DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2020

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

*Justification of Estimates to the
Appropriations Committees*

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORAMTION TECHNOLOGY

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 (IT) 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 2020 Priority Outcomes

- Advancing the availability, accessibility, interoperability, and usability of electronic health information and electronic health records (EHRs);
- Empowering consumer choice in health care through electronic access to health information and the portability of health information;
- Promoting innovation and competition in the health IT industry by establishing expectations for data sharing;
- Supporting open application programming interfaces (API) and user-focused technologies to improve patient and provider experiences with health IT; and
- Contributing to HHS efforts to combat the opioid epidemic through improvements in health IT infrastructure and health information sharing.

ONC's Authorizing and Enabling Legislation

- Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), adopted as part of American Recovery and Reinvestment Act of 2009, Pub. L. 111-5 (Feb. 17, 2009) and adding Title XXX (Health Information Technology and Quality) to the Public Health Service Act.
- Medicare Access and CHIP Reauthorization Act ("MACRA"), Pub. L. 114-10 (Apr. 16, 2015).
- 21st Century Cures Act ("Cures Act"), Pub. L. 114-255 (Dec. 13, 2016), amending Title XXX of the Public Health Service Act.

FY 2020 President's Budget Request

Dear Reader,

I am pleased to present the fiscal year (FY) 2020 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 2020, and also includes annual performance information covering highlights from ONC activities that took place in the most recently concluded fiscal year, FY 2018.

The FY 2020 President's Budget request level for ONC is $43.0 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 FY 2020 President's Budget Request, ONC plans to continue necessary efforts to implement the 21st Century Cures Act (Cures Act), which will enter its fourth year of government-wide implementation in 2020. In particular, ONC will prioritize activities that address Congressional requirements related to: (1) accelerating development and adoption of health information standards, (2) maintaining 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 of experts has a collaborative and innovative track record of providing in-depth health IT expertise to key stakeholders across government and in the health care and health IT industries. 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, and promoting an innovative and competitive health care marketplace in the United States.
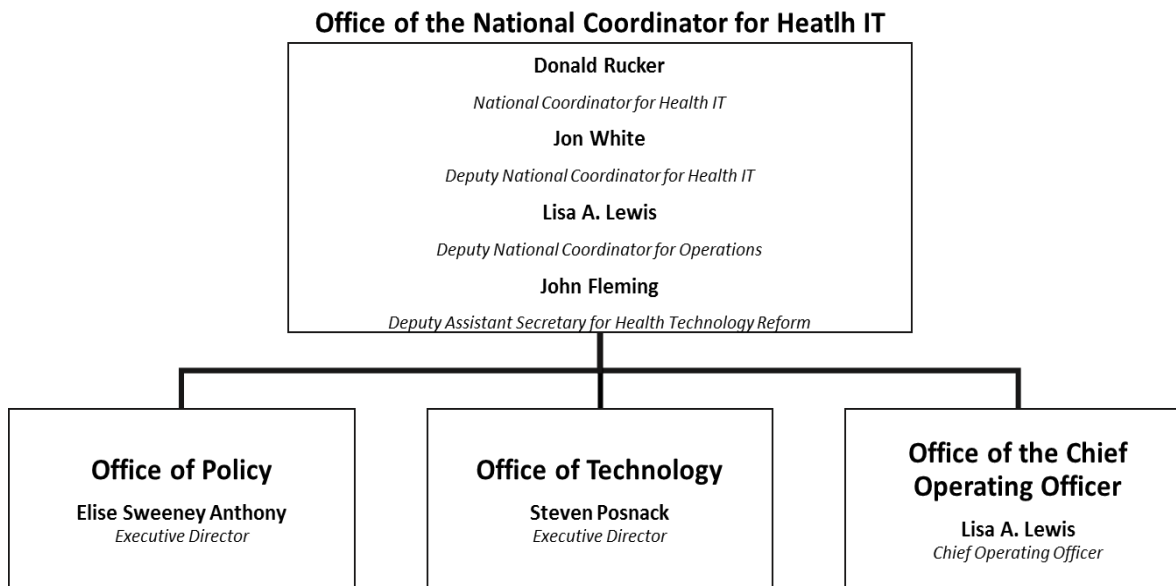

/Donald W. Rucker/
Donald W. Rucker, M.D.
National Coordinator for Health IT

FY 2020 President's Budget
Justification of Estimates to the Appropriations Committees
Office of the National Coordinator for Health Information Technology

Organizational Chart

Office of the National Coordinator for Heatlh IT

Donald Rucker

National Coordinator for Health IT

Jon White

Deputy National Coordinator for Health IT

Lisa A. Lewis

Deputy National Coordinator for Operations

John Fleming

Deputy Assistant Secretary for Health Technology Reform

Office of Policy

Elise Sweeney Anthony
Executive Director

Office of Technology

Steven Posnack
Executive Director

Office of the Chief Operating Officer

Lisa A. Lewis
Chief Operating Officer

Organizational Chart – Text Version

- Immediate Office of the National Coordinator
    - Donald Rucker, M.D. *National Coordinator for Health Information Technology*
    - Jon White, M.D. *Deputy National Coordinator for Health Information Technology*
    - John Fleming, M.D. *Deputy Assistant Secretary for Health Technology Reform*
- Office of Policy
    - Elise Sweeney Anthony, J.D., *Executive Director*
- Office of Technology
    - Steven Posnack, M.S., M.H.S., *Executive Director*
- Office of the Chief Operating Officer
    - Lisa A. Lewis, *Deputy National Coordinator for Operations and 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 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. 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 health care through a nationwide *interoperable* health IT infrastructure.

ONC's mission, goals, and objectives originate from three laws:

- Health Information Technology for Clinical and Economic Health Act (2009).
- Medicare Access and CHIP Reauthorization Act of 2015.
- 21st Century Cures Act (2016).

For the past decade, national leaders have pursued an agenda that promotes innovation in health care built on widespread, interoperable health information. Interoperable health information will improve health and health care by increasing market efficiency, and empowering patients and their providers with access to valuable 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 health care delivery system, increase market competition in health care, and improve the nation's preparedness for and responsiveness to public health crises, such as hurricanes, disease outbreaks, and epidemics (e.g., influenza, opioids).

