

# DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year 2017

Office of the National Coordinator for Health

Information Technology

Justification of Estimates for Appropriations Committee

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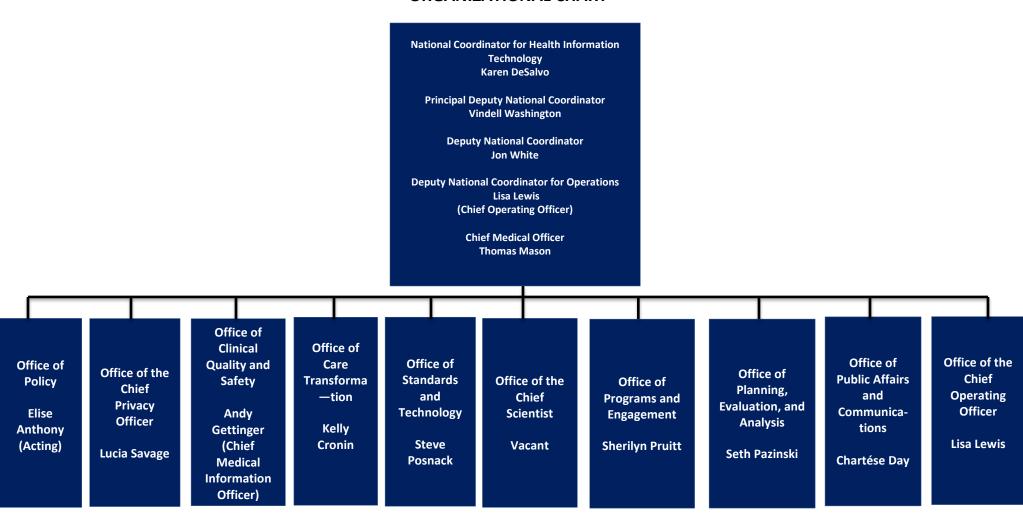
# LETTER FROM THE NATIONAL COORDINATOR

I am pleased to present the fiscal year (FY) 2017 Budget Justification for the Office of the National Coordinator for Health Information Technology (ONC). Access to electronic health information is integral to achieving more affordable, better quality care and healthier people across the nation. ONC leads the U.S. Government's work to ensure that actionable electronic health information is available when and where it matters most so that we move expeditiously to an open, connected community of health. I am proud of the role that the ONC team, our programs, and our local, federal and private partners have played in advancing this goal over the past 11 years, leading to 72 percent of eligible health care professionals and 99 percent of eligible hospitals in the nation adopting certified electronic health record (EHR) technology<sup>1</sup>. These advances in the adoption of health IT have led us to our next critical focus area: secure, seamless data interoperability. To that end, ONC's FY 2017 Budget Justification promotes the unlocking and sharing of electronic health information in order to better serve individuals, caregivers, providers, payers, public health, scientists and ultimately enhance health for everyone.

The ONC FY 2017 Budget Justification includes funding to address critical pathways to achieving near term interoperability and leveraging health IT across the country to build a connected, learning health care system. The funding will advance the refinement, use and where necessary, development of federally recognized, national standards including state of the art privacy and security protections. It also allows us to continue the drive for an improved delivery system to promote better care, smarter spending through value based payments, and ultimately better health outcomes. The funding in the FY 2017 Budget will allow us to continue progress on addressing the near term strategic focus of seeing that usable electronic health information is available, that health IT products are user-friendly and supporting care giving, that the marketplace is transparent and innovative, and that we focus regulatory expectations on health outcomes. This Budget bolsters the nation's efforts to urgently advance the ongoing digitization of the health system and the establishment of a learning health system that not only supports individuals and communities, but also provides critical support for exciting frontiers like Precision Medicine or major public health challenges such as opioid abuse. It also facilitates other important efforts including strengthening patient safety, advancing cybersecurity, bolstering clinical decision-making, facilitating accurate care coordination, ensuring consumers are making informed decisions, enabling more transparent and seamless quality measurement, creating a robust and powerful research community, and maintaining the privacy and security of health information. Taken together, all of this work is crucial to achieve the promise and power of health IT and serve the mission of the Department of Health and Human Services to protect and enhance the health of all Americans.

/ Karen B. DeSalvo/ Karen B. DeSalvo, M.D., M.P.H., M.Sc. National Coordinator for Health IT

<sup>1</sup> More information about this measure, which relates to the FY 2014-15 HHS Priority Goal to "improve health care through meaningful use of health information technology" is at <u>http://www.performance.gov/content/improve-health-care-through-meaningful-use-health-</u> <u>information-technology?view=public#overview</u>.



# ORGANIZATIONAL CHART

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# **ORGANIZATIONAL CHART: TEXT VERSION**

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# **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, programs, and investments. ONC supports HHS Strategic Plan goals 1: Strengthen Health Care and 2: Advance Scientific Knowledge and Innovation.

ONC was established in 2004 by Executive Order and was codified in legislation in 2009, with the enactment of the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act (Recovery Act). HITECH also provided short term funding to HHS in support of a number of health IT related initiatives, including the Medicare and Medicaid Electronic Health Record Incentive Programs under which certain eligible professionals and hospitals may receive payments for adopting and meaningfully using electronic health record (EHR) technology. To date, these programs have provided more than \$31 billion in incentive payments to health care professionals and hospitals that have attested to adopting and meaningfully using EHRs certified by ONC. Additionally, HITECH provided broad, permanent authorities for ONC to promote the widespread adoption of standardized and certified EHR technology, facilitate the secure use and exchange of interoperable health information, and promote the delivery of safe, efficient, cost effective high quality care.

The Patient Protection and Affordable Care Act (ACA), enacted in 2010, further emphasizes the role of health IT and health information exchange in transforming health and health care. The ACA provides incentives for the use of health IT and health information exchange, both through direct requirements for the use of health IT in certain quality reporting programs, and indirectly through new reimbursement policies and value-based payment programs that require advanced health IT and health information exchange capabilities.

