



**DEPARTMENT
of HEALTH
and HUMAN
SERVICES**

Fiscal Year

2021

**Office of the National Coordinator for Health
Information Technology**

*Justification of Estimates
to the Appropriations Committees*



OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY

ABOUT ONC

Departmental Mission

The mission of the U.S. Department of Health and Human Services (HHS) is to enhance the health and well-being of all Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

Agency Description

The Office of the National Coordinator for Health Information Technology (ONC), a staff division of the HHS Office of the Secretary, is charged with formulating the Federal Government's health information technology strategy and promoting coordination of federal health IT policies, technology standards, and programmatic investments.

Federal Health IT Strategic Plan Mission

ONC's mission, adopted from the [Federal Health IT Strategic Plan 2015 – 2020](#), is to improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

ONC's FY 2021 Priorities

- Advancing the, accessibility, **interoperability**, and **usability** of electronic health information and electronic health records (EHRs) by developing the necessary regulatory frameworks and implementing the programs and responsibilities necessary to implement ONC's statutory authorities and delegations from the Secretary;
- Supporting secure, standards-based application programming interfaces (APIs) and user-focused technologies to promote a mobile health app economy that can increase **transparency, competition, and consumer choice** in healthcare;
- Contributing to HHS efforts to combat the **opioid epidemic and other substance use disorders** through collaboration with HHS partners to improve health IT infrastructure and health information sharing.

ONC's Authorizing and Enabling Legislation

Health Information Technology for Economic and Clinical Health Act ("HITECH" Pub. L. No: 111-5), Medicare Access and CHIP Reauthorization Act ("MACRA" P.L. 114-10), 21st Century Cures Act ("Cures Act" P.L. 114-255)



U.S. Department of Health and Human Services

Message from the National Coordinator for Health IT

FY 2021 President's Budget Request

Dear Reader,

I am pleased to present the fiscal year (FY) 2021 President's Budget Request, Justification of Estimates to Appropriations Committees for the Office of the National Coordinator for Health Information Technology (ONC). This budget request outlines a proposed funding level and some expected outcomes for ONC at the President's Budget request level in FY 2021, and also includes annual performance information covering highlights from ONC activities that took place in the most recently concluded fiscal year, FY 2019.

The FY 2021 President's Budget request level for ONC is \$50.7 million. With this budget, ONC will continue its longstanding focus on two critical national priorities for the health care industry: (1) the interoperable exchange of electronic health information, and (2) reducing the administrative burdens facing health care providers.

In furtherance of these goals, and supported by the FY 2021 President's Budget Request, ONC plans to continue necessary efforts to implement the 21st Century Cures Act (Cures Act), which will enter its fifth year of government-wide implementation in 2021. In particular, ONC will prioritize activities that address Congressional requirements related to: (1) facilitating the development and promotion of technology standards that improve infrastructure and interoperability, (2) administering the ONC Health IT Certification Program, (3) enabling trusted and secure health information exchange, and (4) ensuring patients have access to and control of electronic health information stored in their medical records through modern technological approaches such as smartphone applications using application programming interfaces.

Since establishment, ONC has a history of noteworthy successes in implementing Congressional requirements and achieving national goals. ONC's team has a track record for leading efforts that are essential for improving the U. S. health system. ONC's annual discretionary appropriation is fundamental to supporting ONC's infrastructure and advancing national priorities for improving health and health care by empowering patients with their health information, relieving regulatory and administrative burdens hampering providers, building the foundation to support price and product transparency, and promoting an innovative and competitive health care marketplace in the United States.

/Donald W. Rucker/
Donald W. Rucker, M.D.
National Coordinator for Health IT

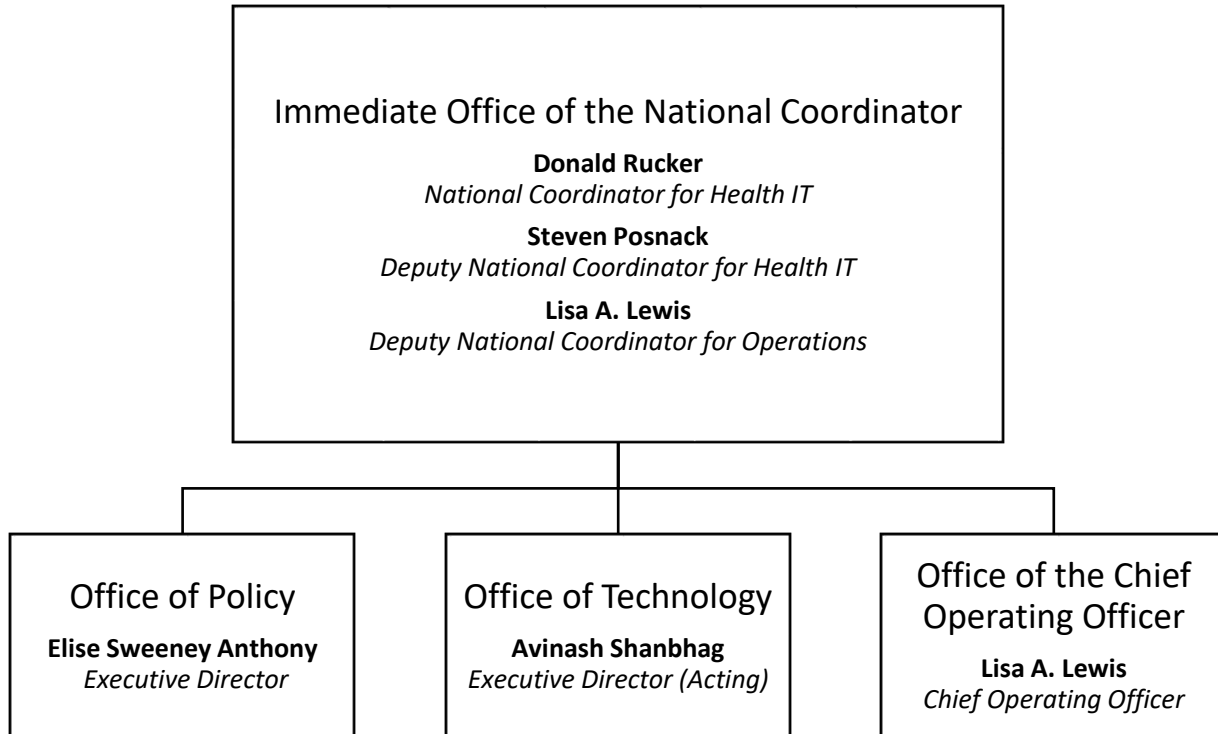
FY 2021 President’s Budget

Justification of Estimates to the Appropriations Committees
Office of the National Coordinator for Health Information Technology

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Organizational Chart



Organizational Chart – Text Version

- Immediate Office of the National Coordinator
 - Donald Rucker, M.D. *National Coordinator for Health IT*
 - Steven Posnack, M.S., M.H.S. *Deputy National Coordinator for Health IT*
 - Lisa Lewis, *Deputy National Coordinator for Operations*
- Office of Policy
 - Elise Sweeney Anthony, J.D., *Executive Director*
- Office of Technology
 - Avinash Shanbhag, *Executive Director (Acting)*
- Office of the Chief Operating Officer
 - Lisa Lewis, *Chief Operating Officer*

Executive Summary

Mission and Introduction

ONC Mission

Improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

ONC Overview

The Office of the National Coordinator for Health Information Technology (ONC) is charged with formulating the Federal Government's health information technology (IT) strategy and leading and promoting effective policies, programs, and administrative efforts to advance progress on national goals for better and safer healthcare through a nationwide *interoperable* health IT infrastructure. ONC is a staff division within the U.S. Department of Health and Human Services (HHS) that reports directly to the Immediate Office of the Secretary for HHS. While ONC is a very small part of federal spending on healthcare, ONC's activities are central to transforming U.S. healthcare into a competitive, patient led system where patients have a support right to their medical records, the necessary price information, and the quality information needed to make informed decisions about their healthcare.

ONC's mission, goals, and objectives originate from three laws, including the Health Information Technology for Clinical and Economic Health Act (2009); Medicare Access and CHIP Reauthorization Act of 2015; and the 21st Century Cures Act (2016).

HHS is taking a holistic approach to its technology related initiatives. This approach centers on putting patients in charge of their own data with interoperable health IT, which will empower patients with the information they need to search for the lowest costs and the highest-quality care. To accomplish this goal, HHS is using multiple policy levers across different agencies and staff divisions. A cornerstone of this work is the implementation of key provisions in title IV of the 21st Century Cures Act (Cures Act). In 2019, ONC issued a proposed rule to implement and support seamless and secure access, exchange, and use of electronic health information. Once finalized, ONC will implement the rule through its programs and activities, including through the Health IT Certification Program, which will continue to drive the electronic access, exchange, and use of health information to both providers and patients.

This proposed rule seeks to inject competition into the healthcare delivery system by addressing the technical barriers and business practices that impede the secure and appropriate sharing of data. A central underpinning of the proposed rule is to facilitate patient access to their electronic health information on their smartphone, growing a nascent patient- and provider-facing app economy, and building the foundation to support price and product transparency. The proposed rule also aims to support the data necessary to promote new business models of care and the clinical information and chart portability that patients need to shop for their care.



For the past decade, national leaders have pursued an agenda that promotes innovation in healthcare built on widespread, interoperable health information. ONC has and will continue to play a transformative role in helping the transition to transparency in healthcare through its health IT coordination. ONC's work builds on the incentives that made medical data electronic and its regulations that required first generation consumer transparency with patient web portals. The standards and interoperability work led by ONC advances the technical infrastructure necessary to support product and price transparency. ONC is also uniquely situated to coordinate the technical activities among different healthcare standards development organizations as we look to a future where a patient's health information is aligned with its related cost information.

Interoperable health information will improve health and healthcare by increasing market transparency and efficiency, and empowering patients and their providers with access to actionable health information from different sources. Improvements in interoperability and the evolution of health IT tools that put health information in practice will ensure patients can access and control their electronic health information, facilitate value-based transformation of the healthcare delivery system, and increase healthcare market competition.

In FY 2019, ONC's appropriated budget authority of \$60.4 million supported a diverse staff and a network of contracted experts spanning a wide range of healthcare, technology, policy, public health, and public administration specialties. ONC staff specialists collaborate with leaders in healthcare, health, and technology in government and industry. This includes contributing to health IT initiatives led by partners and strategic coordination with partner agencies, states, and an extensive network of current and former grantees, leading healthcare sector companies, public interest groups, clinicians, and the congressionally mandated Health IT Advisory Committee (HITAC). ONC promotes the lessons learned from these stakeholder encounters to nearly 2 million visitors who access the policy and technical assistance materials published at <https://HealthIT.gov> each year.

