, on a date that is*
7 *not before January 1, 2016, and not later*
8 *than December 31, 2016, ceased to conduct*
9 *business as such suppliers; and*

10 (ii) *the availability of durable medical*
11 *equipment, during the period beginning on*
12 *January 1, 2016, and ending on December*
13 *31, 2016, to individuals entitled to benefits*
14 *under part A of title XVIII of the Social Se-*
15 *curity Act (42 U.S.C. 1395 et seq.) or en-*
16 *rolled under part B of such title.*

17 (B) *DEFINITIONS.*—*For purposes of this*
18 *subsection, the following definitions apply:*

19 (i) *SUPPLIER; DURABLE MEDICAL*
20 *EQUIPMENT.*—*The terms “supplier” and*
21 *“durable medical equipment” have the*
22 *meanings given such terms by section 1861*
23 *of the Social Security Act (42 U.S.C.*
24 *1395x).*

1 *in making any adjustments under clause (ii) or (iii) of sub-*
2 *paragraph (F), under subsection (h)(1)(H)(ii), or under*
3 *section 1842(s)(3)(B), the Secretary shall—*

4 *“(i) solicit and take into account stake-*
5 *holder input; and*

6 *“(ii) take into account the highest*
7 *amount bid by a winning supplier in a*
8 *competitive acquisition area and a com-*
9 *parison of each of the following with respect*
10 *to non-competitive acquisition areas and*
11 *competitive acquisition areas:*

12 *“(I) The average travel distance*
13 *and cost associated with furnishing*
14 *items and services in the area.*

15 *“(II) The average volume of items*
16 *and services furnished by suppliers in*
17 *the area.*

18 *“(III) The number of suppliers in*
19 *the area.”.*

20 *(b) CONFORMING AMENDMENTS.—(1) Section*
21 *1834(h)(1)(H)(ii) of the Social Security Act (42 U.S.C.*
22 *1395m(h)(1)(H)(ii)) is amended by striking “the Sec-*
23 *retary” and inserting “subject to subsection (a)(1)(G), the*
24 *Secretary”.*

1 (2) *Section 1842(s)(3)(B) of the Social Security Act*
2 *(42 U.S.C. 1395m(s)(3)(B)) is amended by striking “the*
3 *Secretary” and inserting “subject to section 1834(a)(1)(G),*
4 *the Secretary”.*

5 ***TITLE XVII—OTHER MEDICARE***
6 ***PROVISIONS***

7 ***SEC. 17001. DELAY IN AUTHORITY TO TERMINATE CON-***
8 ***TRACTS FOR MEDICARE ADVANTAGE PLANS***
9 ***FAILING TO ACHIEVE MINIMUM QUALITY RAT-***
10 ***INGS.***

11 (a) *FINDINGS.—Consistent with the studies provided*
12 *under the IMPACT Act of 2014 (Public Law 113–185), it*
13 *is the intent of Congress—*

14 (1) *to continue to study and request input on the*
15 *effects of socioeconomic status and dual-eligible popu-*
16 *lations on the Medicare Advantage STARS rating*
17 *system before reforming such system with the input of*
18 *stakeholders; and*

19 (2) *pending the results of such studies and input,*
20 *to provide for a temporary delay in authority of the*
21 *Centers for Medicare & Medicaid Services (CMS) to*
22 *terminate Medicare Advantage plan contracts solely*
23 *on the basis of performance of plans under the*
24 *STARS rating system.*

1 **(b) DELAY IN MA CONTRACT TERMINATION AUTHOR-**
 2 **ITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY**
 3 **RATINGS.**—*Section 1857(h) of the Social Security Act (42*
 4 *U.S.C. 1395w–27(h)) is amended by adding at the end the*
 5 *following new paragraph:*

6 “(3) **DELAY IN CONTRACT TERMINATION AU-**
 7 **THORITY FOR PLANS FAILING TO ACHIEVE MINIMUM**
 8 **QUALITY RATING.**—*During the period beginning on*
 9 *the date of the enactment of this paragraph and*
 10 *through the end of plan year 2018, the Secretary may*
 11 *not terminate a contract under this section with re-*
 12 *spect to the offering of an MA plan by a Medicare Ad-*
 13 *vantage organization solely because the MA plan has*
 14 *failed to achieve a minimum quality rating under the*
 15 *5-star rating system under section 1853(o)(4).”.*

16 **SEC. 17002. REQUIREMENT FOR ENROLLMENT DATA RE-**
 17 **PORTING FOR MEDICARE.**

18 *Section 1874 of the Social Security Act (42 U.S.C.*
 19 *1395kk) is amended by adding at the end the following new*
 20 *subsection:*

21 “(g) **REQUIREMENT FOR ENROLLMENT DATA REPORT-**
 22 **ING.**—

23 “(1) **IN GENERAL.**—*Each year (beginning with*
 24 *2016), the Secretary shall submit to the Committees*
 25 *on Ways and Means and Energy and Commerce of*

1 *the House of Representatives and the Committee on*
 2 *Finance of the Senate a report on Medicare enroll-*
 3 *ment data (and, in the case of part A, on data on in-*
 4 *dividuals receiving benefits under such part) as of a*
 5 *date in such year specified by the Secretary. Such*
 6 *data shall be presented—*

7 *“(A) by Congressional district and State;*

8 *and*

9 *“(B) in a manner that provides for such*
 10 *data based on—*

11 *“(i) fee-for-service enrollment (as de-*
 12 *finied in paragraph (2));*

13 *“(ii) enrollment under part C (includ-*
 14 *ing separate for aggregate enrollment in*
 15 *MA–PD plans and aggregate enrollment in*
 16 *MA plans that are not MA–PD plans); and*

17 *“(iii) enrollment under part D.*

18 *“(2) FEE-FOR-SERVICE ENROLLMENT DE-*
 19 *FINED.—For purpose of paragraph (1)(B)(i), the term*
 20 *‘fee-for-service enrollment’ means aggregate enrollment*
 21 *(including receipt of benefits other than through en-*
 22 *rollment) under—*