ONC supports the Department's goal to strengthen health care by pursuing the modernization of the care delivery infrastructure of the nation through the adoption, meaningful use, implementation and optimization of health IT. ONC is also at the forefront of efforts to apply health IT solutions to Precision Medicine and the public health crisis of prescription drug abuse. ONC seeks to transform care delivery and public and community health to advance a person-centered health and management system.

### Vision

High-quality care, lower costs, healthy population and engaged people

### Mission

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

# Introduction

A successful learning health system relies on interoperable health IT so that information can be collected, shared, and used to improve health, facilitate research, and inform clinical outcomes. Unlocking health data is critical so that health care can be transformed from volume-based fiscal incentives towards an emphasis on high valued care and ultimately to a system that advances public health and science, delivers better care, spends health care dollars more wisely, and results in healthier people.

Advancing the capability and connectivity of health IT remains ONC's primary goal. The HITECH Act and the ACA have dramatically increased adoption of EHRs throughout the nation and stimulated demand for a growing range of health IT and health information exchange products, services, and capabilities. As the national convener for health IT advancement and innovation, ONC is working towards meeting this demand through high level coordination between government and the private sector, ensuring the appropriate collection, sharing and use of data, and developing policy. This includes important work on Precision Medicine, addressing prescription drug abuse and information blocking, and evaluating progress towards interoperability as required under the Medicare Access and CHIP Reauthorization Act (MACRA).

ONC leads the digitization of the health experience and focuses on developing secure, seamless data interoperability pathways by building upon the current infrastructure with the goal to advance health care and health. We do this by focusing on three critical pathways: (1) aligning standards, including application program interfaces (APIs,) and implementation standards; (2) developing clarity about the trust environment—what are the shared expectations and actions around data security and privacy; and (3) building the economic case for interoperability, including increasing incentives and improving the regulatory and business environment--with the goal to advance health.

ONC is continuing to leverage its existing authorities and responsibilities, which include technical standards coordination and harmonization work, a regulatory certification program, and coordination of privacy and security work through a Chief Privacy Officer. These are in addition to ONC's core function of coordinating federal health IT policy through multiple mechanisms, including the Federal Health IT Strategic Plan, through leadership of the Federal Health Architecture (FHA), and through the work of our federal advisory committees. Our work is focused on achieving interoperability for the Nation. First, through our three year agenda (2015-2017) of sending, receiving, finding and using a common clinical data set to improve health and health care quality by 2017, then through expanding interoperable health IT and users to improve health and lower cost by 2020. Finally, we will achieve a learning health care system that allows data to flow in a private and secure manner to enable an environment that links the care delivery system with communities and societal supports in closed loops of electronic health information flow at many different levels to enable continuous learning and improved health.

ONC's unique technical expertise, existing authorities, new authorities requested through legislative proposals, and strong relationships with the private sector make ONC remarkably well suited to champion the technical and policy change necessary to achieve interoperability and the enhanced level of patient centered care and health outcomes all Americans deserve. The following activities describe how ONC is creating a safe, secure, and interoperable health IT infrastructure.

# Policy Development and Coordination

ONC develops and coordinates federal policies through collaboration with a broad range of health IT stakeholders to achieve a robust and interoperable health IT infrastructure and to address emerging

health care challenges, such as prescription drug abuse and critical health IT issues like information blocking. Specific activities include:

- *Health IT Policy*: Engages stakeholders to collaboratively identify emerging issues and forge consensus-based solutions. Investigates alternative solutions in real world settings, incorporating best practices into the Certification Program. Facilitates a coordinated and consistent approach to the federal regulation and the governance of health IT.
- *Privacy and Security*: Provides subject matter expertise and technical assistance to organizations as they navigate the legal, regulatory, and technical issues surrounding the privacy and security of health information. Through direct engagement with stakeholders and coordination of federal regulations, the Chief Privacy Officer ensures that privacy and security standards are addressed in a consistent manner that reinforces the protection of private health information.
- *Health IT Safety and Usability:* Coordinates Departmental health IT safety activities to identify and mitigate the safety risks associated with the use of health IT. The program coordinates activities around health IT design, integrates clinical workflows, educates and trains health IT consumers, and develops processes designed to identify and correct unsafe conditions or uses of health IT.
- *Clinical Quality Improvement (CQI):* Provides a comprehensive approach to integrating clinical knowledge into health IT. Offers subject matter expertise on policies, standards, and tools that give providers and consumers the information and tools needed to identify high risk conditions, assist in decision making, and measure care quality.

# Standards, Interoperability, and Certification

ONC leads a variety of efforts designed to accelerate nationwide progress towards an interoperable health IT infrastructure that supports a transformed delivery system. By developing standards and convening federal agencies and other partners to implement nationwide solutions to Health Information Exchange (HIE), ONC is working to create interoperable health IT infrastructures. Specific activities include:

- Standards Development and Harmonization: Provides the technical infrastructure to support the Certification Program. Through the Standards and Interoperability (S&I) Framework and the Standards Implementation and Testing Environment (SITE) Platform, ONC coordinates and convenes stakeholders to develop and harmonize standards, and provides testing and data infrastructure to ensure the efficiency of proposed standards for inclusion in the Certification Program.
- *Health Information Exchange:* Provides the leadership and resources needed to accelerate the nationwide adoption and utilization of HIE. This work includes engaging HIE participants and assisting them to implement health information exchange services, and providing a focus on the right set of standards, protocols, legal agreements, specifications, and services needed to manage the exchange of health information.
- *Certification and Accreditation:* Provides vendors and developers with clear criteria for developing their products by issuing certification criteria for the Certification Program. Collaborates with National Institute of Standards and Technology (NIST), deploys testing procedures, data, and tools in regard to the standards and certification criteria adopted by regulation for Accredited Testing Labs (ATLs). Separately, ONC accredits authorized certification bodies (ONC-ACBs) to independently validate the ATLs results and certify the product.
- *Federal Health Architecture:* ONC acts as the managing partner of the FHA. Through the FHA, over 20 federal agencies have joined together to implement government-wide solutions to health IT that addresses agency business priorities while protecting citizen privacy.