Overview of Budget Request

The FY 2021 President's Budget Request for ONC is \$50.7 million, which is a \$9.7 million (16 percent) reduction from the FY 2020 Enacted Level. ONC's efforts in FY 2021 will continue to emphasize implementation of national priorities as outlined in the HHS Strategic Plan:

HHS Strategic Plan, 2018-2022	
Goal 1	Reform, Strengthen, and Modernize the Nation's Healthcare System
Objective 2	Expand safe, high-quality healthcare options, and encourage innovation and competition
Priority Health IT Strategies:	
	Advance interoperable clinical information flows so patients, providers, payers, and others can efficiently send, receive, and analyze data across primary care, acute care, specialty care including behavioral healthcare, and post-acute care settings
	Promote implementation of understandable, functional health information technology tools to support provider and patient decision-making, and to support workflows for healthcare providers

ONC will also prioritize actions necessary to meet congressional goals expressed in the Cures Act, the President's October 12, 2017 [Executive Order 13813](#) on **healthcare choice and competition** and the June 24, 2019 [Executive Order](#) on **healthcare price and quality transparency**; [Secretary Azar's 4-part strategy for value-based care](#); and the [HHS 5-point strategy](#) to combat the opioids crisis.

ONC's FY 2021 President's Budget Request explains the office's plan to implement a portfolio of activities driven by congressional requirements and ONC's bipartisan authorities. ONC's budget organization highlights its multifaceted work that weaves together cutting edge policy development on health system transformation with ONC's unique expertise for guiding and facilitating technological innovation through the development and promotion of health information interoperability standards and the operation of the ONC Health IT Certification Program. ONC's budget, although small compared to overall federal healthcare spending, has a transformative impact on the healthcare system. The lack of interoperability and related lack of price and product transparency are massive costs to the U.S. public. ONC's work to rapidly address these issues through its policy development and coordination work, and its standards, certification, and interoperability work is sound public policy.

In FY 2021, ONC will continue to play a pivotal role in providing the regulations and standards needed to increase transparency in healthcare by empowering patients with access to their personal health information they need to search for the lowest costs and the highest-quality care. Performance planning and reporting, and budget request information is organized into the following sections:

- **Policy: Development and Coordination**, including strategic and policy planning, developing regulatory frameworks and administrative procedures, maintaining a Federal Advisory Committee, and conducting coordination with public and private stakeholder groups. These policies are frameworks must be robust and resilient enough to withstand substantial opposition and make interoperability a reality.
- **Technology: Standards, Certification, and Interoperability**, including managing the ONC Health IT Certification Program; facilitating the development and promotion of technology standards that improve infrastructure and interoperability; and sponsoring pilot projects and

industry challenges to accelerate innovation and demonstrate advanced uses of health IT which will enable future ONC standards work to support the Administration's price transparency goals and enable patients to easily access to their health information on their smartphones.

- **Agency-Wide Support**, including providing executive, clinical, and scientific leadership, and coordinating outreach between ONC and key federal stakeholders; maintaining <https://HealthIT.gov> to promote federal policy related to health IT; and ensuring effective operations and management through an integrated operations function.

Overview of Performance

Description of ONC's Performance Management Process

ONC's performance management process prioritizes a continuous focus on improving program results, increasing the efficiency and effectiveness of operations, and finding more cost-effective ways to deliver value through policy, program, and management leadership to health IT stakeholders nationwide.

ONC's routine performance management processes are led by a Strategic Management Council that sets the tone and big picture management plan for ONC's planning efforts. The Council is comprised of ONC's experts in planning, performance measurement, operations, resource allocation, risk management, data analysis, and evaluation. Throughout ONC's performance management process, executives and leaders throughout the organization strive to create a culture of performance management by regularly conducting strategic planning; goal setting, and prioritization; measure development; performance monitoring; data analysis; and strategic communications and reporting activities.

Summary of Performance Information in the Budget Request

Performance information in the President's Budget Request for ONC includes a combination of (1) environmental measures that describe the extent of nationwide interoperable health information exchange and patient and provider access to electronic health information, and (2) agency milestones and measures that highlight key information about activities necessary to implement statutory requirements.

Environmental Measures

ONC often measures the extent and performance of health interoperability. During FY 2019, ONC continued a number of survey and data analysis projects necessary to meet congressional requirements to evaluate progress towards national goals for health system modernization through interoperable health IT. These efforts make possible national-level estimates for the following priority indicators:

Patient Access to Electronic Health Information:¹

- 51 percent of Americans had been given **electronic access** to any part of their healthcare record by their healthcare provider or insurer by 2018.

Health Information Interoperability:^{2, 3}

- 47 percent of physicians and 90 percent of hospitals are **sending or receiving** patient information to providers outside their organization via an EHR.
- 53 percent of physicians and 61 percent of hospitals can **find** patient health information from sources outside their health system through their EHR.
- 28 percent of physicians and 53 percent of hospitals can **integrate** (e.g., without manual entry) health information received electronically into their EHR.
- 32 percent of physicians and 51 percent of hospitals reported having necessary patient information electronically **available** at the point of care through their EHR.

¹ Patel V & Johnson C. (April 2018). Individuals' use of online medical records and technology for health needs. ONC Data Brief, no.40. Office of the National Coordinator for Health Information Technology: Washington DC.
<https://www.healthit.gov/sites/default/files/page/2018-03/HINTS-2017-Consumer-Data-Brief-3.21.18.pdf>

² Health Information National Trends Survey (HINTS), National Institutes of Health (NIH), 2016.

³ These measures were selected to meet MACRA § 106(b) requirements to evaluate progress to widespread interoperability. Physician data are as of 2017; hospital data are as of 2017. 2018 estimates for both measures are expected to become available during calendar year 2019.
https://www.healthit.gov/sites/default/files/fulfilling_section_106b1c_of_the_medicare_access_and_chip_reauthorization_act_of_2015_06.30.16.pdf

Noteworthy ONC Accomplishments

Highlights of key ONC accomplishments from FY 2019 illustrate how the office helps to lead nationwide interoperability and improvements in health IT usability:

- ONC continued to prioritize the transformative requirements set in the **Cures Act**, including undertaking stakeholder coordination and outreach, rulemaking, and policy activities related to:
 - Section 4001: Reduction in Burdens Goal; Certification of Health IT for Medical Specialties and Sites of Service; and Meaningful Use Statistics
 - Section 4002: Enhancements to Certification and EHR Reporting Program
 - Section 4003: Support for Interoperable Network Exchange and Provider Digital Contact Information Index
 - Section 4004: Information Blocking
 - Section 4005: Treatment of Health IT Developers with respect to Patient Safety Organizations
 - Section 4006: Patient Access
- Specific highlights related to Cures Act implementation during FY 2019 include:
 - In February 2019, ONC issued a Proposed Rule to support the right of the patient to get their medical records electronically and on their smartphone.⁴ The Rule seeks to **inject digitally-based competition** into the healthcare delivery system by addressing both technical barriers and business practices that impede the secure and appropriate sharing of data. The Proposed Rule advances progress on many of ONC's implementation responsibilities for the Cures Act, including information blocking and conditions of certification, which can also facilitate investments in the technical infrastructures and data necessary for broader Administration goals such as price and product transparency. Within the rule, we propose that certified health IT developers make available in their products secure, standards-based APIs that could be used to facilitate patients' use of smartphones (or other mobile devices) for accessing electronic health information at no cost.
 - The TEFCA was released for a second round of public comment in April 2019. The TEFCA is designed to provide a single "on-ramp" to nationwide connectivity and advance a landscape where information securely follows the patient where and when it is needed. In September 2019, ONC announced that The Sequoia Project has been awarded a cooperative agreement to serve as the Recognized Coordinating Entity responsible for developing, updating, implementing, and maintaining the Common Agreement in collaboration with ONC.⁵ This Common Agreement will create the baseline technical and legal requirements for networks to share electronic health information across the nation. Additionally, ONC released the first draft of the Qualified Health Information Network Technical Framework,⁶ which describes technical and functional requirements to implement the Common Agreement and enable health information networks to connect to each other.
 - ONC led the development of the draft [Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs](#), which was released for public comment in November 2018 and closed in January 2019. During the public

⁴ <https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health>

⁵ <https://www.hhs.gov/about/news/2019/09/03/onc-awards-the-sequoia-project-cooperative-agreement.html>

⁶ <https://www.healthit.gov/buzz-blog/interoperability/moving-beyond-closed-networks-an-update-on-trusted-exchange-of-health-information>

commenting period ONC received 208 comments with the majority of submissions commenting on health IT usability and user experience.⁷

- ONC continued to implement congressional requirements to operate the **Health IT Certification Program** by maintaining a suite of certification criteria – including automated test procedures and certification companion guides – used to standardize information across **21 federal efforts**.⁸ By the end of FY 2018, the ONC Health IT Certification Program’s website, the [Certified Health IT Product List](#) (CHPL), listed products from more than 700 health IT developers,⁹ and was used to register the EHRs of 550,000 care providers and hospitals participating in Medicare and Medicaid.¹⁰ At the end of 2019, there were 497 2015 Edition products from 342 developers on the CHPL. This means that 98 percent of the hospitals and 94 percent of the clinicians participating in CMS programs have access to a health IT product or upgrade from their current developer that has the latest capabilities outlined by Congress and codified into the ONC Health IT Certification Program’s 2015 Edition Certified Health IT.
- ONC continued to evolve and promote the adoption of a wide range of interoperability standards, including Release 4 of HL7 FHIR standard, which is used to enable API-based access, a key component in increasing interoperability in the app economy, promoting product transparency, and enabling patient access to their health information on their smartphones. ONC also coordinated standards awareness and use through the publication and maintenance of the [Interoperability Standards Advisory](#) (ISA), a resource listing **health information standards, models, and profiles** fitting into more than 60 sub-sections divided by topic/use (e.g., public health, patient information, coordination, clinical care, administration). The 2019 ISA, published in January 2019, added 16 new interoperability needs for a total of 167, providing detailed recommendations for standards, models and profiles to support interoperability. It also includes two new cross-cutting views of recommended standards targeted to assist providers in specialty care and clinical settings including pediatrics and opioids. During the public comment period for the 2019 ISA, ONC received 74 comments with more than 400 individual recommendations for revisions and improvements. In FY 2019, the ISA website has been accessed over 90,000 times, suggesting it is on pace to parallel the over 100,000 views in FY 2018. Public adoption of the FHIR standards work has been rapid. Apple’s “Health App” allows iPhone using patients to access their own health information from dozens of healthcare organizations based on the FHIR implementation guides supported by ONC funding.
- ONC continued to administer the [Health IT Advisory Committee](#) (HITAC), ONC’s **Federal Advisory Committee** mandated by the Cures Act. Now in its second year, the HITAC serves as a priority method for obtaining routine input from a group of 29 health IT experts, representing a broad and balanced spectrum of the healthcare system. Between October 1, 2018, and August 1, 2019, the full **HITAC met 11 times** and its **task forces and work groups met 113 times** to develop recommendations addressing the priority areas identified in the Cures Act. The full HITAC plans to meet at least one more time this fiscal year and three more times before the end of CY 2019. To date, the HITAC has completed a Policy Framework, published the FY 2018 annual report, and provided recommendations on the draft TEFCA and the U.S. Core Data for Interoperability (USCDI), among other topics. As of December 2019, the following HITAC Task Forces and Work Groups meet regularly:
 - Trusted Exchange Framework and Common Agreement Task Force

⁷ <https://www.healthit.gov/burdencomments>

⁸ <https://www.healthit.gov/topic/certification-ehrs/programs-referencing-onc-certified-health-it>.