23 *“(A) part A only;*

24 *“(B) part B only; and*

25 *“(C) both part A and part B.”.*

1 **SEC. 17003. UPDATING THE WELCOME TO MEDICARE PACK-**
2 **AGE.**

3 (a) *IN GENERAL.*—Not later than 12 months after the
4 last day of the period for the request of information de-
5 scribed in subsection (b), the Secretary of Health and
6 Human Services shall, taking into consideration informa-
7 tion collected pursuant to subsection (b), update the infor-
8 mation included in the Welcome to Medicare package to in-
9 clude information, presented in a clear and simple manner,
10 about options for receiving benefits under the Medicare pro-
11 gram under title XVIII of the Social Security Act (42
12 U.S.C. 1395 et seq.), including through the original medi-
13 care fee-for-service program under parts A and B of such
14 title (42 U.S.C. 1395c et seq., 42 U.S.C. 1395j et seq.), Medi-
15 care Advantage plans under part C of such title (42 U.S.C.
16 1395w–21 et seq.), and prescription drug plans under part
17 D of such title (42 U.S.C. 1395w–101 et seq.). The Sec-
18 retary shall make subsequent updates to the information in-
19 cluded in the Welcome to Medicare package as appropriate.

20 (b) *REQUEST FOR INFORMATION.*—Not later than 6
21 months after the date of the enactment of this Act, the Sec-
22 retary of Health and Human Services shall request infor-
23 mation, including recommendations, from stakeholders (in-
24 cluding patient advocates, issuers, and employers) on infor-
25 mation included in the Welcome to Medicare package, in-

1 *cluding pertinent data and information regarding enroll-*
 2 *ment and coverage for Medicare eligible individuals.*

3 **SEC. 17004. NO PAYMENT FOR ITEMS AND SERVICES FUR-**
 4 **NISHED BY NEWLY ENROLLED PROVIDERS OR**
 5 **SUPPLIERS WITHIN A TEMPORARY MORATO-**
 6 **RIUM AREA.**

7 *(a) MEDICARE.—Section 1866(j)(7) of the Social Secu-*
 8 *rity Act (42 U.S.C. 1395cc(j)(7)) is amended—*

9 *(1) in the paragraph heading, by inserting “;*
 10 *NONPAYMENT” before the period; and*

11 *(2) by adding at the end the following new sub-*
 12 *paragraph:*

13 *“(C) NONPAYMENT.—*

14 *“(i) IN GENERAL.—No payment may*
 15 *be made under this title or under a pro-*
 16 *gram described in subparagraph (A) with*
 17 *respect to an item or service described in*
 18 *clause (ii) furnished on or after October 1,*
 19 *2017.*

20 *“(ii) ITEM OR SERVICE DESCRIBED.—*

21 *An item or service described in this clause*
 22 *is an item or service furnished—*

23 *“(I) within a geographic area*
 24 *with respect to which a temporary*

1 *moratorium imposed under subpara-*
2 *graph (A) is in effect; and*

3 *“(II) by a provider of services or*
4 *supplier that meets the requirements of*
5 *clause (iii).*

6 *“(iii) REQUIREMENTS.—For purposes*
7 *of clause (ii), the requirements of this clause*
8 *are that a provider of services or supplier—*

9 *“(I) enrolls under this title on or*
10 *after the effective date of such tem-*
11 *porary moratorium; and*

12 *“(II) is within a category of pro-*
13 *viders of services and suppliers (as de-*
14 *scribed in subparagraph (A)) subject to*
15 *such temporary moratorium.*

16 *“(iv) PROHIBITION ON CHARGES FOR*
17 *SPECIFIED ITEMS OR SERVICES.—In no case*
18 *shall a provider of services or supplier de-*
19 *scribed in clause (ii)(II) charge an indi-*
20 *vidual or other person for an item or service*
21 *described in clause (ii) furnished on or after*
22 *October 1, 2017, to an individual entitled to*
23 *benefits under part A or enrolled under part*
24 *B or an individual under a program speci-*
25 *fied in subparagraph (A).”.*

1 **(b) CONFORMING AMENDMENTS.—**

2 **(1) MEDICAID.—**

3 **(A) IN GENERAL.—***Section 1903(i)(2) of the*
4 *Social Security Act (42 U.S.C. 1396b(i)(2)), as*
5 *amended by section 5005(a)(4), is further*
6 *amended—*

7 *(i) in subparagraph (C), by striking*

8 *“or” at the end; and*

9 *(ii) by adding at the end the following*
10 *new subparagraph:*

11 *“(E) with respect to any amount expended*
12 *for such an item or service furnished during cal-*
13 *endar quarters beginning on or after October 1,*
14 *2017, subject to section 1902(kk)(4)(A)(ii)(II),*
15 *within a geographic area that is subject to a*
16 *moratorium imposed under section 1866(j)(7) by*
17 *a provider or supplier that meets the require-*
18 *ments specified in subparagraph (C)(iii) of such*
19 *section, during the period of such moratorium;*
20 *or”.*

21 **(B) EXCEPTION WITH RESPECT TO AC-**
22 **CESS.—***Section 1902(kk)(4)(A)(ii) of the Social*
23 *Security Act (42 U.S.C. 1396a(kk)(4)(A)(ii)) is*
24 *amended to read as follows:*

25 **“(i) EXCEPTIONS.—**

1 “(I) *COMPLIANCE WITH MORATO-*
2 *RIUM.*—A State shall not be required
3 to comply with a temporary morato-
4 rium described in clause (i) if the
5 State determines that the imposition of
6 such temporary moratorium would ad-
7 versely impact beneficiaries’ access to
8 medical assistance.

9 “(II) *FFP AVAILABLE.*—Notwith-
10 standing section 1903(i)(2)(E), pay-
11 ment may be made to a State under
12 this title with respect to amounts ex-
13 pended for items and services described
14 in such section if the Secretary, in con-
15 sultation with the State agency admin-
16 istering the State plan under this title
17 (or a waiver of the plan), determines
18 that denying payment to the State
19 pursuant to such section would ad-
20 versely impact beneficiaries’ access to
21 medical assistance. ”.

