

DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2023

Office of the National Coordinator for Health Information Technology

Justification of Estimates to the Appropriations Committee



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, coordinating federal health IT policies, technology standards, and programmatic investments, and promoting adoption of health IT and use of health information to enhance the health and well-being of all US residents.

Federal Health IT Strategic Plan Mission

ONC's mission, adopted from the <u>Federal Health IT Strategic Plan 2020 – 2025</u>, 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 2023 Priorities

- 1. Promoting *seamless*, *secure information-sharing* among providers, patients, and other healthcare stakeholders using modern, open-industry, internet-based technologies
- 2. Building on federal investments in electronic health records to improve the access, exchange, and use of electronic health information and advance quality, equitability, safety, efficiency, accessibility, and affordability of US healthcare
- 3. Enabling an *open health IT ecosystem* to ensure a level playing field for innovation and competition to support health IT users, including patients
- 4. Furthering *universal access to secure, usable information exchange technologies* through nationwide networks and application programming interfaces (APIs)
- 5. Fostering the use of health IT and health information to identify and address *health equity* issues in healthcare delivery, public health, and population health
- 6. Facilitating the *success of federal programs* through the effective use of health IT and health information

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 2023 President's Budget Request

Dear Reader,

More than a decade has passed since the HITECH Act set the U.S. health system on a path to creating a truly digital healthcare system. At its passage in 2009, the health system still lagged behind many major industry sectors and industrialized countries with respect to electronic health record (EHR) adoption. Clinicians used pen and paper to capture important information from clinical encounters, which were stored in manila folders and file cabinets. Information sharing for care coordination was limited and at a time when individuals were using the internet throughout their daily lives our health system offered few options for them to easily access their electronic health information.

The foundation set by the HITECH Act and subsequent 21st Century Cures Act dramatically changed this paradigm. The industry has made tremendous progress. By the end of the 2010s the vast majority of hospitals and clinicians use EHRs, clinical data is being captured electronically using common data standards, and electronic health information is routinely being shared via health information networks and, increasingly, modern application programming interfaces (APIs). However, this progress is not universal across the country and is affected by different priorities, resources, and business models among industry actors. Other providers across the care continuum such as long-term and post-acute care, behavioral health, and home and community-based providers who were ineligible for incentive payments lag behind in terms of EHR adoption and, thus, their ability to engage in interoperable exchange.

The COVID-19 pandemic exposed many challenges in the nation's healthcare system, particularly the need for more reliable data, especially to support vulnerable individuals and those persistently marginalized by the medical community. In addition, although significant funding under the HITECH Act propelled EHR adoption among hospitals and physician offices, corresponding levels of resources were not provided to our public health IT systems. As a result, public health agencies at the State, Tribal, Local, and Territorial and federal levels were not able to make full use of the large installed base of EHR systems and we saw one-way data flows, overwhelmed public health data systems, and manual data review that led to limited actional data for decision making and no ability to provide real-time feedback to communities.

As we look towards the future, we are focused on driving change that actively uses the digital foundation built over the past decade. ONC's FY 2023 Budget Request reflects the actions and investments necessary to take these earlier investments to the next level and drive transformation to a "digitally native" healthcare system. ONC will work with partners in the public and private sectors to advance a health IT ecosystem that benefits patients, providers, payers, public health, federal agencies, and developers. This approach will leverage open-industry, platform-based business and technical models that have delivered tremendous efficiency and quality in other parts of the economy and will enable a rich and thriving healthcare app ecosystem to complement the EHR systems in place today to benefit patients as well as providers. Health information networks should operate as information and transaction backbones with high reliability and efficiency and to make basic clinical data available universally across the continuum in a low-cost, consistent way. Most importantly, this system should be built to identify health inequities and facilitate interventions that prevent such inequities from further turning into healthcare disparities.

ONC's FY 2023 Budget Request continues our focus on advancing interoperability, strengthening the public health infrastructure, empowering patients and clinicians with the most advanced information technology, enabling federal agency partners to make the most cost-effective use of health IT, and

accelerating the implementation of the 21st Century Cures Act. Through continued investments in policy development and coordination, along with standards, certification, and interoperability, we will carry out HHS' commitment to ensuring every American can obtain their full health potential.

/Micky Tripathi/ Micky Tripathi, Ph.D. M.P.P National Coordinator for Health IT

FY 2023 Budget Request

Justification of Estimates to the Appropriations Committee
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
 - o Micky Tripathi, Ph.D. M.P.P. National Coordinator for Health IT
 - O Steven Posnack, M.S., M.H.S. Deputy National Coordinator for Health IT
 - o Lisa A. Lewis Person, Deputy National Coordinator for Operations
- Office of Policy
 - o Elise Sweeney Anthony, J.D., Executive Director
- Office of Technology
 - o Avinash Shanbhag, Executive Director
- Office of the Chief Operating Officer
 - o Lisa A. Lewis Person, 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, safer, and more equitable 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.

ONC's mission, goals, and objectives originate from three laws; 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).

While ONC is a small part of Federal spending on healthcare, ONC's activities are central to creating a patient-centric, equitable health system that works to improve the overall quality, safety, efficiency, and affordability of healthcare and identify and address social determinants of health and other health inequities to mitigate health disparities.

The importance of **coordinating** health IT activities across Federal agencies has dramatically increased in recent years. In particular, a growing number of agencies now seek to leverage electronic health records and other health IT capabilities to advance their mission interests in health equity, public health, health services research, drug and device surveillance, integration of healthcare and social services, remote diagnostics, digital therapeutics, telehealth, quality measurement, drug discovery and basic life sciences research, and other areas.

ONC contributes to health IT initiatives led by partners and engages in 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 over 1.5 million visitors who access the policy and technical assistance materials published at https://HealthIT.gov each year.

The availability of data exchange capabilities in electronic health record (EHR) systems significantly contributes to greater interoperability¹. The ONC **Health IT Certification Program** has become an important part of the health IT ecosystem, motivating baseline consistency in EHR systems in an otherwise highly fragmented and decentralized market, and improved health data interoperability for

¹ Yuriy Pylypchuk, Wesley Barker, William Encinosa, Talisha Searcy. Journal of the American Medical Informatics Association, Volume 28, Issue 9, September 2021, Pages 1866–1873, https://doi.org/10.1093/jamia/ocab083

patient care and patient access. The Health IT Certification Program has contributed to the successful deployment of an infrastructure of EHR systems across the country. ONC remains focused on advancing interoperability across those EHR systems by spurring access, exchange, and use of electronic health information, including through secure, standards-based APIs to enable more transparent, more efficient data sharing. In addition to supporting information exchange among those delivering healthcare, ONC's overall work is crucial to advancing patients' access to their health information and responding to public health emergencies like COVID-19.

The **standards** work led by ONC advances the technical infrastructure necessary to support the appropriate and secure **exchange** of electronic health information to individuals, caregivers, and their clinicians, leading to greater interoperability in healthcare. The secure flow of electronic health information can offer insight into health disparities and facilitate trending longitudinal health outcomes so that a care provider can have a comprehensive view of a patient's medical history when caring for patients. Interoperability in healthcare is necessary to provide high-quality, cost-effective care, identify and reducing healthcare disparities and "digital divides," and combat pandemics and public health emergencies such as COVID-19 and the opioid crisis by providing early detection and readily available health information to clinicians and public health entities.

ONC has and will continue to play a critical role in transforming healthcare to be interoperable and more equitable. In fact, as interoperable health IT becomes increasingly vital to the health and well-being of the nation, demand for ONC's assistance is growing rapidly as federal agencies seek to leverage ONC's technical and policy expertise and authorities in coordination, standards, health information exchange and EHR certification. From building on regulations that incentivized the digitization of medical data within electronic health record systems to supporting greater consumer engagement and transparency through technologies, ONC is essential to achieving the Administration's priorities and making health information available when and where it matters most.

Overview of Budget Request

The FY 2023 request is \$103.6 million which is \$17.0 million above the FY 2022 President's Budget and \$41.2 above FY 2022 Annualized Continuing Resolution. This will be entirely available through the Public Health Service Act Evaluation set-aside. ONC's budget, although small compared to the overall Federal healthcare spending, has had transformative impacts on HHS programs, the health system, and private sector investments in health technology. ONC's FY 2023 Budget Request explains the Office's plan to implement a portfolio of activities driven by congressional requirements and ONC's authorities. ONC's budget organization highlights multifaceted work that weaves together **policy** development on value-based, data-driven health system transformation and unique expertise for guiding and facilitating cutting-edge **technology and standards** initiatives that target Federal coordination and investments to spur the development and promotion of an interoperable nationwide health IT infrastructure.

ONC's program level funding is organized into three sections, summarized below, to provide transparency into ONC's strategy for affecting change.

• Policy: Development and Coordination

Includes strategic and policy planning, developing regulatory frameworks and administrative procedures, maintaining a Federal Advisory Committee, and conducting coordination with public and private stakeholder groups. ONC focuses its work in this section on being robust and resilient enough to withstand substantial opposition from industry stakeholders and pragmatically focused on what it takes to make interoperability a reality.