⁹ <https://dashboard.healthit.gov/quickstats/pages/FIG-Vendors-of-EHRs-to-Participating-Professionals.php>.

¹⁰ <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

- U.S. Core Data for Interoperability Task Force
 - Interoperability Standards Priorities Task Force
 - Annual Report Workgroup
 - Information Blocking Task Force
 - Conditions of Certification Task Force
 - Health IT for the Care Continuum Task Force
- **ONC continued to promote improved **federal coordination** through the Federal Health IT Coordinating Council, a voluntary group of **25 agencies** that are actively involved in implementing the national health IT agenda. In FY 2019, the Federal Health IT Coordinating Council convened to address the draft *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs* and the proposed rules from ONC and CMS to support seamless and secure access, exchange, and use of electronic health information. Leveraging federal partner interest in diving deeper into solving problems with health information interoperability, ONC hosted a Federal Interoperability Summit in April 2019 that included 81 representatives from 23 federal organizations. In June 2019, the Coordinating Council met to discuss the update to the [*Federal Health IT Strategic Plan FY 2020 – 2025*](#).**

All-Purpose Table

(Dollars in Thousands)

Activity	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 President's Budget +/- FY 2020 Enacted
TOTAL, ONC Program Level	\$60,163	\$60,367	\$50,717	\$(9,650)
TOTAL, ONC Budget Authority	\$60,163	\$60,367	\$50,717	\$(9,650)

Budget Exhibits

Appropriations Language

For expenses necessary for the Office of the National Coordinator for Health Information Technology, including grants, contracts, and cooperative agreements for the development and advancement of interoperable health information technology, [\$60,367,000] *\$50,717,000*.

Language Analysis

Language Provision	Explanation
For expenses necessary for the Office of the National Coordinator for Health Information Technology, including grants, contracts, and cooperative agreements for the development and advancement of interoperable health information technology, [\$60,367,000] <i>\$50,717,000</i>.	Provides ONC’s budget from Budget Authority.

Amounts Available for Obligation

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
General Fund Discretionary Appropriation:			
Appropriation (L/HHS).....	\$60,367,000	\$60,367,000	\$50,717,000
Subtotal, Appropriation (L/HHS, Ag, or Interior).....	\$60,367,000	\$60,367,000	\$50,717,000
Subtotal, adjusted appropriation.....	\$60,367,000	\$60,367,000	\$50,717,000
Real transfer to: (ACF).....	(\$204,397)	\$0	\$0
Subtotal, adjusted general fund discr. appropriation.....	\$60,162,603	\$60,367,000	\$50,717,000
Total, Discretionary Appropriation.....	\$60,367,000	\$60,367,000	\$50,717,000
Total Obligations.....	\$60,162,603	\$60,367,000	\$50,717,000

Summary of Changes

2020 Enacted		
Total estimated budget authority.....		\$60,367,000
2021 President's Budget		
Total estimated budget authority.....		\$50,717,000
Net Change.....		(\$9,650,000)

	FY 2020 Final	FY 2021 PB FTE	FY 2021 PB BA	FY 2021 +/- FY 2020 FTE	FY 2021 +/- FY 2020 BA
Decreases:					
A. Program:					
1. Health IT.....	\$60,367,000	164	\$50,717,000	-	(\$9,650,000)
Subtotal, Program	\$60,367,000	164	\$50,717,000	-	(\$9,650,000)
Decreases	\$60,367,000	164	\$50,717,000	-	(\$9,650,000)
Total Decreases	\$60,367,000	164	\$50,717,000	-	(\$9,650,000)

Budget Authority by Activity

(Dollars in Thousands)

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
1. Health IT			
Annual Budget Authority.....	\$60,163	\$60,367	\$50,717
Subtotal, Health IT	\$60,163	\$60,367	\$50,717
Total, Budget Authority	\$60,163	\$60,367	\$50,717
FTE	158	164	164

Authorizing Legislation

	FY 2020 Amount Authorized	FY 2020 Amount Appropriated	FY 2021 Amount Authorized	FY 2021 President's Budget
Health IT				
1. Title XXX of PHS Act as added by the HITECH Act (PL 111-5) and the Cures Act (PL 114-255)	Indefinite	\$ -	Indefinite	\$ -
Budget Authority	Indefinite	\$60,367,000	Indefinite	\$50,717,000
Total Request Level		\$60,367,000		\$50,717,000

Appropriations History

Each Year is General Fund Appropriation	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
FY 2012				
Annual.....	\$57,013,000	\$ -	\$42,246,000	\$16,446,000
PHS Evaluation Funds.....	\$21,400,000	\$28,051,000	\$19,011,000	\$44,811,000
Rescissions (P.L. 112-74).....	\$ -	\$ -	\$ -	\$(31,000)
Subtotal.....	\$78,413,000	\$28,051,000	\$61,257,000	\$61,226,000
FY 2013				
Annual.....	\$26,246,000	\$16,415,000	\$16,415,000	\$16,415,000
PHS Evaluation Funds.....	\$40,011,000	\$44,811,000	\$49,842,000	\$44,811,000
Rescissions (P.L. 113-6).....	\$ -	\$ -	\$ -	\$(33,000)
Sequestration.....	\$ -	\$ -	\$ -	\$(826,000)
Subtotal.....	\$66,257,000	\$61,226,000	\$66,257,000	\$60,367,000
FY 2014				
Annual.....	\$20,576,000	\$ -	\$20,290,000	\$15,556,000
PHS Evaluation Funds.....	\$56,307,000	\$ -	\$51,307,000	\$44,811,000
User Fee.....	\$ 1,000,000	\$ -	\$1,000,000	\$ -
Subtotal.....	\$77,883,000	\$ -	\$72,597,000	\$60,367,000
FY 2015				
Annual.....	\$ -	\$61,474,000	\$61,474,000	\$60,367,000
PHS Evaluation Funds.....	\$74,688,000	\$ -	\$ -	\$ -
Subtotal.....	\$74,688,000	\$61,474,000	\$61,474,000	\$60,367,000
FY 2016				
Annual.....	\$ -	\$60,367,000	\$60,367,000	\$60,367,000
PHS Evaluation Funds.....	\$91,800,000	\$ -	\$ -	\$ -
Subtotal.....	\$91,800,000	\$60,367,000	\$60,367,000	\$60,367,000
FY 2017				
Annual.....	\$ -	\$65,367,000	\$60,367,000	\$60,367,000
PHS Evaluation Funds.....	\$82,000,000	\$ -	\$ -	\$ -
Transfers (Secretary's).....	\$ -	\$ -	\$ -	\$(140,000)
Subtotal.....	\$82,000,000	\$65,367,000	\$60,367,000	\$60,227,000
FY 2018				
Annual.....	\$38,381,000	\$38,381,000	\$60,367,000	\$60,367,000
PHS Evaluation Funds.....	\$ -	\$ -	\$ -	\$ -
Transfers (Secretary's).....	\$ -	\$ -	\$ -	\$(150,000)
Subtotal.....	\$38,381,000	\$38,381,000	\$60,367,000	\$60,217,000
FY 2019				
Annual.....	\$38,381,000	\$42,705,000	\$60,367,000	\$60,367,000
Transfers (Secretary's).....	\$ -	\$ -	\$ -	\$(204,397)
Subtotal.....	\$38,381,000	\$42,705,000	\$60,367,000	\$60,162,603
FY 2020				
Annual.....	\$43,000,000		\$60,367,000	\$60,367,000
PHS Evaluation Funds.....		\$60,367,000		
Subtotal.....	\$43,000,000	\$60,367,000	\$60,367,000	\$60,367,000
FY 2021				
Annual.....	\$50,717,000			
Subtotal.....	\$50,717,000			

Narrative by Activity

Health IT

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
BA	\$60,162,603	\$60,367,000	\$50,717,000	\$(9,650,000)
FTE	158	164	164	0

Enabling Legislation Citation Title XXX of PHS Act as added by the HITECH Act (PL 111-5) and amended by the Cures Act (PL 114-255)

Enabling Legislation Status Permanent

Authorization of Appropriations Citation No Separate Authorization of Appropriations

Allocation Method Direct Federal, Contract, Cooperative Agreement, Grant

Program Description

ONC was established in 2004 through Executive Order 13335 and statutorily authorized in 2009 by the HITECH Act. ONC’s responsibilities for leading national health IT efforts was increased by MACRA in 2015 and again by the 21st Century Cures Act in 2016. The range of authorities and requirements assigned to ONC through its authorizing and enabling legislation establish a framework of actions for the agency related to (1) Policy Development and Coordination and (2) Technology Standards, Certification, and Interoperability, and (3) Agency-Wide Support.

In FY 2021, ONC will implement its authorities and requirements to accelerate progress to an interoperable nationwide health IT infrastructure by pursuing the following objectives:

- Advancing the accessibility, **interoperability**, and **usability** of electronic health information and electronic health records (EHRs) by developing the necessary regulatory frameworks and implementing the programs and responsibilities necessary to implement ONC’s statutory authorities and delegation from the Secretary;
- Supporting secure, standards-based APIs and user-focused technologies to promote a mobile health app economy that can increase **transparency, competition, and consumer choice** in healthcare;
- Contributing to HHS efforts to combat the **opioid epidemic and other substance use disorders** through collaborations with HHS partners to improve health IT infrastructure and health information sharing.

Component Activities at ONC ¹¹

ONC's authorities and requirements are implemented through a budget and organizational structure emphasizing the following key components:

Policy: Development and Coordination

Within the Office of Policy, ONC undertakes a range of policy development and coordination activities including: (1) policy and rulemaking activities, such as writing the rule text to implement the Cures Act, MACRA, the HITECH Act, and Executive Order 13335; (2) supporting ONC's domestic policy initiatives; (3) coordinating with executive branch agencies, federal commissions, advisory committees, and external partners; (4) conducting analysis and evaluation of health IT policies for ONC and HHS, including in the areas of interoperability, information blocking, care transformation, privacy and security, and quality improvement; and (5) operating the HITAC, established in the Cures Act. Because a number of the interoperability and pro-consumer requirements of the Cures Act affect large parts of the healthcare delivery system, effective and fair rule-writing that is robust enough to make interoperability a reality is a resource intensive activity. Once a final rule or regulation is complete, it is implemented through ONC's technology activities outlined below.

Technology: Standards, Interoperability, and Certification

Within the Office of Technology, ONC undertakes a range of coordination, technical, and program activities including: (1) executing provisions of law including those in the HITECH Act, MACRA, and the Cures Act; (2) providing technical leadership and coordination within the health IT community to identify, evaluate, and influence the development of standards, implementation guidance, and best practices for standardizing and exchanging electronic health information; (3) coordinating with federal agencies and other public and private partners to implement and advance interoperability nationwide; (4) leading the development of electronic testing tools, resources, and data to achieve interoperability, enhanced usability, and aid in the optimization of health IT; (5) administering the ONC Health IT Certification Program, including the Certified Health IT Product List; and (6) leveraging a team of medical professionals and information scientists that provide leadership to ONC's technical interoperability interests and investments.

Agency-Wide Support

Led by the Immediate Office of the National Coordinator and the Office of the Chief Operating Officer, ONC undertakes a range of agency-wide support activities, including providing overall leadership, executive, strategic, and day-to-day management direction for the ONC organization. Agency-wide support also includes a team of expert clinician advisors who support the National Coordinator and ONC policy and technology leadership; a stakeholder outreach and media relations function, including management of <https://HealthIT.gov/>; and the agency's operations and administration functions.