# Adoption and Meaningful Use of Health IT

ONC supports efforts aimed at the widespread adoption of the latest health IT and disseminates methods by which providers and consumers can meaningfully use Certified Electronic Health Record Technology (CEHRT) to improve decision making. Through coordinated national strategies and direct engagement with the health IT community, ONC maintains a national network of organizations that are focused on supporting individual providers and consumers in adopting and meaningfully using health IT. Specific activities include:

- Provider Adoption Support: Provides a forum –the National Learning Consortium (NLC) through which health IT implementers and providers can collaborate to identify common implementation issues, develop and share best practices to mitigate challenges, and showcase innovative uses of health IT.
- *Consumer eHealth:* Engages directly with consumers to empower them to meaningfully use their health information and actively participate in their health care through improved access to health information provided by CEHRT and Blue Button. Works to ensure consumers are engaged in support of a robust eHealth market.
- Planning, Evaluation, and Monitoring: Leads the development of the Federal Health IT Strategic Plan, and uses internal and external data sources to conduct economic analysis and develop models that describe the value of investing in health IT implementation and progress towards achieving interoperability. Provides health IT monitoring, which measures the costs, benefits, and economic impacts of HITECH and Electronic Health Record Incentive Programs, and provides measurements of program activities. These studies and reports inform and influence health policy and program decisions.
- Engagement and Outreach: Coordinates external communication and dissemination activities through HealthIT.gov and the NLC. Provides internal communication resources through the ONC's intranet.

### Agency Wide Support

ONC's agency-wide support team provides dynamic and flexible support to ONC's offices and programs through administrative and central services with responsibility for overall agency efficiency and effectiveness. Activities include: acquisitions and grants; budget operations; people and culture; program integrity; operational services; monitoring and analysis; systems and planning; and demand management.

# **Overview of Budget Request**

The Fiscal Year (FY) 2017 Budget request for ONC is \$82.0 million in Public Health Service (PHS) Evaluation Funds. The FY 2017 Budget request reflects ONC's commitment to developing a nation-wide, interoperable learning health system that assures that data can be securely collected, used, and shared by the right people at the right time.

The focus of ONC's FY 2017 Budget request is advancing the interoperability of health information technology and leveraging health IT across the country to build a connected, learning health care system. ONC's FY 2017 Budget promotes the unlocking and sharing of electronic health information in order to better serve individuals, caregivers, providers, payers, public health, and scientists and ultimately enhance health for everyone. Interoperability is the ability of a system to exchange information with, and use information from, other systems without special effort on the part of the customer. In FY 2017, ONC will further specify technology standards, lead the development of testing procedures and tools for health IT certification, support on the ground implementation of health IT, and track and monitor progress towards achieving these goals. Unlocking health data will facilitate accurate care coordination, ensure consumers are making informed decisions, enable more transparent and seamless quality measurement, create a robust and powerful research community, maintain privacy and security of health information, and develop an essential infrastructure for the measurement and improvement of quality and safety while bolstering clinical decision-making. These improvements will support priority initiatives, such as those combatting prescription drug abuse and Precision Medicine. Efforts supported by ONC's Budget request also include thwarting information blocking and operationalizing the governance of electronic health information to achieve the system-wide improvements described above.

The most important actions for public and private sector stakeholders to take to enable nationwide interoperability of electronic health information in the near-term are: build the economic case for interoperability, including increasing incentives and improving the regulatory and business environment; bring health IT systems on to a shared set of federally recognized, national standards/technology; expose and discourage health information blocking; enable the use of state of the art privacy and security protections; encourage market transparency and competition; drive EHR product usability improvements and the availability of real world testing; offer technical assistance to providers to help them get the most out of their IT; align quality measures across payment programs, agencies, and the private sector; and help consumers easily and securely access their electronic health information.

The following activities demonstrate how ONC is working to create a safe, secure, and interoperable health IT infrastructure that is improving health and health care for all Americans:

### Policy Development and Coordination (\$28.2 million, +\$15.2 million above FY 2016 Enacted)

These funds support the development and coordination of federal policies and strategies that promote a safe and secure interoperable learning health system. In FY 2017, ONC will promote interoperability and health care transformation by implementing the Federal Health IT Strategic Plan, and continuing to address information blocking and establishing a health IT governance mechanism. ONC will foster innovation within the cross-Departmental initiative targeting prescription drug overdoses, and inspire confidence and trust in health IT through ensuring the privacy and security of patient data, and ensuring that consumers are able to exercise control over their health information. ONC will continue working on

the Health IT Safety Collaborative, a public-private partnership that will build a bridge between health care providers and other entities responsible for health IT safety, to ensure that health IT is integrated into a safe healthcare culture. This effort would be enhanced by the legislative proposal described on page 67.

Standards, Interoperability, and Certification (\$24.1, +\$8.6 million above FY 2016 Enacted) These funds support a variety of efforts designed to accelerate nationwide progress toward an interoperable learning health IT infrastructure that delivers better care, spends health care dollars more wisely, and results in healthier people. In FY 2017, ONC will focus on supporting interoperability by establishing consensus around standards development activities and policies related to health information exchange, Precision Medicine and the Medicare Access and CHIP Reauthorization Act (MACRA). ONC will also continue to support and expand the Certification Program and convene federal agencies, including the Department of Veterans Affairs and the Department of Defense, through the Federal Health Architecture (FHA).