• Technology: Standards, Certification, and Interoperability

Includes administering the ONC Health IT Certification Program; facilitating the development and promotion of technology standards that improve infrastructure and interoperability; and investing in early stage pilot projects, prototypes, and industry challenges to accelerate science and innovation and demonstrate advanced uses of health IT. Taken together, these investments will enable future ONC standards work to support the Administration's equity goals and enable patients to easily access their health information on their smartphones.

• Agency-Wide Support

Includes providing executive, clinical, 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.

ONC's FY 2023 request includes a proposed increase of +\$17.0 million (19.6 percent) above the FY 2022 President's Budget and a +\$41.2 million (66.1 percent) increase above the FY 2022 Annualized Continuing Resolution. Of the +\$41.2 million increase, \$18.0 million will be allocated to Policy Development and Coordination efforts to target interoperability policy work that will accelerate the exchange of information between health information exchanges by establishing common principles, terms, and conditions through the Trusted Exchange Framework and Common Agreement (TEFCA); and \$22.0 million will be allocated to Standards Coordination and Collaboration to target Federal coordination activities to further its equity-by-design approach to increase interoperability and improve

equity. The request also includes an additional \$1.3 million to allow ONC to support their staff and operational activities needed to keep pace with the agency's growing responsibilities.

Overview of Performance

ONC's Mission, Goals, and Objectives

ONC's mission, adopted from the Federal Health IT Strategic Plan 2020 – 2025, is to improve the health and well-being of individuals and communities using technology and health information that is accessible when and where it matters most. ONC advances progress to this mission by formulating the Federal Government's health IT strategy and promoting coordination of Federal health IT policies, technology standards, and programmatic investments. As the breadth and depth of Federal activities leveraging health IT have grown, ONC's coordination role has taken on greater importance in identifying areas of potential misalignment and/or opportunities for synergies across Federal agencies. ONC's annual budget request reflects thoughtful and coordinated plans to advance national goals, particularly the objectives outlined in ONC's authorizing and enabling legislation: the Cures Act, MACRA, and the HITECH Act, and the Executive Order on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats.

This budget request enables ONC to continue to fulfill its ongoing responsibility as the principal Federal entity charged with coordination of nationwide efforts to effectively use health IT and electronic health information exchange to improve healthcare quality, cost, and equity. ONC efforts advance align to Goal 1: Protect and Strengthen Equitable Access to High Quality and Affordable Healthcare, Objective 1.2: "Reduce costs, improve quality of healthcare services, and ensure access to safe medical devices and drugs" of the draft HHS Strategic Plan for 2022-2026.

While ONC is a small part of Federal spending on healthcare, ONC's activities are central to creating a patient-centric, equitable health system that works to improve the overall quality, safety, efficiency, and affordability of healthcare and identify and address social determinants of health and other health inequities to mitigate health disparities. HHS' holistic approach to its technology-related initiatives centers on enabling healthcare providers and public health agencies to have seamless and timely availability of clinical information and ensuring patients have access to their health information through interoperable health IT. ONC is integral to HHS' approach.

Summary of Performance Information in the Budget Request

This budget includes performance reporting for the current fiscal year and budget planning information for the budget request. The performance information in this request includes a combination of contextual measures that describe the extent of nationwide interoperable health information exchange; and milestones and accomplishments that highlight key information about ONC activities that were or need to be taken to implement statutory requirements.

The contextual measures in the budget reflect the research that ONC conducts with other partners in government to better understand the Nation's health IT landscape. These projects seek to understand the types of heath IT capabilities that exist and how those capabilities are being used. The measures included in the budget were selected to provide context for ONC's request *and* demonstrate the long-term impact of ONC's past work. This year's budget request maintains support for several necessary survey and data analysis projects that enable ONC to collaborate with public and private sector partners and meet congressional requirements to evaluate progress toward national goals for interoperable health information exchange.

ONC's Performance Management Process

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

ONC's performance management strategy consists of four phases: (1) Priority Setting, (2) Strategic Planning, (3) Financial and Performance Management, and (4) Evaluation, Review, and Reporting. Activities aligned to these four phases are coordinated by a workgroup of ONC's leaders who represent the agency in strategy, planning, performance, financial and human capital resources, operations, risk management, data analysis, and program/policy evaluation.

ONC's performance and management processes incorporate requirements from law, procedures from Office of Management and Budget (OMB) circulars, and a range of best practices endorsed by oversight and advisory groups. Example resources that provide a foundation for ONC's management process include:

- Government Performance and Results Act of 1993 and the GPRA Modernization Act of 2010 (Public Law 111-352)
- Federal Mangers' Financial Integrity Act (FMFIA) of 1982 (Public Law 97-255),
- OMB Circular A-11: Preparation, Submission, and Execution of the Budget ("A-11")
- OMB Circular A-123: Management's Responsibility for Enterprise Risk Management and Internal Control ("A-123")
- Government Accountability Office (GAO) Standards for Internal Control in the Federal Government ("The Green Book")
- Performance Improvement Council's Performance Principles and Practices Guide ("P3 Playbook")

Impact of the FY 2023 Budget Request on Performance

ONC's FY 2023 request includes a proposed increase of +\$17.0 million above the FY 2022 President's Budget and a +\$41.2 million increase above the FY 2022 Annualized Continuing Resolution. This provides and additional +\$18.0 million will be allocated to Policy Development and Coordination efforts to target interoperability policy work that will accelerate the exchange of information between health information exchanges by establishing common principles, terms, and conditions through the TEFCA; and an additional + \$22.0 million will be allocated to Standards Coordination and Collaboration to target Federal coordination activities to further its equity-by-design approach to increase interoperability and improve equity. The request also includes an additional \$1.3 million to allow ONC to support their staff and operational activities needed to keep pace with the agency's growing responsibilities.

All-Purpose Table

(Dollars in Thousands)

Activity		FY 2021		FY 2022	FY 2023	FY 2023 President's
	FY 2021	Supplemental	FY 2022	Supplemental	President's	Budget +/- FY 2022
	Final	Funding /1	CR /2	Funding /3	Budget	Enacted
TOTAL, ONC	62,180	\$19,500	\$62,367	\$0	\$103,614	\$41,247
Program Level						
TOTAL, ONC	62,180	\$19,500	\$62,367	\$0	\$0	(\$62,367)
Budget Authority						

^{1/} This column includes both supplemental funding and mandatory funds appropriated in the American Rescue Plan Act of 2021, P.L. 117-2 post-transfer and post-reallocation and the supplemental appropriation in the Consolidated Appropriations Act, 2021 (P.L. 116-260)

^{2/} Reflects the annualized amounts provided in the continuing resolution ending 2/18/2022

^{3/} This column includes both supplemental funding and mandatory funds appropriated for FY 2022 in the Infrastructure and Jobs Act and in the Build Back Better Act.

Budget Exhibits

Appropriations Language

From amounts made available pursuant to section 241 of the PHS Act, \$103,614,000 shall be for expenses necessary for the Office of the National Coordinator for Health Information Technology, including for grants, contracts, and cooperative agreements for the development and advancement of interoperable health information technology.

Language Analysis

Language Provision	Explanation
From amounts made available pursuant to	Provides ONC's budget from PHS Evaluation
section 241 of the PHS Act, \$103,614,000 shall	funding.
be for expenses necessary for the Office of the	
National Coordinator for Health Information	
Technology, including for grants, contracts, and	
cooperative agreements for the development and	
advancement of interoperable health	
information technology.	

Amounts Available for Obligation

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
General Fund Discretionary Appropriation:			
Appropriation (L/HHS)	\$62,367,000	\$62,367,000	\$103,614,000
Subtotal, Appropriation (L/HHS, Ag, or Interior)	\$62,367,000	\$62,367,000	\$103,614,000
Subtotal, adjusted appropriation	\$62,367,000	\$62,367,000	\$103,614,000
Real transfer to: (ACF)	(187,241)		\$0
Subtotal, adjusted general fund discr. appropriation	\$62,179,759	\$62,367,000	\$103,614,000
Total, Discretionary Appropriation	\$62,367,000	\$62,367,000	\$103,614,000
Total Obligations	\$62,179,759	\$62,367,000	\$103,614,000

Summary of Changes

		Summa	ly of Cha	nges			
2022 CR Total estimated budget authority							
	FY FTE	2022 CR BA		23 President's Budget PL	FY 2023 FTE	+/- FY 2022 BA/PL	
Increases:						•	
A. Program:							
1. Health IT, PHS Eval	180	\$0	180	\$103,614,000	_	\$103,614,000	
Subtotal, Program Increases Total Increases	180 180	\$0 \$0	180 180	\$103,614,000 \$103,614,000	-	\$103,614,000 \$103,614,000	
Decreases: A. Program							
1. Health IT, BA Subtotal, Program	180	\$62,367,000	180	\$0	-	(\$62,367,000)	
Decreases	180	\$62,367,000	180	\$0	-	(\$62,367,000)	
Total decreases	180	\$62,367,000	180	\$0	-	(\$62,367,000)	
Net Change	-	-	-	-	-	+\$41,247,000	