22 (C) *STATE PLAN REQUIREMENT WITH RE-*
23 *SPECT TO LIMITATION ON CHARGES TO BENE-*
24 *FICIARIES.*—Section 1902(kk)(4)(A) of the Social
25 Security Act (42 U.S.C. 1396a(kk)(4)(A)) is

1 amended by adding at the end the following new
2 clause:

3 “(iii) *LIMITATION ON CHARGES TO*
4 *BENEFICIARIES.*—With respect to any
5 amount expended for items or services fur-
6 nished during calendar quarters beginning
7 on or after October 1, 2017, the State pro-
8 hibits, during the period of a temporary
9 moratorium described in clause (i), a pro-
10 vider meeting the requirements specified in
11 subparagraph (C)(iii) of section 1866(j)(7)
12 from charging an individual or other per-
13 son eligible to receive medical assistance
14 under the State plan under this title (or a
15 waiver of the plan) for an item or service
16 described in section 1903(i)(2)(E) furnished
17 to such an individual.”.

18 (2) *CORRECTING AMENDMENTS TO RELATED*
19 *PROVISIONS.*—

20 (A) *SECTION 1866(J).*—Section 1866(j) of the
21 *Social Security Act (42 U.S.C. 1395cc(j))* is
22 amended—

23 (i) in paragraph (1)(A)—

24 (I) by striking “paragraph (4)”
25 and inserting “paragraph (5)”;

1 (II) by striking “moratoria in ac-
2 cordance with paragraph (5)” and in-
3 serting “moratoria in accordance with
4 paragraph (7)”; and

5 (III) by striking “paragraph (6)”
6 and inserting “paragraph (9)”; and

7 (ii) by redesignating the second para-
8 graph (8) (redesignated by section 1304(1)
9 of Public Law 111–152) as paragraph (9).

10 (B) SECTION 1902(KK).—Section 1902(kk) of
11 such Act (42 U.S.C. 1396a(kk)) is amended—

12 (i) in paragraph (1), by striking “sec-
13 tion 1886(j)(2)” and inserting “section
14 1866(j)(2)”;

15 (ii) in paragraph (2), by striking “sec-
16 tion 1886(j)(3)” and inserting “section
17 1866(j)(3)”;

18 (iii) in paragraph (3), by striking
19 “section 1886(j)(4)” and inserting “section
20 1866(j)(5)”;

21 (iv) in paragraph (4)(A), by striking
22 “section 1886(j)(6)” and inserting “section
23 1866(j)(7)”.

1 **SEC. 17005. PRESERVATION OF MEDICARE BENEFICIARY**
2 **CHOICE UNDER MEDICARE ADVANTAGE.**

3 *Section 1851(e)(2) of the Social Security Act (42*
4 *U.S.C. 1395w-21(e)(2)) is amended—*

5 *(1) in subparagraph (C)—*

6 *(A) in the heading, by inserting “FROM 2011*
7 *THROUGH 2018” after “45-DAY PERIOD”; and*

8 *(B) by inserting “and ending with 2018”*
9 *after “beginning with 2011”; and*

10 *(2) by adding at the end the following new sub-*
11 *paragraph:*

12 *“(G) CONTINUOUS OPEN ENROLLMENT AND*
13 *DISENROLLMENT FOR FIRST 3 MONTHS IN 2016*
14 *AND SUBSEQUENT YEARS.—*

15 *“(i) IN GENERAL.—Subject to clause*
16 *(ii) and subparagraph (D)—*

17 *“(I) in the case of an MA eligible*
18 *individual who is enrolled in an MA*
19 *plan, at any time during the first 3*
20 *months of a year (beginning with*
21 *2019); or*

22 *“(II) in the case of an individual*
23 *who first becomes an MA eligible indi-*
24 *vidual during a year (beginning with*
25 *2019) and enrolls in an MA plan, dur-*
26 *ing the first 3 months during such*

1 *year in which the individual is an MA*
2 *eligible individual;*

3 *such MA eligible individual may change the*
4 *election under subsection (a)(1).*

5 “(ii) *LIMITATION OF ONE CHANGE*
6 *DURING OPEN ENROLLMENT PERIOD EACH*
7 *YEAR.—An individual may change the elec-*
8 *tion pursuant to clause (i) only once during*
9 *the applicable 3-month period described in*
10 *such clause in each year. The limitation*
11 *under this clause shall not apply to changes*
12 *in elections effected during an annual, co-*
13 *ordinated election period under paragraph*
14 *(3) or during a special enrollment period*
15 *under paragraph (4).*

16 “(iii) *LIMITED APPLICATION TO PART*
17 *D.—Clauses (i) and (ii) of this subpara-*
18 *graph shall only apply with respect to*
19 *changes in enrollment in a prescription*
20 *drug plan under part D in the case of an*
21 *individual who, previous to such change in*
22 *enrollment, is enrolled in a Medicare Ad-*
23 *vantage plan.*

24 “(iv) *LIMITATIONS ON MARKETING.—*
25 *Pursuant to subsection (j), no unsolicited*

1 *marketing or marketing materials may be*
 2 *sent to an individual described in clause (i)*
 3 *during the continuous open enrollment and*
 4 *disenrollment period established for the in-*
 5 *dividual under such clause, notwithstanding*
 6 *marketing guidelines established by the Cen-*
 7 *ters for Medicare & Medicaid Services.”.*

8 **SEC. 17006. ALLOWING END-STAGE RENAL DISEASE BENE-**
 9 **FICIARIES TO CHOOSE A MEDICARE ADVAN-**
 10 **TAGE PLAN.**

11 *(a) REMOVING PROHIBITION.—*

12 *(1) IN GENERAL.—Section 1851(a)(3) of the So-*
 13 *cial Security Act (42 U.S.C. 1395w–21(a)(3)) is*
 14 *amended—*

15 *(A) by striking subparagraph (B); and*

16 *(B) by striking “ELIGIBLE INDIVIDUAL”*
 17 *and all that follows through “In this title, subject*
 18 *to subparagraph (B),” and inserting “ELIGIBLE*
 19 *INDIVIDUAL.—In this title,”.*

20 *(2) CONFORMING AMENDMENTS.—*

21 *(A) Section 1852(b)(1) of the Social Secu-*
 22 *rity Act (42 U.S.C. 1395w–22(b)(1)) is amend-*
 23 *ed—*

24 *(i) by striking subparagraph (B); and*

1 (ii) by striking “BENEFICIARIES” and
2 all that follows through “A
3 Medicare+Choice organization” and insert-
4 ing “BENEFICIARIES.—A Medicare Advan-
5 tage organization”.