# Adoption and Meaningful Use of Health IT (\$11.5 million, +\$1.0 million above FY 2016 Enacted)

ONC supports efforts aimed at the widespread adoption of certified health IT products and disseminates methods by which providers and consumers can use health IT to improve decision making. In 2017, ONC will advance the interoperability of health information technology so that electronic health information can be used in support of payment and delivery system reform by disseminating guides and best practices through the National Learning Consortium and working with consumers and caregivers so that they can meaningfully use their health information and actively participate in their health care. In FY 2017, ONC will gather data and evaluate progress toward achieving interoperability as required under MACRA.

# Agency Wide Support (\$18.1 million, -\$3.2 million below FY 2016 Enacted)

ONC's agency-wide support team provides dynamic and flexible support to ONC's offices and programs through administrative and central services with responsibility for overall agency efficiency and effectiveness. Activities include: acquisitions and grants; budget operations; human capital; program oversight and systems and planning; and operational services.

# **Overview of Performance**

In continuation of its mission to provide national leadership in formulating the federal government's health IT strategy and coordinating related federal policies, standards, programs, and investments, this Budget request supports ONC's performance measurement and monitoring framework and informs ONC and its stakeholders about current levels of:

- health IT adoption;
- health information exchange capability, activity, and interoperability;
- consumer engagement and attitudes about health IT; and
- the impacts of related federal investments.

ONC is continuing to evolve its measurement focus through assessing the increasingly sophisticated adoption of health IT and the development and use of electronic health information and records. While most measures presented here are national in scope and only annual in frequency, they still provide a robust framework to inform health IT stakeholders' discussions. ONC routinely segments these measures, and others, by geography, setting, and entity type, among other attributes, and provides the results of analyses to stakeholders and public bodies to promote transparent and informed decision-making.

ONC's approach to developing and maintaining a portfolio of national health IT measures supports the Department's strategic planning, monitoring, and evaluation of the health care industry. Related, ONC is making an effort to reduce the number of measures reported in the President's Budget by shifting the focus to health information exchange capability, activity, and interoperability measures. While ONC will reduce the number of official measures, the broader measurement portfolio will be maintained for structuring a comprehensive narrative that is both adaptable to the pace of industry advancement and useful for multi-year reporting of performance trends.

ONC's measurement framework closely aligns with the following HHS priority and plan areas:

- HHS strategic plan goals for Electronic Health Record (EHR) adoption 2014-2018: <u>http://www.hhs.gov/strategic-plan/priorities.html</u>
- Federal Health IT Strategic Plan 2015-2020: <u>http://www.healthit.gov/policy-researchers-implementers/health-it-strategic-planning</u>
- HHS Delivery System Reform: <u>http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26.html</u>
- ONC Health Information Exchange Acceleration: <u>http://www.healthit.gov/policy-researchers-implementers/accelerating-health-information-exchange-hie</u>
- A Shared Nationwide Interoperability Roadmap: <u>http://www.healthit.gov/policy-researchers-implementers/interoperability</u>

Included within this Budget request are investments enabling ONC to address Congressional requests outlined in Pub. L. No: 114-10, Medicare Access and CHIP Reauthorization Act (MACRA), particularly that ONC assess the extent of interoperable health information exchange through the use of certified EHRs by Medicare/Medicaid participating providers in the U.S. by 2018.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> https://www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf

Notable performance updates reflecting the most recently available data include:

- In 2014, 76 percent of non-federal acute care hospitals had implemented at least a basic EHR system an increase of 17 percentage points from 2013. Alongside increases in basic EHR adoption, in 2014, 76 percent of hospitals were electronically sharing patient information with providers outside their organization, a 14 percentage point increase from the 2013 baseline.
- In 2014, 56 percent of office-based primary care providers had implemented at least a basic EHR system – an increase of 3 percentage points from 2013. Despite increases in basic EHR adoption, only 26 percent of office-based physicians were electronically sharing patient information with providers outside their organization.
- The Centers for Medicare and Medicaid Services (CMS) EHR Incentive Programs continue to garner widespread participation among hospitals, health care professionals, and software developers. As of November 2015, more than 481,000 eligible professionals had received at least one incentive payment, including 72 percent of eligible professionals and 99 percent of eligible hospitals. Beginning in FY 2015, providers began meeting Stage 2 requirements, and, as of November 2015, more than 58,000 professionals and 1,580 hospitals had successfully attested to Stage 2 requirements and received an incentive payment.
- Along with generally increasing EHR adoption trends and the successes of the Health Information Technology for Economic and Clinical Health (HITECH) Act and CMS EHR Incentive Programs, health information exchange capability, particularly among hospitals, has steadily risen in recent years. In 2014, 69 percent of non-federal acute care hospitals had exchanged health information with outside ambulatory providers, a 12 percentage point increase from 2014 and nearly double the rate from 2008.

# **Description of ONC's Performance Management Process**

The planning and performance management process at ONC is embedded across policy, standards, and program management activities. The process includes activities that provide ONC executives, managers, and staff the opportunity to develop clear and common goals, monitor and discuss progress towards goal attainment, and when necessary, revise established plans appropriately.

ONC's planning and performance management process is built on a common government-wide framework of performance processes and standards, including targeted activities that focus teams with respect 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. ONC's process implements many of the best practices and requirements outlined in the Government Performance and Results Act (GPRA) and the GPRA Modernization Act, and are in accordance with OMB circulars (e.g., A-11, 19, 102, 123) and management directives.

# 1. Priority Setting

ONC's HITECH Act authorizing legislation, annual appropriations, and implemented budgets form the basis for the multi-year and annual priority setting processes. ONC also regularly receives and integrates into its priorities requests from Congress, such as updates on ONC activities or renewed or reformed focus on emerging aspects of health IT. In addition to responsiveness to Congressional and Administration priorities, ONC regularly receives input from a group of Federal Advisory Committees (FACAs) – including the Health IT Policy and Standards Committees (Policy and Standards Committees, respectively) – and federal partners participating in the Federal Health Architecture (FHA) and Federal Health IT Council.

For more information about ONC's health IT advisory committees visit: http://www.healthit.gov/facas/.

