



DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2019

Office of the National Coordinator for Health Information Technology

> Justification of Estimates for Appropriations Committee

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LETTER FROM THE NATIONAL COORDINATOR

I am pleased to present the fiscal year (FY) 2019 Congressional Justification for the Office of the National Coordinator for Health Information Technology (ONC). This budget focuses on two key priorities: (1) the interoperability of health information, and (2) provider burden reduction through increased usability of health information technology (health IT). The secure transmission of health information is central to the U.S. Department of Health and Human Services's (HHS) core mission to enhance and protect the health and well-being of all Americans. Within the embedded landscape of large health care delivery networks as well as hundreds of thousands of small providers, ensuring the flow of information requires a technical, policy, and stakeholder engagement driven approach. In order to achieve this goal, achieve ONC's key priorities, and facilitate a competitive IT enabled marketplace, this budget prioritizes work in the areas of policy coordination and interoperability. In addition, we will engage our stakeholder community and develop policies that improve the usability of health IT. These priorities will allow ONC to support efficient clinical care and advance the health of the country.

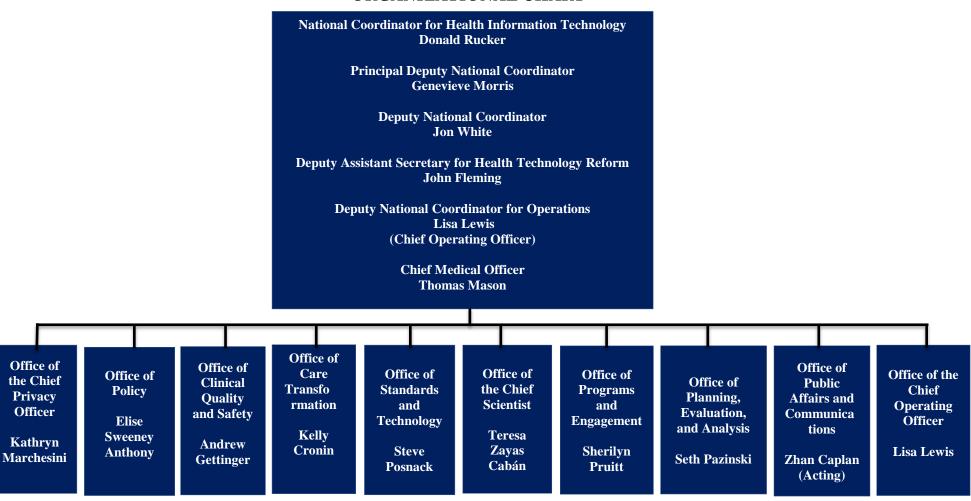
To date, ONC's policies have materially increased the use of health IT. Moreover, payment incentives authorized by Congress for electronic health record (EHR) adoption and use have resulted in 58 percent of office-based physicians (from 17 percent in 2008) and 84 percent of non-federal acute care hospitals (from 9 percent in 2008) using electronic health record technology as of 2015. Now that the healthcare system has a digital footprint, ONC's FY 2019 Budget Request targets increasing interoperability and addressing the provider burden while improving the usability of health IT.

ONC's focus in FY 2019 on the interoperability of health information and burden reduction are priorities in ONC's Budget Request and also in the legislatively mandated priorities in the 21st Century Cures Act (Cures Act). The Cures Act directs ONC to implement activities that advance interoperability through continued work to address information blocking and to advance health information exchange. A collective national goal of a more efficient healthcare system with manageable costs cannot be met without significant improvements in clinical data liquidity and administrative provider burden reduction. To facilitate this IT enabled market competition, ONC has built a two-part framework, consisting of (1) standards and (2) policies. The administrative infrastructure needed to deliver the complex messages surrounding these policies and standards is also critical. In FY 2019, ONC will coordinate federal efforts to ensure the reduction of regulatory and administrative burden related to the use of health IT, continue to improve the ONC Health IT Certification Program's efficiency and effectiveness, and advance ONC's work coordinating Health IT activities across the Federal Government.

In FY 2019, ONC will continue to efficiently lead the U.S. Government's efforts to ensure that electronic health information is available and can be securely and safely shared to improve the health and care of the American public. Thus, ONC's FY 2019 Budget Request ensures ONC promotes public and private sector efforts to foster a cultural change with the flow of health information, including addressing information blocking and promoting common standards, as well as reducing the burdens associated with health IT use. Taken together, this work is crucial to achieving the promise and power of health IT that serves the needs of the American people and the mission of HHS.

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

ORGANIZATIONAL CHART¹



¹ ONC is undergoing a reorganization which is planned to be completed in April 2018. The reorganization will gain organizational efficiencies by reducing the number of subordinate offices from ten to three and reallocating staff from across ONC to the Office of Policy and Office of Technology. The Office of the Chief Operating Officer continues to provide agency-wide services and support. This shift in FTE resources will allow ONC to more acutely focus on implementing the key provisions of the 21st Century Cures Act.

ORGANIZATIONAL CHART: TEXT VERSION²

National Coordinator for Health Information Technology

o Donald Rucker, M.D.

Principal Deputy National Coordinator

Genevieve Morris

Deputy Assistant Secretary for Health Technology Reform

o John Fleming, M.D.

Deputy National Coordinator

o Jon White, M.D.

Deputy National Coordinator for Operations

o Lisa Lewis

Chief Medical Officer

o Thomas Mason, M.D.

The following offices report directly to the Immediate Office of the National Coordinator:

- Office of the Chief Privacy Officer
 - o Kathryn Marchesini
- Office of Policy
 - o Elise Sweeney Anthony, J.D.
- Office of Clinical Quality and Safety
 - o Andrew Gettinger, M.D.
- Office of Care Transformation
 - o Kelly Cronin
- Office of Standards and Technology
 - o Steven Posnack, M.S., M.H.S.
- Office of the Chief Scientist
 - o Teresa Zayas Cabán, Ph.D.
- Office of Programs and Engagement
 - o Sherilyn Pruitt
- Office of Planning, Evaluation and Analysis
 - Seth Pazinski
- Office of Public Affairs and Communications
 - o Zhan Caplan (Acting)
- Office of The Chief Operating Officer
 - o Lisa Lewis

² ONC is undergoing a reorganization which is planned to be completed in April 2018. The reorganization will gain organizational efficiencies by reducing the number of subordinate offices from ten to three and reallocating staff from across ONC to the Office of Policy and Office of Technology. The Office of the Chief Operating Officer continues to provide agency-wide services and support. This shift in FTE resources will allow ONC to more acutely focus on implementing the key provisions of the 21st Century Cures Act.

EXECUTIVE SUMMARY

Introduction and Mission

Agency Overview

The Office of the National Coordinator for Health Information Technology (ONC), a staff division of the U.S. Department of Health and Human Services (HHS), is the lead agency charged with formulating the Federal Government's health information technology strategy and coordinating federal health IT policies, standards, and investments.

The 2016 enactment of the 21st Century Cures Act (the Cures Act) represented a pivotal point in ONC's history. Under the Cures Act, ONC is charged with improving the flow and exchange of electronic health information, advancing interoperability, prohibiting information blocking, and supporting patient access to their personal health information. Since ONC's inception through executive order in 2004 and codification in 2009 through the Health Information Technology for Economic and Clinical Health (HITECH) Act, ONC's mission has always been to improve the quality, safety, and efficiency of healthcare through interoperable health systems. The Cures Act strengthened this mission through its provisions that address the current state of health IT in the nation's healthcare system.

Prior to the Cures Act, ONC helped drive the rapid adoption of health IT and the digitization of the healthcare system. ONC was instrumental in leading the adoption by 2015 of at least basic electronic health record (EHR) technology by 58 percent of office-based physicians, an increase from 17 percent in 2008, and 84 percent of non-federal acute care hospitals, an increase from 9 percent in 2008. Building upon that success and expertise, the Cures Act directed the HHS Secretary to adopt standards and policies that increase health IT interoperability, privacy, and security; to enable and stimulate the trusted exchange of electronic health information when and where it is needed; and to encourage the development of more user-friendly technologies and solutions that support a broader range of healthcare delivery needs. As ONC continues to fully implement the Cures Act, there is a significant need of resources in order to execute specific requirements and policies regarding information blocking and nationwide measurement of EHR interoperability and usability.

Vision

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.

Mission

To help lower healthcare costs, empower consumer choice, and improve provider satisfaction, ONC will work to make health information more accessible, decrease the documentation burden, and support EHR usability.

Introduction

Achieving nationwide interoperability is a foundational pillar at ONC, and a major provision in the Cures Act. Interoperable health IT supports a healthcare system that promotes high-quality care and increases access by reducing costs, encouraging free market innovation, and stimulating consumer choice. A major key to interoperability is the ability for data to move freely. Data liquidity can lead to new and not yet anticipated market efficiencies and heightened competition in multiple inpatient and outpatient markets.

Rapid EHR adoption has stimulated demand for interoperability and the need for a growing range of health IT products and services. ONC is working towards meeting this demand by coordinating between the government and the private sector, advancing federally recognized standards, enhancing the certification program, and delivering key policy directives. ONC's work in standards and policies

provides extraordinary value to the country by providing entry points for market forces which can lower the cost of care and put patients back in control. ONC's multi-pronged approach is addressing the technical, policy, and stakeholder requirements necessary to achieving interoperability.