In FY 2018, ONC's appropriated budget authority of $60.4 million supported a diverse staff and a network of contracted experts spanning a wide range of health care, technology, policy, public health, and public administration specialties. ONC staff specialists regularly collaborate with leaders in health care, health, and technology in government and industry. This includes closely 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 health care 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 online at https://HealthIT.gov each year.

Overview of Budget Request

The FY 2020 President's Budget Request for ONC is $43.0 million, which is a $17.4 million (29 percent) reduction from the enacted FY 2019 level. Enabled by its authorities and propelled by annual appropriations, ONC's efforts in FY 2020 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 Health Care 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 health care, 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 health care providers

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In FY 2020, ONC will prioritize actions necessary to meet Congressional goals expressed in the Cures Act, the President's goals for promoting health care choice and competition expressed through Executive Order (EO) 13813 and the MyHealthEData Initiative, and HHS priorities expressed in Secretary Azar's 4-part Strategy for value based care, the HHS 5-point strategy to combat the opioids crisis, and the Centers for Medicare & Medicaid Services (CMS) Patients Over Paperwork initiative.

ONC's FY 2020 President's Budget request explains the agency's plan to implement a portfolio of activities rooted in its requirements and authorities to undertake health IT:

- **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.

- **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 enable interoperable information exchange, and sponsoring pilot projects and industry challenges to accelerate innovation and demonstrate advanced uses of health IT, such as promoting API access to EHR data and impactful innovation in consumer health apps.

- **Agency-Wide Support**, including providing executive, clinical, and scientific leadership, and coordinating outreach between the Office of the National Coordinator and key federal stakeholders, maintaining https://healthIT.gov to promote federal policy related to health IT, and ensuring effective ONC agency operations and management through an integrated operations function.

Overview of Performance

Description of ONC's Performance Management Process

ONC's performance management process prioritizes ensuring compliance with statutory requirements and promoting a continuous focus on improving results, efficiency and effectiveness of operations, and finding more cost-effective ways to deliver policy, program, and management leadership to stakeholders.

The routine performance management process incorporates a number of specific efforts related to ensuring strategic understanding; undertaking planning and stakeholder coordination; translating requirements and authorities into tactical plans; implementing projects; reporting; and strategic reviews. Throughout the process, ONC executives create a culture of performance management through the use of administrative data and information. Across each facet of policy, technical, and operational leadership at ONC, the executive team uses all available information to create measurable improvements in the effectiveness and efficiency of programs and activities. Alongside the routine priority setting process, ONC regularly receives and addresses requests from Congress, the Government Accountability Office (GAO), and the HHS Office of the Inspector General (OIG).

Summary of Performance Information in the Budget Request

Performance information in the President's Budget request for ONC includes a combination of *contextual research measures* that describe the extent of nationwide interoperable health information exchange and patient and provider access to health IT and *agency information and measures* that highlight key information about activities necessary to implement statutory requirements and achieve ONC's goals.

As a foundation for its work, ONC often conducts research to better understand and explain the extent of health IT adoption and use in health care. The research gives ONC and its partners the insight necessary for informed decision making. During FY 2018, 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 ONC's national-level estimates for the following priority national indicators of health IT adoption and use:

Patient Access to Electronic Health Information: [1]
- 52 percent of Americans had been given **electronic access** to any part of their health care record by their health care provider or insurer by 2017.

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[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

Health Information Interoperability: [2, 3]

- 48 percent of physicians and 90 percent of hospitals are **sending or receiving** patient information to providers outside their organization via an EHR.

- 34 percent of physicians and 61 percent of hospitals can **find** patient health information from sources outside their health system through their EHR.

- 31 percent of physicians and 53 percent of hospitals can **integrate** (e.g., without manual entry) health information received electronically into their EHR.

- 36 percent of physicians and 51 percent of hospitals reported having necessary patient information electronically **available** at the point of care through their EHR.

In the FY 2020 President's Budget, ONC's reporting of agency performance measures includes both implementation-focused measures and survey based, contextual measures. This approach to performance measurement allows ONC to use the Budget to report performance information describing recent ONC activities and highlighting key explanatory information about ONC programs' reach, depth, and coordination activity.

Highlights of key ONC accomplishments from FY 2018 that exemplify how the agency helps to lead the way for nationwide interoperable health information exchange and improvements in health IT usability include:

- ONC continued to implement Congressional requirements to operate the **Health IT Certification Program** by maintaining nearly **60 certification criteria –** including test procedures and certification companion guides – used to standardize information across **21 federal efforts**.[4] By FY 2018, the ONC Health IT Certification Program's website, the Certified Health IT Product List (CHPL), listed products from more than 600 health IT developers,[5] and was used to register the EHRs of 550,000 care providers and hospitals participating in Medicare and Medicaid.[6] As of November 2018, there are 405 2015 Edition products from 267 developers on the CHPL. This means that 95 percent of the hospitals and 91 percent of the clinicians participating in CMS programs has access to an EHR product or upgrade from their current vendor that has the latest capabilities outlined by Congress and codified into the ONC Health IT Certification Program's 2015 Certification Edition EHRs.

- ONC continued to evolve and promote adoption of a wide range of common standards enabling interoperability of health information through the publication and maintenance of the Interoperability Standards Advisory (ISA) a tool containing endorsements of the best **151 health information standards, models, and profiles** covering more than 60 interoperability needs (e.g., public health, patient information, coordination, clinical care, administration). The ISA website,

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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 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.

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

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

6   https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.

which contains detailed technical information to support software programmers efforts to create tools intended to share health information inter-operably, was accessed over 100,000 times in FY 2018.