# 1.1 Strategic Planning

Establishing multi-year strategic plans is critical to formulating and advancing a coordinated long-term vision for a modernized, value-based health care system. ONC references a number of Federal and nationwide strategic plans as the basis for articulating and refining its related vision and planning efforts. These plans include:

- Healthy People 2020: <u>http://www.healthypeople.gov/</u>
- Department of Health and Human Services, Strategic Plan 2014-2018: <u>http://www.hhs.gov/strategic-plan/priorities.html</u>
- National Quality Strategy: <u>http://www.ahrq.gov/workingforquality/</u>
- Roadmap for Patient Safety and Health IT: <u>http://www.healthit.gov/policy-researchers-implementers/health-it-and-safety</u>

Additionally, according to ONC's HITECH Act authorizing legislation, ONC must construct a Federal Health IT Strategic Plan that addresses the following:

- Use of electronic exchange, health information, and the enterprise integration of such information;
- Utilization of an EHR for each person in the United States;
- Incorporation of privacy and security protections for the electronic exchange of an individual's identifiable health information;

- Use of security methods to ensure appropriate authorization and electronic authentication of health information and specifying technologies or methodologies for rendering health information unusable, unreadable, or indecipherable;
- Specification of a framework for coordination and flow of recommendations and policies among the Secretary, the National Coordinator, the advisory committees, and other health information exchanges and relevant entities;
- Use of methods to foster the public understanding of health IT;
- Employment of strategies to enhance the use of health IT to improve health care quality, reduce medical errors, reduce health disparities, improve public health, increase prevention and coordination with community resources, and improve the continuity of care among health care settings; and,
- Implementation of specific plans for ensuring that populations with unique needs, such as children, are appropriately addressed in the technology design, as appropriate, which may include technology that automates enrollment and retention for eligible individuals.<sup>3</sup>

During FY 2015, ONC led federal stakeholders and the public through the process of revising the Federal Health IT Strategic Plan for the 2015-2020 timeframe. The revised plan is available on the ONC website at: <a href="http://www.healthit.gov/policy-researchers-implementers/health-it-strategic-planning">http://www.healthit.gov/policy-researchers-implementers/health-it-strategic-planning</a>.

# 1.2 Tactical & Action Planning

In addition to multi-year strategic plans, ONC undertakes a number of discreet planning exercises that refine strategies into implementable action and milestone lists that can be managed and monitored regularly. ONC uses some of the following action plans as the basis for developing its multi-year and annual action/milestones plans:

- Federal Health Architecture: <u>http://www.healthit.gov/policy-researchers-implementers/federal-health-architecture-fha</u>;
- Health Information Exchange Acceleration Plan: <u>http://www.healthit.gov/policy-researchers-implementers/accelerating-health-information-exchange-hie;</u> and,
- Nation-wide Interoperability Roadmap: <u>http://www.healthit.gov/policy-researchers-implementers/interoperability</u>.

# 1.3 Aligning Plans to Performance

ONC's multi-year strategic and action plans inform the development of performance plans that align organizational components, senior executives, initiative leads, and staff. Specifically, ONC's annual organization 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 ambitious milestones that must occur in the upcoming fiscal year to accomplish ONC's policy, program, and operational objectives. The annual milestone plan is established during the August to September timeframe alongside development of the following fiscal year's operating budget.

Once the organizational and National Coordinator's plans are finalized, the critical milestones are cascaded into the performance plans for ONC's senior executives. Each ONC senior executive has a performance plan listing milestones they are responsible to oversee that are related to the organization's program and policy goals. SES plans also include critical elements related to on-going

<sup>&</sup>lt;sup>3</sup> Pub. L. 111-5, Sec. 3001(c)(3)(A).

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. <u>Measurement and Analysis</u>

# 2.1 Evaluation of HITECH Program Effectiveness

The HITECH Act required ONC to conduct program evaluations of the: (1) overall implementation of HITECH, (2) Health IT Extension Program, (3) Health IT Workforce Program, (4) State Health Information Exchange Program, and (5) Beacon Community Program. These evaluations also generate useful analyses that can impact the implementation of the programs. For example, several of the HITECH evaluations are developing grantee typologies that help ONC project officers and grantees understand and address common problems.

2.2 Survey Research and Analysis to Assess Nationwide Health IT Adoption and Interoperability

Through a variety of survey research and evaluation projects focused on the national health IT market, ONC's researchers, program evaluators, and program and policy analysts support a cross-cutting evaluation and analysis agenda. This agenda focuses on identifying barriers to health IT adoption, patterns of successful implementation, and gaps where additional research is needed to further motivate health system improvements. Together, ONC's analytics activities enable the agency to set clear nation-wide goals that define success, motivate members of the stakeholder community, and enable ONC to assess patterns of change at the national, regional, and provider-group levels. ONC's work within this area includes fulfilling statutory responsibilities for measuring and evaluating the extent of nationwide adoption of health IT and the interoperability of health information—i.e., MACRA section 106(b).

# 2.3 Analysis and Reporting to Assist Program and Operations

ONC's performance-based policy and program management processes are supported by numerous information management systems that enable the consistent collection and analysis of ONC data. Program and operations data are regularly captured, analyzed, and presented across staff and manager groups through tools such as: ONC Intranet, HealthIT.gov, particularly through the National Learning Consortium, FACA portal, and Health IT Dashboard websites. Deliverables from ONC's HITECH and health IT studies and evaluations are available at <a href="http://dashboard.healthit.gov/evaluations/">http://dashboard.healthit.gov/evaluations/</a>

# 3. <u>Regular Performance Review</u>

The regular review of performance information is ingrained at all levels of ONC through 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;
- 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 EHR Adoption 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 in a place where change is the expectation is necessarily robust and on-going. Through a predictable set of senior leadership team meetings, cross-cutting priority group meetings, and planning exercises, each ONC office has an important contribution to leading the planning and monitoring exercises that are needed to ensure that objectives are met.