In addition to achieving greater interoperability, ONC is also committed to advancing the usability and development of health IT, while reducing provider burden. These burdens are felt by providers who are responsible for adhering to complex documentation and reporting requirements. ONC's clinical perspective provides a unique insight into addressing numerous policies impacting providers, and how those policies can reduce EHR-related burdens. Rulemaking that minimizes unintended consequences and unnecessary regulatory burden is time and labor intensive, as is the implementation of the rules. ONC will continue to work with stakeholders to identify where the burdens exist and support efforts across the federal government to consider how health IT can best be used to support the needs of health professionals and their patients for patient-centered and provider-focused care.

ONC's unique technical and policy expertise, leveraging of existing authorities, and strong relationships with the private sector make ONC pivotal and fundamental to achieving interoperability and enhancing the level of patient-centered and provider-focused health IT systems to ultimately provide the healthcare all Americans deserve.

Policy Development and Coordination

ONC develops and coordinates federal policies that are outlined in legislation such as the Cures Act, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), and the HITECH Act. The aforementioned legislation increased ONC's ability to foster innovative solutions that reduce provider burden and coordinate policies to encourage an interoperable learning health system. Specific activities include:

- *Health IT Policy*: As a part of implementing the Cures Act, ONC stood up a single Health IT Advisory Committee, which has aided in ONC's policy development, in early 2018. ONC also engages stakeholders through other methods, such as meetings and listening sessions, to continue to forge consensus-based solutions. As public and private value-based programs advance, providers and communities can benefit from health IT that supports interoperability and promotes patient access to their health information.
- *Health IT Usability and Burden Reduction*: ONC works to identify new tools and activities that will advance the usability and timeliness of health IT, clinical decision support (CDS), and quality measurement. ONC's unique expertise allows for new innovations to be fostered that reduces providers' data-related burdens, improve the care they provide, and ensure accurate performance measurement.
- Privacy of Health IT and Patient Access to Health Information: ONC, working closely with HHS's Office for Civil Rights (OCR), ensures that privacy and security standards are addressed in a consistent manner that reinforces the protection of private health information. A core element of an interoperable health system is patients' trust in the privacy and security of their health data.
- Strategic Planning: Under the HITECH Act, ONC is required to prepare the Federal Health IT
 Strategic Plan. As a reflection of collective efforts of federal entities, this plan advances personcentered care, fosters research, encourages innovation, and enhances the nation's health IT
 infrastructure.

Standards, Interoperability, and Certification

ONC leads a variety of efforts designed to accelerate nationwide progress towards an interoperable health IT infrastructure. By providing standards coordination and development, participating and encouraging pilot activities, and supporting industry-wide health IT testing, ONC helps to create innovative and interoperable health IT solutions. Specific activities include:

- Standards and Technology Coordination: In order to enable secure and interoperable health IT systems, ONC collaborates with industry to identify best practices and common approaches to implementing security technologies and techniques. ONC focuses on ways to accelerate consensus and, where necessary, convenes broad communities together for the purposes of identifying and developing additional standards guidance. ONC supports health IT development, implementation, and post-deployment use through investing in testing tools and resources that tackle specific interoperability challenges. ONC provides health IT developers with clear criteria for developing their products by issuing certification criteria for the ONC Health IT Certification Program. ONC administers the ONC Health IT Certification Program, which includes oversight of ONC-Authorized Certification Bodies (ONC-ACBs) and ONC-Authorized Testing Labs (ONC-ATLs) which, together, test and certify health IT products.
- *Scientific Innovation*: ONC develops and establishes scientific policy related to health IT. This fosters healthcare advancement by anticipating, identifying, and tracking innovation of health IT.

Agency Wide Support

ONC's agency-wide support team provides dynamic and flexible support to ONC's offices and programs through centralized services with responsibility for overall agency efficiency and effectiveness. Activities include: acquisitions and grants; budget formulation and performance management, execution and financial management; travel and conference management; human capital; program integrity; facilities management; monitoring and analysis of ONC's financial, human capital, and operational internal controls and data; ethics and freedom of information act; executive secretariat; and ONC's internal information technology deployment, systems planning and management; and maintaining ONC's statutorily required website, HealthIT.gov. Agency-wide support also provides resources for the shared services that are required by HHS for ONC to operate.

Overview of Budget Request

The FY 2019 Budget Request for ONC is \$38.4 million in Budget Authority. The FY 2019 Budget Request focuses on the interoperability of health information and provider burden reduction through increased usability of EHRs. The Budget prioritizes ONC's work supporting policy, rulemaking, standards implementation, and certification efforts to fulfill ONC's commitment to efficiently create a nationwide interoperable health system. With a landscape of large health care delivery networks and hundreds of thousands of small providers, achieving interoperability among various health IT systems requires ONC to focus on technical, policy, and stakeholder engagement. ONC's FY 2019 Budget emphasizes ONC's continued policy development and coordination work, while using ONC's Health IT Advisory Committee to inform ONC's policy and program development. ONC will also focus on preventing and reducing information blocking, and other policy and rulemaking activities required under the Cures Act, MACRA, and the HITECH Act.

In FY 2019, ONC will accelerate industry progress towards the interoperability of health information through its work on standards coordination, implementation, and testing. ONC will also continue to focus on the liquidity of health information. Improved data liquidity will improve patients' ability to be an active member of their care team and their ability to competitively shop for healthcare services. Data liquidity is not only key to enabling a truly competitive healthcare market, but it also supports HHS's goal of delivering person-centered care that marries human services and healthcare. ONC will help coordinate federal efforts to ensure the improvement of health IT usability. Efforts funded by ONC's FY 2019 Budget also include continued updates to HealthIT.gov and performance planning, evaluation, and monitoring activities required under the Cures Act, MACRA, and the HITECH Act.

The following activities demonstrate how ONC is working to create a safe, secure, and interoperable health IT infrastructure, in order to improve health and healthcare for all Americans:

Policy Development and Coordination

The FY 2019 Budget supports the development and coordination of federal policies that aim to combat information blocking and increase market competition to support an interoperable health system, and addresses burdens felt by providers. In FY 2019, ONC will move FY 2018 close-out costs for adoption and meaningful use programs to Standards, Interoperability, and Certification. This request supports ONC's continued work implementing the Cures Act. This includes funding to support the Health IT Advisory Committee, which informs ONC's policies and programs. In FY 2019, ONC will combat information blocking and advance other rulemaking activities as required under the Cures Act, MACRA, and the HITECH Act. This request also includes ongoing policy work to ensure consumers and healthcare providers are engaged and participated in the policy development and coordination process. As required by the HITECH Act, ONC will continue to formulate the Federal Health IT Strategic Plan, which reflects the collective efforts of multiple federal entities to appropriately send, receive, find, integrate, and use interoperable health information to improve healthcare, individual, community and public health, and advance research, all in collaboration with private industry.

Standards, Interoperability, and Certification

The FY 2019 Budget supports programs and efforts that underpin nationwide progress towards an interoperable and modern health IT infrastructure. In FY 2019, ONC will focus on supporting interoperability among health IT systems by establishing consensus with stakeholders around standards development activities and policies related to the Cures Act, MACRA, and the HITECH Act. To ensure proper implementation of the Cures Act, ONC will continue to administer and provide oversight to the ONC Health IT Certification Program; support modifications to the Certified Health IT Product List (CHPL); support testing tools to ensure products conform to the technical standards adopted for use as

part of the ONC Health IT Certification Program, FHIR standards, and other potential standards referenced in the Interoperability Standards Advisory; use the Health IT Advisory Committee to identify priority use cases for health IT; and further improve the implementation and ongoing evolution of application programming interfaces (APIs). In addition to the aforementioned provisions, ONC will conduct targeted research and analysis to assess interoperability progress throughout the health IT community.

Agency-Wide Support

ONC's agency-wide support team provides dynamic and flexible support to ONC's offices and programs through centralized services with responsibility for overall agency efficiency and effectiveness. In FY 2019, the Performance Management, and Engagement and Outreach activities will be moved to Agency-Wide Support. These funds continue to support the shared services required by HHS for ONC to operate, including financial and grants management systems, as well as contract management fees and costs related to ONC's space in HHS's Southwest Complex. ONC's Agency-Wide Support team provides expertise in the areas of acquisitions and grants; budget formulation and performance management, execution and financial management; travel and conference management; human capital; program integrity; facilities management; monitoring and analysis of ONC's financial, human capital, and operational internal controls and data; ethics and freedom of information act; executive secretariat; and ONC's internal information technology deployment, systems planning and management. Another key function of the Agency-Wide Support team is maintaining and updating HealthIT.gov with content related to ongoing FACA, interoperability, and rulemaking activities, including activities related to ONC's implementation of the Cures Act.

Overview of Performance

ONC's authorizing legislation and overarching mission are set forth in the HITECH Act, and its current priorities are defined in relation to MACRA and the Cures Act.

- Pub. L. No: 111-5 Title VIII, Health Information Technology for Economic and Clinical Health (HITECH) Act https://www.congress.gov/111/plaws/publ5/PLAW-111publ5.pdf
- Pub. L. No: 114-10, Medicare Access and CHIP Reauthorization Act (MACRA): https://www.healthit.gov/sites/default/files/fulfilling_section_106b1c_of_the_medicare_access_and_chip_reauthorization_act_of_2015_06.30.16.pdf
- Pub L. No: 114-255, 21st Century Cures Act, https://www.congress.gov/bill/114th-congress/house-bill/34

During FYs 2016 and 2017, ONC's efforts were built upon numerous, successful federal and private partnerships that made progress to the ONC mission outlined in the Federal Health IT Strategic Plan. These efforts also galvanized ONC towards achieving the national goal of widespread interoperable health information exchange by FY 2019. ONC's efforts specifically targeted making electronic health information more accessible, decreasing EHR related documentation burdens, and supporting EHR usability under the Cures Act and MACRA.