6 (B) Section 1859(b)(6) of the Social Secu-
7 rity Act (42 U.S.C. 1395w–28(b)(6)) is amended,
8 in the last sentence, by striking “may waive”
9 and all that follows through “subparagraph
10 and”.

11 (3) EFFECTIVE DATE.—The amendments made
12 by this subsection shall apply with respect to plan
13 years beginning on or after January 1, 2021.

14 (b) EXCLUDING COSTS FOR KIDNEY ACQUISITIONS
15 FROM MA BENCHMARK.—Section 1853 of the Social Secu-
16 rity Act (42 U.S.C. 1395w–23) is amended—

17 (1) in subsection (k)—

18 (A) in paragraph (1)—

19 (i) in the matter preceding subpara-
20 graph (A), by striking “paragraphs (2) and
21 (4)” and inserting “paragraphs (2), (4),
22 and (5)”; and

23 (ii) in subparagraph (B)(i), by strik-
24 ing “paragraphs (2) and (4)” and inserting
25 “paragraphs (2), (4), and (5)”; and

1 (B) by adding at the end the following new
2 paragraph:

3 “(5) *EXCLUSION OF COSTS FOR KIDNEY ACQUISITIONS FROM CAPITATION RATES.*—After determining
4 the applicable amount for an area for a year under
5 paragraph (1) (beginning with 2021), the Secretary
6 shall adjust such applicable amount to exclude from
7 such applicable amount the Secretary’s estimate of the
8 standardized costs for payments for organ acquisitions
9 for kidney transplants covered under this title
10 (including expenses covered under section 1881(d)) in
11 the area for the year.”; and
12

13 (2) in subsection (n)(2)—

14 (A) in subparagraph (A)(i), by inserting
15 “and, for 2021 and subsequent years, the exclu-
16 sion of payments for organ acquisitions for kid-
17 ney transplants from the capitation rate as de-
18 scribed in subsection (k)(5)” before the semicolon
19 at the end;

20 (B) in subparagraph (E), in the matter
21 preceding clause (i), by striking “subparagraph
22 (F)” and inserting “subparagraphs (F) and
23 (G)”; and

24 (C) by adding at the end the following new
25 subparagraph:

1 “(G) *APPLICATION OF KIDNEY ACQUISITIONS ADJUSTMENT.*—The base payment amount
2 specified in subparagraph (E) for a year (begin-
3 ning with 2021) shall be adjusted in the same
4 manner under paragraph (5) of subsection (k) as
5 the applicable amount is adjusted under such
6 subsection.”

8 (c) *FFS COVERAGE OF KIDNEY ACQUISITIONS.*—

9 (1) *IN GENERAL.*—Section 1852(a)(1)(B)(i) of
10 the Social Security Act (42 U.S.C. 1395w-
11 22(a)(1)(B)(i)) is amended by inserting “or coverage
12 for organ acquisitions for kidney transplants, includ-
13 ing as covered under section 1881(d)” after “hospice
14 care”.

15 (2) *CONFORMING AMENDMENT.*—Section 1851(i)
16 of the Social Security Act (42 U.S.C. 1395w-21(i)) is
17 amended by adding at the end the following new
18 paragraph:

19 “(3) *FFS PAYMENT FOR EXPENSES FOR KIDNEY*
20 *ACQUISITIONS.*—Paragraphs (1) and (2) shall not
21 apply with respect to expenses for organ acquisitions
22 for kidney transplants described in section
23 1852(a)(1)(B)(i).”

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 (d) *EVALUATION OF QUALITY.*—

5 (1) *IN GENERAL.*—*The Secretary of Health and*
6 *Human Services (in this subsection referred to as the*
7 *“Secretary”) shall conduct an evaluation of whether*
8 *the 5-star rating system based on the data collected*
9 *under section 1852(e) of the Social Security Act (42*
10 *U.S.C. 1395w–22(e)) should include a quality meas-*
11 *ure specifically related to care for enrollees in Medi-*
12 *care Advantage plans under part C of title XVIII of*
13 *such Act determined to have end-stage renal disease.*

14 (2) *PUBLIC AVAILABILITY.*—*Not later than April*
15 *1, 2020, the Secretary shall post on the Internet*
16 *website of the Centers for Medicare & Medicaid Serv-*
17 *ices the results of the evaluation under paragraph (1).*

18 (e) *REPORT.*—*Not later than December 31, 2023, the*
19 *Secretary of Health and Human Services (in this subsection*
20 *referred to as the “Secretary”) shall submit to Congress a*
21 *report on the impact of the provisions of, and amendments*
22 *made by, this section with respect to the following:*

23 (1) *Spending under*—

1 (A) the original Medicare fee-for-service pro-
2 gram under parts A and B of title XVIII of the
3 Social Security Act; and

4 (B) the Medicare Advantage program under
5 part C of such title.

6 (2) The number of enrollees determined to have
7 end-stage renal disease—

8 (A) in the original Medicare fee-for-service
9 program; and

10 (B) in the Medicare Advantage program.

11 (3) The sufficiency of the amount of data under
12 the original Medicare fee-for-service program for indi-
13 viduals determined to have end-stage renal disease for
14 purposes of determining payment rates for end-stage
15 renal disease under the Medicare Advantage program.