- ONC continued to fulfill its longstanding Congressional requirement to obtain public input through a **Federal Advisory Committee**, now called the Health IT Advisory Committee (HITAC), which held its initial convening in January 2018. The HITAC serves as a priority method for obtaining routine input from a group of 30 health IT experts, representing a broad and balanced spectrum of the health care system. By the end of FY 2018, the HITAC and its task forces had **met 35 times** to develop recommendations addressing the priority areas identified in the Cures Act. To date, input from the HITAC has contributed to ONC efforts related to the Trusted Exchange Framework and Common Agreement, U.S. Core Data for Interoperability, and the Strategy for Reducing Regulatory and Administrative Burden relating to the use of health IT and EHRs, among other topics.

- 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. Among the topics addressed at coordination meetings were: 21st Century Cures Act implementation (ONC and CMS): MyHealthEData Initiative (CMS), Digital Health (FDA), and HIPAA Audits and HIPAA Access Right (OCR). Priority collaborations between ONC and CMS through the Council helped create increased attention to interoperability within the Administration and in specific CMS policies and programs.

- ONC continued to prioritize implementation of requirements set in the **21st Century Cures Act**, including undertaking stakeholder coordination, rulemaking, and outreach 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

Impact of FY 2020 Budget Request on ONC's Performance

Funding ONC at the FY 2020 President's Budget request level would result in *broad and thematic changes* to overall Agency spending. The FY 2020 President's Budget request represents a reduction of $17.4 million in budget authority compared to the enacted FY 2019 level. At this level, ONC would reduce its baseline contract budget almost entirely. Although the FY 2020 Budget Request for ONC includes funding for new work related to combatting the opioid epidemic, the overall reduction to ONC's baseline contract budget would impact performance in the following areas:

- Support for public and private partnerships focused on providing technical assistance to allow the standards development and adoption needed to achieve interoperability and enable consumers unfettered access to and control of their health care information;

- Outreach and engagement efforts to promote use of ONC policy and technology assistance materials via https://healthIT.gov.

All Purpose Table

(Dollars in Thousands)

Activity	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 President's Budget +/- FY 2019 Enacted
ONC				
TOTAL, ONC Program Level...........................	$60,217	$60,367	$43,000	$(17,367)
TOTAL, ONC Budget Authority	60,217	60,367	43,000	(17,367)
NEF				
ONC IT Infrastructure for 21st Century Cures Activities...	-	7,000	-	(7,000)

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] *$43,000,000*.

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] $43,000,000.	Provides ONC's budget from Budget Authority.

Amounts Available for Obligation

	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
General Fund Discretionary Appropriation:			
Appropriation (L/HHS)...	$60,367,000	$60,367,000	$43,000,000
Subtotal, Appropriation (L/HHS)	60,367,000	60,367,000	43,000,000
Subtotal, adjusted appropriation...................................	60,367,000	60,367,000	43,000,000
Real transfer to: (ACF)	(150,000)	-	-
Subtotal, adjusted general fund discr. Appropriation...	60,217,000	60,367,000	43,000,000
Total, Discretionary Appropriation	60,367,000	60,367,000	43,000,000
Total Obligations...	60,217,000	60,367,000	43,000,000

Summary of Changes

(Dollars in Thousands)

2019 Enacted
  Total estimated budget authority $60,367

2020 President's Budget
  Total estimated budget authority $43,000

Net Change ....$(17,367)

	FY 2019 Final	FY 2020 PB FTE	FY 2020 PB BA	FY 2020 +/- FY 2019 FTE	FY 2020 +/- FY 2019 BA
Decreases					
A. Program..................	$60,367,000	164	$43,000,000	-	$(17,367,000)
1. Health IT	60,367,000	164	43,000,000	-	(17,367,000)
Subtotal, Program					
Decreases	60,367,000	164	43,000,000	-	(17,367,000)

Budget Authority by Activity

(Dollars in Thousands)

	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Health IT			
Annual Budget Authority	$60,217	$60,367	$43,000
Subtotal, Health IT	**60,217**	**60,367**	**43,000**
Total, Budget Authority	**60,217**	**60,367**	**43,000**
FTE	176	164	164

Authorizing Legislation

	FY 2019 Amount Authorized	FY 2019 Amount Appropriated	FY 2020 Amount Authorized	FY 2020 President's Budget
Health IT				
1. Title XXX of PHS Act as added by the HITECH Act (PL 111-5) and amended by the Cures Act (PL 114-255)	Indefinite	$ -	Indefinite	$ -
Budget Authority	Indefinite	$60,367,000	Indefinite	$43,000,000
Total Request Level		**$60,367,000**		**$43,000,000**

Appropriations History

	Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriation
FY 2011				
Annual B.A.	$78,334,000	$69,842,000	$59,323,000	$42,331,000
PHS Evaluation Funds	-	-	$19,011,000	$19,011,000
Rescissions (Secretary's)..............	-	-	-	($85,000)
Subtotal	$78,334,000	$69,842,000	$78,334,000	$61,257,000
FY 2012				
Annual B.A.	$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 B.A.	$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 B.A.	$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 B.A.	-	$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 B.A.	-	$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 B.A.	-	$65,367,000	$60,367,000	$60,227,000
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 B.A.	$38,381,000	$38,381,000	$60,367,000	$60,367,000
Transfers (Secretary's)	-	-	-	($150,000)
Subtotal	$38,381,000	$38,381,000	$60,367,000	$60,217,000
FY 2019				
Annual B.A.	$38,381,000	$42,705,000	$60,367,000	$60,367,000
Subtotal	$38,381,000	$42,705,000	$60,367,000	$60,367,000
FY 2020				
Annual B.A.	$43,000,000			
Subtotal	$43,000,000			

Narrative by Activity

Health IT

(Dollars in Thousands)

	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Budget Authority	$60,217,000	$60,367,000	$43,000,000	$(17,367,000)
FTE	176	164	164	-

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 role in leading national health IT efforts was bolstered 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 2020, ONC will implement its authorities and requirements to accelerate progress to an interoperable nationwide health IT infrastructure by pursuing the following objectives:

- Implementing Cures Act requirements that support the access, exchange, and use of electronic health information, including conditions and maintenance of certification requirements for health IT developers under the **ONC Health IT Certification Program**, reasonable and necessary activities that do not constitute information blocking, and the voluntary certification of health IT for use by pediatric health care providers;
- Advancing the availability, accessibility, **interoperability**, and **usability** of electronic health information and EHRs;
- Empowering consumer **choice** in health care through electronic access to health information and health information portability;
- Promoting **innovation** and **competition** in the health IT industry by fostering innovation and development of useful health information standards and establishing expectations for data sharing;
- Supporting open APIs and user-focused technologies to **improve patient and provider experiences** with health IT; and
- Contributing to HHS efforts to **combat the opioid epidemic** through improvements in health IT infrastructure and health information sharing.