Below are examples of deliverables produced through ONC's efforts implemented in FY 2017. These accomplishments demonstrate the type of work undertaken by ONC with funding provided during the FYs 2016 and 2017 timeframe.

Deliverables and Accomplishments from FY 2017

Health IT Certification Program

- Enhanced Oversight and Accountability Final Rule was published
- Certified Health IT Product List (CHPL) was updated with corrective action plans for developers

Federal Rulemaking and Guidance

- Leading and supporting health IT components of HHS rulemaking efforts, including:
 - CMS rulemaking, including Long-Term Care Facility CoP Final Rule, 2017 Physician Fee Schedule Final Rule, Quality Payment Program, Outpatient Perspective Payment Systems Rule, Episode Payment Model Rule
 - o Substance Abuse and Mental Health Services Administration (SAMHSA) rulemaking, including SAMHSA Part 2 rule
- Guidance on policies related to health IT interoperability and usability
 - o 2017 Interoperability Standards Advisory published

Health IT Demonstrations

- Health IT Playbook was updated with sections related to EHR safety and patient portals
- Security Risk Assessment Tool was updated to reflect 2017 policies
- EHR Contract Guide with model contract terms was published
- Roadmap on state privacy policy was published in collaboration with National Governors Association
- Numerous pilots and challenge grants to spur private sector innovations were launched

Federal Coordination

- Interoperability standards measurement framework proposal was published with a comment period
- Policy framework for patient generated health data was published

In keeping with ONC's focus on achieving widespread interoperable exchange of health information, and in continuation of the strategy set in FY 2016 for meeting MACRA §106(b) requirements, the performance measures reported in this document focus on providers' capabilities for interoperable health information exchange, including sending, receiving, finding, and using a common clinical dataset. ONC also continues to monitor the consumer perspective with a measure following consumer access to any information from their EHR.

Measure: Provider capability in key domains of interoperable health information exchange (2015)³

	Provid Office- based physicians (2015)	er group Non-federal acute care hospitals (2016)
• are electronically sending or receiving patient information with any providers outside their organization	48%	89%
• can electronically find patient health information from sources outside their health system	34%	55%
• can easily integrate (e.g. without manual entry) health information received electronically into their EHR	31%	41%
 had necessary patient information electronically available from providers or sources outside their systems at the point of care 	36%	48%

Measure Group: Citizen's perspective on consumer access and attitudes⁴

• In 2016, 52 percent of Americans have been given electronic access to any part of their healthcare record by their healthcare provider or insurer.

⁴ 2016 estimates will be computed during fall 2017.

³ 2016 estimates will not be computable for physicians due to delays in the survey fielding process that occurred during 2016. At the President's Budget request level, funding for the two annual surveys used to create these measures may not be available.

Description of ONC's Performance Management Process

The performance management process at ONC crosscuts policy, standards, and agency-wide efforts. The process gives ONC and its stakeholders a framework to understand agency goals, monitor and discuss progress towards goal attainment, and make revisions to established plans when necessary.

ONC's process includes specific efforts related to: (1) priority setting, (2) measurement and analysis, (3) regular performance reviews, and (4) priority, strategic, and/or operational updates based on findings from performance reviews.

(1) Priority Setting

Priority setting in ONC is driven by a set of complementary processes related to (1.1) complying with specific legislative authorities and dated requirements; (1.2) conducting federal strategic planning; (1.3) establishing tactical and action plans; and (1.4) performance management and reporting. Alongside this process, ONC regularly receives and integrates requests from Congress, the Government Accountability Office (GAO), and the Office of the Inspector (OIG) into its priorities and plans for updates on ONC activities, or new or reformed efforts focused on emerging topics.

1.1 Complying with Specific Legislation Authorities, Requirements, and Requests ONC's authorizing legislation, the HITECH Act, outlines a number of responsibilities and authorities that ONC prioritizes significantly. The HITECH authorities and requirements establish the need for a portfolio of regulatory, convening, program management and coordination, and planning/research projects. Additionally, other legislation, such as annual appropriations, and more recently MACRA and the 21st Century Cures Act, regularly establish new requirements.

1.2 Conducting Federal Strategic Planning

Pursuant to HITECH Section 3001(c) (3) (A), ONC coordinates the development of a federal health IT strategic plan. The current plan covering 2015 – 2020 contains the following goals and can be accessed online at http://healthit.gov/strategic-plan/.

- Goal 1: Advance Person-Centered and Self-Managed Health
- Goal 2: Transform Health Care Delivery and Community Health
- Goal 3: Foster Research, Scientific Knowledge, and Innovation
- Goal 4: Enhance Nation's Health IT Infrastructure

ONC will be coordinating federal partners to update the strategic plan during the FY 2018 – 2019 timeframe. Additionally, pursuant to the 21st Century Cures Act Section 4001(a), during FYs 2017 and 2018, ONC is leading an HHS-wide effort to establish a goal, strategy, and recommendations for reducing regulatory and administrative burden relating to the use of EHRs.

1.3 Tactical and Action Planning

To implement multi-year strategic plans, ONC routinely translates vision, goal, and strategy documents into implementable tactical action plans that can be managed and monitored regularly. The following action plans have helped form the basis for ONC's current tactical orientation:

- Nationwide Interoperability Roadmap: http://www.healthit.gov/policy-researchers-implementers/interoperability; and,
- Roadmap for Patient Safety and Health IT: http://www.healthit.gov/buzz-blog/health-it-safety/roadmap-improving-health-safety/.

1.4 Performance Management and Reporting

ONC's multi-year strategic and action plans inform the development of performance plans that align organizational components, senior executives, initiative leads, and staff to shared priorities. ONC's annual organizational and National Coordinator's performance plans are formulated according to the Department's Senior Executive Service (SES) performance planning schedule, which is aligned to the fiscal year calendar. In practice, the method for establishing these plans involves a disciplined and detail-oriented series of conversations where the National Coordinator, ONC's executives, and subject matter experts define and align milestones that must occur in the upcoming fiscal year. Typically, the plan is organized according to ONC's roles in federal coordination, rulemaking, certification program management, and health IT demonstrations. An annual milestone plan and priority monitoring list is then established alongside development of the following fiscal year's operating budget.

Once the organizational and National Coordinator's performance plans are finalized, key information is cascaded into the performance plans of senior executives. Each ONC senior executive has a performance plan listing milestones they are responsible to oversee. SES plans also include critical elements related to on-going exhibition of core management and leadership competencies. After the National Coordinator and SES performance plans are in place, typically by December, the process to cascade align employee performance plans with expected milestones begins.

(2) Measurement and Analysis

Research, data analysis, and evaluation projects are routine throughout ONC, enabling its leaders to make informed decisions. The research, data analysis, and evaluation activities directly support the agency's needs to have the best administrative, program and external data available when and where they need it most.

Because of the relevance of ONC analyses to the federal policy and program administration decision-making processes, the agency makes many of its findings public. The findings are found throughout the federal advisory committee website https://www.healthit.gov/hitac/ and throughout the agency's websites at http://dashboard.healthit.gov/.

(3) Regular Performance Reviews

The regular review of performance information is commonplace at all levels of ONC using a number of management meetings, documents, and coordination mechanisms, including the following:

- Weekly Senior Leadership Management and Policy Meetings;
- Monthly Performance Planning and Risk Reviews;
- Quarterly Dashboards (reports) of Progress to Critical Milestones;
- Quarterly Office Reconciliation Meetings;
- Quarterly Leadership Risk Reviews;
- Semi-Annual Progress Reviews (e.g., portfolio analyses, mid-year SES and PMAP assessments);
- Annual Assessments of Progress to Goal (e.g., Organizational Assessment, end-of-year SES and PMAP assessments, Annual Performance Report); and,
- Multi-year, summative reviews (Congressional Health IT Adoption & Use Report, Health IT Strategic Plan Progress Reports).

(4) Priority, Strategic and/or Operational Updates Based on Findings from the Review
The processes for planning, reviewing progress, and re-establishing priorities is robust and continuous in an organization where change is expected. Through a culture of continuous quality improvement, a predictable set of senior leadership team meetings, crosscutting priority group meetings, and planning exercises, each ONC staff person has an important contribution to ensuring the most effective and efficient methods are used to achieve agency goals.

Outputs and Outcomes Tables

ONC's FY 2018 and 2019 budget performance measures follow nationwide trends in interoperable health information exchange capability and consumer access to the electronic health information maintained by their providers. The measures are based on nationally representative surveys and lag performance of the nation by six months to one year. As such, these measures are best understood as contextual indicators depicting the extent of progress towards nationwide health IT goals. The measures are not meant for depicting the marginal benefit/short-term return on investment for ONC activities. To an extent that the measures can be viewed as outcome measures reflecting on specific ONC activity, it is reasonable to believe that agency efforts undertaken during the 2014-15 timeframe bore impacts on the changes to national measures reported for 2016-17 timeframe.

For more information on the relationship of recent advancements in health IT adoption to HHS and ONC policy efforts, see "<u>HITECH Act Drove Large Gains In Hospital Electronic Health Record Adoption</u>" in the peer reviewed journal Health Affairs.⁵

Taken together, the measures shown in ONC's budget demonstrate the need for continued efforts and progress in order to achieve nationwide interoperability goals.