16 (f) IMPROVEMENTS TO RISK ADJUSTMENT UNDER
17 MEDICARE ADVANTAGE.—

18 (1) IN GENERAL.—Section 1853(a)(1) of the So-
19 cial Security Act (42 U.S.C. 1395w–23(a)(1)) is
20 amended—

21 (A) in subparagraph (C)(i), by striking
22 “The Secretary” and inserting “Subject to sub-
23 paragraph (I), the Secretary”; and

24 (B) by adding at the end the following new
25 subparagraph:

1 “(I) *IMPROVEMENTS TO RISK ADJUSTMENT*
2 *FOR 2019 AND SUBSEQUENT YEARS.*—

3 “(i) *IN GENERAL.*—*In order to deter-*
4 *mine the appropriate adjustment for health*
5 *status under subparagraph (C)(i), the fol-*
6 *lowing shall apply:*

7 “(I) *TAKING INTO ACCOUNT TOTAL*
8 *NUMBER OF DISEASES OR CONDI-*
9 *TIONS.*—*The Secretary shall take into*
10 *account the total number of diseases or*
11 *conditions of an individual enrolled in*
12 *an MA plan. The Secretary shall make*
13 *an additional adjustment under such*
14 *subparagraph as the number of dis-*
15 *eases or conditions of an individual in-*
16 *creases.*

17 “(II) *USING AT LEAST 2 YEARS OF*
18 *DIAGNOSTIC DATA.*—*The Secretary*
19 *may use at least 2 years of diagnosis*
20 *data.*

21 “(III) *PROVIDING SEPARATE AD-*
22 *JUSTMENTS FOR DUAL ELIGIBLE INDI-*
23 *VIDUALS.*—*With respect to individuals*
24 *who are dually eligible for benefits*
25 *under this title and title XIX, the Sec-*

1 *retary shall make separate adjustments*
2 *for each of the following:*

3 *“(aa) Full-benefit dual eligi-*
4 *ble individuals (as defined in sec-*
5 *tion 1935(c)(6)).*

6 *“(bb) Such individuals not*
7 *described in item (aa).*

8 *“(IV) EVALUATION OF MENTAL*
9 *HEALTH AND SUBSTANCE USE DIS-*
10 *ORDERS.—The Secretary shall evaluate*
11 *the impact of including additional di-*
12 *agnosis codes related to mental health*
13 *and substance use disorders in the risk*
14 *adjustment model.*

15 *“(V) EVALUATION OF CHRONIC*
16 *KIDNEY DISEASE.—The Secretary shall*
17 *evaluate the impact of including the se-*
18 *verity of chronic kidney disease in the*
19 *risk adjustment model.*

20 *“(VI) EVALUATION OF PAYMENT*
21 *RATES FOR END-STAGE RENAL DIS-*
22 *EASE.—The Secretary shall evaluate*
23 *whether other factors (in addition to*
24 *those described in subparagraph (H))*
25 *should be taken into consideration*

1 when computing payment rates under
2 such subparagraph.

3 “(ii) *PHASED-IN IMPLEMENTATION.*—
4 *The Secretary shall phase-in any changes to*
5 *risk adjustment payment amounts under*
6 *subparagraph (C)(i) under this subpara-*
7 *graph over a 3-year period, beginning with*
8 *2019, with such changes being fully imple-*
9 *mented for 2022 and subsequent years.*

10 “(iii) *OPPORTUNITY FOR REVIEW AND*
11 *PUBLIC COMMENT.*—*The Secretary shall*
12 *provide an opportunity for review of the*
13 *proposed changes to such risk adjustment*
14 *payment amounts under this subparagraph*
15 *and a public comment period of not less*
16 *than 60 days before implementing such*
17 *changes.”.*

18 (2) *STUDIES AND REPORTS.*—

19 (A) *REPORTS ON THE RISK ADJUSTMENT*
20 *SYSTEM.*—

21 (i) *MEDPAC EVALUATION AND RE-*
22 *PORT.*—

23 (I) *EVALUATION.*—*The Medicare*
24 *Payment Advisory Commission shall*
25 *conduct an evaluation of the impact of*

1 *the provisions of, and amendments*
2 *made by, this section on risk scores for*
3 *enrollees in Medicare Advantage plans*
4 *under part C of title XVIII of the So-*
5 *cial Security Act and payments to*
6 *Medicare Advantage plans under such*
7 *part, including the impact of such pro-*
8 *visions and amendments on the overall*
9 *accuracy of risk scores under the Medi-*
10 *care Advantage program.*

11 *(II) REPORT.—Not later than*
12 *July 1, 2020, the Medicare Payment*
13 *Advisory Commission shall submit to*
14 *Congress a report on the evaluation*
15 *under subclause (I), together with rec-*
16 *ommendations for such legislation and*
17 *administrative action as the Commis-*
18 *sion determines appropriate.*

19 *(ii) REPORTS BY SECRETARY OF*
20 *HEALTH AND HUMAN SERVICES.—Not later*
21 *than December 31, 2018, and every 3 years*
22 *thereafter, the Secretary of Health and*
23 *Human Services shall submit to Congress a*
24 *report on the risk adjustment model and the*
25 *ESRD risk adjustment model under the*

1 *Medicare Advantage program under part C*
2 *of title XVIII of the Social Security Act, in-*
3 *cluding any revisions to either such model*
4 *since the previous report. Such report shall*
5 *include information on how such revisions*
6 *impact the predictive ratios under either*
7 *such model for groups of enrollees in Medi-*
8 *care Advantage plans, including very high*
9 *and very low cost enrollees, and groups de-*
10 *fined by the number of chronic conditions of*
11 *enrollees.*

12 *(B) STUDY AND REPORT ON FUNCTIONAL*
13 *STATUS.—*

14 *(i) STUDY.—The Comptroller General*
15 *of the United States (in this subparagraph*
16 *referred to as the “Comptroller General”)*
17 *shall conduct a study on how to most accu-*
18 *rately measure the functional status of en-*
19 *rollees in Medicare Advantage plans and*
20 *whether the use of such functional status*
21 *would improve the accuracy of risk adjust-*
22 *ment payments under the Medicare Advan-*
23 *tage program under part C of title XVIII of*
24 *the Social Security Act. Such study shall*
25 *include an analysis of the challenges in col-*

1 lecting and reporting functional status in-
 2 formation for Medicare Advantage plans
 3 under such part, providers of services and
 4 suppliers under the Medicare program, and
 5 the Centers for Medicare & Medicaid Serv-
 6 ices.