¹¹ For a more complete explanation of the alignment of ONC's organizational chart to its responsibilities, see the May 2018 Statement of Organization, Functions, and Delegations of Authority; Office of the National Coordinator for Health Information Technology: <https://www.federalregister.gov/documents/2018/05/02/2018-09361/statement-of-organization-functions-and-delegations-of-authority-office-of-the-national-coordinator>.

Agency Background

Since its establishment by Executive Order 13335 in **2004**, ONC has been tasked with providing leadership to stakeholders across the Federal Government and the healthcare and health IT industries in the shared effort to advance nationwide implementation of an interoperable health IT infrastructure.¹² At its inception, ONC's primary efforts focused on strategic planning, establishing the Federal Health Architecture, building the National Health Information Network, and stimulating collaboration among a growing network of federal agencies interested in health IT.

After 5 years of progress implementing its founding mission, Congress statutorily authorized ONC when it enacted the HITECH Act of **2009**. The Act codified the responsibilities outlined in the Executive Order and provided ONC and CMS with financial resources to incentivize and guide the development and adoption of a more comprehensive nationwide health IT infrastructure via the Medicare EHR Incentive Program, commonly referred to as meaningful use. During the time that CMS and ONC implemented HITECH programs, the availability and use of certified EHR technology significantly increased, and EHR adoption among hospitals and office-based professionals increased to more than three quarters.¹³

Throughout **2014-15**, ONC built upon the Nation's momentum toward widespread health information interoperability and its position of leadership by working closely with stakeholders to develop and publish a *Shared Nationwide Interoperability Roadmap*. The *Roadmap* was developed through extensive coordination across the government and industry, and was supported widely for its more than 150 detailed commitments and calls to action.¹⁴

While nationwide stakeholders worked to implement commitments in the *Roadmap*,¹⁵ in **2015** Congress placed further emphasis on achieving widespread interoperability in MACRA. With MACRA introduced, the Medicare EHR Incentive Program (meaningful use) was transitioned to become one of the four components of the new Merit-Based Incentive Payment System (MIPS), which itself is part of MACRA. CMS's implementation of MACRA, and ONC's continued progress to fulfill requirements outlined in HITECH and MACRA, contributed substantially to the progress of nearly all hospitals and three quarters of physicians using certified EHRs.¹⁶

In **2016**, the Nation's health IT agenda received continued congressional direction through the landmark 21st Century Cures Act, which addressed key barriers to interoperability. Among the Cures Act requirements, Congress charged ONC with enhancing its Health IT Certification Program to require modern standards-based application programming interfaces and in parallel preventing anti-competitive business practices related to health information exchange (e.g., information blocking). The bipartisan goal was to promote patient access to and control of their personal electronic health information. We expect patients' electronic control of their medical record will help patients to shop for care and simultaneously allow new business models of lower cost and better healthcare.

¹² Executive Order 13335: <https://www.gpo.gov/fdsys/pkg/WCPD-2004-05-03/pdf/WCPD-2004-05-03-Pg702.pdf>.

¹³ Hospitals: <https://dashboard.healthit.gov/evaluations/data-briefs/non-federal-acute-care-hospital-ehr-adoption-2008-2015.php>. Physicians: <https://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php>.

¹⁴ <https://www.healthit.gov/topic/interoperability/interoperability-road-map-statements-support>.

¹⁵ <https://www.healthit.gov/sites/default/files/12-19-YearInReviewPrezi-508-LowRes.pdf>.

¹⁶ <https://www.healthit.gov/buzz-blog/health-data/numbers-progress-digitizing-health-care/>.

Most recently, Executive Order 13877, “Improving Price and Quality Transparency in American Healthcare to Put Patients First,” was signed in June 2019.¹⁷ This Executive Order outlines lack of patient access to price and quality information as major barrier to patients making fully informed decision about their care. ONC activities to promote interoperability and patient access to data through the development of secure, standards-based APIs is fundamental to transparency around both the healthcare product and service offered as well as its cost.

FY 2019 Major Accomplishments

Policy: Development and Coordination

- ONC continued to **coordinate federal partners** throughout FY 2019, including working closely with key stakeholders in the HHS Office of the Secretary, Assistant Secretary for Planning and Evaluation (ASPE), Office for Civil Rights (OCR), Centers for Medicare & Medicaid Services (CMS), Health Resources and Services Agency (HRSA), National Institutes for Health (NIH), Centers for Disease Control and Prevention (CDC), and HHS Office of Inspector General (OIG). Throughout FY 2019, ONC responded to numerous Administration requests to provide targeted senior-executive expertise to key stakeholders, including to the CMS Office of the Administrator, the Veterans Health Administration, and the Department of Commerce. ONC has a long history of lending the expertise of its leaders to key stakeholders during times of critical importance.
- ONC worked closely with partners in the Department to promote patient access to electronic health information through public assistance materials and awareness campaigns related to the Privacy Act and patient rights as required by the Cures Act. This is a crucial first step to enable price and product transparency and patient access to their health information on their smart phone. ONC continued to disseminate the [Guide to Getting and Using Your Health Information](#) and to promote the [Get IT, Check IT, and Use IT](#) campaign as part of the All of Us Research Program. Additionally, ONC developed and launched an ad campaign to promote patient access.
- In February 2019, ONC issued a detailed Proposed Rule to support the seamless and secure access, exchange, and use of electronic health information as required by the Cures Act.¹⁸ The Rule seeks to **inject competition** into the healthcare delivery system by addressing both technical barriers and business practices that impede the secure and appropriate sharing of data. The Proposed Rule sets as key expectation that certified health IT developers make available in their products secure, standards-based APIs that could be used to facilitate patients’ use of smartphones (or other mobile devices) for accessing electronic health information at no cost. Importantly the proposed rule builds out the regulatory framework to allow patients control of their information in a secured protected way. Using APIs patients control their medical data and which applications get to access that data.
- ONC received 2,013 comment submissions on the Proposed Rule to improve the interoperability of health information. Comment will be synthesized and considered as a part of the final publication.
- ONC continued to plan the implementation of the **EHR Reporting Program** pursuant to Cures Act section 4002 requirements. The EHR Reporting Program will provide publicly available, comparative information about certified health IT products. ONC has taken multiple steps to obtain stakeholder input to develop the program’s criteria including holding **seven listening session** across the country in 2019 and issuing a Request for Information (RFI) which comment period closed in October 2018.

¹⁷ Executive Order 13877: <https://www.federalregister.gov/documents/2019/06/27/2019-13945/improving-price-and-quality-transparency-in-american-healthcare-to-put-patients-first>

¹⁸ <https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health>

In response to the RFI, ONC received 77 public comment submissions from health IT developers and provider organizations representing all major segments of the provider community, payers and health plans covering millions of beneficiaries, and consumer and quality improvement organizations representing patients and consumers.

- In March 2019, ONC organized a full day HITAC hearing in collaboration with the National Committee on Vital Health Statistics, which focused on better understanding the landscape, burdens and potential solutions related to prior authorization. ONC continues to meet with industry stakeholders to learn about how we can support emerging technologies and standards that enable seamless electronic prior authorization to occur to substantially reduce provider burden and allow for improved patient care.
- Pursuant to Cures Act section 4001, ONC and CMS jointly led a team of policy experts and clinicians to produce a draft [Strategy to Reduce Regulatory and Administrative Burdens](#) affecting healthcare providers. Throughout FY 2018, ONC communicated extensively with patients, providers, health IT developers, and federal partners to better understand challenges and opportunities. ONC hosted multiple listening sessions to better understand stakeholders’ issues. The input ONC garnered from stakeholders informed collaborations between ONC and CMS and contributed to making much needed progress at easing burdens and improving clinician experiences with health IT. The draft strategy was released for public comment in November 2018 and closed in January 2019. The Burden Reduction Strategy received widespread public comment and support from stakeholder across the spectrum. Burden reduction work has been initiated in federally required patient note documentation requirements, the prior authorization process, and federal requirements for quality measurement.

★ - Stakeholder Feedback & Action Planning on Burden Reduction Efforts - ★

ONC was tasked by Congress through the 21st Century Cures Act section 4001 to work with healthcare stakeholders and CMS to reduce clinician burden associated with health IT. CMS and ONC heard from stakeholders – specifically physicians, nurse practitioners, physician assistants, and other clinicians who bill Medicare – that the *evaluation and management documentation requirements* create a large amount of administrative burden and are frequently medically unnecessary.

Through research, stakeholders learned that the “boilerplate” template generated text that the current Evaluation & Management code billing requirements generate makes ambulatory office notes in the United States four times as long as those in the rest of the world (4,000 vs. 1,000 characters). Stakeholders agree that the clutter squanders national resources not only in the efforts required to generate the text but in trying to find actual clinical facts when reading the notes.¹⁹

In response this information, ONC and CMS worked together to address the burdens generated by the underlying 1995 regulation. On November 1, 2018, the 2019 Medicare Physician Fee Schedule Final Rule was published in the Federal Register.²⁰ The Final Rule adopts a number of documentation, coding, and payment changes recommended in the draft [Strategy to Reduce Regulatory and Administrative Burdens](#) to *improve flexibility and reduce documentation requirements* associated with office/outpatient evaluation and management (E/M) visits.

¹⁹ Reference: Ann Intern Med. 2018 Jul 3;169(1):50-51. doi: 10.7326/M18-0139. Epub 2018 May 8. Physician Burnout in the Electronic Health Record Era: Are We Ignoring the Real Cause? Downing NL1, Bates DW2, Longhurst CA3.

²⁰ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/>.

These historic changes will take place from 2019 to 2021 with immediate savings beginning in 2019. These changes may result in significantly less documentation burden for clinicians treating Medicare beneficiaries. This historic shift should lead to more efficient, effective use of EHRs in clinicians' offices by improving the workflows needed to support patient-centered care instead of a focus on documentation for billing requirements.²¹

- ONC continued to administer the [Health IT Advisory Committee](#) (HITAC), ONC's **Federal Advisory Committee**. To date, the HITAC has completed a Policy Framework, published the FY 2018 annual report, and provided recommendations on the TEFCA and the USCDI, among other topics.
- Between March and May 2019, the [HITAC](#) held six full committee meetings and 72 Task Force meetings – all to deliberate and provide commendations to support the final publication of the proposed rule to improve interoperability of health information.
- The **Trusted Exchange Framework and Common Agreement** (TEFCA) was released for a second round of public comment in April 2019. The [Trusted Exchange Framework](#) will establish a set of common principles, terms, and conditions that facilitate exchange between health information networks. These principles support the ability of stakeholders to access, exchange, and use relevant electronic health information across different networks and sharing arrangements. The terms and conditions focus on the areas of variation among currently existing trust agreements that impede nationwide interoperability. The Sequoia Project was awarded a cooperative agreement to serve as the Recognized Coordinating Entity responsible for developing, updating, implementing, and maintaining the **Common Agreement** in collaboration with ONC.²² Additionally, ONC released the first draft of the **Qualified Health Information Network** Technical Framework.²³
- The second draft of the Trusted Exchange Framework garnered over 100 public comments, which are being considered as a part of the final product.
- ONC took steps to **promote modern technology standards** and address the interoperability goals of the Cures Act by proposing the [U.S. Core Data for Interoperability \(USCDI\)](#) (launched in 2019) as a standard in the Proposed Rule. The USCDI identifies a common set of healthcare record data classes that are required for interoperable exchange. ONC's Certification Program will test that health IT products meet this new standard. The USCDI has been developed through close coordination with a dedicated HITAC task force that is providing recommendations on data class priorities and a process and proposed frequency for expanding the USCDI.²⁴
- ONC continued to provide health IT and policy expertise and technical assistance by leading the [Health IT Resource Center](#) project, which collaborates closely with CMS support to 15 CMS State Innovation Model (SIM)/All-Payer states and Medicaid Innovation Accelerator Program awardees. ONC's policy and technical assistance addressed many topics, including the Cures Act, the Trusted

²¹ <https://www.healthit.gov/buzz-blog/health-it/onc-supports-cms-proposed-cy-2019-physician-fee-schedule/>.