Description of Sub-Activities at ONC [7]

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

Policy: Development and Coordination

Led by the Office of Policy, ONC undertakes a range of policy development and coordination activities addressing: (1) policy and rulemaking activities, including implementation of provisions in the HITECH Act, MACRA, the Cures Act, and Executive Order 13335: Incentives for the Use of Health IT and Establishing the Position of the National Health Information Technology Coordinator; (2) ONC's domestic policy initiatives; (3) coordination with executive branch agencies, federal commissions, advisory committees, and external partners; (4) advanced 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) operation of the HITAC, established in the Cures Act.

Technology: Standards, Interoperability, and Certification

Led by 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.

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[7] For a more complete explanation of the alignment of ONC's organizational chart to its responsibilities, see the May 2008 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 health care, health, and health IT industries in the shared effort to advance nationwide implementation of an interoperable health IT infrastructure.[8] 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 an infusion of financial resources to incentivize and guide the development and adoption of a more comprehensive nationwide health IT infrastructure. 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.[9]

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.[10]

While nationwide stakeholders worked to implement commitments in the *Roadmap,*[11] in **2015** Congress took action to accelerate progress to national goals by including in MACRA further emphasis on achieving widespread interoperability through adoption of certified health IT. MACRA sought to continue to utilize the Medicare and Medicaid programs to encourage providers to adopt and use increasingly sophisticated certified EHRs. 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.[12]

In **2016**, the Nation's health IT agenda received continued Congressional direction through the landmark 21st Century Cures Act, which addressed numerous barriers to achieving national goals for interoperability. Among the Cures Act requirements, Congress charged ONC with enhancing its Health IT Certification Program, developing a strategy to address administrative burdens in EHRs, taking action to prevent anti-competitive business practices related to health information exchange (e.g., information blocking), and promoting patient access to, and control of, electronic health information.

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[8]   Executive Order 13335: https://www.gpo.gov/fdsys/pkg/WCPD-2004-05-03/pdf/WCPD-2004-05-03-Pg702.pdf.
[9]   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.
[10]   https://www.healthit.gov/topic/interoperability/interoperability-road-map-statements-support.
[11]   https://www.healthit.gov/sites/default/files/12-19-YearInReviewPrezi-508-LowRes.pdf.
[12]   https://www.healthit.gov/buzz-blog/health-data/numbers-progress-digitizing-health-care/.

FY 2018 Accomplishments

Policy Development and Coordination

- ONC continued to **coordinate federal partners** throughout FY 2018, 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 2018, 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 HHS OCR to promote patient access to electronic health information through public assistance materials and awareness campaigns related to the Privacy Act and patient rights. Notably, ONC and OCR published the Guide to Getting and Using Your Health Information and promoted the Get IT, Check IT, and Use IT campaign as part of the All of Us Research Program.

- Pursuant to Cures Act section 4001, ONC led a team of policy experts and clinicians within HHS to produce a draft Strategy to Reduce Regulatory and Administrative Burdens affecting health care 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.

- ONC took action to implement sections 4002, 4003, and 4004 of the Cures Act through **rulemaking**, which includes addressing 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 health care providers, developing the Trusted Exchange Framework and Common Agreement, and defining reasonable and necessary activities that do not constitute information blocking.

- ONC continued to plan the implementation of a **EHR Reporting Program** pursuant to Cures Act section 4002 requirements. The EHR Reporting Program is expected to provide publicly available, comparative information about certified health IT products. In 2018, ONC developed a request for information (RFI) and used the resulting information to inform stakeholder meetings and advance planning activities. 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.

★ - HIGHLIGHT - ★

ONC was tasked by Congress through the 21st Century Cures Act section 4001 to work with health care 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 4 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.[13]

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.[14] The Final Rule adopts a number of documentation, coding, and payment changes to *improve flexibility and reduce documentation requirements* associated with office/outpatient evaluation and management (E/M) visits.

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.[15]

- To fulfill the Cures Act requirements in section 4003, ONC operated a **Federal Advisory Committee**, the Health IT Advisory Committee (HITAC), which held its inaugural convening in January 2018. The HITAC fulfills a Congressional mandate and priority method for obtaining routine input from a group of 30 members who are experts across a representative spectrum of the health care system. Members are appointed by HHS Secretary, ONC, and GAO, and must have expertise in federal health IT policy, standards, privacy and security, and electronic exchange and use of health information and include patient advocates, consumers, purchasers, health IT developers, and health plan representatives. By the end of FY 2018, the HITAC and its task forces had met 35 times to make recommendations to the National Coordinator to address the priority target areas identified in the Cures Act.

- ONC took steps to implement the Cures Act section 4003 related to support for interoperable network exchange, including extensive outreach and coordination efforts to inform development of ONC policy and programs. ONC convened over 1,200 stakeholders across three events to inform the

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13   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.

14   https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.

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

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development of the draft **Trusted Exchange Framework**, a critical piece of the Cures Act, which was released for public comment in January 2018 and approved by the HITAC through recommendations in March 2018. The Trusted Exchange Framework will establish a set of common principles, terms, and conditions that facilitate trust between health information networks. Specifically, these principles support the ability of stakeholders to access, exchange, and use relevant electronic health information across different networks and sharing arrangements. The Trusted Exchange Framework also outlines a minimum set of required terms and conditions that align with the principles. The terms and conditions focus on the areas of variation among currently existing trust agreements that impede nationwide interoperability.