Budget Authority by Activity

(Dollars in Thousands)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
1. Health IT			
Annual Budget Authority	\$62,180	\$62,367	\$0
Annual Program Level	\$62,180	\$62,367	\$103,614
Subtotal, Health IT	\$62,180	\$62,367	\$0
Total, Budget Authority	\$62,180	\$62,367	\$0
Total, Program Level	\$62,180	\$62,367	\$103,614
FTE	180	180	180

Authorizing Legislation

	FY 2022 Amount Authorized	FY 2022 Amount Appropriated	FY 2023 Amount Authorized	FY 2023 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 Program Level Total Request Level	Indefinite	\$62,367,000 \$ - \$62,367,000	Indefinite	\$ - \$103,614,000 \$103,614,000

Appropriations History

Each Year is General Fund Appropriation	Request to Congress	House Allowance	Senate Allowance	Appropriation
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		
Transfers (Secretary's)				(\$114,000)
Subtotal	\$43,000,000	\$60,367,000	\$60,367,000	\$60,253,000
FY 2021				
Annual	\$50,717,000	\$60,367,000	\$60,367,000	\$62,367,000
Transfers (Secretary's)				(\$187,241)
Subtotal	\$50,717,000	\$60,367,000	\$60,367,000	\$62,179,759
FY 2022				
Annual				62,367,000
PHS Evaluation Funds	\$86,614,000	\$86,614,000	\$86,614,000	
Subtotal	\$86,614,000	\$86,614,000	\$86,614,000	
FY 2023				
Annual				
PHS Evaluation Funds	\$103,614,000			
Subtotal	\$103,614,000			

Narrative by Activity

Health IT

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
BA	\$62,179,759	\$62,367,000	\$0	-\$62,367,000
PHS Eval Funds	\$0	\$0	\$103,614,000	\$103,614,000
PL	\$62,179,759	\$62,367,000	\$103,614,000	+\$41,247,000
FTE	180	180	180	0

Authorizing Legislation

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

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 were increased by MACRA in 2015 and again by the 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 2023, ONC will implement its authorities and requirements to accelerate progress to an interoperable nationwide health IT infrastructure by pursuing the following objectives:

- 1. Promoting *seamless*, *secure information-sharing* among providers, patients, and other healthcare stakeholders using modern, open-industry, internet-based technologies
- 2. Building on federal investments in electronic health records *to improve the access, exchange, and use of electronic health information* and advance quality, equitability, safety, efficiency, accessibility, and affordability of US healthcare
- 3. Enabling an *open health IT ecosystem* to ensure a level playing field for innovation and competition to support health IT users, including patients
- 4. Furthering *universal access to secure, usable information exchange technologies* through nationwide networks and application programming interfaces (APIs)
- 5. Fostering the use of health IT and health information to identify and address *health equity* issues in healthcare delivery, public health, and population health
- 6. Facilitating the *success of federal programs* through the effective use of health IT and health information

Sub Activities at ONC²

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 under relevant statutes and executive orders, including: (1) policy and rulemaking activities, such as writing the rule text to implement the Cures Act; (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.

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; scientific advisors who support leveraging standardized clinical data to advance discovery and innovation; a stakeholder outreach and media relations function, including management of HealthT.gov; and the agency's operations and administration functions.

² 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.³ At its inception, ONC's primary efforts focused on strategic planning, building the National Health Information Network, supporting health IT certification, and stimulating collaboration on health IT standards 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 Centers for Medicare & Medicaid Services (CMS) with financial resources to incent and guide the development and adoption of a more comprehensive nationwide health IT infrastructure via the Medicare and Medicaid 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.⁴

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. It was supported widely for its more than 150 detailed commitments and calls to action.⁵

While nationwide stakeholders worked to implement commitments in the *Roadmap*, ⁶ in **2015** Congress placed further emphasis on achieving widespread interoperability in MACRA. With MACRA introduced, the Medicare EHR Incentive Program for eligible professionals 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.⁷

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 APIs and in parallel prevent anti-competitive business practices related to the access, exchange, and use of electronic health information, which are now referred to as "information blocking." The bipartisan goal was to promote friction-free information-sharing among providers and other healthcare delivery actors, and with patients. We expect increased information-sharing will benefit

³ Executive Order 13335; https://www.gpo.gov/fdsvs/pkg/WCPD-2004-05-03/pdf/WCPD-2004-05-03-Pg702.pdf.

⁴ 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.

⁵ https://www.healthit.gov/topic/interoperability/interoperability-road-map-statements-support.

 $^{^{6} \ \}underline{\text{https://www.healthit.gov/sites/default/files/12-19-YearInReviewPrezi-508-LowRes.pdf.}}$

⁷ https://www.healthit.gov/buzz-blog/health-data/numbers-progress-digitizing-health-care/

the entire healthcare system by opening up new technology approaches and business models that also directly engage patients themselves.

In March 2020, ONC released the <u>Cures Act Final Rule</u> which seeks to improve 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 Rule is to facilitate providers' and patients' access to their electronic health information and empower their healthcare decisions.

Major Accomplishments

The following performance highlights explain how ONC's investments in previous years have resulted in impactful deliverables, noteworthy accomplishments, and continued progress towards national goals for a healthcare system that has higher quality, lower costs, and is more equitable by design.

Policy: Development and Coordination

- Advancing Policy and Coordination for Public Health Data Systems: In FY 2021 ONC's policy related work contributed significantly to building a stronger infrastructure to support the intersection of public health with clinical data systems. ONC's HITAC established the Public Health Data Systems Task Force 2021, which consisted of 21 industry and federal experts and provided 52 recommendations on a variety of public health data systems needs. Topics addressed in the recommendations include laboratory and case reporting, immunizations, syndromic surveillance, situational awareness, infrastructure, health equity, and individual engagement. The HITAC recommendations are informing HHS's response to President Biden's Executive Order on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats. With funding from the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), the Strengthening the Technical Advancement and Readiness of Public Health Agencies via Health Information Exchange (STAR HIE) Program continued efforts to build innovative health information exchange services that benefit public health agencies and improve the health information exchange services available to support communities disproportionately impacted by the COVID-19 pandemic. As of January 2022, the following has been accomplished:
 - Thirteen awardees have signed new or modified existing public health memoranda of understanding or data sharing agreements facilitating easier access to lab reporting, case reporting, and/or immunization data;
 - Seven awardees have developed and offered new enriched data reports and data visualization tools; and
 - Nine awardees have increased data sharing between HIEs and jurisdictional Immunization Information Systems (IIS).

Additionally, new COVID-19 provider notification tools have been deployed under the STAR HIE Program.

 HEALTHeLINK, a regional health information organization covering Western New York, developed an approach to deliver COVID-19 test result notifications via Direct Message (Admission, Discharge, and Transfer alerts) and reports to providers, hospitals, and health departments as needed.

- O HealthShare Exchange of Southeastern Pennsylvania (HSX) improved their region's pandemic response by developing bulk reports of patients' vaccine status to organizations doing outreach. Reports are pushed to the organizations several times a week with updated results, compared to one patient at a time lookups from the vaccine registries.
- O Bronx RHIO expanded their COVID-19 test result alerts and reporting to include alerts and reporting on vaccination status.

Through the STAR HIE Program, new vaccination reporting tools have also been established.

- o Indiana Health Information Exchange (IHIE) successfully launched a COVID-19 vaccination reporting tool.
- The Kansas Health Information Network (KHIN) is reducing physician and public health burden by developing a solution for providers to electronically report COVID-19 lab results to their public health agency.
- The Texas Health Services Authority is demonstrating standards-based, real-time reporting of hospital capacity data for the purpose of reducing burden on hospitals and improving data quality.

Finally, the STAR HIE Program is advancing broader health equity goals.