²² <https://www.hhs.gov/about/news/2019/09/03/onc-awards-the-sequoia-project-cooperative-agreement.html>

²³ <https://www.healthit.gov/buzz-blog/interoperability/moving-beyond-closed-networks-an-update-on-trusted-exchange-of-health-information>

²⁴ <https://www.healthit.gov/hitac/committees/us-core-data-interoperability-task-force>.

Exchange Framework, substance use disorders and 42 CFR Part 2 considerations,²⁵ health information exchange, and global budget models.

- In alignment with [The President's Commission on Combating Drug Addiction and the Opioid Crisis](#), ONC led collaborations with CMS, CDC, numerous states, and representatives from **first responder groups** to identify the most critical stakeholder needs for combatting the opioid epidemic through health IT and improved health information interoperability. As part of this work, ONC and CMS collaborated closely, and in June 2018, CMS published a **letter to State Medicaid Directors** that detailed recommendations for integrating Prescription Drug Monitoring Programs (PDMPs) and EHR data; deploying predictive models coupled with targeted case management; leveraging telehealth-enabled medication assisted therapy; and combining emergency medical system data with other data sources for better care coordination.²⁶ ONC also continued to promote its [Health IT Playbook](#) which contains resources giving providers information about connecting to state PDMPs, integrating data, and electronic prescribing of controlled substances.²⁷

★ - Technical Assistance from ONC Experts - ★

ONC continued to provide technical assistance to CMS [State Innovation Model](#) (SIM) participants. In FY 2019, ONC responded to **38** SIM Technical Assistance Request Cases, **15** All-Payer Model Technical Assistance Requests, participated in **18** SIM Virtual and In-Person State visits, attended **three** All-Payer In-Person State Visits, Hosted **four** Meeting Events, **three** Learning Events, **three** Affinity Groups, and developed **three** resources. The Health IT Resource Center also provided support for **32** SIM Operation Plan and Document Reviews, and **13** SIM Quarterly Progress Report Reviews.

Technology: Standards, Interoperability, and Certification

- ONC continued to implement the statutorily required **ONC Health IT Certification Program** during FY 2019. Pursuant to requirements in the Cures Act (including sections 4001 through 4004), ONC has updated the Certification Program to establish technical and organizational requirements aimed at transparent data sharing, including prohibiting information blocking, publishing APIs, and conducting real world testing of certified products.

The Certification Program maintains test procedures and certification companion guides for 60 certification criteria,²⁸ used to standardize information across 21 distinct programs and initiatives taking place at CMS, the Department of Defense (DOD), the Veterans Health Administration (VHA), the Health Resources and Services Administration (HRSA), and the Substance Abuse and Mental Health Services Administration (SAMHSA).²⁹ ONC's Proposed Rule impacts this program which will carry out part of the implementation of the finalized rule. Additionally, the Health IT Certification Program website, the [Certified Health IT Product List](#) (CHPL), grew to include more than 700 health IT developers' products, and was used to register the EHR products of more than 550,000 healthcare providers and hospitals participating in Medicare and Medicaid programs.³⁰

²⁵ <https://www.samhsa.gov/newsroom/press-announcements/201805020200>.

²⁶ "Leveraging Medicaid Technology to Address the Opioid Crisis," <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18006.pdf>.

²⁷ <https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/>.

²⁸ <https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method>.

²⁹ <https://www.healthit.gov/topic/certification-ehrs/programs-referencing-onc-certified-health-it>.

³⁰ <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

By CY 2018, nearly all hospitals and over half of office-based physicians in the nation had implemented a health IT product certified through the capabilities prioritized by Congress and included in the “2014 edition” certification standards. The most current edition of certified health IT products, dubbed the “2015 Edition,” also became increasingly available for upgrade throughout 2018. At the end of FY 2019, there were 497 2015 Edition products from 342 developers on the CHPL, meaning that there is an EHR product with the latest capabilities available for 98 percent of the eligible hospitals and 94 percent of the eligible clinicians in CMS programs. Widespread adoption of 2015 edition EHRs among providers participating in the CMS programs is expected throughout the FY 2018-2020 timeframe.

- ONC continued to evolve and promote the adoption of a wide range of interoperability standards, including Release 4 of Health Level Seven International’s (HL7) **Fast Healthcare Interoperability Resources (FHIR®)** standard, which is used to enable API-based access. ONC also coordinated standards awareness and use through the publication and maintenance of the [Interoperability Standards Advisory \(ISA\)](#), a resource listing **health information standards, models, and profiles** fitting into more than 60 sub-sections divided by topic/use (e.g., public health, patient information, coordination, clinical care, administration). During the public comment period for the 2019 ISA, ONC received 74 comments with more than 400 individual recommendations for revisions and improvements. In FY 2019, the ISA website has been accessed over 90,000 times, suggesting it is on pace to parallel the over 100,000 views in FY 2018.

★ - Third National Interoperability Forum - ★

ONC hosted the third national [Interoperability Forum](#) that took place from August 21 – 22, 2019 and brought together nearly 1,000 health IT stakeholders, to learn about recent effort to advance interoperability nationwide and to identify concrete actions in response to interoperability barriers.

During the 2-day event, participants from across the Federal Government and healthcare and technology sectors collaborated to identify barriers, showcase demonstrations and innovative health IT solutions, and partake in workgroups focused on various aspects of interoperability, such as the deployment of APIs, improving clinicians’ experience with interoperability, patient matching, and health IT security.

- ONC continued to lead segments of the Precision Medicine Initiative (PMI), including the Sync for Science and Sync for Genes projects. In collaboration with partners at NIH, ONC established pilot sites and improved coordination for the PMI effort. Additional ONC-led activities were targeted to increase health information exchange, develop Implementation Guides for data standards, and finalize a FHIR Release 4 Clinical Genomic Standard. The project team also conducted needs assessments and provided advanced technical guidance to policy leaders to determine gaps that could affect the future of widespread electronic sharing of genomic information for research and healthcare.

★ - Leading Edge Acceleration Projects - ★

In March 2019, ONC announced [an Interest in Applications](#) for a **Leading Edge Acceleration Projects (LEAP)** funding opportunity to address standardization of patient information for seamless access, exchange, and use. The grant advances 21st Century Cures Act’s requirements related to improving the interoperability of health information, facilitating information exchange, addressing barriers to interoperability, and reducing clinician burden relative to EHRs. This funding opportunity is specifically targeted at creating innovative solutions and advances in the following areas:

Area 1: Standardization and Implementation of Scalable HL7 FHIR Consent Resource.

Area 2: Design, Develop, and Demonstrate Enhanced Patient Engagement Technologies for Care and Research.

Agency-Wide Support

- ONC continued to implement workplace improvement initiatives to maintain recent increases in employee engagement. ONC's commitment to employee engagement is aligned with the goals in the HHS Annual Performance Plan Goal 5, Objective 2 related to managing human capital. In FY 2018, ONC established the Workforce Engagement (WE) Team to continue to enrich employee experience within the organization. In 2019, ONC achieved an Employee Engagement Index of 77 percent and Global Satisfaction Index of 72 percent. Additionally, ONC achieved an official response rate of 93 percent on the 2019 Federal Employee Viewpoint Survey, the highest of any HHS StaffDiv.
- ONC's websites garnered 1.2 million visitors so far during FY 2019, an average of over 188,000 sessions per month and 4.3 million page views throughout the year. Almost ninety percent of visitors were from outside the National Capitol area (DC, Maryland, and Virginia). Additionally, ONC's main website, <https://HealthIT.gov>, attracted users referred from 6,880 external websites.

Five Year Funding History

Funding History	
FY 2017 Enacted	60,367,000
FY 2018 Enacted	60,367,000
FY 2019 Enacted	60,367,000
FY 2020 Enacted	60,367,000
FY 2021 President’s Budget	50,717,000

Budget Request

ONC’s budget is a very small portion of federal healthcare spending, yet it has made a transformative impact on the U.S. healthcare system. The lack of interoperability and related, extensive lack of price and product transparency are massive costs to the U.S. public. These deficits keep patients from accessing their medical records, limits patients’ ability to be engaged in their healthcare choices, and dramatically reduces market competition at high cost to the American public. ONC’s work to rapidly address these issues through its policy development and coordination work, and its standards, certification, and interoperability work is sound public policy to promote quality healthcare in the US.

The ONC FY 2021 President’s Budget Request is for \$50.7 million, a decrease of \$9.7 million (16 percent) from the FY 2020 Enacted Level. The Budget Request outlines activities required by the Cures Act, MACRA, and HITECH Act, and continues ONC’s longstanding commitment to engage and respond to the needs of patients, providers, public health agencies, and researchers who rely on health IT. ONC’s FY 2021 Request supports work to advance the technical infrastructure necessary to support price and product transparency and implement the Cures Act, and improve the interoperability of electronic health information. This work would move the healthcare system into a future where financial and clinical data about patients are more aligned. The FY 2021 President’s Budget does not include dedicated funding for the national surveys related to the development, adoption, and use of health IT, or to support ONC’s work related to combatting the opioid epidemic.

No additional FTEs are requested.

Policy Development and Coordination

ONC’s FY 2021 Budget Request reflects ONC’s continued commitment to achieving the Nation’s goals by effectively implementing available policy and coordination levers mandated and necessary to fulfill requirements outlined in the Cures Act, MACRA, and HITECH Act; and work to promote transparency and patient access to their health information. ONC’s progress in promoting and advancing nationwide interoperability depends on the coordinated action of its stakeholders, and the budget request shows how ONC will work closely with partners to advance toward these goals through health IT policy development and coordination. Priorities within ONC’s FY 2021 policy development and coordination portfolio include:

Policy Development and Support

- **Interoperability Policy** – ONC will continue to lead implementation of the TEFCA, which seeks to accelerate health information exchange by establishing common principles, terms, and conditions to facilitate trust between health information networks. In 2021, ONC will continue to promote and facilitate adoption of the TEFCA by major delivery networks and health information exchanges.