7 (ii) *REPORT*.—Not later than June 30,
 8 2018, the Comptroller General shall submit
 9 to Congress a report containing the results
 10 of the study under clause (i), together with
 11 recommendations for such legislation and
 12 administrative action as the Comptroller
 13 General determines appropriate.

14 **SEC. 17007. IMPROVEMENTS TO THE ASSIGNMENT OF BENE-**
 15 **FICIARIES UNDER THE MEDICARE SHARED**
 16 **SAVINGS PROGRAM.**

17 Section 1899(c) of the Social Security Act (42 U.S.C.
 18 1395jjj(c)) is amended—

19 (1) by striking “utilization of primary” and in-
 20 serting “utilization of—

21 “(1) in the case of performance years beginning
 22 on or after April 1, 2012, primary”;

23 (2) in paragraph (1), as added by paragraph (1)
 24 of this section, by striking the period at the end and
 25 inserting “; and”;

1 (3) by adding at the end the following new para-
2 graph:

3 “(2) in the case of performance years beginning
4 on or after January 1, 2019, services provided under
5 this title by a Federally qualified health center or
6 rural health clinic (as those terms are defined in sec-
7 tion 1861(aa)), as may be determined by the Sec-
8 retary.”.

9 **TITLE XVIII—OTHER**
10 **PROVISIONS**

11 **SEC. 18001. EXCEPTION FROM GROUP HEALTH PLAN RE-**
12 **QUIREMENTS FOR QUALIFIED SMALL EM-**
13 **PLOYER HEALTH REIMBURSEMENT ARRANGE-**
14 **MENTS.**

15 (a) *AMENDMENTS TO THE INTERNAL REVENUE CODE*
16 *OF 1986 AND THE PATIENT PROTECTION AND AFFORDABLE*
17 *CARE ACT.*—

18 (1) *IN GENERAL.*—Section 9831 of the Internal
19 Revenue Code of 1986 is amended by adding at the
20 end the following new subsection:

21 “(d) *EXCEPTION FOR QUALIFIED SMALL EMPLOYER*
22 *HEALTH REIMBURSEMENT ARRANGEMENTS.*—

23 “(1) *IN GENERAL.*—For purposes of this title (ex-
24 cept as provided in section 4980I(f)(4) and notwith-
25 standing any other provision of this title), the term

1 ‘group health plan’ shall not include any qualified
2 small employer health reimbursement arrangement.

3 “(2) *QUALIFIED SMALL EMPLOYER HEALTH RE-*
4 *IMBURSEMENT ARRANGEMENT.*—For purposes of this
5 subsection—

6 “(A) *IN GENERAL.*—The term ‘qualified
7 small employer health reimbursement arrange-
8 ment’ means an arrangement which—

9 “(i) is described in subparagraph (B),
10 and

11 “(ii) is provided on the same terms to
12 all eligible employees of the eligible em-
13 ployer.

14 “(B) *ARRANGEMENT DESCRIBED.*—An ar-
15 rangement is described in this subparagraph if—

16 “(i) such arrangement is funded solely
17 by an eligible employer and no salary re-
18 duction contributions may be made under
19 such arrangement,

20 “(ii) such arrangement provides, after
21 the employee provides proof of coverage, for
22 the payment of, or reimbursement of, an eli-
23 gible employee for expenses for medical care
24 (as defined in section 213(d)) incurred by
25 the eligible employee or the eligible employ-

1 *ee's family members (as determined under*
2 *the terms of the arrangement), and*

3 *“(iii) the amount of payments and re-*
4 *imbursements described in clause (ii) for*
5 *any year do not exceed \$4,950 (\$10,000 in*
6 *the case of an arrangement that also pro-*
7 *vides for payments or reimbursements for*
8 *family members of the employee).*

9 *“(C) CERTAIN VARIATION PERMITTED.—For*
10 *purposes of subparagraph (A)(ii), an arrange-*
11 *ment shall not fail to be treated as provided on*
12 *the same terms to each eligible employee merely*
13 *because the employee's permitted benefit under*
14 *such arrangement varies in accordance with the*
15 *variation in the price of an insurance policy in*
16 *the relevant individual health insurance market*
17 *based on—*

18 *“(i) the age of the eligible employee*
19 *(and, in the case of an arrangement which*
20 *covers medical expenses of the eligible em-*
21 *ployee's family members, the age of such*
22 *family members), or*

23 *“(ii) the number of family members of*
24 *the eligible employee the medical expenses of*
25 *which are covered under such arrangement.*

1 *The variation permitted under the preceding sen-*
2 *tence 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 is*
9 *not covered by an arrangement for the en-*
10 *tire 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) be*
14 *in effect for such individual for such year*
15 *under subparagraph (B)(iii) as the number*
16 *of months for which such individual is cov-*
17 *ered by the arrangement for such year bears*
18 *to 12.*

19 “(ii) *INFLATION ADJUSTMENT.—In the*
20 *case of any year beginning after 2016, each*
21 *of the dollar amounts in subparagraph*
22 *(B)(iii) shall be increased by an amount*
23 *equal to—*

24 “(I) *such dollar amount, multi-*
25 *plied by*

1 “(II) the cost-of-living adjustment
2 determined under section 1(f)(3) for
3 the calendar year in which the taxable
4 year begins, determined by substituting
5 ‘calendar year 2015’ for ‘calendar year
6 1992’ in subparagraph (B) thereof.