Performance Measures

Measure to Report against MACRA Section 106(b)(1)

	Most Recent Result / Target /	FY 2018	FY 2019	FY 2019 Target +/ FY 2018
Program/Measure	Summary	Target	Target	Target
Office-Based Professionals^				
1.E.11 Percent of office-based physicians who	FY 2015:	Not Set	Not Set	
can easily integrate (e.g. without manual entry)	31%			
health information received electronically into their EHR	(Baseline)			
1.E.14 Percent of office-based physicians who can electronically find (query) patient health	FY 2015: 34%	Not Set	Not Set	
information from sources outside their health	(Baseline)			
system	FY 2015:	Not Set	Not Set	
1.E.16 Percent of office-based physicians who had necessary patient information electronically	36%	Not Set	Not Set	
available from providers or sources outside their systems at the point of care	(Baseline)			

⁵ HITECH Act Drove Large Gains In Hospital Electronic Health Record Adoption in *Health Affairs*: http://content.healthaffairs.org/content/36/8/1416.abstract

Program/Measure	Most Recent Result / Target / Summary	FY 2018 Target	FY 2019 Target	FY 2019 Target +/ FY 2018 Target
1.E.17 Percent of office-based physicians who	FY 2015:	Not Set	Not Set	
are electronically sending or receiving patient	48%			
information with any providers outside their	(D. 11.)			
organization	(Baseline)			
Non-Federal Acute Care Hospitals^^	T	T		
1.E.12 Percent of non-federal acute care	FY 2016:	Not Set	Not Set	
hospitals that can easily integrate (e.g. without	41%			
manual entry) health information received				
electronically into their EHR	Target: 45%			
	(Target not			
	met but			
15125	improved)	N C	N. O.	
1.E.13 Percent of non-federal acute care	FY 2016:	Not Set	Not Set	
hospitals that can electronically find (query)	55%			
patient health information from sources outside	Towast Not			
their health system	Target: Not Set			
1.E.15 Percent of non-federal acute care	FY 2016:	Not Set	Not Set	
hospitals that had necessary patient information	48%	Not Set	Not Set	
electronically available from providers or	4070			
sources outside their systems at the point of care	Target: Not			
sources outside their systems at the point of care	Set			
1.E.18 Percent of non-federal acute care	FY 2016:	Not Set	Not Set	
hospitals that are electronically sending or	89%			
receiving patient information with any				
providers outside their organization	Target: Not Set			

Measures to Understand Consumer Access

Program/Measure	Most Recent Result / Target / Summary	FY 2018 Target	FY 2019 Target^^^^	FY 2019 Target +/ FY 2018 Target
1.F.1 Percent of Americans who have been given electronic access to any part of their health care record by their health care provider or insurer	FY 2016: 52% Target: 50%	Not Set	Not Set	

Data Sources & Notes:

Physician measures: National Electronic Health Records Survey (NEHRS), which is a
supplemental mail survey to the National Ambulatory Medical Care Survey (NAMCS). The
NERHS was formerly called the NAMCS EMR Supplement. ONC partially funds the supplement
through interagency agreements with the CDC National Center for Health Statistics, which fields

- the broader survey. Due to funding delays and constraints during FY 2016, 2016 estimates will not be available. FY 2017 estimates will be reported during the fall of 2018.
- Hospital measures: American Hospital Association (AHA) Information Technology (IT)
 Supplement to the AHA Annual Survey, which ONC partially funds through cooperative
 agreement.
- The Office of the National Coordinator for Health Information Technology's (ONC) Consumer Survey of Attitudes toward the Privacy and Security Aspects of Electronic Health Records and Health Information Exchange. The survey was conducted by NORC at the University of Chicago with MITRE in FY 2013 and 2014, however due to funding constraints, ONC did not field the survey in FY 2014, and so for FY 2015 no estimates will be available. In FY 2015, the survey questions were merged into the NIH-sponsored Health Information National Trends (HINTS) Survey. The next survey estimates will be available for FY 2016, which will be report during calendar year 2017.
- Targets are not set for the performance measures currently in ONC's Budget Request due to the effects of resource constraints on the underlying surveys and ONC's research team, which has shifted to support other aspects of the agency's agenda. Efforts are currently underway within ONC to revise the President's Budget measures away from the current survey-based measures to measures that better reflect the product and near term benefits of investments in ONC.

All Purpose Table (Dollars in Thousands)

Program	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 President's Budget +/- FY 2018 Annualized CR
Budget Authority	60,227	59,957	38,381	-21,576
Total, ONC	60,227	59,957	38,381	-21,576

BUDGET EXHIBITS

Appropriations Language

For expenses necessary for the Office of the National Coordinator for Health Information Technology, including grants, contracts, and cooperative agreements for the development and advancement of interoperable health information technology, \$38,381,000.

Language Analysis

Language Provision	Explanation
\$38,381,000	Provides ONC's budget from Budget Authority

Amounts Available for Obligation

	FY 2017	FY 2018	FY 2019
Detail	Final	Annualized CR	President's Budget
General Fund Discretionary Appropriation:			
Annual, B.A	60,367,000	60,367,000	38,381,000
Subtotal, Appropriation	60,367,000	60,367,000	38,381,000
Transfer of Funds to: "ACF"	140,000		
Across-the-board Reductions (L/HHS)		409,952	38,381,000
Subtotal, Adjusted Budget Authority	60,227,000	59,957,048	38,381,000
Total, Discretionary Appropriation	60,367,000	59,957,048	38,381,000
Total Obligations	60,227,000	59,957,048	38,381,000

Summary of Changes (Dollars in Thousands)

2018 Annualized CR						
Total estimated program level						59,957
2019 President's Budget						
Total estimated program level						
Net Change program level -21,576						
						FY 2019
FY 2018 Annualized					+/-	
		CR	FY	7 2019 PB		FY 2018
				Program		
	FTE	Program Level	FTE	Level	FTE	Program Level
Decreases:						
A. Program:						
1. Health IT	164	59,957	164	38,381	0	-21,576
Subtotal, Program Decreases	164	59,957	164	38,381	0	-21,576
Net Change	164	59,957	164	38,381	0	-21,576

Budget Authority by Activity (Dollars in Thousands)

Activity	FY 2017 Final FTE	FY 2017 Final	FY 2018 Annualized CR FTE	FY 2018 Annualized CR	FY 2019 President's Budget FTE	FY 2019 President's Budget
Health IT						
Annual Budget Authority	187	60,227	164	59,957	164	38,381
Total, Annual Budget Authority	187	60,227	164	59,957	164	38,381
Total, Program Level	187	60,227	164	59,957	164	38,381

Authorizing Legislation (Dollars in Thousands)

	2018	2018	2019	2019
Health Information Technology Activity:	Authorized	Amount Appropriated	<u>Authorized</u>	President's Budget
Title XXX of PHS Act as added by the HITECH Act (PL 111-5) and the Cures Act (PL 114-255)	Indefinite	-	Indefinite	-
Budget Authority	Indefinite	59,957	Indefinite	38,381
Total Request Level		59,957		38,381

Appropriations History (Dollars in Thousands)

Details		Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriations
	2010	ě			
Annual B.A.		\$42,331	\$0	\$42,331	\$42,331
PHS Evaluation Funds		\$19,011	\$61,342	\$19,011	\$19,011
Subtotal		\$61,342	\$61,342	\$61,342	\$61,342
	2011	1 - 7-	1 - 3-	1 - 7-	1 2 72
Annual B.A.		\$78,334	\$69,842	\$59,323	\$42,331
PHS Evaluation Funds		\$0	\$0	\$19,011	\$19,011
Rescissions (Secretary's)					(\$85)
Subtotal		\$78,334	\$69,842	\$78,334	\$61,257
	2012				
Annual B.A.		\$57,013	\$0	\$42,246	\$16,446
PHS Evaluation Funds		\$21,400	\$28,051	\$19,011	\$44,811
Rescissions (P.L. 112-74)					(\$31)
Subtotal		\$78,413	\$28,051	\$61,257	\$61,226
	2013				
Annual B.A.		\$26,246	\$16,415	\$16,415	\$16,415
PHS Evaluation Funds		\$40,011	\$44,811	\$49,842	\$44,811
Rescissions (P.L. 113-6)					(\$33)
Sequestration					(\$826)
Subtotal		\$66,257	\$61,226	\$66,257	\$60,367
	2014				
Annual B.A.		\$20,576		\$20,290	\$15,556
PHS Evaluation Funds		\$56,307		\$51,307	\$44,811
User Fee		\$1,000		\$1,000	\$0
Subtotal		\$77,883	\$0	\$72,597	\$60,367
	2015				
Annual B.A.		\$0	\$61,474	\$61,474	\$60,367
PHS Evaluation Funds		\$74,688			\$0
Subtotal		\$74,688	\$61,474	\$61,474	\$60,367
	2016				
Annual B.A.		\$0	\$60,367	\$60,367	\$60,367
PHS Evaluation Funds		\$91,800	\$0	\$0	\$0
Subtotal		\$91,800	\$60,367	\$60,367	\$60,367
	2017				
Annual B.A.		\$0	\$65,367	\$60,367	\$60,227
PHS Evaluation Funds		\$82,000	\$0	\$0	\$0
Subtotal		\$82,000	\$65,367	\$60,367	\$60,227
	2018				
Annual B.A.		\$38,381	\$38,381	\$60,367	\$59,957
PHS Evaluation Funds		\$0	\$0	\$0	\$0
Subtotal		\$38,381	\$38,381	\$60,367	\$59,957
	2019				
Annual B.A.		\$38,381			
PHS Evaluation Funds		\$0			
Subtotal		\$38,381			

NARRATIVE BY ACTIVITY

Health IT

Budget Summary

(Dollars in Thousands)

Health IT	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 +/- FY 2018
Budget Authority	60,227	59,957	38,381	-21,576
Total, Program Level	60,227	59,957	38,381	-21,576
FTE	187	164	164	-

Authorizing Legislation:

Program Description and Accomplishments

A health IT system that allows clinical data to move freely and reduces provider burden is key to achieving a more efficient healthcare system with reduced costs. The nearly unanimously enacted Cures Act provided ONC with powerful tools to encourage market competition and personal electronic ownership of data, and to combat information blocking. In order to achieve an efficient healthcare system with manageable costs, significant improvements in clinical data liquidity and administrative provider burden reduction must be made. To facilitate this IT enabled market competition, ONC has built a two-part framework, consisting of: (1) Policy and (2) Standards. An administrative infrastructure is also crucial to ensuring the complex messages surrounding these policies and standards are delivered adequately.