- **Rulemaking** – ONC will publish and implement rules pertaining to sections 4002, 4003, and 4004 of the Cures Act. The proposed rules and regulations include provisions on conditions and maintenance of certification requirements for health IT developers under the ONC Health IT Certification Program, the voluntary certification of health IT for use by pediatric healthcare providers, health information network voluntary attestation to the adoption of the TEFCA in support of network-to-network exchange, and defining reasonable and necessary activities that do not constitute information blocking. Upon the publication of the finale rule ONC must implement these provisions through activities in the Standards, Interoperability and Certification portfolio. The implementation of these provisions will advance interoperability and support the access, exchange, and use of electronic health information through secure, standards-based APIs and transparent and uninhibited data sharing. Both interoperability and standards-based APIs are crucial to achieving patient access to their health information and price transparency, enabling patients to shop for care in the future.
- **Usability and Burden Reduction** – ONC will seek to advance implementation of recommendations included in the Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs.
- **Privacy and Security** – ONC will continue to work closely with OCR in response to Cures Act requirements and to address emerging challenges related to HIPAA and the privacy and security of electronic health information. ONC remains unwavering in its long standing goal to promote and ensure secure patient access to, and exchange of, electronic health information. A fundamental part of ONC's interoperability efforts is ensuring the privacy and security of patient data. For patient data to be shared it must be requested and directed by patients. ONC is encouraging and permitting entities to educate patients on the risks of sharing their medical data, as well as things they should consider before sharing their data with anyone.
- **EHR Reporting Program** – ONC will continue necessary activities to develop and implement the EHR Reporting Program. This includes the development of the technical infrastructure to collect confidential feedback and information on reporting program criteria; the development of detailed and summary reports based on information collected; and using the data collected and experiences gained in the previous performance periods, develop and submit to ONC an evaluation report with recommendations for enhancements and mechanisms to move forward with the program.

Stakeholder Coordination

- **Federal Coordination** – As stated previously, ONC will continue leading and engaging agencies which contribute to the Federal Health IT Strategic Plan³¹ and participate in the Federal Health IT Coordinating Council. Within these collaborative forums, ONC will prioritize projects required by the Cures Act, MACRA, and HITECH Act, including work with CMS to reform existing programs and fee schedules, and to engage stakeholders to support provider participation; with HHS OCR to ensure and promote secure patient access to electronic health information and the privacy and security of health IT; and with the HHS OIG, FTC, and DOJ to define and enforce standards for data sharing and prohibiting information blocking.

³¹ https://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf.

- **Federal Advisory Committee** – ONC will continue to lead and engage the HITAC to inform the development of federal health IT policies and the implementation of its programs impacted by the policies and HHS and administration priorities.

Strategic Planning and Reporting

- **Federal Health IT Strategic Planning** – As stated previously, ONC plans to update the Federal Health IT Strategic Plan during FY 2019 – 2020. To create the new plan, ONC will coordinate with federal agencies and seek contributions from key stakeholders group including Congress and the public. Upon publication of the plan, ONC will begin regular collaboration with key stakeholders to plan, monitor, and report progress in support of priority implementation activities.
- **Congressional Reports** – ONC will continue to meet requirements for preparing and submitting annual reports to Congress, including the HITECH Annual Report describing actions taken to address barriers to accomplishing national health IT goals, and to support the HITAC in producing its Annual Report describing progress toward priority target areas identified in the Cures Act related to interoperability, privacy and security, and patient access.

Standards, Interoperability, and Certification

The FY 2021 Budget Request reflects ONC's plans to meet statutory requirements and advance progress toward national goals for widespread interoperability, which includes implementing the impacts of ONC's rulemaking. The request includes funding for coordination and technical activities, such as updates to ONC's Certification Program, that implement changes enacted by the Cures Act and ONC's subsequent rulemaking activities. The standards and interoperability work led by ONC advance the technical infrastructure necessary to support the Administration's price and product transparency goals and enables individuals to get access to their health information on their smartphones.

The Request supports the Conditions of Certification program requirements contained in section 4002 of the Cures Act; standards development and coordination work that promote product transparency and value-based care; development, promotion, and adoption of common standards, with a focus on next generation privacy, security, and interoperability standards; integration of social and behavioral data into electronic health records; and improving patient matching and promote interoperability of data in PDMPs.

Health IT Certification, Testing, and Reporting

- **ONC Health IT Certification Program** – ONC will continue to operate the Certification Program according to statutory requirements. ONC will make updates to the Certified Health IT product list and testing tools, and continue to implement the Conditions of Certification program requirements from section 4002 of the Cures Act, which necessitates substantial program oversight change.

In FY 2021, ONC will continue to oversee the ONC-Authorized Testing Labs and ONC-Authorized Certification Bodies, and maintain a library of useful certification companion guides, test procedures, and electronic test tools to help developers with creating certified health IT.

- **Performance Measurement** – ONC will end support for the national surveys related to the development, adoption, and use of health IT in order to shift funding to critical work implementing the Cures Act such as the Proposed Rule, and Certification Program.

Standards Development and Technology Coordination

- **Standards Development Coordination** – ONC will continue to play a key role as a leader and convener of the health IT community to identify best practices and common approaches to implementing secure, interoperable health IT systems. The standards and interoperability work led by ONC advance the technical infrastructure necessary to support the Administration's price and product transparency goals, empowering patients with the information they need to search for the lowest costs and the highest-quality care. As part of this effort, ONC will continue to coordinate with private sector standards development organizations and promote innovative industry-led projects that improve adoption of mature standards, implement secure APIs, and promote standardized approaches for population level access to health data. Specific projects included in the 2021 Budget include:
 - Ensuring that the next generation of privacy and security standards are ready for widespread adoption as the Nation progresses to widespread adoption of APIs in healthcare, which is a key component of increasing price and product transparency,
 - Promoting adoption of common health information interoperability standards by accelerating the readiness of interoperability standards for adoption into the U.S. Core Data for Interoperability (USCDI), and
 - Addressing growing demand for a national strategy, resources, and demonstrable progress with integrating social and behavioral data and measures into EHRs.
- **Demonstrations and Pilots** – As resources permit, ONC will continue to sponsor and encourage demonstration projects and pilots that tackle critical interoperability challenges. ONC will prioritize projects that emphasize clinical uses of health IT related to the identification and harmonization of existing technical specifications.

Scientific Innovation

- **Scientific Initiatives** – ONC will continue to provide leadership to partners and foster healthcare advancement by anticipating, identifying, and participating in innovation projects spanning health IT development and use. ONC will work closely with stakeholders responsible for implementing the Precision Medicine Initiative (PMI), patient-centered outcomes research (PCOR), artificial intelligence, and international projects.
- **Innovation** – The Cures Act identifies ONC as a leading agency for advancing interoperability to reduce barriers to scientific innovation. ONC's Chief Scientist and clinical experts regularly partner with CMS, NIH, FDA, and others, to implement solutions to public health and scientific innovation through projects of national importance. In FY 2021, ONC will continue to coordinate with stakeholders to develop health IT policy and standards that advance interoperability in biomedical and health services research.

Agency-Wide Support

The FY 2021 President's Budget Request reflects the ONC's commitment to continue advancing progress toward national goals for widespread interoperability. The request includes coordination and ONC management activities that implement changes enacted in the Cures Act.

- **Communications and Engagement** - In FY 2021, ONC will continue to maintain its statutorily required website, <https://HealthIT.gov/>, as a key method of coordinating and disseminating best practices to common challenges facing health IT policymakers, providers, and consumers. ONC

will also continue to maintain a required repository of Federal Advisory Committee meeting documents at <https://HealthIT.gov/HITAC>.

- **Management and Governance** - In FY 2021, ONC will continue to implement and improve its existing strategic and operational management processes. ONC's FY 2021 Budget Request includes funding for the HHS-controlled shared services that ONC is mandated by HHS to pay for and use, including fees for financial and grants management systems, contract management, and ONC's office space located in HHS's Southwest Complex. ONC will continue to identify opportunities for savings and efficiencies by improving the management of central costs through negotiations with service providers. At this level, department controlled shared services make up about 15 percent of the available budget.

Output and Outcomes Table

Measure Group / Measure Text	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/- FY 2020 Target
Policy Development and Coordination				
Number of federal agencies actively participating in ONC-led health IT coordination efforts	FY 2019: 25 Target: Maintain (Target Met)	Maintain	Maintain	--
Standards, Interoperability, and Certification				
Number of interoperable data elements included in certification criteria adopted into the ONC Health IT Certification Program to meet congressional requirements	FY 2019: 60 criterion in 2015 edition Target: Maintain (Target Met)	Increase related to Cures Act Implementation	Maintain	--
Number of interoperability needs areas supported by standards and implementation specifications included in the annual Interoperability Standards Advisory Reference Edition	FY 2019: 2019 reference edition ISA published in January contained 167 (+16) standards and implementation specifications ³² (Baseline)	Maintain ISA & Publish annual update by March 2020	Maintain ISA & Publish annual update by March 2021	--
Agency Wide Support				
Number of visitors to ONC’s websites to use health IT policy and technology assistance material	FY 2019: 1.8 million (Baseline)	Maintain	Maintain	--

³² Includes 6 implementation specifications which are considered “profiles and models” and not traditional standards.

Environmental Measures

Measure: Provider capability in key domains of interoperable health information exchange³³

	Office- based physicians	Non-federal acute care hospitals
• are electronically <u>sending or receiving</u> patient information with any providers outside their organization	47%	90%
• can electronically <u>find</u> patient health information from sources outside their health system	53%	61%
• can easily <u>integrate</u> (e.g. without manual entry) health information received electronically into their EHR	28%	53%
• had necessary patient information electronically <u>available</u> from providers or sources outside their systems at the point of care	32%	51%

Measure: Citizen’s perspective on consumer access

- 51 percent of Americans have been given electronic access to any part of their healthcare record by their healthcare provider or insurer.

³³ These measures were selected to meet MACRA § 106(b) requirements to evaluate progress to widespread interoperability. Physician data are as of 2015; hospital data are as of 2017. 2018 estimates for both measures are expected to become available during calendar year 2019.
https://www.healthit.gov/sites/default/files/fulfilling_section_106b1c_of_the_medicare_access_and_chip_reauthorization_act_of_2015_06.30.16.pdf.

Nonrecurring Expenses Fund

Budget Summary

(Dollars in Thousands)

	FY 2019 ³⁴	FY 2020 ³⁵	FY 2021 ³⁶
Notification ³⁷	\$7,000	TBD	TBD

Authorization Section 223 of Division G of the Consolidated Appropriations Act, 2008
 Allocation Method Direct Federal, Competitive Contract

Program Description and Accomplishments

The Nonrecurring Expenses Fund (NEF) permits HHS to transfer unobligated balances of expired discretionary funds from FY 2008 and subsequent years into the NEF account. Congress authorized use of the funds for capital acquisitions necessary for the operation of the department, specifically information technology (IT) and facilities infrastructure acquisitions.

In FY 2019, NEF resources supported the development of electronic (software-based) testing tools for the Health IT Certification Program and software development associated to build a data-reporting platform. These two interdependent IT infrastructure capacity-building activities directly tie to implementing Section 4002 of the 21st Century Cures Act. To support these activities, ONC awarded non-severable contracts to software development firms. An additional contract for this work will be issued in early FY 2020. The new testing tools and the reporting platform will allow ONC to conduct oversight and continuous monitoring of targeted electronic health record technologies and “real world testing” of certified products, and to build a data-reporting platform to capture and publish new data elements as required by the Act.