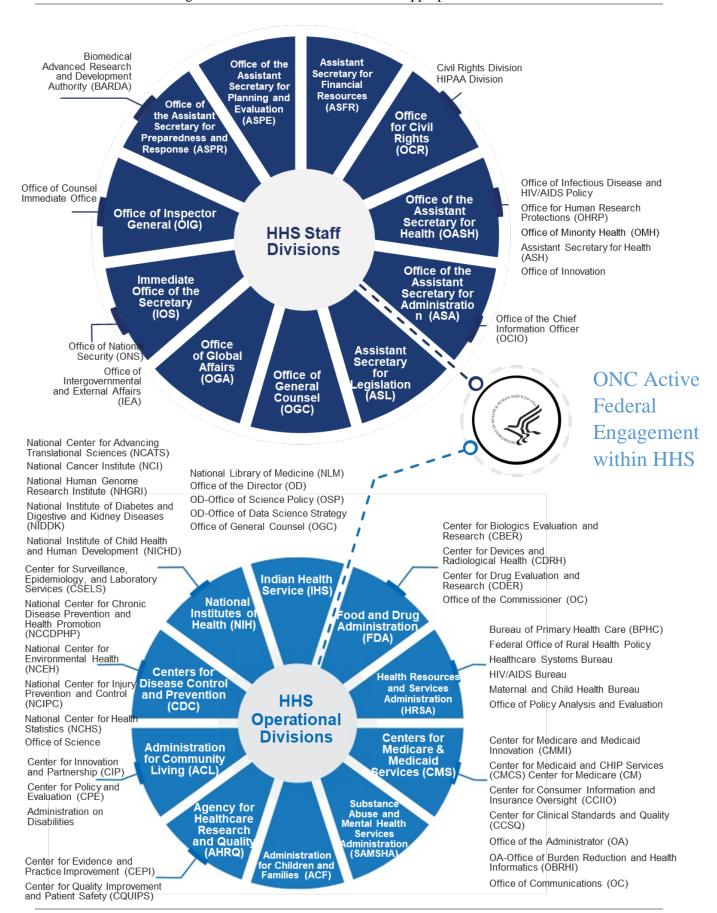
- HSX currently produces surveillance reports for their members, including data on race.
 The surveillance reports highlight the disproportionate impact on communities of color down to a zip code level to allow their members to identify and address areas for improvement.
- West Virginia Health Information Network (WVHIN) has finalized specifications for race, ethnicity, and geocoding for vaccines to enhance use of this data by public health and to address vaccination hesitancy and outreach to underserved populations.
- Cures Act Final Rule: Due to the COVID-19 pandemic, ONC published the Interim Final Rule in November 2020 to extend certain compliance dates and timeframes for Information Blocking and the ONC Health IT Certification Program that were outlined in the ONC Cures Act Final Rule (Final Rule) that was released to the public in March 2020. The Cures Act Final Rule supports a patient's right to get their electronic health information and addresses both technical barriers and business practices that impede the secure and appropriate sharing of data. The Final Rule advances progress on many of ONC's implementation responsibilities in the Cures Act, including information blocking and conditions of certification for health IT developers under the ONC Health IT Certification Program. It also promotes seamless, secure information sharing among providers, patients, and other healthcare providers using modern, open-industry, internet-based technologies. The Final Rule requires that certified health IT developers make available in their products secure, standards-based APIs that help to enable an open health IT ecosystem where patients and providers have choices of applications and devices, including mobile devices, that best meet their needs and preferences for accessing, exchanging, and using electronic health

⁸ https://www.healthit.gov/curesrule/

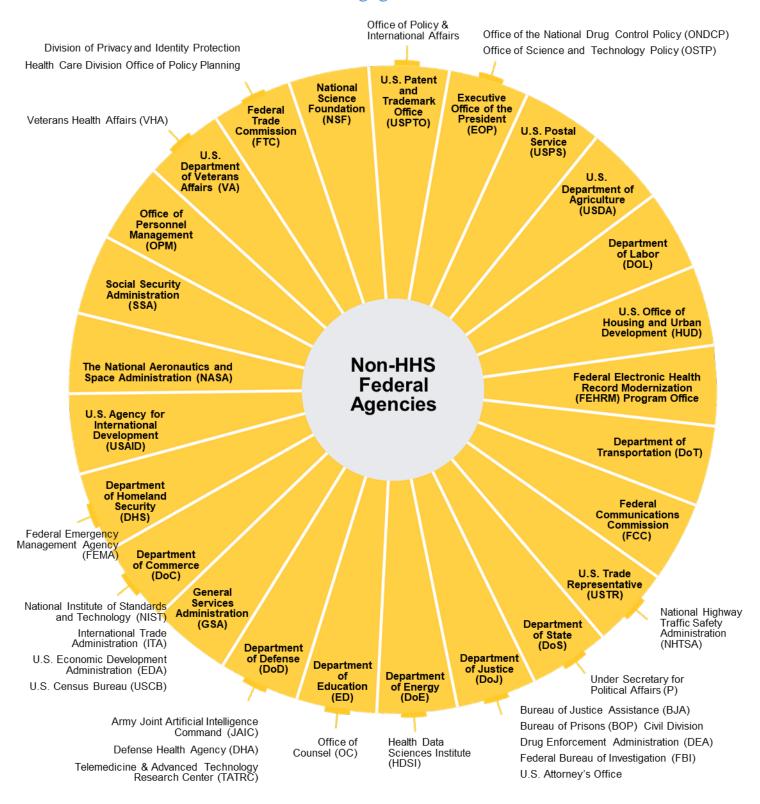
information. The Final Rule also adopts the United States Core Data for Interoperability (USCDI) as a standard to establish the baseline set of information that can be exchanged across health IT for clinical data exchange and patient access.

- Information Blocking Outreach and Engagement: Throughout FY 2021 and FY 2022, ONC emphasized outreach and education to the providers, developers, and health information networks and exchanges who need to understand both what information blocking is and what it is not, specifically in context of what the exceptions established in the Cures Act Final Rule are and how they work. ONC's outreach has included hosting office hours and webinars which are recorded and posted on healthIT.gov, publishing frequently asked questions (FAQs) and fact sheets on the ONC website, and participating in stakeholder-led education sessions on information blocking in general as well as specific topics. ONC's engagement activities in FY 2021 and FY 2022 included listening sessions for a wide variety of stakeholder groups share with us their experiences and questions regarding information blocking.
- Federal Health IT Coordinating Council: ONC improved Federal coordination through the Federal Health IT Coordinating Council, a voluntary group of nearly 40 Federal departments, agencies, and offices that are actively involved in implementing the national health IT agenda. In FY 2021, the Federal Health IT Coordinating Council convened five times including an average of 75 Federal representatives across 22 organizations. In FY 2021, the Coordinating Council influenced draft FHIR Guidance for Federal partners, supported efforts to update the USCDI, shared Federal progress made towards the 2020-2025-Federal Health IT Strategic Plan, and assisted in Federal health IT coordination activities related to COVID-19. The Coordinating Council also convened two work groups focused on Federal health IT standards coordination, specifically related to the FHIR standard and the USCDI.





ONC Active Federal Engagement outside of HHS



• Federal Advisory Committee: ONC continued to administer the Health IT Advisory Committee (HITAC), ONC's Federal Advisory Committee mandated by the Cures Act. Now in its fourth year, the HITAC serves as a priority method for obtaining routine input from a group of 27 health IT experts and 6 federal representatives, representing a broad and balanced spectrum of the healthcare system. Between October 1, 2020, and January 2022, the full HITAC held 13 meetings and its subcommittees met over 70 times to develop recommendations addressing the priority areas identified in the Cures Act. In February 2021, the HITAC published the FY 2020 Annual Report. In FY 2021, there were four HITAC Task Forces and Work Groups that provided recommendations to the National Coordinator on such public health data systems, priority uses of health IT, and health IT standards. 10

Active

- Annual Report Workgroup
- Interoperability Standards Priorities Task Force 2021
- Public Health Data Systems Task Force 2021
- U. S. Core Data for Interoperability Task Force 2021
- o Inactive
 - Interoperability Standards Priorities Task Force 2018
 - Intersection of Clinical and Administrative Data Task Force
 - Trusted Exchange Framework Task Force
- o Sunset
 - Conditions of Certification Task Force
 - Health IT for the Care Continuum Task Force
 - Information Blocking Task Force
 - U.S. Core Data for Interoperability Task Force 2019
 - U.S. Core Data for Interoperability Task Force 2020
- Trusted Exchange Framework and Common Agreement (TEFCA): ONC published the Trusted Exchange Framework and the Common Agreement Version 1 in Q1 of 2022. The Common Agreement creates baseline legal and technical requirements that will enable secure, information sharing across different networks nationwide. The publication of TEFCA was made possible due to extensive public engagements, webinars and workgroup sessions conducted under a four-year cooperative agreement with The Sequoia Project as the TEFCA Recognized Coordinating Entity (RCE). This partnership leverages the RCE's extensive private sector experience to develop, implement, update, and maintain the Common Agreement component of TEFCA. As of January 2022, there had been 45 webinars with almost 5,000 total participants. In addition, the RCE received and analyzed public stakeholder feedback to inform several aspects of TEFCA, including the Common Agreement itself, the technical framework for TEFCA, and proposed metrics that will be collected to measure success. As next steps, ONC and the RCE will perform public education activities and will work to inform potential signatories to the Common

⁹ https://www.healthit.gov/hitac/committees/health-information-technology-advisory-committee-hitac/membership

¹⁰ https://www.healthit.gov/topic/federal-advisory-committees/subcommittees

¹¹ https://www.healthit.gov/sites/default/files/page/2022-

^{01/}Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf

Agreement, with the goal of seeing live data sharing before the end of 2022.

Strategic Planning: In October 2020, ONC released the final Federal Health IT Strategic Plan 2020-2025. This plan explains how the Federal Government intends to use health IT to: 1) Promote Health and Wellness; 2) Enhance the Delivery and Experience of Care; 3) Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation; and 4) Connect Healthcare with Health Data. The plan was developed by the ONC in collaboration with more than 25 Federal organizations and informed by nearly 100 public comment submissions. The Federal EHR Modernization Office used the goals from the Federal Health IT Strategic Plan for the Interoperability Modernization Strategy for the U.S. Department of Defense and U.S. Department of Veterans Affairs. Additionally, ONC led the development of National Health IT Priorities for Research: A Policy and Development Agenda, which articulates a vision of a health IT infrastructure that supports alignment between the clinical and research ecosystems. The Agenda, developed in collaboration with Federal partners and with input from stakeholders, outlines nine priorities, including concrete steps that stakeholders can take to achieve that vision and enable research to happen more quickly and effectively.