ONC continues to support the development and coordination of federal policies and rulemaking activities, which promote interoperability and reduce provider burden. ONC also supports interoperability among health IT infrastructures, by working to develop consensus around standards development activities and policies. ONC uses its statutorily required website, HealthIT.gov, as a key method of engaging stakeholders, educating and disseminating nationwide best practices and solutions to common challenges that providers and consumers face related to adoption and use of health IT. ONC's unique technical and policy expertise and strong relationships with the private sector make ONC pivotal to achieving interoperability and enhancing the level of patient-centered and provider-focused health IT systems, ultimately providing the healthcare all Americans deserve.

Policy Development and Coordination

ONC coordinates federal policies and strategies to build the necessary data and technology foundation for an interoperable learning health system that can support a wide variety of national priorities and assure that data can be securely captured, and shared with, and used by, the right people at the right time. This will advance a patient-centered health care system which focuses on promoting quality care, while

increasing accessibility and affordability, augmenting innovation, and empowering patients. Achieving interoperability will lead to informed consumers who have a choice in their healthcare.

Within the embedded landscape of large insular health care delivery networks, and a vast number of smaller providers, achieving interoperability requires a technical, policy, and stakeholder engagement driven approach. In collaboration with federal partners and by engaging with a broad range of health IT stakeholders, ONC sets the direction of federal health IT policy, seeking to achieve interoperability and providing a policy framework to address emerging health IT issues regarding the use and exchange of electronic health information. This policy framework inspires trust and confidence in health IT by integrating privacy, security, and clinical best practices into every phase of health IT policy development and implementation. ONC's health IT policies enable care transformation through improved care coordination, increased patient engagement, and enhanced population health management.

ONC identifies emerging issues, and gaps in existing policies; formulates solutions; and provides guidance to federal agencies and stakeholders so that individuals, care providers, and public health workers can get the health information they need in an electronic format when and how they need it. By integrating a clinical perspective into its policy development and coordination activities, ONC helps foster innovative solutions to reduce health IT-related burdens on providers. These federal health IT policies support interoperability, health IT usability, and support tools like quality measures that help providers manage the vast array of information needed to deliver the safest and best care possible.

ONC develops and coordinates federal health IT policy to achieve national priorities set forth by the Administration and the HHS Secretary in accordance with statutory requirements under the Cures Act, MACRA, and the HITECH Act, among other laws. MACRA, and specifically the Quality Payment Program, provides new tools and resources to support providers as they transition to value-based reimbursement and methods of delivering care. As public and private value-based programs advance, providers and communities can benefit from health IT that supports interoperability, and promotes patient access to their health information.

Stakeholder Coordination and Support

ONC guides the achievement of goals and objectives outlined in the Federal Health IT Strategic Plan 2015-2020 through ongoing collaboration with federal partners, states, and engagement of stakeholders. ONC monitors the progress of and aligns federal activities with national priorities, goals, and objectives. Accomplishments include:

- As required by the Cures Act, ONC is transitioning its current Health IT Policy and Health IT Standards Federal Advisory Committees—established by the HITECH Act—to a single Health IT Advisory Committee. The stakeholder input received from these two sunsetted committees played a critical role in ONC's policy development. The committees also helped ONC better understand the needs of patients and providers, develop pilots, studies, and other programs, and advance standards, implementation specifications, and certification criteria that support interoperability. ONC expects the new committee, whose inaugural meeting occurred in January 2018, will play a similar role in advising ONC's work.
- ONC finalized implementation of the "ONC Health IT Certification: Enhanced Oversight and Accountability" final rule which further enhances the safety, reliability, transparency, and accountability of certified health IT for users. This rule furthers ONC's ability to address and correct non-conformities found in certified health IT products that cause or contribute to serious risks to public health or safety. Additionally, the rule empowers health IT consumers to make more informed choices by making more information available about how an individual certified health IT product performs in the field.
- ONC implemented the 2015 Edition Certification Rule which builds on past certification rules and is designed to support innovation and the establishment of a nationwide interoperable health

information infrastructure. To support stakeholder implementation of the final rule, ONC issued certification, surveillance, and transparency guidance and education materials, including the creation of a website that compiles certified health IT product information to provide more transparency to users regarding what a product does or does not do.

Interoperability of Health Information Exchange

ONC is working with stakeholders, health information organizations, service providers, and other entities to ensure trust among participants, as well as interoperability across networks, so that health information can follow a patient regardless of where and when they access care. For example, ONC enabled a web-based public comment mechanism for stakeholders to inform ONC's work on critical elements of health information exchange that could advance patient care and will inform ONC's work to implement provisions in Section 4003 of the Cures Act related to the establishment of a national trusted exchange framework and the development or support of a common agreement.

Health IT Usability and Burden Reduction

ONC provides leadership and coordinates activities with key stakeholders to advance the availability, usability, and timeliness of health information, clinical decision support (CDS), and quality measurement. In accordance with Section 4001 of the Cures Act, ONC will continue to identify usability challenges that impede providers from efficiently providing care. Ensuring providers have adequate resources and improving the usability of health information technology will help improve direct care to patients and reduce provider burden.

Automated measurement tools, such as electronically specified clinical quality measures (eCQMs) and clinical data registries that automate data abstraction from EHRs, allow for timely performance feedback and patient outcomes monitoring, while reducing providers' data-related burdens. CDS brings clinical best practices to the point of care, converting data to knowledge in user-friendly, actionable electronic forms. CDS helps clinicians better manage the vast array of information needed to deliver the safest and best care possible, especially to those with multiple, chronic or rare conditions. CDS helps providers by ensuring they have the most up-to-date and clinically relevant information to identify the best course(s) of treatment, and promoting discussion of those options with the patient. There is significant potential for this support to improve our state of preparedness for response to emergent public health threats, such as infectious-disease outbreaks or environmental emergencies. Accomplishments include:

- Developed an electronically specified measure of patient safety, which addresses meaningful issues to
 patients and providers, without adding to their data burden by ensuring that the measure relies on data
 already generated during care. This measure, and the results of its feasibility testing for use within
 patient settings, will be available in the first half of 2018.
- Developed and tested a usability-improvement toolkit for hospital and provider practice IT and performance improvement teams. The toolkit is designed to help small, rural, and other hospitals and practices without access to specialized usability expert resources. The toolkit will help provider IT and performance improvement teams determine how to make their systems work better and pose fewer usability challenges for their providers, patients, and other care team members. The toolkit will be available in the first half of 2018.

Privacy of Health IT and Patient Access to Health Information

Patient trust in the privacy and security of health data is a core requirement of an interoperable health system. ONC ensures this requirement is met by advising on health information privacy, security, and data stewardship policies. Key components of the work involve working with the HHS Office for Civil Rights (OCR), in order to demonstrate how the Health Insurance Portability and Accountability Act (HIPAA) and other privacy laws and regulations support, rather than impede, information flow in an electronic environment. ONC also develops and supports approaches that ensure information is shared electronically and is kept secure. Accomplishments include:

- In accordance with the access provisions of Section 4006 of the Cures Act, worked with OCR to develop education materials and guidance for providers and policymakers on how HIPAA enables data sharing.
- Updated the Model Privacy Notice (MPN) and launched the Privacy Policy Snapshot Challenge. The MPN is a voluntary, openly available resource designed to help developers clearly convey information about their privacy and security policies to their users. The Privacy Policy Snapshot Challenge leveraged updated MPN content, with feedback from OCR, the Federal Trade Commission, and other private and public stakeholders that identify certain areas that should be highlighted for the consumer.

Strategic Planning

ONC develops the Federal Health IT Strategic Plan. This Plan reflects the collective efforts of federal entities to advance person-centered health and self-management; transform health care delivery and community health; foster research, scientific knowledge, and innovation; and enhance the nation's health IT infrastructure. Accomplishments include:

- Published The Federal Health IT Strategic Plan 2015 2020, representing the collaborative efforts across the Federal Government, with more than 35 federal entities contributing to its development. In 2017, ONC convened the Federal Health IT Coordinating Council, an internal federal body with the mission of coordinating federal health IT policy decisions and creating a forum to discuss program alignments for existing and emerging health and health IT matters. The 2017 task of this body was to coordinate and prioritize implementation accountabilities to advance interoperability and the health IT provisions in the Cures Act.
- In 2016, in accordance with MACRA, established metrics to determine if, and the extent to which, Congress's national objective to achieve widespread exchange of health information through interoperable certified EHR technology nationwide by December 31, 2018, is accomplished.