³⁴ Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use

³⁵ Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on December 4, 2018

³⁶ HHS has not yet notified for FY 2020

³⁷ HHS has not yet notified for FY 2021

Supplementary Tables

Budget Authority by Object Class

(Dollars in Thousands)

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
<u>Personnel compensation:</u>				
Full-time permanent (11.1).....	18,686	19,265	19,265	-
Other than full-time permanent (11.3).....	940	969	969	-
Other personnel compensation (11.5).....	746	769	769	-
Military personnel (11.7).....	253	261	269	8
Special personnel services payments (11.8).....	9	9	9	-
Subtotal personnel compensation	20,634	21,274	21,281	8
Civilian benefits (12.1).....	6,229	6,422	6,422	-
Military benefits (12.2).....	107	110	114	3
Benefits to former personnel (13.0).....	-	-	-	-
Total Pay Costs	26,970	27,806	27,817	11
Travel and transportation of persons (21.0).....	330	330	330	-
Transportation of things (22.0).....	-	-	-	-
Rental payments to GSA (23.1).....	1,934	1,934	1,934	-
Rental payments to Others (23.2).....	-	-	-	-
Communication, utilities, and misc. charges (23.3).....	137	137	137	-
Printing and reproduction (24.0).....	-	-	-	-
<u>Other Contractual Services:</u>				
Advisory and assistance services (25.1).....	37	37	37	-
Other services (25.2).....	12,931	12,931	10,748	(2,184)
Purchase of goods and services from government accounts (25.3).....	11,309	11,309	9,126	(2,184)
Operation and maintenance of facilities (25.4).....	284	284	284	-
Research and Development Contracts (25.5).....	-	-	-	-
Medical care (25.6).....	-	-	-	-
Operation and maintenance of equipment (25.7).....	-	-	-	-
Subsistence and support of persons (25.8).....	-	-	-	-
Subtotal Other Contractual Services	26,962	26,962	22,595	(4,367)
Supplies and materials (26.0).....	286	286	286	-
Equipment (31.0).....	19	19	19	-
Land and Structures (32.0).....	-	-	-	-
Investments and Loans (33.0).....	-	-	-	-
Grants, subsidies, and contributions (41.0).....	5,739	5,294	-	(5,294)
Interest and dividends (43.0).....	-	-	-	-
Refunds (44.0).....	-	-	-	-
Total Non-Pay Costs.....	6,044	5,599	305	(5,294)
Total Budget Authority by Object Class	59,976	60,367	50,717	(9,650)

Salaries and Expenses

(Dollars in Thousands)

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel compensation:				
Full-time permanent (11.1)	18,686	19,265	19,265	-
Other than full-time permanent (11.3)	940	969	969	-
Other personnel compensation (11.5)	746	769	769	-
Military personnel (11.7).....	253	261	269	8
Special personnel services payments (11.8).....	9	9	9	-
Subtotal personnel compensation.....	20,634	21,274	21,281	8
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Military benefits (12.2).....	107	110	114	3
Benefits to former personnel (13.0).....	-	-	-	-
Total Pay Costs	26,970	27,806	27,817	11
Travel and transportation of persons (21.0).....	330	330	330	-
Transportation of things (22.0).....	-	-	-	-
Rental payments to GSA (23.1).....	1,934	1,934	1,934	-
Rental payments to Others (23.2).....	-	-	-	-
Communication, utilities, and misc. charges (23.3)	137	137	137	-
Printing and reproduction (24.0)	-	-	-	-
Other Contractual Services:				
Advisory and assistance services (25.1).....	37	37	37	-
Other services (25.2).....	12,931	12,931	10,748	(2,184)
Purchase of goods and services from government accounts (25.3)	11,309	11,309	9,126	(2,184)
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Research and Development Contracts (25.5)	-	-	-	-
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	-	-	-	-
Subsistence and support of persons (25.8)	-	-	-	-
Subtotal Other Contractual Services	26,962	26,962	22,595	(4,367)
Supplies and materials (26.0)	286	286	286	-
Total Non-Pay Costs.....	286	286	286	-
Total Salary and Expense	54,218	55,054	50,698	(4,356)
Direct FTE	158	164	164	-

Detail of Full-Time Equivalent Employment (FTE)

	2019 Actual Civilian	2019 Actual Military	2019 Actual Total	2020 Est. Civilian	2020 Est. Military	2020 Est. Total	2021 Est. Civilian	2021 Est. Military	2021 Est. Total
Direct:	156	2	158	162	2	164	162	2	164
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	156	2	158	162	2	164	162	2	164
ONC FTE Total	156	2	158	162	2	164	162	2	164

Average GS Grade

	Grade:	Step:
FY 2017.....	13	9
FY 2018.....	13	8
FY 2019.....	13	7
FY 2020.....	13	7
FY 2021.....	13	7

Detail of Positions

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Executive level	-	-	-
Total - Exec. Level Salaries	-	-	-
ES.....	6	6	6
Total - ES Salary	1,195,222	1,223,011	1,223,011
GS-15.....	46	46	46
GS-14.....	41	41	41
GS-13.....	43	44	44
GS-12.....	10	10	10
GS-11.....	5	12	12
GS-10.....	-	-	-
GS-9.....	7	16	16
GS-8.....	-	-	-
GS-7.....	-	1	1
GS-6.....	-	-	-
GS-5.....	-	1	1
GS-4.....	-	-	-
GS-3.....	-	-	-
GS-2.....	-	-	-
GS-1.....	-	-	-
Subtotal	152	171	171
Total - GS Salary	19,750,966	20,210,176	20,210,176
Average ES salary.....	199,204	203,835	203,835
Average GS grade.....	13-10	13-6	13-6
Average GS salary.....	129,941	118,188	118,188

Programs Proposed for Elimination

No programs are proposed for elimination.

Physicians’ Comparability Allowance Worksheet

	PY 2019 (Actual)	CY 2020 (Estimate)	BY 2021 (Estimate)
Number of Physicians Receiving PCAs.....	1	3	3
Number of Physicians with One-Year PCA Agreements	0	0	0
Number of Physicians with Multi-Year PCA Agreements	0	3	3
Average Annual PCA Physician Pay (without PCA payment).	\$192,190	\$159,028	\$159,028
Average Annual PCA Payment	\$30,000	\$16,000	\$16,000

Explain the recruitment and retention problem(s) justifying the need for the PCA pay authority.

ONC needs physicians with a strong medical background to engage clinical stakeholders and to provide an in-depth clinically based perspective on ONC policies and activities such as EHR safety, usability, clinical decision support, and quality measures.

Without the PCA, it is unlikely that ONC could have recruited and maintained its current physicians, nor is it likely that ONC would be able to recruit and maintain physicians without PCAs in future years.

Explain the degree to which recruitment and retention problems were alleviated in your agency through the use of PCAs in the prior fiscal year.

ONC was able to retain physicians with strong medical background so the agency was better able to engage clinical stakeholders and provide a clinically based perspective on ONC policies and activities such as EHR safety, reducing administrative burden on providers, usability, clinical decision support, and quality measures.

Modernization of the Public-Facing Digital Services - 21st Century Integrated Digital Experience Act

On Dec. 20, 2018, President Trump signed the 21st Century Integrated Digital Experience Act (IDEA), which requires data-driven, user-centric website and digital services modernization, website consolidation, and website design consistency in all Executive Agencies. Departments across the federal landscape are beginning to implement innovative digital communications approaches to increase efficiency and create more effective relationships with their intended audiences. The American public expects instant and impactful communications – desired, trusted content available when they want it, where they want it, and in the format they want it. If the consumer is not satisfied they move on and our opportunity for impact is lost.

Modernization Efforts

In FY 2019 HHS engaged Department leadership and developed a Digital Communications Strategy that aligns with the requirements of IDEA. As the result of a comprehensive review of costs associated with website development, maintenance, and their measures of effectiveness, HHS will prioritize:

- modernization needs of websites, including providing unique digital communications services, and
- develop estimated costs for achieving performance metrics.

Over the next five years HHS will continue to implement IDEA by focusing extensively on a user-centric, Digital First approach to both external and internal communications and developing performance standards. HHS will focus on training, hiring, and tools that drive the communication culture change necessary to successfully implement IDEA.

Over the next year, HHS Agencies and Offices will work together to continue to implement IDEA and the HHS Digital Communications Strategy across all communications products and platforms.

Significant Items in Appropriation Committee Reports

Patient Data Matching: *The Committee is aware that one of the most significant challenges inhibiting the safe and secure electronic exchange of health information is the lack of a consistent patient data matching strategy. With the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, a clear mandate was placed on the Nation's healthcare community to adopt electronic health records and health exchange capability. Although the Committee continues to carry a prohibition against HHS using funds to promulgate or adopt any final standard providing for the assignment of a unique health identifier for an individual until such activity is authorized, the Committee notes that this limitation does not prohibit HHS from examining the issues around patient matching. Accordingly, the Committee continues to encourage the Secretary, acting through the ONC and CMS, to provide technical assistance to private-sector-led initiatives to develop a coordinated national strategy that will promote patient safety by accurately identifying patients to their health information. (Page 168, H.Rept. 116-62)*

Action to Be Taken

ONC will continue to provide technical assistance to private-sector-led initiatives to develop a coordinated national strategy that will promote patient safety by accurately identifying patients to their health information.

Good Accounting Obligation in Government Act Report

The information below addresses the requirements of the Good Accounting Obligation in Government Act (GAO-IG Act; Public Law 115-414) to provide a report identifying each public recommendation issued by the Government Accountability Office (GAO) and federal Offices of Inspectors General (OIG) which remains unimplemented for one year or more from the annual budget justification submission date. The recommendations below apply specifically to this division of HHS. Please refer to the General Departmental Management budget justification for more information on the Department’s overall progress in implementing GAO and OIG recommendations.

Appendix 1: OIG-GAO Open Recommendations

Report Number	Report Title	Report Date	Recommendation Text	Concur / Non-Concur	Implementation Timeline	Implementation Status	Implementation Updates and Constraints
<u>GAO-17-305</u>	Health Information Technology: HHS Should Assess the Effectiveness of Its Efforts to Enhance Patient Access to and Use of Electronic Health Information	3/15/2017	To help ensure that its efforts to increase patients' electronic access to health information are successful, the Secretary of HHS should direct ONC to use the information these performance measures provide to make program adjustments, as appropriate. Such actions may include, for example, assessing the status of program operations or identifying areas that need improvement in order to help achieve program goals related to increasing patients' ability to access their health information electronically.	Concur	NA	In Progress	ONC continues to take actions in response to and to close out GAO's recommendation. Specifically, in our latest open recommendation update, ONC noted it currently uses program data to reassess and improve upon its initiatives. For example, the Patient Engagement Playbook for providers is updated on a quarterly basis through user feedback to provide relevant and timely information. Similarly, the Blue Button Connector website for consumers is currently being redesigned to create a more engaging and beneficial experience for users seeking their health information. In each of these projects and when developing other tools and resources focused on increasing electronic access to health information, ONC will continue to implement user-centered design principles to ensure that all products and materials developed are effective and impactful. Additionally, ONC will rely on web metrics, stakeholder feedback and input, comments and feedback from users, and internal program analysis to update and improve these efforts. ONC is committed to leveraging data from its program evaluations to facilitate program improvement.
<u>OEI-01-11-00570</u>	Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology	12/9/2013	Audit logs be operational whenever EHR technology is available for updates or viewing.	Concur	2020	Awaiting Disposition	ONC submitted an NFA to OIG in 2016 informing OIG no further action would be taken, but OIG has not yet closed out the recommendations.
<u>OEI-01-11-00570</u>	Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology	12/9/2013	ONC and CMS strengthen their collaborative efforts to develop a comprehensive plan to address fraud vulnerabilities in EHRs.	Concur	2020	Awaiting Disposition	ONC submitted an NFA to OIG in 2019 informing OIG no further action would be taken, but OIG has not yet closed out the recommendations.