Technology: Standards, Interoperability, and Certification

- Advancing Standards and Technology for Public Health Data Systems: In FY 2021, ONC's technology related work contributed significantly to building a stronger infrastructure to support the intersection of public health with clinical data systems. Examples include: A report on public health data standards, which solidified the best options for scaling FHIR-based standards and implementation guides to support expansion of interoperable data systems, a review of the technical barriers to bi-directional exchange of immunization data by the Association of State and Territorial Health Officials (ASTHO), and coordination of immunization appointment scheduling with private industries, state government health officials and various U.S. Government systems using the ONC-supported SMART Scheduling specifications to support www.vaccinefinder.org through the use of ONC developed testing infrastructure. ONC issued guidance to industry that enabled FHIR-based eCR Now application developed by the public health community to be relied for use as part of certified health IT module to demonstrate conformance with the electronic case reporting certification criterion in the regulation. This guidance helped providers and hospitals take rapid advantage of the eCR Now application while meeting the requirements of CMS Promoting Interoperability program, in support of addressing COVID-19 efforts. ONC also supported the rapid development of LOINC® codes that have been critical in accurately reporting COVID-19 infections across the country. ONC supported the operations of several standards development organizations, including HL7, IHE and LOINC that enabled health IT industry to rapidly develop solutions to address the public health needs during the pandemic.
- ONC Health IT Certification Program: ONC continued to implement congressional requirements to operate the ONC Health IT Certification Program by maintaining a suite of certification criteria including test procedures and certification companion guides and test tools to advance interoperability and support numerous HHS Programmatic goals. The Certification Program updated the compliance timelines for the program in support of ONC's

Interim Final Rule. Additionally, the <u>Certified Health IT Product List</u> (CHPL) website was updated to provide stakeholders with appropriate information on the certification status. The Certification Program published several program resource guides to ensure that health IT industry would be able to meet the regulations efficiently. ONC also continued to make updates to the testing infrastructure that is used by the ONC-Authorized Testing Labs to support conformance to regulations.

As of September 30, 2021, the ONC Health IT Certification Program listed more than 490 certified health IT developer on the CHPL ¹² and supported over 550,000 care providers and hospitals participating in Medicare and Medicaid. ¹³ At the end of FY 2021, there were 715 products from 490 developers on the CHPL certified to the 2015 Edition. This means that 98 percent of the hospitals and over 95 percent of the clinicians participating in Centers for Medicare & Medicaid Services (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. The Certification Program maintains test procedures and certification companion guides for 58 certification criteria and six conditions and maintenance of certification requirements, ¹⁴ used to standardize information across 21 distinct programs and initiatives taking place at CMS, Department of Defense (DOD), Veteran Health Administration (VHA), Health Resources and Services Administration (HRSA), and the Substance Abuse and Mental Health Services Administration (SAMHSA). ¹⁵

ONC also developed and received public feedback and HITAC recommendations on draft measures for developers to report under the EHR Reporting Program. ONC intends to implement the EHR Reporting Program via notice and comment rulemaking. Data collected and reported under the program will address information gaps in the health IT marketplace and provide insights on how certified health IT is being used. ONC anticipates the initial set of EHR Reporting Program measures will focus on interoperability of electronic health information.

• United States Core Data for Interoperability (USCDI): In July 2021, ONC finalized and published USCDI Version 2 (USCDI v2), a standardized set of health data classes and constituent data elements required in the Cures Rule for nationwide, interoperable health information exchange. As part of the USCDI v2 development process, the health IT community submitted more than 600 data classes and elements for consideration to be added to USCDI. Consistent with the Biden Administration's executive orders, new data elements were included in USCDI v2 to support the Administration's efforts to advance health equity, including data elements for sexual orientation, gender identity, and social determinants of health. USCDI v2 includes three new data classes and a total of 22 new data elements. The new data elements laid the foundation for the provider community to start addressing health equity considerations in the clinical setting. The USCDI Version 3 was released in January 2022. Version 3 builds on previous versions by adding data elements which intentionally address areas of healthcare inequity and disparities, underserved communities, and public health data requirements around reporting, investigations,

 $^{^{12}\} https://dashboard.healthit.gov/quickstats/pages/FIG-Vendors-of-EHRs-to-Participating-Professionals.php.$

¹³ https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.

¹⁴ https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method.

¹⁵ https://www.healthit.gov/topic/certification-ehrs/programs-referencing-onc-certified-health-it

and emergency response. These areas align with the Administration's focus in Executive Orders Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats.

- Standards Version Advancement Process (SVAP): As part of the Cures Act Final Rule, ONC established an annual process to identify and permit certified health IT developers to voluntarily use a more advanced version of standard(s) and implementation specification(s) approved by the National Coordinator than is adopted in the ONC 2015 Edition Certification Criteria, known as SVAP. During the comment period for 2020 SVAP-eligible standards and implementation specifications (September – November 2020), a total of 34 comments were received from stakeholders on 22 standards and implementation specifications. Following a detailed review and assessment, ONC finalized a list of five versions of standards and implementation specifications that can be advanced to under the ONC Health IT Certification Program as of March 12, 2021. As part of ONC's ongoing charge to coordinate health IT across federal and industry stakeholders, we determined it was necessary to adjust our Standards Version Advancement Process (SVAP) timeline to align with standards development activity in standards development organizations. The new SVAP timeline was announced in October 2021 which will allow standards development activities to be completed in a timely manner and enabling industry adoption of latest version of USCDI. As the annual SVAP cycle continues, ONC expects developers will take advantage of newer standards versions, thus promoting interoperability more rapidly than regulatory cycles may otherwise allow.
- standards Advisory: ONC 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 ISA is widely used by federal agencies for their programs and serves a useful resource to the broader health IT community. The 2021 ISA, published in January 2021, added a new sub-section on the COVID-19 Novel Coronavirus Pandemic, as well as a Specialty Care and Settings "tag" for COVID-19 related interoperability needs across the ISA. In addition to the COVID-19 sub-section and Specialty Care and Settings listing, ONC added four interoperability needs connected to public health emergency response. These include sections on healthcare personnel status, the use of hospital/facility beds, lab operations (population lab surveillance), and population-level morbidity and mortality. Together, these elements can help emergency officials maintain situational awareness around public health emergencies and optimize emergency operations. The ISA website was accessed over 371,000 times in FY 2021, almost four times the 95,000 views in FY 2020.

In January 2022, ONC published the 2022 Interoperability Standard Advisory (ISA). The 2022 ISA adds two new, interoperability needs related to labs, Representing Laboratory Test Ordered and Representing Laboratory Test Performed. The 2022 ISA also adds a Work Information section with Work Information Templates interoperability need. In addition, the 2022 ISA created a new interoperability need called Representing Mass Vaccination Status within the Vocabulary/Code Set/Terminology: Public Health Emergency Preparedness and Response.

- Advancing Modern Application Program Interface (API) for Health IT: ONC partnered with Health Level Seven (HL7) standards development organization to advance the adoption and use of Fast Healthcare Interoperability Resources (FHIR) API standard. ONC supported the development of US Core, Bulk Data Access, COVID-19 FHIR Profile Library and International Patient Summary implementation guides.
- Precision Medicine Activities: ONC is advancing standards development to improve the interoperability of new and diverse types of health data, with the goal of making them easier to share, curate, aggregate, and synthesize. The Advancing Standards for Precision Medicine (ASPM) project was established to enable the collection and sharing of high-impact data found outside the care such as mobile health, sensor, and wearable data; and social determinants of health (SDOH) data. ONC undertook two demonstration projects to investigate and inform the collection and use of these data. Lessons learned from the development and demonstration projects were disseminated via a final report issued in January 2021. Additionally, ONC continued to lead segments of the Precision Medicine Initiative (PMI), including the Sync for Science and Sync for Genes projects. In November 2020, ONC published a report documenting the experiences of provider sites engaged by ONC to pilot the use of third-party applications and supporting standards-based application programming interfaces to allow patients to share their health data with researchers.

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.
- ONC's websites garnered 2.5 million visitors during FY 2021, an average of over 292,000 sessions per month and 6.8 million page views throughout the year. Over ninety percent of visitors were from outside the National Capitol area (DC, Maryland, and Virginia). Additionally, ONC's main website, HealthIT.gov, attracted users referred from 7,749 external websites

Five Year Funding History

Fiscal Year	Amount
FY 2019 Enacted	60,367,000
FY 2020 Enacted	60,367,000
FY 2021 Final	62,179,759
FY 2022 CR	62,367,000
FY 2023 President's Budget	103,614,000

Budget Request

ONC's FY 2023 request includes a proposed increase of +\$17.0 million (19.6 percent) above the FY 2022 President's Budget and a +\$41.2 million (66.1 percent) increase above the FY 2022 Annualized Continuing Resolution. Of the +\$41.2 million increase above the Annualized Continuing Resolution, \$18.0 million will be allocated to Policy Development and Coordination efforts to target interoperability policy work that will accelerate the exchange of information between health information exchanges by establishing common principles, terms, and conditions through the TEFCA; and \$22.0 million will be allocated to Standards Coordination and Collaboration to target Federal coordination activities to further an equity-by-design approach to increase interoperability and improve health equity. The request also includes an additional \$1.3 million to allow ONC to support their staff and operational activities needed to keep pace with the agency's growing responsibilities.