Standards, Interoperability, and Certification

ONC makes strategic investments in standards coordination, implementation, testing, and pilots, to accelerate industry progress in specific areas that require interoperability. This work focuses on interoperability improvements related to care coordination, medication management, patient engagement, clinical research, privacy and security, and population health.

Through the ONC Health IT Certification Program, ONC outlines processes for health IT developers to demonstrate how their health IT conforms to specific certification criteria and standards. ONC supports the creation and publication of "certification companion guides" and test procedures under the Certification Program. In collaboration with the National Institute of Standards and Technology (NIST) and health IT stakeholders, ONC leads the development of the electronic testing tools and test procedures that are used to test health IT products to specific certification criteria. ONC strives to maintain an innovative health IT environment by continuing to support entrepreneurs and health technology developers as they seek to improve the accessibility and usability of health information. These initiatives work together to advance the national health IT infrastructure and improve the health and well-being of the nation.

Standards and Technology Coordination

ONC will continue to play a key role as a leader and convener of the health IT community through structured coordination and collaboration. In order to continue to improve interoperability, it is necessary for the health IT ecosystem to reduce variability and consistently implement common standards that enable specific functionalities that are relevant to the end user. Moreover, ONC collaborates with industry to identify best practices and common approaches to implementing security technologies and techniques in order to enable secure, interoperable health IT systems. ONC focuses on ways to accelerate consensus

and, where necessary, convenes broad communities together for the purposes of identifying and developing additional standards guidance. Accomplishments include:

- Published the <u>Interoperability Standards Advisory</u> via an online platform that provides a detailed list
 of the standards and implementation specifications that can be used to address various interoperability
 needs.
- Awarded a cooperative agreement in collaboration with a standards development organization to support the acceleration and development of new technology specifications for application programming interfaces (APIs).
- Supported and participated in public-private partnerships that advance technology interests consistent with the Cures Act.
- Collaborated with OCR and health IT stakeholders to identify and provide technical security information and guidance associated with implementing APIs and other health IT capabilities.
- Supported the Interoperability Proving Ground (IPG), which is an open community platform where users can share, learn, and be inspired by interoperability projects occurring in the United States (and around the world). The IPG currently has over 200 entries of on-the-ground efforts that advance the interoperable exchange of health information. Entries have been submitted by stakeholders across the health IT industry such as developers, health information exchanges (HIEs), standards developing organizations (SDOs), and health insurers.

Certification

The ONC Health IT Certification Program provides comprehensive and independent mechanisms for health IT to be evaluated for conformance to standards and functional requirements adopted in regulation. ONC also maintains the <u>Certified Health IT Product List</u> (CHPL), a publicly available list on ONC's website of all health IT products certified through the ONC Health IT Certification Program. The CHPL generates a CMS EHR ID number that is representative of the Certified Electronic Health Record Technology (CEHRT) used to participate in several CMS payment programs. Accomplishments include:

- ONC, in collaboration with NIST, completed development of, and deployed, the 2015 Edition Test
 Method for the adopted 2015 Edition certification criteria, which includes test procedures, test data,
 and test tools for use by Accredited Testing Labs (ATLs). The 2015 Edition adheres to more rigorous
 conformance criteria than were used for prior editions and includes more electronic and automated
 testing tools.
- Supported the ongoing maintenance of <u>Certification Companion Guides (CCG)</u> to help health IT developers quickly understand and interpret ONC's regulatory requirements so they may focus on product development. A CCG has been developed for each certification criterion and will serve as the single, consolidated information source for any clarifications related to a certification criterion.
- Revised the CHPL website to align with the 2015 Edition final rule's additional data needs and offered
 new ways to view product details in order to support greater transparency and open data accessibility.
 The new CHPL website includes additional functionality, such as advance search, product compare, and
 API methods to enable stakeholders the ability to openly access and combine CHPL data with their
 datasets.
- Approved private sector developed testing methods for use as alternatives to the government-developed test methods in the ONC Health IT Certification Program.

Public-Private Testing

To reach nationwide interoperability, ONC continues to invest in priority testing tools and resources that support health IT development, implementation, post-implementation, and use. ONC provides an open testing environment that allows health IT developers and the provider community to verify that their systems have implemented interoperability standards in a consistent manner. Each ONC-led activity tackles a critical interoperability challenge through processes that recognize and consider the clinical uses

in scope, identification, and harmonization of existing technical specifications, implementation guidance, pilot projects, and mechanisms for feedback to evaluate effectiveness. Accomplishments include:

- <u>Standards Implementation and Testing Environment</u> (SITE) provides conformance testing and validation tools for certain health IT functionality, in support of the ONC Health IT Certification Program. SITE facilitates resolution of standards implementation issues by working closely with the standards community and IT developers. SITE also provides an established venue to disseminate identified solutions to a broad community of health IT developers and users.
- Created a Consolidated Clinical Document Architecture (C-CDA) scorecard ("<u>C-CDA Scorecard</u>") to give both health IT developers and providers the ability to benchmark system performance.
- Created the "One Click Scorecard" which enables health care providers to test the performance of their health IT (relative to direct transactions and the C-CDA) as it's deployed in real world settings.

Health IT Infrastructure and Innovation

ONC leads efforts designed to encourage a vibrant health IT marketplace, where systems are interoperable and stakeholders have the ability to obtain "best-of-breed" solutions from among a number of choices. ONC works to encourage the development of innovative solutions to health IT challenges, and also to find ways to better support the innovation community. ONC encourages innovation in health IT by coordinating vendors, startups, the venture capital community, incubators, providers, and researchers that are at the leading edge of health IT. Accomplishments include:

- Supported a market transparency project that helped health care stakeholders more easily identify the costs associated with health IT interoperability services.
- Hosted publicly available webinars on various health IT topics to showcase interoperability in action and inform a broader stakeholder base about interoperability and innovation activities.

Scientific Innovation

ONC makes critical advancements in interoperability in the service of biomedical and health services research. ONC continues to foster healthcare advancement by anticipating, identifying, and fostering innovation of health IT. In particular, ONC plays a vital role in the Precision Medicine Initiative (PMI) and is spearheading relevant patient-centered outcomes research (PCOR) projects. Accomplishments include:

- Completed the technical development for the Sync for Science (S4S) project, conducted with the National Institutes of Health (NIH). Following S4S integration with NIH's All of Us Research Program (AoURP) application programing interface (API), participants at pilot sites will be able to utilize the API to share their electronic health data with the AoURP. Pilot testing is planned to begin early 2018.
- Concluded the S4S Privacy and Security project (S4SPS), in which several S4S EHR developers and health care provider organizations agreed to participate. Independent testing and assessment results were shared with participants to address any potential privacy and security issues uncovered during testing. Aggregate testing results and key findings were shared with NIH and OCR.
- The first phase of the Sync for Genes project, established to facilitate clinical genomics at the point of care, and in research studies such as the NIH AoURP, concluded in June 2017. In Phase 1, five pilots focused on testing the HL®FHIR® Clinical Genomics standard utilizing use cases that were identified as priority focus areas to support the AoURP. The pilot participants provided feedback which was relayed back to the HL7 Clinical Genomics Work Group. The pilot process, feedback, lessons learned, and recommendations for next steps, are available in the final report, which was released in the Fall of 2017.
- ONC's ongoing PCOR projects continued to address interoperability challenges. In 2017, ONC
 executed prize challenges focusing on patient matching, health data provenance, and Block chain, and
 funded the development of implementation guides to expand the ability of users to create value out of
 their data. Additionally, ONC partnered with stakeholders on pilot tests and demonstrations to field

- test resources developed across the PCOR projects, focusing on topics such as patient-generated health data and structured data capture.
- Completed a patient matching algorithm challenge and launched security challenges, including a data provenance challenge and secure API server challenge.

Agency-Wide Support

ONC launched a number of crosscutting efforts to ensure ONC's management is enhanced, customer service is improved, programs are efficiently supported, grantee and contractor performance is optimized, a world-class workforce continues to be developed, and budget processes and operational services are enhanced. Development is collaborative in nature, and ONC continues to increase efficiency in its program support partnership activities. These cost effective efforts ensure that ONC is exemplifying care of public resources, in order to advance a health care system centered on the patient, and focusing on promoting quality care, increasing accessibility, bolstering innovation, and empowering patients.

Procurement and Grants Management

ONC enhanced its grants management and procurement efforts, implementing best practices to optimize grantee and contractor performance. Using a risk-based financial monitoring framework for grants and contracts, ONC fosters program success and financial accountability. ONC has built a strong monitoring, analysis, and data management capability, and manages nimble procurement and grants training programs to ensure proper stewardship of federal funds.

Enterprise Risk Management

ONC carries out financial and programmatic oversight responsibilities, employing a robust internal review methodology to achieve high-impact results and fostering data-driven and risk-based decision making. ONC enhanced its operational reporting and data management capabilities, and established an Enterprise Risk Management framework within ONC. In addition, ONC improved its ethics, audit liaison, and executive secretariat processes.

Human Capital

ONC's human capital experts provide leadership, oversight, and guidance to ONC in hiring and maintaining a talented workforce. ONC optimizes its strong and high-performing organization through strategic workforce planning and innovative recruitment and retention strategies, including those for students and Veterans and through enhanced professional development opportunities.