7 If any dollar amount increased under the
8 preceding sentence is not a multiple of \$50,
9 such dollar amount shall be rounded to the
10 next lowest multiple of \$50.

11 “(3) OTHER DEFINITIONS.—For purposes of this
12 subsection—

13 “(A) ELIGIBLE EMPLOYEE.—The term ‘eli-
14 gible employee’ means any employee of an eligi-
15 ble employer, except that the terms of the ar-
16 rangement may exclude from consideration em-
17 ployees described in any clause of section
18 105(h)(3)(B) (applied by substituting ‘90 days’
19 for ‘3 years’ in clause (i) thereof).

20 “(B) ELIGIBLE EMPLOYER.—The term ‘eli-
21 gible employer’ means an employer that—

22 “(i) is not an applicable large em-
23 ployer as defined in section 4980H(c)(2),
24 and

1 “(ii) does not offer a group health plan
2 to any of its employees.

3 “(C) *PERMITTED BENEFIT.*—The term ‘per-
4 mitted benefit’ means, with respect to any eligi-
5 ble employee, the maximum dollar amount of
6 payments and reimbursements which may be
7 made under the terms of the qualified small em-
8 ployer health reimbursement arrangement for the
9 year with respect to such employee.

10 “(4) *NOTICE.*—

11 “(A) *IN GENERAL.*—An employer funding a
12 qualified small employer health reimbursement
13 arrangement for any year shall, not later than
14 90 days before the beginning of such year (or, in
15 the case of an employee who is not eligible to
16 participate in the arrangement as of the begin-
17 ning of such year, the date on which such em-
18 ployee is first so eligible), provide a written no-
19 tice to each eligible employee which includes the
20 information described in subparagraph (B).

21 “(B) *CONTENTS OF NOTICE.*—The notice re-
22 quired under subparagraph (A) shall include
23 each of the following:

1 “(i) A statement of the amount which
2 would be such eligible employee’s permitted
3 benefit under the arrangement for the year.

4 “(ii) A statement that the eligible em-
5 ployee should provide the information de-
6 scribed in clause (i) to any health insurance
7 exchange to which the employee applies for
8 advance payment of the premium assistance
9 tax credit.

10 “(iii) A statement that if the employee
11 is not covered under minimum essential
12 coverage for any month the employee may
13 be subject to tax under section 5000A for
14 such month and reimbursements under the
15 arrangement may be includible in gross in-
16 come.”.

17 (2) *LIMITATION ON EXCLUSION FROM GROSS IN-*
18 *COME.*—Section 106 of such Code is amended by add-
19 ing at the end the following:

20 “(g) *QUALIFIED SMALL EMPLOYER HEALTH REIM-*
21 *BURSEMENT ARRANGEMENT.*—For purposes of this section
22 and section 105, payments or reimbursements from a quali-
23 fied small employer health reimbursement arrangement (as
24 defined in section 9831(d)) of an individual for medical
25 care (as defined in section 213(d)) shall not be treated as

1 *paid or reimbursed under employer-provided coverage for*
 2 *medical expenses under an accident or health plan if for*
 3 *the month in which such medical care is provided the indi-*
 4 *vidual does not have minimum essential coverage (within*
 5 *the meaning of section 5000A(f)).”.*

6 (3) *COORDINATION WITH HEALTH INSURANCE*
 7 *PREMIUM CREDIT.—Section 36B(c) of such Code is*
 8 *amended by adding at the end the following new*
 9 *paragraph:*

10 “(4) *SPECIAL RULES FOR QUALIFIED SMALL EM-*
 11 *PLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—*

12 “(A) *IN GENERAL.—The term ‘coverage*
 13 *month’ shall not include any month with respect*
 14 *to an employee (or any spouse or dependent of*
 15 *such employee) if for such month the employee is*
 16 *provided a qualified small employer health reim-*
 17 *bursement arrangement which constitutes afford-*
 18 *able coverage.*

19 “(B) *DENIAL OF DOUBLE BENEFIT.—In the*
 20 *case of any employee who is provided a qualified*
 21 *small employer health reimbursement arrange-*
 22 *ment for any coverage month (determined with-*
 23 *out regard to subparagraph (A)), the credit oth-*
 24 *erwise allowable under subsection (a) to the tax-*
 25 *payer for such month shall be reduced (but not*

1 *below zero) by the amount described in subpara-*
2 *graph (C)(i)(II) for such month.*

3 “(C) *AFFORDABLE COVERAGE.*—*For pur-*
4 *poses of subparagraph (A), a qualified small em-*
5 *ployer health reimbursement arrangement shall*
6 *be treated as constituting affordable coverage for*
7 *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 plan*
13 *offered in the relevant individual*
14 *health insurance market, over*

15 “(II) *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) *1/12 of 9.5 percent of the employ-*
20 *ee’s household income.*

21 “(D) *QUALIFIED SMALL EMPLOYER HEALTH*
22 *REIMBURSEMENT ARRANGEMENT.*—*For purposes*
23 *of this paragraph, the term ‘qualified small em-*
24 *ployer health reimbursement arrangement’ has*

1 *the meaning given such term by section*
 2 *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 by*
 8 *substituting ‘the number of months during the*
 9 *year for which such arrangement was provided’*
 10 *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 subsection*
 16 *(b)(3)(A)(ii).”.*

17 (4) *APPLICATION OF EXCISE TAX ON HIGH COST*
 18 *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 HEALTH*
4 *REIMBURSEMENT ARRANGEMENTS.*—*In the case*
5 *of applicable employer-sponsored coverage con-*
6 *sisting of coverage under any qualified small em-*
7 *ployer health reimbursement arrangement (as de-*
8 *fined in section 9831(d)(2)), the cost of coverage*
9 *shall be equal to the amount described in section*
10 *6051(a)(15).”.*