The FY 2023 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, federal agencies, state/territorial/local/tribal public health agencies, and researchers who rely on health IT. ONC's FY 2023 request supports continuously expanding work to advance the technical infrastructure necessary to support safe, equitable, and affordable healthcare; implement Cures Act requirements, and improve the interoperability of electronic health information.

Policy Development and Coordination

ONC's FY 2023 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 health equity and reduce health disparities. This budget includes an increase of \$18.0 million above the Annualized Continuing Resolution level, which will fund interoperability policy work that will accelerate the exchange of information between health information exchanges by establishing common principles, terms, and conditions through the TEFCA, and build the future healthcare data infrastructure needed to better respond to and prepare for public health emergencies.

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.

Planned activities within ONC's FY 2023 policy development and coordination portfolio include:

Policy Development and Support

• **Interoperability Policy** – ONC will continue to lead implementation of TEFCA, which seeks to create baseline legal and technical requirements to enable secure information sharing across different healthcare networks nationwide.

In FY 2023, following the publication of the <u>Common Agreement</u> in January 2022, ONC will promote the adoption of TEFCA by a wide range of healthcare entities, including major delivery networks and health information exchanges.

Increased funding will position ONC to make TEFCA-related investments to build the future healthcare data infrastructure needed to better respond to and prepare for public health emergencies, including the COVID-19 pandemic. To do this, ONC will create a cooperative agreement and/or grant program that will provide funding to public health entities, health information networks, health information exchanges, and certain providers to speed readiness, onboarding, and infrastructure activities related to participation in the network-to-network exchange ecosystem created by TEFCA, thereby better enabling health data to be available when and where it is needed.

The effort will accelerate adoption of and wider-scale participation in TEFCA, meaning that patients and providers will have access to more data within electronic health records, resulting in better care and broad reaching impacts to public health. It will also mean that data service companies will be able to offer more accurate and more useful data analytics for providers and payers, resulting in better quality and reduced healthcare costs.

ONC will dedicate funding for the TEFCA Recognized Coordinating Entity (RCE) - ONC's non-profit partner that leverages its extensive private sector experience to develop, implement, update, and maintain the Common Agreement component of TEFCA - to accelerate work expanding network privacy and security enforcement and oversight. This is especially critical because healthcare networks, similar to other parts of the nation's critical infrastructure (e.g., transportation and energy sectors), are under increasing cyber threat.

ONC will provide resources for the TEFCA to support grants or cooperative agreements to state, territorial, local, and tribal public health agencies that are seeking improved outcomes relating to public health, such as investigations related to outbreaks, disease surveillance, and/or patient outreach related to vaccination efforts. The grants or cooperative agreements will address cost and sustainability barriers preventing funding recipients from leveraging the entirety of the TEFCA network.

• **Rulemaking** – A central underpinning of all ONC rulemakings is to facilitate providers' and patients' access to electronic health information and empower them to make better healthcare decisions. ONC will continue to administer rules that advance interoperability; support the access, exchange, and use of electronic health information.

In FY 2023, ONC will continue to administer rules implementing certain provisions of the Cures Act, as well as in accordance with Sec. 3004 of the Public Health Service Act (PHSA). ONC's next rule includes provisions related to: the EHR Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program; a process for health information networks that voluntarily adopt the TEFCA to attest to such adoption of the framework and agreement; and enhancements to support information sharing under the

information blocking regulations.

The rulemaking would also include proposals for new standards and certification criteria under the Certification Program related to real-time benefit tools and electronic prior authorization and potentially other revisions to the Certification Program.

- **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 the intersection of HIPAA Privacy and Security Rules with health IT. 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. ONC also continues to partner with industry stakeholders to advance privacy and security education.
- EHR Reporting Program ONC intends to implement the EHR Reporting Program via notice and comment rulemaking. ONC will establish the necessary program infrastructure to support data collection and reporting of the EHR Reporting Program measures by certified health IT developers. Data collected and reported under the program will address information gaps in the health IT marketplace and provide insights on how certified health IT is being used. ONC anticipates the initial set of EHR Reporting Program measures will be interoperability focused.

Stakeholder Coordination

• **Federal Coordination** – As stated previously, ONC will continue leading and engaging agencies which contribute to the Federal Health IT Strategic Plan¹⁶ 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 payment policy and programs, 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.

Federal coordination efforts will also focus on expanding the USCDI standard and the new ONC initiative called USCDI+ to support the identification and establishment of domain or program-specific datasets that will operate as extensions to the existing USCDI. The USCDI+ initiative included USCDI+ Public Health which standardizes public health dataset to improve the U.S. public health data infrastructure; and USCDI+ Quality which improves quality measures to be less burdensome for providers.

ONC is currently coordinating with 16 federal entities on USCDI and USCDI+. USCDI+ is a service that ONC will provide to federal partners who have a need to establish, harmonize, and advance the use of interoperable datasets that extend beyond the core data in the USCDI in order

¹⁶ https://www.healthit.gov/topic/2020-2025-federal-health-it-strategic-plan

to meet agency-specific programmatic requirements. This approach will allow ONC to better serve its federal partners, assure that extensions build from the same core USCDI foundation, and create the opportunity for aligning similar data needs across agency programs. USCDI+ efforts for quality measurement and public health are starting with the Centers for Medicare & Medicaid Services and Centers for Disease Control and Prevention, and more may be added. In addition to USCDI, ONC will continue to coordinate with over 20 federal entities to accelerate the development and use of the FHIR® standard to improve electronic health information exchange needs of federal agencies. Other time limited and topic focused workgroups administered under the Federal Health IT Coordinating Council include, TEFCA, digital health innovations, and federal health IT systems.

- 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. HITAC consists of over 25 members and six federal representatives. In FY 2021, ONC convened the HITAC 10 times and held over 65 subcommittee meetings. HITAC provided over 130 recommendations. ¹⁷ In addition to requirements that the HITAC annually addresses updates to the USCDI standard and priority ONC Interoperability Standards Advisory interoperability needs, the HITAC workgroups and recommendations also addressed a range of priority issues, including public health data systems, health equity by design, information blocking, TEFCA, EHR Reporting Program.
- **Health IT Safety** ONC will continue to help address emerging health IT safety challenges and foster the development of tools such as standards, and evidence-based practice guidance to help healthcare providers more effectively use health IT to deliver safe care to all their patients.

Strategic Planning and Reporting

- Federal Health IT Strategic Planning In FY 2023, ONC will start the next update of the Federal Health IT Strategic Plan in consultation with the Federal Health IT Coordinating Council. ONC will continue to implement the 2020 2025 Federal Health IT Strategic Plan during FY 2023, regularly collaborating with key stakeholder groups (including Congress and the public) to monitor and report progress of priority activities. Key activities include, but are not limited to:
 - o Convening federal and industry stakeholders to understand health IT and interoperability needs;
 - o Monitoring and reporting progress on the Plan;
 - Coordinating with federal and industry stakeholders on critical health IT infrastructure efforts related to APIs, USCDI, FHIR, information blocking, and electronic health information exchange.
- 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

¹⁷ https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it

Cures Act related to interoperability, privacy and security, and patient access. The HITECH Annual Report provides an update on progress against the Federal Health IT Strategic Plan.

Standards, Interoperability, and Certification

In FY 2023, ONC will continue to meet statutory requirements and advance progress toward national goals for equitable, widespread interoperability, which includes implementing the Cures Act related activities and impacts of ONC's rulemaking. The request includes an additional \$22.0 million in funding above the FY 2022 Annualized Continuing Resolution for standards coordination and adoption activities, such as enhancements to ONC's Health IT Certification Program, which will implement changes enacted by the Cures Act and ONC's subsequent rulemaking activities. It also includes an increase in funding for improving interoperability among health information networks to enable them to participate more comprehensively in TEFCA and adapt to the new standards and implementation guides developed to support facilitated and brokered FHIR exchange. The standards advancement work led by ONC will enhance the technical infrastructure necessary to support the Administration's goals related to an equitable and data-driven response to the pandemic.

The Request also supports the Conditions of Certification program requirements contained in section 4002 of the Cures Act; standards development and coordination work that promote equity by design; 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 for nationally relevant issues included opioid use. These efforts help to respond to the current COVID-19 pandemic and are integral to responding to future public health emergencies.

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 2023, ONC will continue to oversee the ONC-Authorized Testing Labs and ONC-Authorized Certification Bodies, and maintain a library of required certification companion guides, test procedures, and electronic test tools to support developers with creating certified health IT.

Increased funding will go towards certification work to implement the Cures Act Final Rule which supports the right of the patient to get their own health information electronically. The additional funds are needed to expand ONC's investment in a robust testing infrastructure that is used by the ONC-Authorized Testing Labs to ensure health IT industry meet the requirements of the Cures Act. Several new capabilities have been identified in the Cure Act Final Rule, including expanding availability of equity enhancing health information for patients and providers, which will require continued advancement of the API by the health IT industry. ONC's investment in robust testing infrastructure enables the health IT industry to focus their investments on improving health IT rather than duplicating testing infrastructure across all the industry. ONC testing is also now a critical part of the feedback standards developers receive to improve standards. Testing generates direct, hands-on implementation experiences and ONC uses those insights work with stakeholders to make future standards versions better. Increased funding enables ONC to develop new testing tools for future certification program requirements including

but not limited to prior authorization, real time prescription drug benefits, and public health certification.