- ONC took steps to **promote modern technology standards** and address the interoperability goals of the Cures Act by launching the US Core Data for Interoperability (USCDI) in 2018. The USCDI aims to specify a common set of health care record data classes that are required for interoperable exchange. The USCDI has been developed through close coordination with a dedicated HITAC task force that is providing recommendations on approaches to receive stakeholder feedback on data class priorities; proposed categories for which data classes would be promoted and objective characteristics for promotion; and a process and proposed frequency for expanding the USCDI.[16]

- To meet Cures Act section 4005 requirements, ONC collaborated closely with the HHS Agency for Healthcare Research and Quality (AHRQ) and other partners to research best practices and produce a **Report to Congress** on current trends among patient safety organizations to improve the integration of health IT into clinical practice.

- 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 Exchange Framework, substance use disorders and 42 CFR Part 2 considerations,[17] 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.[18] 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.[19]

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[16] https://www.healthit.gov/hitac/committees/us-core-data-interoperability-task-force.
[17] https://www.samhsa.gov/newsroom/press-announcements/201805020200.
[18] "Leveraging Medicaid Technology to Address the Opioid Crisis," https://www.medicaid.gov/federal-policy-guidance/downloads/smd18006.pdf.
[19] https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/.

- ONC continued to sponsor **pilots** in state and local health information exchange, including one such collaboration with California seeking to successfully pilot and test Patient Unified Lookup System for Emergencies (PULSE), an electronic system that provides first responders with access to patient health records. Additionally, in partnership with the CDC and National Vaccine Program Office, ONC launched two pilots to improve information on implementation of consumer access and cross-jurisdictional exchange of health information in immunization information service (IIS) systems.

★ - HIGHLIGHTS - ★

- The Health IT Advisory Committee (HITAC) and its task forces met 35 times by the end of the fiscal year to make recommendations to the National Coordinator, addressing the priority target areas identified in the Cures Act.

- ONC coordinated with CMS on a Data Element Library which assists health IT developers in consistently implementing 1,200 commonly used health care data elements that map to health IT standards.

- ONC's Patient Engagement Playbook and Guide to Getting and Using your Health Records continued to assist patients and providers with using health IT and attracted over 135,000 page views in FY 2018.

- ONC continued to provide technical assistance to CMS State Innovation Model (SIM) participants, including leading 29 in-person state consultations; 5 multi-state meeting events; 63 technical assistance requests; 33 state-to-state learning events; 11 lunch and learn presentations; and content analysis on 96 program-related documents.

Technology: Standards, Interoperability, and Certification

- ONC continued to implement the statutorily required **ONC Health IT Certification Program** during 2018 through technical and policy coordination, regulatory development, and engaging with health care, patient, and technology leaders through the HITAC. With the stakeholder input garnered through these interactions, ONC implemented mandated administrative procedures and regulatory frameworks that translate policy outcomes into health care delivery models and software requirements.

  Pursuant to requirements in the Cures Act (including sections 4001 through 4004), ONC has undertaken rulemaking for the Certification Program to establish functional requirements that developers of certified health IT products must meet to maintain certification. These requirements implement the Cures Act provisions aimed at upgrading the capabilities of health IT and establishing expectations for transparent data sharing, including prohibiting information blocking, publishing open application programming interfaces, and conducting real world testing of certified products.

As of the end of CY 2018, the Certification Program maintains test procedures and certification companion guides for 60 certification criteria,[20] 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).[21] Additionally, the Health IT Certification Program website, the Certified Health IT Product List (CHPL), grew to include more than 600 health IT developers' products, and was used to register the EHR products of more than 550,000 health care providers and hospitals participating in Medicare and Medicaid programs.[22]

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. As of November 2018, there are 405 2015 Edition products from 267 developers on the CHPL, meaning that there is an EHR product with the latest capabilities available for 95 percent of the eligible hospitals and 91 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.

- In CY 2017, ONC announced "A 5-Year Goal to Transition the ONC Health IT Certification Program's Testing Portfolio" to include as many industry-developed and maintained testing tools as possible. In August 2018, ONC reached an important milestone toward this goal when the National Council for Prescription Drug Programs (NCPDP) formally took over the stewardship of the electronic prescribing testing tool approved for use under the ONC Health IT Certification Program.[23]

- ONC continued efforts to improve the Nation's interoperable health IT infrastructure by promoting the development and use of *common standards and interoperability test tools*. One method ONC used to promote adoption of common interoperability standards, the **Interoperability Standards Advisory (ISA)**, continued expanding in FY 2017 and FY 2018, with the 2018 Reference Edition ISA including recommendations related to 151 interoperability needs, models, and profiles spanning 60 clinical use cases (e.g., allergies, smoking status, family health history).[24] By the end of FY 2018, ONC and stakeholders have continued to endorse new standards, consolidate like standards, and remove old standards, with 14 changes being made. Comparing the Reference Edition ISAs from 2017 and 2018, the additions and changes address important clinical information, such as pregnancy status, care plans, imaging, patient identification, public health reporting, consumer access, and provider-to-provider communication.[25] The ISA tool was accessed by over 100,000 users throughout FY 2018. In July 2018, ONC issued its third annual call for comments to suggest changes and updates to the ISA. A 2019 Reference Edition ISA is forthcoming.

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[20] https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method.
[21] https://www.healthit.gov/topic/certification-ehrs/programs-referencing-onc-certified-health-it.
[22] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.
[23] https://www.healthit.gov/buzz-blog/health-it/a-new-home-for-the-electronic-prescribing-testing-tool/.
[24] https://www.healthit.gov/isa/sites/default/files/2018%20ISA%20Reference%20Edition.pdf.
[25] https://www.healthit.gov/isa/recent-isa-updates.

★ - HIGHLIGHT - ★

ONC hosted a second national Interoperability Forum that took place from August 6 – 8, 2018, and brought together more than 1,250 key stakeholders, to identify concrete actions to address current interoperability barriers and share lessons learned from recent efforts to advance interoperability nationwide.

During the 3-day event, stakeholders from across the Federal Government and health care 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.

Among the accomplished health IT leaders contributing to the forum were the CMS Administrator, leaders from CDC, academia (e.g., Harvard, University of California), EHR and consumer health IT developers (e.g., Apple Inc., Microsoft, Cerner, Medisafe), health information exchange networks (e.g., Commonwell Health Alliance, Sequoia), and interoperability standards development bodies (e.g., Health Level Seven International (HL7)).