# All Purpose Table

(Dollars in Millions)

Program	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 Request (+/-) FY 2016 Enacted
Budget Authority	60.367	60.367	0.000	-60.367
PHS Evaluation Funds	0.000	0.000	82.000	+82.000
Total, ONC	60.367	60.367	82.000	+21.633

# **BUDGET EXHIBITS**

# **Appropriations Language**

For expenses necessary for the Office of the National Coordinator for Health Information Technology, including grants, contracts, and cooperative agreements for the development and advancement of interoperable health information technology, [\$60,367,000] *\$82,000,000 shall be available from amounts available under section 241 of the PHS Act.* (Consolidated Appropriations Act, 2016)

# Language Analysis

Language Provision	Explanation
\$82,000,000 shall be available from amounts available under section 241 of the PHS Act.	Provides ONC's budget from PHS Evaluation funding.

	FY 2015	FY 2016	FY 2017
Detail	Final	Enacted	President's Budget
General Fund Discretionary Appropriation:			
Annual appropriation	60,367,000	60,367,000	82,000,000
Subtotal, Appropriation	60,367,000	60,367,000	82,000,000
Total, Discretionary Appropriation	60,367,000	60,367,000	82,000,000
Total Obligations	60,367,000	60,367,000	82,000,000

# Amounts Available for Obligation

# Summary of Changes (Dollars in Thousands)

2016								
Total estimated program level								60,367
2017								
Total estimated program level								82,000
Net Change program level +21,633								
FY 2016 FY 2017 +/- FY								
	E	nacted		FY 2	2017 PB			2016
	Program Program					Program		
	FTE	Level		FTE	Level		FTE	Level
Increases:								
A. Program:								
1. Policy Development & Coordination	55	13,019		55	28,209		+0	+15,189
2. Standards, Interoperability, and Certification.	40	15,528		40	24,135		+0	+8,607
3. Adoption, Utilization, & Meaningful Use	50	10,514		50	11,523		+0	+1,010
Subtotal, Program Increases	145	39,061		145	63,867		+0	+24,806
Decreases								
A. Program:								
1. Agency Wide Support	55	21,306		55	18,133		+0	-3,173
Subtotal, Program Decreases	55	21,306		55	18,133		+0	-3,173
Net Change	200	60,367		200	82,000		+0	+21,633

# Budget Authority by Activity (Dollars in Thousands)

	FY 2015	FY 2015	FY 2016	FY 2016	FY 2017	FY 2017
Activity	Actual FTE	Actual	Enacted FTE	Enacted	President's Budget FTE	President's Budget
Policy Development and Co	ordination					
Budget Authority	0	13,112	0	13,019	0	0
PHS Evaluation Funds	37	0	55	0	55	28,209
Total, Policy Development and Coordination	37	13,112	55	13,019	55	28,209
Standards, Interoperability,	, and Certifico	ntion				
Budget Authority	0	15,425	0	15,528	0	0
PHS Evaluation Funds	26	0	40	0,000	40	24,135
Total, Standards, Interoperability, and Certification	26	15,425	40	15,528	40	24,135
Adoption, Utilization, and N	Meaningful U	se				
Budget Authority	0	10,524	0	10,514	0	0
PHS Evaluation Funds	42	0,000	50	0	50	11,523
Total, Adoption, Utilization, and Meaningful Use	42	10,524	50	10,514	50	11,523
Agency-wide Support						
Budget Authority	0	21,306	0	21,306	0	0
PHS Evaluation Funds	55	0	55	0	55	18,133
Total, Agency-wide Support	55	21,306	55	21,306	55	18,133
Total, Budget Authority	160	60,367	200	60,367	0	0
Total, PHS Evaluation Funding	0	0	0	0	200	82,000
Total, Program Level	160	60,367	200	60,367	200	82,000

# Authorizing Legislation (Dollars in Thousands)

Authorizing Legislation	2016	2016	2017	2017
Health Information Technology Activity:	<u>Authorized</u>	<u>Enacted</u>	<u>Authorized</u>	<u>President's</u> <u>Budget</u>
Health Information Technology PHS Act 42 U.S.C. 201	Indefinite	-	Indefinite	-
PHS Evaluation Funds (non-add)	Indefinite	60,367	Indefinite	82,000
Total Request Level		60,367		82,000

# **Appropriations History**

(Dollars in Thousands)

	Budget	House	Senate	
Details	Estimates to Congress	Allowance	Allowance	Appropriations
2008				
Base	\$89,872	\$13,302	\$43,000	\$42,402
PHS Evaluation Funds	\$28,000	\$48,000	\$28,000	\$18,900
Rescissions (P.L. 110- 160)				(\$741)
Subtotal	\$117,872	\$61,302	\$71,000	\$60,561
2009				
Base	\$18,151	\$43,000	\$60,561	\$43,552
PHS Evaluation Funds	\$48,000	\$18,900	\$0	\$17,679
ARRA (P.L. 111-5)				\$2,000,000
Subtotal	\$66,151	\$61,900	\$60,561	\$2,061,231
2010				
Base	\$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				
Base	\$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				
Base	\$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				
Base	\$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

Details	Budget Estimates to Congress	House	Senate	Appropriations
2014				
Base	\$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		\$72,597	\$60,367
2015				
Base	\$0	\$61,474	\$61,474	
PHS Evaluation Funds	\$74,688			\$0
Subtotal	\$74,688	\$61,474	\$61,474	\$60,367
2016				
Base	\$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				
Base	\$0			
PHS Evaluation Funds	\$82,000			
Subtotal	\$82,000			

# NARRATIVE BY ACTIVITY

# **Policy Development and Coordination**

(Dollars in Thousands)						
Policy Development and Coordination	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 (+/-) FY 2016		
Budget Authority	13,112	13,019	0	-13,019		
PHS Evaluation Funds	0	0	28,209	+28,209		
Total, Program Level	13,112	13,019	28,209	+15,190		
FTE	37	55	55	0		
Authorizing Legislation:						
Enabling Legislation CitationPHS Act 42 U.S.C. 201						
Enabling Legislation StatusPermanent						
Authorization of Appropriations Cita	tion	No Sep	barate Authori	zation of Appro	priations	

Budget Summary

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### **Program Description and Accomplishments**

ONC coordinates federal policies and activities necessary to develop a robust and interoperable learning health system that assures that data can be securely captured, shared with, and used by the right people at the right time to achieve better care, smarter spending, and healthier people. 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 and provides 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, weaknesses, 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 ensures that federal health IT policies support delivery system reform efforts, interoperability, patient safety, health IT usability, and clinical quality improvement, while addressing barriers to interoperability such as information blocking.