Performance Measurement – ONC will conduct research and analyses to assess the degree to
which ONC is advancing an interoperable nationwide health IT infrastructure by meeting its
objectives. This includes continuing support for evidence-building activities such as national
surveys related to the development, adoption, and use of health IT to advance the implementation
of ONC authorities and responsibilities for strategic planning and evidence-based policy making

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 and curate the standards, implementation specifications, and common approaches to enable secure, equitable, and interoperable health IT systems. The standards and interoperability work led by ONC advances the technical infrastructure necessary to support the Administration's goals to move healthcare to a more equitable future. To do this, ONC will continue to coordinate with industry led standards development organizations and promote innovative industry-led equity by design, projects that improve adoption of mature standards, implement secure APIs, and promote standardized approaches for population level access to health data. Specific projects in the FY 2023 budget include:
 - Promoting the use of health IT and health information to address health equity, healthcare delivery, and public health issues by accelerating the readiness of interoperability standards for adoption and enhancing the USCDI by adding data elements to support those efforts, and
 - Ensuring that the next generation of privacy and security standards are ready for widespread adoption by coordinating the development, testing, piloting, and refining them as the nation progresses to widespread adoption of secure APIs in healthcare, which is a key component of making healthcare more equitable,
 - o Addressing health IT interoperability challenges related to social and behavioral health information to support healthcare.

With the increased funding requested in the FY 2023 Budget, ONC will further invest in identifying additional equity focused data elements and engaging and investing with the appropriate standards development organizations to create, refine, and release updated standards. In parallel, ONC will work with appropriate stakeholders to rapidly pilot such standards and evaluate their ability to be adopted more broadly. This includes:

O Addressing gaps and challenges related to SDOH standards – including social service data among managed by stakeholders and across federal programs. ONC will take an equity-by-design approach to advance the use of interoperable, standardized data to represent social needs and the conditions in which people live, learn, work, and play. Health data, including data on race/ethnicity and SDOH, can help to identify health disparities and to inform efforts to improve health outcomes at an individual and population level.

- o ONC will also continue to work on integrating SDOH and human and social services data to help improve the health outcomes and the patient experience.
- **Demonstrations and Pilots** ONC will continue to sponsor and encourage demonstration projects and pilots that address fast emerging and future challenges to advance the development and use of interoperable health IT. It is critical that the field of healthcare innovate and leverage the latest technological advancements and breakthroughs far quicker than it currently does to optimize real-time solutions. This includes expanding and advancing demonstration sites and pilots under the Leading Edge Acceleration Projects (LEAP) program. The goal of the LEAP program is to advance health IT development as well as to inform the innovative implementation and refinement of standards, methods, and techniques for overcoming major barriers and challenges. LEAP in Health IT projects tackle the creation of new standards, methods, and tools to improve care delivery and advance research capabilities. Through this work, ONC will support real world demonstrations and pilots around health equity, public health, APIs, research, and social determinants of health data exchange through this work.

Science and Innovation

- Scientific Initiatives ONC will continue to foster advancement of health IT by identifying and participating in using innovative technologies such as Artificial Intelligence (Ai) and machine learning. ONC will work closely with stakeholders in the scientific research community to connect their goals and interests to the advancement that ONC has fostered, including standards work in the area of precision medicine. More specifically, ONC will continue to lead and drive the efforts around standardizing and broad adoption of genomic information among laboratories, providers, patients, and researchers.
- Innovation The HITECH Act and reinforced by the Cures Act identifies ONC as a leading agency for advancing interoperability, competition, and innovation in the health IT ecosystem. In FY 2023, ONC will continue to coordinate with stakeholders to develop health IT standards that advance interoperability in less mature areas. This includes leading and working with industry and partners around patient generated health data used by clinicians and researchers and innovative approaches/tools to capturing and integrating data from remote monitoring devices and wearables in EHR systems. It also includes, where applicable, the administration of prize competitions and other industry spotlight engagements to advance novel approaches, standards, and technologies.

Agency-Wide Support

The FY 2023 budget request reflects the ONC's commitment to continue advancing progress toward national goals for widespread interoperability. The budget request includes an increase of \$1.3 million to support HHS's shared costs for shared services, physical and IT security, and legal support. The request also includes communications and engagement, and ONC management activities.

Communications and Engagement – In FY 2023, 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 2023, ONC will continue to implement and improve its existing strategic and operational management processes. ONC's FY 2023 budget request includes funding for the HHS's shared costs, 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

	Year and Most Recent Result /			
	Target for Recent Result /			FY 2023 Target +/-
Measure Group /	(Summary of	FY 2022	FY 2023	FY 2022
Measure Text Policy Development and Coordinatio	Result)	Target	Target	Target
Number of federal agencies actively participating in ONC-led health IT coordination efforts	FY 2021: 22 Target: Maintain Prior Year	Maintain 20+ active agencies	Maintain 20+ active agencies	
	(Baseline)			
Standards, Interoperability, and Cerr Number of certification criteria	tification FY 2021: 64	Maintain	Maintain	1
number of certification criteria and conditions of maintenance requirements included in the ONC Health IT Certification Program to	criterion in 2015 edition 18	Maintain	Maintain	
meet congressional requirements for interoperable health data	Target: Maintain (Target Met)			
Number of interoperability needs areas supported by standards and implementation specifications included in the annual Interoperability Standards Advisory (ISA) Reference Edition	FY 2021: 2021 reference edition ISA contained 185 (+5) standards and implementation specification ¹⁹ (Target Met)	Maintain ISA with necessary updates & Publish annual update by March 2022	Maintain ISA with necessary updates & Publish annual update by March 2023	
Agency Wide Support				•
Number of visitors to ONC's https://healthIT.gov websites to use health IT policy and technology assistance material	FY 2021: 2.5 million Target: Maintain prior year baseline of 1.5M (Target Exceeded)	Maintain	Maintain	

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

¹⁹ Includes 6 implementation specifications which are considered "profiles and models" and not traditional standards.

Contextual Measures

Measure Area: Provider capability in key domains of interoperable health information exchange.

These measures were selected to meet MACRA § 106(b) requirements that ONC evaluate nationwide progress to widespread health information interoperability.

	Office- based physicians	Non-federal acute care hospitals
• are electronically <u>sending or receiving</u> patient information with any providers outside their organization	42%	93%
• can electronically <u>find</u> patient health information from sources outside their health system	49%	75%
can easily <u>integrate</u> (e.g., without manual entry) health information received electronically into their EHR	29%	71%
 had necessary patient information electronically <u>available</u> from providers or sources outside their systems at the point of care 	47%	53%

Measure Area: Citizen's perspective on consumer access to their electronic health information

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

Nonrecurring Expenses Fund

Budget Summary

(Dollars in Millions)

	FY 2021 ²	FY 2022 ³	FY 2023 ⁴
Notification ¹	-	2.750	2.000

Authorizing Legislation:

AuthorizationSection 223 of Division G of the Consolidated Appropriations Act, 2008

Allocation MethodDirect 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 2023, ONC is planning to utilize \$2 million in NEF funding for Certified Health IT Product List (CHPL) enhancements. NEF funds will be used to upgrade the overall CHPL public user interface, as well as a planned public usage and usability analysis. These funds will also allow for the specific development, testing, and implementation of a CHPL reporting module for collecting, verifying, and reporting required information in support of establishing the new EHR Reporting Program as required by the Cures Act.

In FY 2022, ONC will received a total of \$2.750 million in NEF funding to build the Health IT Data Dashboard and the Tool for ISA Comment Transparency and Improved Workflow.

In FY 2019, ONC received \$7.0 million in NEF resources to support 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 Cures Act.

¹ Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on June 17, 2021.

² Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on October 22, 2020.

³Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planed use.