11 (5) *ENFORCEMENT OF NOTICE REQUIREMENT.*—
12 *Section 6652 of such Code is amended by adding at*
13 *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 pro-*
17 *vide a written notice as required by section 9831(d)(4), un-*
18 *less it is shown that such failure is due to reasonable cause*
19 *and not willful neglect, there shall be paid, on notice and*
20 *demand of the Secretary and in the same manner as tax,*
21 *by the person failing to provide such written notice, an*
22 *amount equal to \$50 per employee per incident of failure*
23 *to provide such notice, but the total amount imposed on*
24 *such person for all such failures during any calendar year*
25 *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 “, and”,
6 and by inserting after paragraph (14) the fol-
7 lowing 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 re-
12 spect 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 and
16 Affordable Care Act is amended by redesignating
17 subparagraph (B) as subparagraph (C) and by
18 inserting after subparagraph (A) the following
19 new subparagraph:

20 “(B) *CERTAIN INDIVIDUAL HEALTH INSUR-*
21 *ANCE POLICIES OBTAINED THROUGH SMALL EM-*
22 *PLOYERS.*—The amount of the enrollee’s per-
23 mitted 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 pro-*
5 *vided in this paragraph, the amendments made*
6 *by this subsection shall apply to years beginning*
7 *after December 31, 2016.*

8 (B) *TRANSITION RELIEF.*—*The relief under*
9 *Treasury Notice 2015–17 shall be treated as ap-*
10 *plying to any plan year beginning on or before*
11 *December 31, 2016.*

12 (C) *COORDINATION WITH HEALTH INSUR-*
13 *ANCE PREMIUM CREDIT.*—*The amendments made*
14 *by paragraph (3) shall apply to taxable years be-*
15 *ginning 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 Rev-*
23 *enue Code of 1986 (as added by this Act),*
24 *a person shall not be treated as failing to*
25 *provide a written notice as required by sec-*

1 *tion 9831(d)(4) of such Code if such notice*
2 *is so provided not later than 90 days after*
3 *the date of the enactment of this Act.*

4 *(E) W-2 REPORTING.—The amendments*
5 *made by paragraph (6)(A) shall apply to cal-*
6 *endar years beginning after December 31, 2016.*

7 *(F) INFORMATION PROVIDED BY EXCHANGE*
8 *SUBSIDY APPLICANTS.—*

9 *(i) IN GENERAL.—The amendments*
10 *made by paragraph (6)(B) shall apply to*
11 *applications for enrollment made after De-*
12 *cember 31, 2016.*

13 *(ii) VERIFICATION.—Verification under*
14 *section 1411 of the Patient Protection and*
15 *Affordable Care Act of information provided*
16 *under section 1411(b)(3)(B) of such Act*
17 *shall apply with respect to months begin-*
18 *ning after October 2016.*

19 *(iii) TRANSITIONAL RELIEF.—In the*
20 *case of an application for enrollment under*
21 *section 1411(b) of the Patient Protection*
22 *and Affordable Care Act made before April*
23 *1, 2017, the requirement of section*
24 *1411(b)(3)(B) of such Act shall be treated as*
25 *met if the information described therein is*

1 *provided not later than 30 days after the*
2 *date on which the applicant receives the no-*
3 *tice described in section 9831(d)(4) of the*
4 *Internal Revenue Code of 1986.*

5 (8) *SUBSTANTIATION REQUIREMENTS.*—*The Sec-*
6 *retary of the Treasury (or his designee) may issue*
7 *substantiation requirements as necessary to carry out*
8 *this subsection.*

9 (b) *AMENDMENTS TO THE EMPLOYEE RETIREMENT*
10 *INCOME SECURITY ACT OF 1974.*—

11 (1) *IN GENERAL.*—*Section 733(a)(1) of the Em-*
12 *ployee Retirement Income Security Act of 1974 (29*
13 *U.S.C. 1191b(a)(1)) is amended by adding at the end*
14 *the following: “Such term shall not include any quali-*
15 *fied small employer health reimbursement arrange-*
16 *ment (as defined in section 9831(d)(2) of the Internal*
17 *Revenue Code of 1986).”.*

18 (2) *EXCEPTION FROM CONTINUATION COVERAGE*
19 *REQUIREMENTS, ETC.*—*Section 607(1) of such Act (29*
20 *U.S.C. 1167(1)) is amended by adding at the end the*
21 *following: “Such term shall not include any qualified*
22 *small employer health reimbursement arrangement*
23 *(as defined in section 9831(d)(2) of the Internal Rev-*
24 *enue Code of 1986).”.*

1 (3) *EFFECTIVE DATE.*—*The amendments made*
2 *by this subsection shall apply to plan years beginning*
3 *after December 31, 2016.*

4 (c) *AMENDMENTS TO THE PUBLIC HEALTH SERVICE*
5 *ACT.*—

6 (1) *IN GENERAL.*—*Section 2791(a)(1) of the*
7 *Public Health Service Act (42 U.S.C. 300gg–91(a)(1))*
8 *is amended by adding at the end the following: “Ex-*
9 *cept for purposes of part C of title XI of the Social*
10 *Security Act (42 U.S.C. 1320d et seq.), such term*
11 *shall not include any qualified small employer health*
12 *reimbursement arrangement (as defined in section*
13 *9831(d)(2) of the Internal Revenue Code of 1986).”.*

14 (2) *EXCEPTION FROM CONTINUATION COVERAGE*
15 *REQUIREMENTS.*—*Section 2208(1) of the Public*
16 *Health Service Act (42 U.S.C. 300bb–8(1)) is amend-*
17 *ed by adding at the end the following: “Such term*
18 *shall not include any qualified small employer health*
19 *reimbursement arrangement (as defined in section*
20 *9831(d)(2) of the Internal Revenue Code of 1986).”.*

1 (3) *EFFECTIVE DATE.*—*The amendments made*
2 *by this subsection shall apply to plan years beginning*
3 *after December 31, 2016.*

Attest:

Clerk.

114TH CONGRESS
2^D SESSION

H.R. 34

**HOUSE AMENDMENT TO
SENATE AMENDMENT**