As a highly visible example of the potential implicit in modern FHIR standards, Apple Inc. presented a session on *Enabling Individuals' Access, Sharing, and Use of Health Records* that featured the company's latest efforts to bring usable patient health information directly to consumers via an application native to the iPhone. Through the Apple "Health Records" app development process, the company worked with the health care community to take a consumer-friendly approach, creating the app based on HL7 FHIR (Fast Healthcare Interoperability Resources), a standard for transferring electronic medical records that ONC and HL7 have encouraged and promoted since its inception.[26]

- 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 health care.

- ONC continued to implement a portfolio of **health IT prize challenges** throughout FY 2018. The projects sought to encourage the development and implementation of new tools and technologies that can improve health IT safety and market transparency. ONC's *Easy EHR Issue Reporting Challenge* was launched in May 2018 to help EHR users identify, document, and report potential health IT safety issues. As part of the challenge, developers are encouraged to create an application that integrates with an EHR's workflow, minimizes the time and effort needed to create an issue report,

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[26]   https://www.apple.com/newsroom/2018/01/apple-announces-effortless-solution-bringing-health-records-to-iPhone/.

allows users to choose the parties to whom they report issues, and be EHR platform-agnostic.[27] In May 2018, ONC announced the winner of the *Secure API Server Showdown* challenge, which sought to achieve Cures Act goals by demonstrating how developers can use API-access and exchange EHR data without "special effort."[28] Another ONC challenge, the *CHPL Data Challenge,* was launched in July 2018 to encourage software developers to use ONC's administrative data from the ONC Health IT Certification Program to enrich providers' and consumers' understanding of certified health IT.[29]

★ - HIGHLIGHT - ★

To advance the 21st Century Cures Act's requirements that ONC continue working to improve the interoperability of health information, facilitate information exchange, address barriers to interoperability, and reduce clinician burden relative to EHRs, in September 2018, ONC awarded two grants for **Leading Edge Acceleration Projects** (LEAP) grants. This funding opportunity is specifically targeted at creating innovative solutions and advances in the following areas:

Area 1: Expanding the scope, scale, and utility of population-level data-focused APIs.

Area 2: Advancing clinical knowledge at the point of care by transforming isolated risk calculators into open standards-based applications.

Agency-Wide Support

- ONC implemented an agency-wide reorganization in May 2018. The reorganization reduced the number of offices within ONC from 10 to 3, a change that improves ONC's staffing alignment and organizational posture to implement the Administration's priorities and the requirements set out by the Cures Act.[30] Amidst the reorganization, ONC continued to implement workplace improvement initiatives to maintain recent increases in employee engagement. In 2018, ONC exceeded the HHS average for the annual Federal Employee Viewpoint Survey's **Employee Engagement Index**, scoring 73 percent. 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.

- ONC's websites garnered 1.8 million visitors during FY 2018, an average of over 152,000 sessions per month and 7.2 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 9,155 external websites. In April 2018, ONC launched a redesigned website to improve usability, including embedding methods for obtaining user feedback to set the stage for further user-centered design and communications management improvements.

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[27] https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/a-new-challenge-competition-can-you-help-make-ehr-safety-reporting-easy/.
[28] https://www.hhs.gov/about/news/2018/05/17/secure-api-server-showdown-winner-announced.html.
[29] https://www.healthit.gov/buzz-blog/healthit-certification/certified-health-it-product-list-chpl-data-challenge/.
[30] https://www.federalregister.gov/documents/2018/05/02/2018-09361/statement-of-organization-functions-and-delegations-of-authority-office-of-the-national-coordinator.

Five Year Funding History

Fiscal Year	Amount
FY 2016	$60,367,000
FY 2017	60,367,000
FY 2018	60,367,000
FY 2019 Enacted	60,367,000
FY 2020 President's Budget	43,000,000

Budget Request

The ONC President's Budget request for FY 2020 is for $43.0 million, a decrease of $17.4 million (29 percent) from the FY 2019 appropriated level.

The Budget Request outlines activities required by the Cures, MACRA, and HITECH Acts, 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. The $4.6 million in funding above the FY 2019 budget request level requested supports work related to combatting the opioid epidemic, implementing the Trusted Exchange Framework and Conditions of Certification program requirements contained in the Cures Act, and conducting national surveys to determine the extent of health IT adoption and use, including health information exchange activity, interoperability, and patient access to the electronic health information.

Policy Development and Coordination

The 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, MACRA, and HITECH Acts, and to address the national opioid epidemic. ONC's progress in promoting and advancing nationwide interoperability depends on the coordinated action of its stakeholders, and this 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 2020 policy development and coordination portfolio include:

Policy Development and Support

- **Interoperability Policy -** ONC will continue to lead implementation of the Trusted Exchange Framework and the Common Agreement (TEFCA), which seeks to accelerate health information exchange by establishing common principles, terms, and conditions to facilitate trust between health information networks. The FY 2020 President's Budget request level supports ONC's efforts 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 rules implementing these sections 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 health care

providers, health information network voluntary attestation to the adoption of a trusted exchange framework and common agreement in support of network-to-network exchange, and defining reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions through rulemaking would advance interoperability and support the access, exchange, and use of electronic health information through open APIs and transparent and uninhibited data sharing. ONC continues to hear from many entrepreneurs about the need for information blocking rules to allow third parties to compete in using clinical data.

- **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 to reduce regulatory and administrative burdens relating to the use of EHRs as required by Section 4001 of the Cures Act. ONC released the Strategy for public comment in December 2018. The final Strategy is planned for final publication in FY 2019.

- **Privacy and Security -** ONC will continue to work closely with OCR to develop and implement responses to the requirement in the Cures Act 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.

- **Opioid Epidemic -** ONC will support continued HHS efforts to combat the opioid epidemic through improvements in health IT infrastructure and health information sharing, including by seeking ways to better connect first responders to opioid prescription data.