⁴ The NEF CJ indicates the amounts HHS intends to notify for in 2023; these amounts are planned estimates and subject to final approval

Supplementary Tables

Budget Authority by Object Class

(Dollars in Thousands)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Personnel compensation:				
Full-time permanent (11.1)	22,159	22,757	23,804	1,047
Other than full-time permanent (11.3)	494	507	531	23
Other personnel compensation (11.5)	1,240	1,273	1,332	59
Military personnel (11.7)	-	-	-	-
Special personnel services payments (11.8)	-	-	-	
Subtotal personnel compensation	23,893	24,538	25,667	1,128
Civilian benefits (12.1)	7,955	8,170	8,546	376
Military benefits (12.2)	-	-	-	-
Benefits to former personnel (13.0)	-	-	-	
Total Pay Costs	31,848	32,708	34,212	1,505
Travel and transportation of persons (21.0)	8	8	8	-
Transportation of things (22.0)	42	42	42	-
Rental payments to GSA (23.1)	1,890	1,890	1,890	-
Rental payments to Others (23.2)	-	-		-
Communication, utilities, and misc. charges (23.3)	20	20	20	-
Printing and reproduction (24.0)	3	3	3	-
Other Contractual Services:				
Advisory and assistance services (25.1)	-			-
Other services (25.2)	11,821	11,821	11,821	-
government accounts (25.3)	10,391	10,391	10,391	-
Operation and maintenance of facilities (25.4)	282	282	282	-
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	24,457	24,457	24,457	-
Supplies and materials (26.0)	213	213	213	-
Equipment (31.0)	-	-	-	-
Land and Structures (32.0)	-	-	-	-
Investments and Loans (33.0)	-	-	-	-
Grants, subsidies, and contributions (41.0)	5,590	4,989	44,732	39,743
Interest and dividends (43.0)	-	-	-	-
Refunds (44.0)	-		-	

Total Non-Pay Costs	5,803	5,202	44,945	39,743
Total Budget Authority by Object Class	62,108	62,367	103,614	41,248

Salaries and Expenses

(Dollars in Thousands)

			FY 2023	
	FY 2021		President's	FY 2023 +/-
	Final	FY 2022 CR	Budget	FY 2022
Personnel compensation:				
Full-time permanent (11.1)	22,159	22,757	23,804	1,047
Other than full-time permanent (11.3)	494	507	531	23
Other personnel compensation (11.5)	1,240	1,273	1,332	59
Military personnel (11.7)	-	_	-	-
Special personnel services payments (11.8)	-	_	-	-
Subtotal personnel compensation	23,893	24,538	25,667	1,129
Civilian benefits (12.1)	7,955	8,170	8,546	376
Military benefits (12.2)	-	_	-	-
Benefits to former personnel (13.0)	-	_	-	-
Total Pay Costs	31,848	32,708	34,212	1,505
Travel and transportation of persons (21.0)	8	8	8	-
Transportation of things (22.0)	42	42	42	-
Rental payments to GSA (23.1)	1,890	1,890	1,890	-
Rental payments to Others (23.2)	-	_	-	-
Communication, utilities, and misc. charges (23.3)	20	20	20	-
Printing and reproduction (24.0)	3	3	3	-
Other Contractual Services:				
Advisory and assistance services (25.1)	-	_	-	-
Other services (25.2)	11,821	11,821	11,821	-
Purchase of goods and services from				
government accounts (25.3)	10,391	10,391	10,391	-
Operation and maintenance of facilities (25.4)	282	282	282	-
Research and Development Contracts (25.5)	-	-	-	-
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	-	-	-	-
Subsistence and support of persons (25.8)		_	=	<u>-</u>
Subtotal Other Contractual Services	24,457	24,457	24,457	-
Supplies and materials (26.0)	213	213	213	-
Total Non-Pay Costs	213	213	213	-
Total Salary and Expense	56,518	57,378	58,882	1,505
Direct FTE	180	180	180	-

Detail of Full-Time Equivalent Employment (FTE)

	2021 Actual Civilian	2021 Actual Military	2021 Actual Total	2022 Est. Civilian	2022 Est. Military	2022 Est. Total	2023 Est. Civilian	2023 Est. Military	2023 Est. Total
Direct:	180	-	180	180	-	180	180	-	180
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	180	-	180	180	-	180	180	-	180
ONC FTE Total	180	_	180	180	_	180	180	_	180

Average GS Grade

	Grade:	Step:
FY 2019	13	7
FY 2020	13	9
FY 2021	13	6
FY 2022	13	6
FY 2023	13	6

Detail of Positions

	FY 2021 Final	FY 2022 Enacted	FY 2023 President's Budget
Executive level	-	-	-
Total - Exec. Level Salaries	-	-	-
ES	6	6	6
Total - ES Salary	1,287,181	1,321,935	1,382,744
GS-15	47	49	49
GS-14	49	53	53
GS-13	46	44	44
GS-12	15	16	16
GS-11	9	16	16
GS-10	-	-	-
GS-9	7	12	12
GS-8	-	-	-
GS-7	-	-	-
GS-6	-	-	-
GS-5	-	-	-
GS-4	1	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	174	190	190
Total - GS Salary	22,182,176	22,781,095	23,829,025
Average ES salary	214,530	220,322	230,457
Average GS grade	13-8	13-4	13-6
Average GS salary	127,474	119,900	125,416

Programs Proposed for Elimination

No programs are proposed for elimination.

Physicians' Comparability Allowance Worksheet

	PY 2021	$CY\ 2022^{20}$	BY 2023
	(Actual)	(Estimate)	(Estimate)
Number of Physicians Receiving PCAs	0	1	3
Number of Physicians with One-Year PCA Agreements	0	0	0
Number of Physicians with Multi-Year PCA Agreements	0	0	3
Average Annual PCA Physician Pay (without PCA payment).	\$0	\$159,028	\$159,028
Average Annual PCA Payment	\$0	\$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.

²⁰ FY 2022 data will be approved during the FY 2022 Budget cycle

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

The 21st Century Integrated Digital Experience Act (IDEA) was signed into law on Dec. 20, 2018. It 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 working 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. In FY 20, HHS Digital Communications Leaders began implementation of the Strategy in alignment with IDEA, beginning to align budgets to modernization requirements.

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,
- continue developing estimated costs and impact measures for achieving IDEA.

Over the next four 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

FY 2022 House Appropriations Committee, Labor/HHS/Education Subcommittee, H.Rept. 117-96

Accessibility of Online Telehealth Platforms: The Committee recognizes that the COVID–19 pandemic led to the increased use of online portals and web services for patients seeking information, scheduling, and accessing remote services. However, the Committee is concerned that many online platforms are not user-friendly, especially for less digitally literate communities, including seniors. The Committee urges the Secretary, working through ONC, to coordinate with the Agency for Healthcare Research & Quality (AHRQ), the Centers for Medicare & Medicaid Services (CMS), and Office for Civil Rights (OCR) on any Federal efforts that can be made to evaluate the accessibility of digital health platforms for Federally-supported providers, including any assessments of how seniors and persons with disabilities are included in the design and testing of the platforms. Further, the Committee directs the Secretary, working through ONC, AHRQ, CMS, and OCR, to establish best practices for healthcare providers to improve their online telehealth platforms for seniors, individuals with disabilities, and individuals with limited English proficiency. (Page 248-249, H. Rept. 117-96)

Public Health Data Utility: The Committee notes the COVID-19 pandemic has exposed serious gaps in our healthcare system and the challenges of responding to major public health threats. Real-time data is essential for responding to a pandemic and for improving public health outcomes broadly. The Committee acknowledges some States have advanced capacities to collect and share real-time data and effectively respond to public health threats through their Health Information Exchange (HIE). These States can lead the way by maximizing current capabilities and sharing across the Nation. The Committee encourages the Office of the National Coordinator, in coordination with the Assistant Secretary for Preparedness and Response, to coordinate with State based health data utilities to better plan and prepare for a public health threat. (Page 249, H. Rept. 117-96)

Recording Vaping in Electronic Health Records: The Committee understands that despite the prevalence of e-cigarette use among youths and the potential risk of serious side effects, consensus on how to screen adolescents for e-cigarette use is lacking. Providers may not ask about use of these devices, and electronic health records (EHRs) currently do not provide options for recording use of e-cigarettes, water pipes, and other types of smoking in consistent computable ways, potentially resulting in underreporting, and a dearth of data that can be used to understand long-term health outcomes. The Committee urges the Secretary, working through the Centers for Disease Control and Prevention, Food and Drug Administration, and ONC, to consider developing strategies to enhance accurate data collection and timely reporting of e-cigarette use, including consideration of the role of EHRs, as aligned with applicable clinical practice guidelines. (Page 249, H. Rept. 117-96)

Standards for Interoperability: The recommendation includes not less than \$5,000,000 to support Fast Healthcare Interoperability Resource standards-related activities needed to successfully achieve interoperability and information sharing for better health and health care. (**Page 249, H. Rept. 117-96**)

Action to Be Taken

ONC spent the additional \$2.0 million in funding provided in the FY 2021 bill to support HL7 FHIR standards-related activities. Specifically, funds supported an HL7 cooperative agreement, coordinating FHIR activities with information health exchanges (IHE) (including to support its future use for EMS providers); some funds supported federal FTE time/labor to coordinate public and private sector activities through the FHIR at Scale Taskforce (FAST), leading the Federal Health IT Coordinating Council to help scale the use of FHIR within other Federal agencies, and to lend additional support of Leading Edge Acceleration Projects (LEAP) in Health IT, especially those working to unite community providers and clinicians related to FHIR-based patient consent tools.

Proposed Law

1. Advisory Opinions for Information Blocking

Provide HHS the authority to create an advisory opinion process and issue advisory opinions for information blocking practices governed by section 3022 of the Public Health Service Act (PHSA), 42 USC 300jj-52. The opinion would advise the requester whether, in the Department's view, a specific practice would violate the information blocking statutory and regulatory provisions; it would be binding on the Department, such that the Department would be barred from taking enforcement action against the practice. In addition, provide ONC with the authority to collect and retain fees charged for issuance of such opinions, and to use such fees to offset the costs of the opinion process.