Budget, Performance Management and Operational Services

ONC's Budget, Performance Management, and Operational Services functions include budget formulation and execution and space and facilities management, along with the crosscutting policy, technical, and program management efforts which provide different levels of ONC staff with clear and common agency-wide goals. ONC initiated improvements in its annual budget processes and budget/performance integration. In addition, ONC continues to strengthen management controls over its financial processes. ONC's telecommunications and technical infrastructure initiatives have yielded cost savings and improved value. These initiatives include ONC's space consolidation efforts within the HHS Southwest Complex, and improvements in ONC's internal information technology deployment strategies.

Stakeholder Engagement

ONC's statutorily required website, HealthIT.gov, is a key method of educating and disseminating, nationwide, best practices and solutions to common challenges that providers and consumers face with respect to the adoption and use of health IT. ONC's website is updated with ongoing federal advisory committee, interoperability, and rulemaking activities.

Funding History

Health IT			
Fiscal Year	Amount		
FY 2015	60,367,000		
FY 2016	60,367,000		
FY 2017	60,367,000		
FY 2018 Annualized CR	59,957,048		
FY 2019 President's Budget	38,381,000		

Budget Request

Health IT

ONC requests \$38.4 million in FY 2019 to support activities related to policy development and coordination, standards and technology, and scientific innovation, a decrease of \$21.6 million below the FY 2018 Annualized CR. This request includes funding for 164 FTEs. These funds will continue to support ONC's mission of achieving a health IT system that allows clinical data to move freely and reduces provider burden in order to achieve a more efficient healthcare system with reduced costs. ONC continues to support the development and coordination of federal policies, rulemaking and activities, and interoperability among health IT infrastructures which promote interoperability and reduce provider burden.

Policy Development and Coordination

The FY 2019 Budget reflects a continued commitment to improving care for the nation by enabling a secure, interoperable health system that reduces burden and improves patient access. ONC will continue to combat information blocking by prioritizing the policy and rulemaking activities that are included in the Cures Act, MACRA, and the HITECH Act. ONC will continue to use the Health IT Advisory Committee to inform ONC's policies and programs. ONC will continue to support privacy and patient safety by developing rules and policies that enhance the safety, reliability, transparency, and accountability of certified health IT. In FY 2019, ONC will also revise the Federal Health IT Strategic Plan. These specific policy priorities will allow ONC to be a more lean and effective organization, while still striving to achieve widespread interoperability and usability of health IT.

ONC's budget request supports continued health IT efforts required under the HITECH Act, MACRA, and the Cures Act to meet the needs of providers, patients, and researchers who rely on health IT, as well as work with stakeholders and policymakers at the federal, state, and provider level to propel the safe and secure movement of health information in order to ensure that care teams have the right information when and where it is needed.

Stakeholder Coordination and Support

Funding will support ONC's continuous operation of the Health IT Advisory Committee, which is required in the Cures Act. This committee will play a critical role in ONC's policy development and the advancement of standards, implementation specifications, and certification criteria to support interoperability across the care continuum. Through these efforts, ONC is able to work directly with relevant stakeholder groups to more quickly understand where improvements to interoperability could be made and determine where more focused industry coordination is necessary.

In FY 2019, ONC will work to support implementation of the recommendations included in the planned report to Congress, as required by Section 4001 of the Cures Act (to be released in 2019), addressing strategies and recommendations with respect to the reduction of regulatory or administrative burdens relating to the use of electronic health records. ONC will continue its engagement with Congress, federal

partners, and other stakeholders to implement the strategies and recommendations outlined in legislatively required reporting.

Interoperability of Health Information

Section 4003 of the Cures Act directs ONC to develop or support a trusted exchange framework, including a common agreement among health information networks nationally. In FYs 2017 and 2018, ONC engaged, and continues to engage, with stakeholders to receive comment and feedback on a trusted exchange framework and common agreement related to health information exchange. The framework and common agreement will help (1) advance health information exchange, (2) advance the interoperable flow of health information across disparate networks, and (3) create supportive principles related to enabling trusted exchange nationally. In FY 2019, ONC will focus on the implementation of the framework and common agreement completed in FY 2018, including working with the private sector and identifying technical needs to support interoperable exchange across disparate networks.

In accordance with Section 4004 of the Cures Act, ONC will continue to address and discourage information blocking by finalizing and aggressively implementing ONC Certification Program rules, creating and promoting clear channels for reporting information blocking, and providing technical assistance to the HHS Office of Inspector General (OIG) and OCR on mechanisms for enforcing information blocking provisions, as directed by the Cures Act.

Health IT Usability and Burden Reduction

ONC will further its goal of enhancing the usability of health IT to decrease documentation burden, and support new business models and software applications that promote intuitive and functional health IT tools for patients and clinicians. In accordance with Section 4001 of the Cures Act, ONC is required to engage with stakeholders including other federal partners to develop a goal, strategy, and recommendations to leverage health IT to reduce provider, administrative, and regulatory burden. In FY 2019, ONC will implement strategies and recommendations related to burden reduction, as presented to Congress pursuant to Section 4001 of the Cures Act. As described in the Cures Act, these will include activities related to health information technology certification; standards; patient access; simplifying quality measurement; and aligning data requirements across federal programs and other payers. Consistent with Section 4001 of the Cures Act, ONC anticipates recommendations will address actions that help clinicians improve patient care quality and safety, such as by ensuring that complete and accurate information on each person's current medications, medical conditions, and any allergies, is available whenever and wherever that person needs care.

ONC will continue to work with CMS on the implementation of MACRA provisions associated with the Quality Payment Program. Specifically, ONC will work with CMS to engage with stakeholders, and to develop and implement policies supporting provider participation in the CMS Quality Payment Program and alternate payment models established under MACRA. This will ensure health IT serves as a tool to reduce physician administrative reporting burden and administrative burden associated with chart abstraction, while trimming the waste of misaligned reporting requirements across programs and incentivizing program participation that provides actionable feedback based on a health care organization's specialty and patient population.

Privacy of Health IT and Patient Access to and Control over Health Information

ONC will continue to work with OCR to address privacy and security concerns that may serve as a barrier to interoperability. ONC will address information blocking and enhance usability by continuing to clarify how HIPAA supports the exchange of electronic health information and consumer access to their health information. ONC will continue to assure that policies that address the protection of private and secure health information are in place. ONC will also work with OCR on efforts to clarify patients' rights to access and share health information. In accordance with Section 4006 of the Cures Act, ONC will provide

subject matter expertise on how HIPAA and health IT innovation support patient access rights, and work to resolve issues such as identity management that might impede health information exchange.

Strategic Planning

In FY 2019, ONC will update the Federal Health IT Strategic Plan: 2020-2024. The plan will provide a federal blueprint to further the goals of interoperability and reduction of provider burden across the federal landscape.

Standards, Interoperability, and Certification

The FY 2019 budget will support advancing nationwide interoperability and coordinating the technical activities needed to advance the standards and health IT certification requirements envisioned by the Cures Act. ONC will engage the public and private sectors to identify and fill gaps in the current health IT infrastructure. ONC will also coordinate standards development and enhancement, and ensure that the governance of our nation's health data supports equity, scalability, integrity and sustainability of information sharing for everyone in the United States. Achieving interoperability will lead to shoppers who have an informed choice in their healthcare.

Standards Coordination and Collaboration

In FY 2019, ONC's efforts will build upon recent accomplishments to make continued progress toward modernizing the nation's health IT infrastructure, in order to support transformative, interoperable learning health care. Further, ONC will continue to support collaborative initiatives to accomplish accelerated and coordinated standards work. Achieving interoperability requires a technical, policy, and stakeholder engagement driven approach. This funding and work is important for ONC, and for the many other HHS agencies that ONC has collaborated with in the past, including CMS, the Assistant Secretary for Planning and Evaluation (ASPE), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Agency for Healthcare Research and Quality (AHRQ),⁶ the Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD), the Department of Veterans Affairs (VA), and other federal agencies.

ONC will focus on coordinating the interoperability, standards, and certification requirements outlined in the Cures Act, and will continue to play a key role as a leader and convener of the health IT community. Additionally, ONC will focus on ways to accelerate consensus and, where necessary, convene broad communities together for the purposes of identifying and developing additional standards and implementation guidance. ONC will support advances in interoperability throughout the entire health IT community by conducting research and analysis, as well as maintaining the Interoperability Standards Advisory. Further, ONC will support Cures Act requirements in Section 4003 that require the Health IT Advisory Committee to identify priority use cases for health IT and the standards and implementation specifications available to support such use cases. Through this work, ONC seeks to ensure that technical developments are aligned with, and connected to, the business and regulatory drivers of health care and vice versa.

In FY 2019, ONC's standards coordination will include a focus on application programming interface (API) standards in order to improve the specificity, implementation, and use of APIs. This will include working with industry on clinical data standardization, as well as on the security standards necessary to enable patient- and provider-facing applications and services to innovate in a competitive marketplace. Similarly, staff will provide coordination and technical expertise within HHS associated with the development and implementation of policies focused on Section 4001 of Cures Act and provider burden reduction.

⁶ The FY 2018 Budget consolidates AHRQ's activities within the National Institutes of Health (NIH).

Certification

Funding will support the ongoing maintenance of standards conformance test tools, ONC Health IT Certification Program administration and oversight, and the ongoing support of the Certified Health IT Product List (CHPL), which provides detailed information on each certified product and open data access on each product. Resources will also be allocated to support new testing, certification, and surveillance requirements, and to the CHPL modifications that are necessary to implement the Cures Act. In coordination with NIST, ONC will maintain the testing tools necessary for certification and work with the industry to coordinate the development of test methods to ensure products conform to the technical standards. The program will continue its oversight responsibilities, and look to improve its overall surveillance of certified products for ongoing adherence to technical, security, and regulatory requirements for interoperability, as well as any potential for information blocking.