Stakeholder Coordination

- **Federal Coordination -** ONC will continue leading and engaging the 35 agencies that contributed to the Federal Health IT Strategic Plan 2015 – 2020[31] and working closely with the 20 agencies that regularly participate in the Federal Health IT Coordinating Council. Within these collaborative forums, ONC will prioritize projects required by the Cures, MACRA, and HITECH Acts, 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, Federal Trade Commission (FTC), and Department of Justice (DOJ) to define and enforce standards for data sharing and prohibiting information blocking.

- **Federal Advisory Committee -** ONC will continue to lead and engage the Health IT Advisory Committee (HITAC) to inform the development of federal health IT policies and the implementation of its programs and HHS and administration priorities. At the President's Budget request level, ONC's ability to support workgroups and task forces and to sponsor in-person meetings may be limited.

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

Strategic Planning and Reporting

- **Federal Health IT Strategic Planning -** ONC plans to update the Federal Health IT Strategic Plan during FY 2019 – 2020. To create the new plan, ONC will coordinate with the more than 35 agencies that contributed to the current Strategic Plan 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.

- **Research -** ONC will continue national surveys related to the development, adoption, and use of, health IT capabilities, including aspects of EHR usability, interoperable health information exchange, and patient access to electronic health information.

Technology: Standards, Interoperability, and Certification
The FY 2020 President's Budget request reflects ONC's plans to meet statutory requirements and advance progress toward national goals for widespread interoperability. The request includes funding for coordination and technical activities that implement changes enacted in the Cures Act. Funding above the FY 2019 budget request level supports the Conditions of Certification program requirements contained in section 4002 of the Cures Act.

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. 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 APIs, and promote population level access to health data.

- **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.

- **Opioid Epidemic -** ONC will coordinate with other HHS components and stakeholders to promote the establishment of standardized data structures for patient matching that can be used to exchange opioid data between prescription drug monitoring programs and health IT systems.

Health IT Certification, Testing, and Reporting

- **ONC Health IT Certification Program** - ONC will continue to operate the Certification Program according to statutory requirements, including the Conditions of Certification program

requirements from section 4002 of the Cures Act, which necessitates modest updates to the CHPL, overseeing the ONC-Authorized Testing Labs and ONC-Authorized Certification Bodies, and maintaining a library of useful certification companion guides, test procedures, and automated and semi-automated test tools to help developers with creating certified health IT. ONC will also implement actions outlined in the planned Certification and Interoperability Enhancements Rule. ONC will continue to promote testing tools and resources that support health IT development, implementation, and use aligned with the Certification Program.

- **EHR Reporting Program -** ONC will continue necessary activities to develop and implement the EHR Reporting Program. Throughout FY 2019, ONC will build on the request for information published in August 2018 by incorporating feedback from responders to inform stakeholder planning activities. Further implementation of the planned activities to establish the EHR Reporting Program will be dependent on availability of funds. Potential resource constraints at the President's Budget request level could limit ONC's ability to quickly implement the program.

Scientific Innovation

- **Scientific Initiatives -** ONC will continue to provide leadership to partners and foster health care 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 the CMS, NIH, FDA, and others, to implement solutions to public health and scientific innovation through projects of national importance. In FY 2020, 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 2020 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 2020, 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. Significant resource constraints at the President's Budget FY2020 request level will reduce ONC's ability to update and adapt its website to meet the needs of stakeholders.

- **Management and Governance -** In FY 2020, ONC will continue to implement its existing strategic and operational management processes. ONC's FY 2020 budget request includes resources for the shared services mandated by HHS, 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.

Output and Outcomes Table

Measure Group / Measure Text	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/- FY 2019 Target
Policy Development and Coordination				
Number of federal agencies actively participating in ONC-led health IT coordination efforts	FY 2018: 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 2018: 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 2018: 2018 reference edition ISA contained 151 standards and implementation specifications[32] (Baseline)	Maintain	Maintain	--
Agency Wide Support				
Number of visitors to ONC's websites to use health IT policy and technology assistance material	FY 2018: 1.8 million (Baseline)	Maintain	Maintain	--

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[32] Includes 6 implementation specifications which are considered "profiles and models" and not traditional standards.

Contextual Measures

Measure: Provider capability in key domains of interoperable health information exchange[33]

	Office- based physicians	Non-federal acute care hospitals
• are electronically <u>sending or receiving</u> patient information with any providers outside their organization	48%	90%
• can electronically <u>find</u> patient health information from sources outside their health system	34%	61%
• can easily <u>integrate</u> (e.g. without manual entry) health information received electronically into their EHR	31%	53%
• had necessary patient information electronically <u>available</u> from providers or sources outside their systems at the point of care	36%	51%

Measure: Citizen's perspective on consumer access

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

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[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

(Dollars in Thousands)

	FY 2018 [34]	FY 2019 [35]	FY 2020
Notification	--	$7,000	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 will support the development of electronic (software-based) testing tools for the Health IT Certification Program ($4 million) and software development associated to build a data-reporting platform ($3 million). These two interdependent IT infrastructure capacity-building activities directly tie to implementing Section 4002 of the 21st Century Cures Act. For each of these activities, ONC will award a single, non-severable contract to a software development firm. 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.

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[34] There was no Congressional notification for the planned uses of NEF funds in FY 2018.
[35] Notification #6 submitted to the Committees on Appropriations in the House of Representatives and the Senate on December 4, 2018.