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Report Number	Report Title	Report Date	Recommendation Text	Concur / Non-Concur	Implementation Timeline	Implementation Status	Implementation Updates and Constraints
GAO-14-207	Electronic Health Record Programs: Participation Has Increased, but Action Needed to Achieve Goals, Including Improved Quality of Care	3/6/2014	To ensure that CMS and ONC can effectively monitor the effect of the EHR programs and progress made toward goals, the Secretary of Health and Human Services should direct the agencies to develop performance measures to assess outcomes of the EHR programs—including any effects on health care quality, efficiency, and patient safety and other health care reform efforts that are intended to work toward similar outcomes.	Concur	2020	Awaiting Disposition	<p>In its latest open recommendation update, ONC noted, in-depth, efforts to implement this recommendation, including: (1) regularly/publicly reporting on how program participants are progressing in the program and related impacts; (2) funding a series of external program evaluations designed to assess the impact of the programs funded under HITECH, including the EHR Incentive Programs; and, (3) continuing to explore potential outcome measures to incorporate into EHR programs.</p> <p>GAO responded to ONC’s update noting “to fully implement this recommendation, CMS needs to develop performance measures that enable the agency to assess whether the Promoting Interoperability programs are improving outcomes, . . .”</p> <p>CMS has indicated that the new scoring submission window ends in the Spring of 2020 and the final data, for the first year, should be available by late 2020.</p>
GAO-14-207	Electronic Health Record Programs: Participation Has Increased, but Action Needed to Achieve Goals, Including Improved Quality of Care	3/6/2014	To ensure that CMS and ONC can effectively monitor the effect of the EHR programs and progress made toward goals, the Secretary of Health and Human Services should direct the agencies to use the information these performance measures provide to make program adjustments, as appropriate, to better achieve program goals.	Concur	2021	Awaiting Disposition	<p>In addition to actions taken in response to recommendation GAO-14-207-2, to implement recommendation GAO-14-207-3, the information gathered through the monitoring activities noted above was used to inform ONC and CMS programs. For example, information collected was regularly presented to ONC’s Federal Advisory Committees to inform their decision-making.</p> <p>CMS and ONC have continued to leverage information gathered through previously noted program monitoring activities to inform rulemaking necessary to implement requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and the 21st Century Cures Act (CURES). Both of these legislations build upon the requirements under HITECH and thus might alter the anticipated outcomes of current programs going forward.</p> <p>GAO responded to ONC’s update noting “to fully implement this recommendation, CMS needs to develop outcome-oriented performance measures and then demonstrate it is using them to make appropriate program adjustments. . . .”</p> <p>CMS indicated that they expect to be able to close this recommendation once HHS has identified the performance based measures. CMS will not receive the 2019 reporting period data until spring of 2020 and the final validated data until late 2020.</p>

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Report Number	Report Title	Report Date	Recommendation Text	Concur / Non-Concur	Implementation Timeline	Implementation Status	Implementation Updates and Constraints
GAO-17-184	Electronic Health Records: HHS Needs to Improve Planning and Evaluation of Its Efforts to Increase Information Exchange in Post-Acute Care Settings	2/27/2017	To improve efforts to promote EHR use and electronic exchange of health information in post-acute care settings, the Secretary of Health and Human Services should direct the Centers for Medicare & Medicaid Services (CMS) and ONC to evaluate the effectiveness of HHS's key efforts to determine whether they are contributing to HHS's goal for increasing the use of EHRs and electronic exchange of health information in post-acute care settings.	Concur	2019	Awaiting Disposition	<p>In its latest open recommendation update, ONC noted, in-depth, the efforts taken to implement this recommendation, including but not limited to, noting ONC conducted activities to evaluate HIT adoption and interoperability for PAC settings, including conducting and analyzing the results of 3 surveys regarding rates of interoperability among skilled nursing facilities and home health agencies. These surveys established important baseline data for EHR adoption and interoperability by skilled nursing home and home health; the results of these analyses were published by ONC in 2 data briefs published in 2017 and 2018; and, ONC presented the results of these analyses to CMS and the public. Also in July 2015, ONC issued 12 two-year cooperative agreements to state-designated entities and state government agencies under the Advance Interoperable Health Information Technology Services to Support Health Information Exchange (AHIE) program. The awards funded efforts to provide training, education, and technical assistance to support clinical and non-clinical caregivers with incorporating HIE into their existing workflows. The goal was to leverage investments and lessons learned from the initial State HIE projects to increase the adoption and use of interoperable HIT to improve care coordination. Each awardee was asked to develop a set of measures unique to their projects that would demonstrate their progress toward these milestones and an evaluation of awardee efforts was also conducted. ONC believes it has addressed the recommendations made in the GAO report that are within ONC’s authority and considers the recommendation fully implemented.</p> <p>In August 2019 CMS submitted the Data Element Library response to GAO. It is our understanding that ONC will provide a response regarding the State Medicaid matching funds and additional responses related to their efforts. The program area is hopeful that this closes out both recommendations of this audit for CMS.</p>

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Report Number	Report Title	Report Date	Recommendation Text	Concur / Non-Concur	Implementation Timeline	Implementation Status	Implementation Updates and Constraints
GAO-17-184	Electronic Health Records: HHS Needs to Improve Planning and Evaluation of Its Efforts to Increase Information Exchange in Post-Acute Care Settings	2/27/2017	To improve efforts to promote EHR use and electronic exchange of health information in post-acute care settings, the Secretary of Health and Human Services should direct CMS and ONC to comprehensively plan for how to achieve the department's goal related to the use of EHRs and electronic information exchange in post-acute care settings. This planning may include, for example, identifying specific actions related to post-acute care settings and identifying and considering external factors.	Concur	2019	Awaiting Disposition	<p>ONC noted the following in its latest open recommendation update. In 2015, ONC published a federal strategic plan to advance the adoption and interoperability of HIT, including in post-acute care (PAC) settings: Federal Health IT Strategic Plan 2015 – 2020 (the Plan). Contributors to the Plan included representatives from across the federal government, including CMS.</p> <p>The Plan: (1) addresses the federal HIT strategy for all health care industry segments that are health information exchange partners, including long-term care and post-acute; (2) explains how the federal government is working to achieve the mission of ‘improving the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most’; (3) applies broadly to stakeholders across the care continuum, including PAC providers, and aims to modernize the U.S. HIT infrastructure so individuals, providers, and communities can use it to help achieve health and wellness goals; (4) includes goals, objectives, and strategies intended to drive the actions needed to improve HIT adoption and PAC interoperability; and, (5) states “long-term and post-acute care plays an integral role in helping to keep individuals healthy and have numerous situations that necessitate collaboration and sharing of information with the greater health community.” ONC has also taken actions to advance HIT adoption and interoperability for PAC providers through outreach/collaboration, supports for HIT adoption, and standards/initiatives specific to PAC.</p> <p>ONC believes it has addressed the recommendations made in the GAO report that are within ONC’s authority and considers the recommendation fully implemented.</p> <p>In August 2019 CMS submitted the Data Element Library response to GAO. It is our understanding that ONC will provide a response regarding the State Medicaid matching funds and additional responses related to their efforts. The program area is hopeful that this closes out both recommendations of this audit for CMS.</p>

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 FY 2021 President’s Budget: Justification of Estimates to the Office of Management and Budget

Report Number	Report Title	Report Date	Recommendation Text	Concur / Non-Concur	Implementation Timeline	Implementation Status	Implementation Updates and Constraints
GAO-17-5	Health Care Quality: HHS Should Set Priorities and Comprehensively Plan Its Efforts to Better Align Health Quality Measures	10/13/2016	To make it more likely that HHS will achieve its goals to reduce quality measure misalignment and associated provider burden, the Secretary of HHS should direct CMS and the Office of the National Coordinator for Health Information Technology to prioritize their development of electronic quality measures and associated standardized data elements on the specific quality measures needed for the core measure sets that CMS and private payers have agreed to use.	Concur	2020	Awaiting Disposition	<p>CMS does prioritize the development of electronic quality measures and associated standardized data elements on the specific quality measures needed in the cores sets. We have highlighted leveraging the Core Quality Measures Collaborative in our strategic approach for measure development priorities for MACRA, as noted in the CMS Quality Measure Development Plan (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf). The following section and language throughout the MDP is documentation of that prioritization: “CMS intends to prioritize the development of electronic measures in a manner that ensures relevance to patients, improves measure quality, increases clinical data availability, accelerates development cycle times, and drives innovation. Specifically, CMS, in concert with ONC and the private sector, is championing electronic measure development in the areas of standards, tools, and processes that are open to all measure developers.” In addition, we anticipate soon awarding an Eligible Clinician (EC) eCQM maintenance and development contract where the contractor shall identify clinical quality measure concepts for eCQMs that reflect the following CMS priorities: 1) improve quality, safety, and efficiency and reduce health disparities, 2) engage patients and families, 3) improve care and coordination, 4) ensure adequate privacy and security protections for personal health information, and 5) improve population and public health. Measure concepts will be for the EC setting as well as for other health care settings, such as post-acute care setting like skilled nursing facilities, home health, and dialysis facilities. We note that up to 4 new (de novo or retooled) Eligible Clinician eCQMs may be developed during each period of performance of the contract, according to the QPP, Agency and HHS needs and priorities.</p> <p>Although CMS has implemented measures from the Core Quality Measures Collaborative’s agreed-upon measure sets, ONC understands that only some of the measures across all of the agreed-upon core sets have been fully developed and specified for EHR reporting. ONC has implemented the 2015 Edition Health IT Certification Criteria (2015 Edition) and its associated testing and certification procedures to support the efforts of CMS and other measure developers who are prioritizing development of core measures, including private payers and clinical specialty societies. Certification to the 2015 Edition ensures a health IT product is capable of capturing and exchanging a defined catalog of data elements in conformance with interoperability standards, all identified in our regulations. Thus, the 2015 Edition provides a foundational set of standardized data elements that CMS and other measure developers can use to develop and specify additional measures for EHR reporting. ONC continues to prioritize interoperability of health data to support patient choice, clinical care, public health, value-conscious purchasing and improved care value. ONC does not plan to take further action(s), other than those actions previously taken, in response to this recommendation. ONC believes efforts to prioritize CMS’ development of measures from the core measure sets that they and private payers have agreed to use should be addressed by CMS.</p>