As part of Section 4002 of the Cures Act, the Secretary must establish and administer new "conditions of certification" requirements for health IT developers, in order to address a broad range of topics, including deterring unreasonable business practices that interfere with the exchange of health information or prevent providers from reporting or discussing issues with their technology; requiring real-world testing of certified technologies; and requiring the publication of APIs to promote interoperability of existing technologies and enable new and innovative solutions. In FY 2019, ONC will support a limited implementation of this provision through staff activities focused on:

- Developing and publishing regulatory, guidance, and educational materials; and
- Incorporating public input in the ongoing development of maintenance of certification health IT policies, through request(s) for public comment, convening federal advisory committee workgroup(s), and facilitating intra- and inter-agency meetings to develop policy priorities, options, and decisions (consistent with applicable law).

Public-Private Testing

ONC will continue to engage with industry through public-private partnerships to enhance existing interoperability testing tools and encourage greater industry-driven testing to advance nationwide interoperability. ONC will continue to support, through the <u>Standards Implementation and Testing Environment</u> (SITE), an open testing environment that allows health IT developers and the provider community to verify that their systems have implemented interoperability standards in a consistent manner.

Federal Health Architecture

The Federal Health Architecture (FHA) will sunset by the end of FY 2019. ONC will continue to serve as the program manager for FHA on behalf of HHS by continuing to provide staff support for the management and oversight of FHA while the projects close out. A select number of projects will continue to be transitioned throughout FY 2019 to be run by federal agencies such as the Department of Defense, or through public-private partnerships. ONC will continue coordinating with other federal agencies and Departments such as the Department of Veterans Affairs and the Department of Defense, through the Federal Health IT Coordinating Council.

Scientific Innovation

ONC is identified by the Cures Act as a leading agency for advancing interoperability to reduce barriers to scientific innovation. ONC's Chief Scientist partners with the NIH, FDA and others to implement scientific initiatives of national importance. In FY 2019, ONC will continue to coordinate with the public and private sectors to develop health IT policy and standards that advance interoperability in the service of biomedical and health services research.

Agency-Wide Support

In FY 2019, ONC will continue the cost reductions included in the FY 2018 President's Budget related to information technology, staff training, and agency travel. ONC will continue to seek further reductions in these costs through negotiations with ONC's HHS partners and service providers. The FY 2019 Budget also moves Performance Management, and Engagement and Outreach activities to Agency Wide Support. ONC's FY 2019 request continues to fund the shared services required by HHS for ONC to operate, including financial and grants management systems, as well as contract management fees and costs related to ONC's space in HHS's Southwest Complex.

SUPPORTING EXHIBITS

Budget Authority By Object Class - Program Level(Dollars in Thousands)

Object Class Code	Description	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 +/- FY 2018
11.1	Full-time permanent	18,532	17,899	17,984	-85
11.3	Other than full-time permanent	2,255	1,519	1,526	-7
11.5	Other personnel compensation	573	554	557	-3
11.7	Military personnel	318	322	329	-7
Subtotal	Personnel Compensation	21,678	20,294	20,396	-102
12.1	Civilian personnel benefits	6,600	5,161	5,186	-25
12.2	Military benefits	126	126	129	-3
13	Benefits for former personnel	0	0	0	0
Total	Pay Costs	28,404	25,581	25,710	-129
21	Travel and transportation of persons	382	191	191	0
22	Transportation of things	2	2	2	0
23.1	Rental payments to GSA	3,784	2,268	2,160	-108
23.3	Communications, utilities, and misc. charges Printing and reproduction	588 131	411 125	411	0
25.1	Advisory and assistance services	585	100	100	0
25.2	Other services from non-Federal sources	12,152	14,635	4,100	-10,535
25.3	Other goods and services from Federal sources	11,697	15,873	4,811	-11,062
25.4	Operation and maintenance of facilities	254	191	191	0
25.5	Research and development contracts	0	0	0	0
25.6	Medical care	45	0	0	0
25.7	Operation and maintenance of equipment	15	8	8	0
25.8	Subsistence and support of persons	536	268	268	0
Subtotal	Other Contractual Services	30,171	34,072	12,367	-21,705
26	Supplies and materials	275	192	192	0
31	Equipment	177	112	112	0
32	Land and Structures	0	0	0	0
41	Grants, subsidies, and contributions	1,200	0	0	0
42	Insurance claims and indemnities	0	0	0	0
44	Refunds	0	0	0	0
Total	Non-Pay Costs	1,652	304	304	0
Total	Total Budget Authority by Object Class	60,227	59,957	38,381	-21,576

Salary & Expenses (Dollars in Thousands)

Object Class Code	Description	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 +/- FY 2018
11.1	Full-time permanent	18,532	17,899	17,984	-85
11.3	Other than full-time permanent	2,255	1,519	1,526	-7
11.5	Other personnel compensation	573	554	557	-3
11.7	Military personnel	318	322	329	-7
Subtotal	Personnel Compensation	21,678	20,294	20,396	-102
12.1	Civilian personnel benefits	6,600	5,161	5,263	-102
12.2	Military benefits	126	126	129	-2
13	Benefits for former personnel	0	0	0	0
Total	Pay Costs	28,404	25,581	25,787	-206
21	Travel and transportation of persons	382	191	191	0
22	Transportation of things	2	2	2	0
23.3	Communications, utilities, and misc. charges	588	411	411	0
24	Printing and reproduction	131	125	125	0
25.1	Advisory and assistance services	585	100	100	0
25.2	Other services from non-Federal sources	12,152	14,635	4,100	-10,535
25.3	Other goods and services from Federal sources	11,697	15,873	4,811	-11,062
25.4	Operation and maintenance of facilities	254	191	191	0
25.5	Research and development contracts	0	0	0	0
25.6	Medical care	45	0	0	0
25.7	Operation and maintenance of equipment	15	8	8	0
25.8	Subsistence and support of persons	536	268	268	0
Subtotal	Other Contractual Services	26,387	31,804	10,207	-21,597
26	Supplies and materials	275	192	192	0
Subtotal	Non-Pay Costs	275	192	192	0
Total	Salary and Expenses	55,066	57,577	36,186	-21,391
23.1	Rental payments to GSA	3,784	2,268	2,160	-108
Total	Salaries, Expenses, and Rent	58,850	59,845	38,346	-21,499
Total	Direct FTE	187	164	164	0

Detail Of Full-Time Equivalent (FTE) Employment

Detail	FY 2017 Civilian	FY 2017 Military	FY 2017 Total	FY 2018 Civilian	FY 2018 Military	FY 2018 Total	FY 2019 Civilian	FY 2019 Military	FY 2019 Total
Direct	185	2	187	162	2	164	162	2	164
Reimbursable									
Total FTE	185	2	187	162	2	164	162	2	164

Average GS Grade

	Grade:	Step:
FY 2015	13	8
FY 2016	13	8
FY 2017	13	9
FY 2018	13	9
FY 2019	13	9

Detail Of Positions

	FY 2017	FY 2018	FY 2019		
Detail	Final	Annualized CR	President's Budget		
Executive level	0	0	0		
Total - Exec. Level Salaries	0	0	0		
SES	8	8	8		
Total - SES Salaries	1,253,958	1,783,179	1,790,312		
Total - ES Salary	1,253,958	1,783,179	1,790,312		
GS-15	57	45	45		
GS-14	58	51	51		
GS-13	45	38	38		
GS-12	18	12	12		
GS-11	12	8	8		
GS-10					
GS-9	9	2	2		
GS-8		1	1		
GS-7	1				
GS-6					
GS-5					
GS-4	1	1	1		
GS-3					
GS-2					
GS-1					
Subtotal	209	166	166		
Total, GS Salary	20,624,483	18,188,507	18,195,782		
Commissioned Corps	2	2	2		
Total, Commissioned Corps Salary	318,302	322,314	329,083		
Total Positions	211	168	168		
Total FTE	187	164	164		

Physicians' Comparability Allowance

		FY 2017 (Actual)	FY 2018 (Estimates)	FY 2019 (Estimates)
1) Number of Physicians Receiving PCAs		4	3	3
2) Number of Physicians with C	ne-Year PCA Agreements	0	0	0
3) Number of Physicians with M	Iulti-Year PCA Agreements	4	3	3
4) Average Annual PCA Physician Pay (without PCA payment)		\$134,226	\$136,273	\$136,273
5) Average Annual PCA Payment		\$23,444	\$19,000	\$19,000
	Category I Clinical Position	0	0	0
6) Number of Physicians	Category II Research Position	0	0	0
Receiving PCAs by Category (non-add)	Category III Occupational Health	0	0	0
	Category IV-A Disability Evaluation	0	0	0
	Category IV-B Health and Medical Admin.	4	3	3

In 2017, ONC needed physicians with prominent medical backgrounds to engage with a wide variety of clinical stakeholders and to provide a clinically based perspective on ONC policies and activities. This includes clinical issues around EHR safety, usability, clinical decision support, and quality measures.

Without PCA, it is unlikely that ONC could have recruited its current physicians, nor is it likely that ONC will be able to recruit without PCAs in future years. PCAs were awarded at the maximum amount allowed in all of these cases.