Supplementary Tables

Budget Authority by Object Class

(Dollars in Thousands)

Object Class	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel compensation:				
Full-time permanent (11.1)	$18,210	$16,954	$16,954	-
Other than full-time permanent (11.3)	1,796	1,796	1,796	-
Other personnel compensation (11.5)	643	643	643	-
Military personnel (11.7)	242	248	256	8
Special personnel services payments (11.8)	15	15	15	-
Subtotal Personnel Compensation	**20,906**	**19,656**	**19,664**	**8**
Civilian benefits (12.1)	6,260	5,828	5,828	-
Military benefits (12.2)	107	110	113	3
Benefits to former personnel (13.0)	-	-	-	-
Subtotal Pay Costs	**27,273**	**25,594**	**25,605**	**11**
Travel and transportation of persons (21.0)	177	177	177	-
Transportation of things (22.0)	-	-	-	-
Rental payments to GSA (23.1)	1,901	1,901	1,901	-
Rental payments to others (23.2)	170	170	170	-
Communication, utilities, and misc. charges (23.3)	176	176	176	-
Printing and reproduction (24.0)	1	1	1	-
Other Contractual Services:				
Advisory and assistance services (25.1)	47	47	47	-
Other services (25.2)	16,166	17,217	6,769	(10,448)
Purchase of goods and services from government accounts (25.3)	9,596	10,374	7,608	(2,766)
Operation and maintenance of facilities (25.4)	343	343	343	-
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	**28,577**	**30,406**	**17,192**	**(13,214)**
Supplies and materials (26.0)	91	91	91	-
Equipment (31.0)	112	112	112	-
Land and Structures (32.0)	-	-	-	-
Investments and Loans (33.0	-	-	-	-
Grants, subsidies, and contributions (41.0)	4,164	4,164	-	(4,164)
Interest and dividends (43.0)	-	-	-	-
Refunds (44.0)	-	-	-	-
Total Non-Pay Costs	**4,367**	**4,367**	**203**	**(4,164)**
Total Direct Obligations	**60,217**	**60,367**	**43,000**	**(17,367)**

Salaries and Expenses

(Dollars in Thousands)

	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel compensation:				
Full-time permanent (11.1).....................................	18,210	16,954	16,954	-
Other than full-time permanent (11.3)..................	1,796	1,796	1,796	-
Other personnel compensation (11.5)	643	643	643	-
Military personnel (11.7)......................................	242	248	256	8
Special personnel services payments (11.8)	15	15	15	-
Subtotal personnel compensation	**20,906**	**19,656**	**19,664**	**8**
Civilian benefits (12.1)	6,260	5,828	5,828	-
Military benefits (12.2)...	107	110	113	3
Benefits to former personnel (13.0)..........................	-	-	-	-
Total Pay Costs	**27,273**	**25,594**	**25,605**	**11**
Travel (21.0)	177	177	177	-
Transportation of things (22.0)	-	-	-	-
Rental Payments to GSA (23.1)...............................	1,901	1,901	1,901	-
Rental payments to Others (23.2)	170	170	170	-
Communication, utilities, and misc. charges (23.3)..	176	176	176	-
Printing and reproduction (24.0)...............................	1	1	1	-
Other Contractual Services:				
Advisory and assistance services (25.1)	47	47	47	-
Other services (25.2)...	16,166	17,217	6,769	(10,448)
Purchase of goods and services from government accounts (25.3)	9,596	10,374	7,608	(2,766)
Operation and maintenance of facilities (25.4)....	343	343	343	-
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............	**28,577**	**30,406**	**17,192**	**(13,214)**
Supplies and materials (26.0)...................................	91	91	91	-
Total Non-Pay Costs...	**91**	**91**	**91**	**-**
Total Salary and Expenses.....................................	**55,941**	**56,091**	**42,888**	**(13,203)**
Direct FTE..	**176**	**164**	**164**	**-**

Detail of Full-Time Equivalent Employment (FTE)

	2018 Actual Civilian	2018 Actual Military	2018 Actual Total	2019 Est. Civilian	2019 Est. Military	2019 Est. Total	2020 Est. Civilian	2020 Est. Military	2020 Est. Total
Direct	174	2	176	162	2	164	162	2	164
Reimbursable ...	-	-	-	-	-	-	-	-	-
Total.................	174	2	176	162	2	164	162	2	164

Average GS Grade

Fiscal Year	Grade	Step
FY 2016..	13	8
FY 2017..	13	9
FY 2018..	13	8
FY 2019..	13	8
FY 2020..	13	8

Detail of Positions

	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Executive Level	-	-	-
Total - Exec. Level Salaries	-	-	-
Senior Executive Service (SES)	7	7	7
Total - SES Salary	$1,385,556	$1,385,556	$1,385,556
GS-15	50	49	49
GS-14	47	47	47
GS-13	44	44	44
GS-12	12	12	12
GS-11	1	1	1
GS-10	-	-	-
GS-9	7	7	7
GS-8	-	-	-
GS-7	1	1	1
GS-6	-	-	-
GS-5	1	1	1
GS-4	-	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	163	162	162
Total, GS Salary[36]	18,360,940	18,254,172	18,262,210
Average ES salary	197,937	197,937	197,937
Average GS grade	13-6	13-6	13-6
Average GS salary	112,644	112,680	112,730

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[36] FY 2019 estimate includes an assumption of +2.6 percent pay raise for military/Commissioned Corps staff and FY 2020 includes an assumption of +3.1 percent pay raise for military/Commissioned Corps staff.

Physicians' Comparability Allowance Worksheet

	PY 2018 (Actual)	CY 2019 (Estimate)	BY 2020 (Estimate)
Number of Physicians Receiving PCAs	3	3	3
Number of Physicians with One-Year PCA Agreements	0	0	0
Number of Physicians with Multi-Year PCA Agreements	3	3	3
Average Annual PCA Physician Pay (without PCA payment)	$159,028	$159,028	$159,028
Average Annual PCA Payment	$16,000	$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.

Significant Items in Appropriations Committee Reports

Office of the National Coordinator for Health IT (ONC) - *The Secretary shall provide a status report on rulemaking as described in section 239 of division B of H.R. 6157 as passed by the Senate on August 23, 2018.* ***(Page 56, Joint Explanatory Statement, House Report 115-952)***

Action Take or To Be Taken
ONC continues to make progress implementing rulemaking and administrative requirements pursuant to statutory requirements and provided a status update to Congress on December 11, 2018 when the National Coordinator provided testimony before the House Committee on Energy & Commerce, Subcommittee on Health.[37] ONC continues to work with key stakeholders in government to complete clearance and publication of the proposed rule.

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[37] https://energycommerce.house.gov/committee-activity/hearings/hearing-on-implementing-the-21st-century-cures-act-an-update-from-the.