### Health IT Policy

ONC develops and coordinates federal health IT policy to achieve national health priorities set forth by the White House and Secretary of HHS, and to implement statutory requirements such as those identified in Health Information Technology for Economic and Clinical Health (HITECH) Act and the Medicare Access and CHIP Reauthorization Act (MACRA). Further, ONC guides achievement of goals and objectives outlined in the Federal Health IT Strategic Plan through collaboration with federal partners and engagement of stakeholders. ONC monitors progress toward the goals and objectives and works to align federal activities with national priorities, goals, and objectives.

Using our unique convening authority, ONC engages a diverse group of private, non-profit, and public sector stakeholders to identify health IT policy issues and forge consensus-based solutions. By investigating alternative and creative solutions, ONC designs programs to remove barriers that limit market progress in achieving interoperability that supports health care delivery reform. These solutions must keep pace with the evolving health IT market by continuing to create new opportunities for investment and improve purchasers' confidence in their health IT choices.

ONC maintains two Federal Advisory Committee Act (FACA) bodies, also known as advisory committees: the Health IT Policy Committee (Policy Committee) and the Health IT Standards Committee (Standards Committee). ONC works in collaboration with its stakeholders to promulgate regulations defining the policy and technical standards and specifications for the Certification Program.

ONC solicits recommendations from the Policy Committee in order to inform policy decisions and guide the development of pilots, studies, and other programs that are used to inform future stages of policy development. ONC works with the Standards Committee to ensure that the standards, implementation specifications, and certification criteria (established by the Secretary in regulation) support federal health IT policies and are responsive to the needs of the health IT community and marketplace and promote interoperability. ONC also utilizes more traditional mechanisms to obtain information for policy objectives and strategies, including town hall meetings, Requests for Comment, and various social media resources.

Accomplishments include:

- Produced ONC response to Congressional Request on Information Blocking. In response to Pub. L. No. 113-235, ONC <u>submitted a report</u> detailing our findings on the extent and nature of health information blocking as determined by detailed analysis on this issue gathered through anecdotes, empirical research, and discussions with industry sources. The report describes steps the federal government can take to help mitigate some types of information blocking, including congressional intervention.
- ONC is using standard-based approaches to promote better opioid prescribing practices in order to support better care for patients. ONC is working with industry experts to integrate information on controlled substance dispensing from state Prescription Drug Monitoring Programs within prescriber health IT systems. Availability of this information is crucial for quality care and pain management as well as reducing diversion associated with controlled substance prescribing.
- The 2015 Edition rule, which supports Stage 3 of the Electronic Health Record (EHR) Incentive Program and the broader health care continuum, was completed. This rule builds on past certification rules to use health IT certification to support the establishment of an interoperable nationwide health information infrastructure. It includes new and updated criteria that support interoperability and safety that facilitate the accessibility and exchange of health information. The final rule also enhances transparency and surveillance of certified health IT.

# Interoperability and Governance of Health Information Exchange

ONC is working with stakeholders, health information organizations, health information service providers, and other governance 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. Through coordination and convening of key governance entities and grants to test alternative approaches, ONC is supporting nationwide efforts to enhance health information exchange (HIE) practices. Accomplishments include the development of the 10-year Interoperability Roadmap,

which developed interoperability principles and critical action items for the three, seven and 10 year time increments.

### Privacy and Security

Patient trust in the privacy and security of health data is a core requirement of an interoperable and learning health system. The Chief Privacy Officer ensures this requirement is met by advising the National Coordinator on health information privacy, security, and data stewardship policies in such domains as policies on big data, patient centered outcomes research (PCOR), and the Precision Medicine Initiative. ONC coordinates with states and regions, federal agencies, and other countries on health information privacy and security law and policy issues. ONC also develops and distributes toolkits, multimedia technical assistance and educational materials on privacy and security of health IT and health information exchange. ONC is committed to developing these materials in formats that are in plain language, concise, well-organized, and varied to meet different users' learning styles.

Development of Health IT Privacy and Security Policy, Standards, and Adoption Strategies Through analysis and public and private sector stakeholder engagement including the Privacy and Security Work Group (PSWG) of the Policy Committee and the Transport and Security Standards Work Group of the Standards Committee (TSSWG), ONC identifies the evolving ways that health information is electronically collected, stored, and exchanged; determines whether there are gaps and weaknesses in existing privacy and security legal protections, industry policies, practices or technical capabilities; identifies or develops potential legal, policy, or technical solutions; obtains feedback on potential solutions through a variety of means; and takes steps to make the solutions a reality. Accomplishments include:

- Served as ONC privacy and security liaison, subject matter expert or leader on the following work groups:
  - The President's <u>Precision Medicine Initiative (PMI): Privacy and Security Trust Framework.</u> Released in November 2015; ONC's <u>Interoperability Roadmap</u>; and ONC's <u>Health</u> <u>Information Blocking Report</u> to Congress.
  - <u>White House's Open Data Initiative</u>, where the National Coordinator transmitted a <u>study of</u> <u>gaps in oversight for Big Health Data</u> to the White House in November 2015. <u>ONC</u> <u>coordinated three public hearings and formulated recommendations</u> on big health data uses and privacy and security to ensure privacy protection for big data analyses in health IT.
- Supported HHS rulemaking efforts in a wide variety of areas to ensure new rules promote use of Health information technology while maintaining privacy and security of data:
  - Developed key policy papers in support of privacy and security certification standards in the ONC 2015 Certification Final Rule and Fact Sheets including: Data Segmentation for Privacy (DS4P), Authentication, Audit Reports, Amendments, Auto Access, Emergency Access, End-User Encryption, Integrity, Accounting of Disclosures, and Send and Receive. Contributed primary content for the supplementary material/pre-amble to the Final Rule.
  - Coordinated ONC input and policy formulation surrounding use of Application Programming Interfaces (APIs) to support patient access measures and objectives in ONC 2015 Edition
     Final Rule and Centers for Medicare and Medicaid Services (CMS) <u>Meaningful Use Stage 3</u> <u>Final Rule</u>.
- Authored or coauthored the following:
  - An <u>ONC data brief</u> based on the results of a nationwide surveys conducted by ONC in 2012 and 2013 exploring consumer attitudes and preferences regarding the privacy and security aspects of electronic health records and health information exchange.

- An article entitled "<u>Consumer Attitudes and Perceptions on mHealth Privacy and Security:</u> <u>Findings from a Mixed-Methods Study</u>" use of mobile devices to send/receive health information to/from their providers.
- An article entitled "<u>The Role of Health Care Experience and Consumer Information Efficacy</u> in Shaping Privacy and Security Perceptions of Medical Records: National Consumer Survey <u>Results</u>". The article analyzes the responses to questions the ONC contributed to the Health Information National Trends Survey 2012, which explore consumer attitudes and preferences regarding the privacy and security of health information technology.

# Safeguarding Health Information

ONC coordinates with public and private sector stakeholders to help ensure that electronic health information is secure and protected. ONC uses multiple strategies to address security, including provider education, assistance, and outreach; provision of guidance on threat and vulnerability analysis and mitigation planning and implementation; and identification of breach prevention technology. Accomplishments include:

- Awarded a <u>State Privacy Project Funding Opportunity Announcement (FOA)</u> to work with states to
  engage state health policy makers with health policy experts in areas of privacy and security and to
  provide technical assistance and educational materials about current federal health information
  privacy law (HIPAA).
- Finalized and released a revised <u>Guide to Privacy and Security of Electronic Health Information</u> (published in 2011) and <u>educational video</u> for small and medium sized provider practices and other stakeholders. The Guide includes information on issues like <u>cybersecurity</u>, patient access through CEHRT, and other EHR technology features available under the 2014 Edition Certification rule. The Guide includes new, practical examples of the HIPAA <u>Privacy</u> and <u>Security</u> Rules in action.
- Updated the <u>Security Risk Assessment (SRA) Tool</u> in June 2015. The SRA Tool is a user friendly tool which takes users through each HIPAA requirement by asking a question about their organization's activities. The SRA tool is one of the most downloaded tools on ONC's website.

# Provider and Patient Identity Management

In close coordination with the ONC FACAs, ONC investigates and identifies potential means for providing a high level of assurance for identity management when providers and patients are accessing and exchanging health information. Accomplishments include:

- Supported Standards Committee recommendations on user authentication standards and best practices.
- Continued to work closely with National Institute of Standards and Technology (NIST) to promote National Strategy on Trusted Identities in Cyberspace (NSTIC) in the health care sector by serving as technical advisor to NSTIC and grant awardees on <u>NIST grant-funded pilots</u>, four of which have a focus on health IT.

# Patient Control over Use and Disclosure of Personal Health Information (PHI)

ONC continues to carry out efforts to ensure that patients are able to exercise control over their health information pursuant to existing law. Accomplishments include:

- Released the *Electronic Consent Management: Landscape Assessment, Challenges, and Technology* report. The conclusion of this the report is that there are not technical barriers to widespread electronic consent management, but there are policy challenges.
- Completed a Pre-Discovery and Report on Data Segmentation for Clinical Decision Support (DS4CDS) project to better understand the current capabilities of health IT systems to use tagged or sensitive

health information in clinical decision support systems and rights management – including the primary technological and developmental challenges.

• Spearheaded the <u>Data Provenance S&I Initiative</u>. Sponsored and facilitated the development of the HL7 Implementation Guide for CDA, Release 2: Data Provenance, Release 1 - US Realm (Data Provenance CDA IG) as a Draft Standard for Trial Use (DSTU). Provenance is the technical way to identify with tags where electronic health information originated, which is important to data integrity and patient safety. ONC OCPO also started a pilot to test the Provenance standard.

# Health IT Safety and Usability

ONC is committed to ensuring that health information technologies are safely designed and implemented and that they are used in ways that help improve care. ONC provides leadership and coordinates activities and resources to help all stakeholders with responsibility for health IT safety implement the shared improvement strategies and actions described in the <u>HHS Health IT Patient Safety</u> <u>Action and Surveillance Plan</u>. Accomplishments include:

- Engaged the National Quality Forum to: develop a comprehensive, consensus framework for assessment of health IT safety measurement; report on best practices and challenges in this measurement; analyze measure gaps; and provide recommendations for gap filling.
- Published the following:
  - <u>Safety Assurance Factors for EHR Resilience (SAFER) Guides</u>, which offer evidence-based recommended practices on health IT safety in nine areas of known risks.
  - In collaboration with the Food and Drug Administration (FDA) and the Federal Communications Commission (FCC), published <u>a report and recommendations for Congress</u> on an appropriate risk-based regulatory framework for health IT safety, as required by the FDA Safety and Innovation Act (FDASIA). Held a three-day public workshop to solicit feedback on the report and recommendations, and convened a Health IT Safety Task Force within the Policy Committee to provide input on the report's recommendations for a Health IT Safety Collaborative.
- Developed, with input from a task force of public and private sector stakeholders, a report describing structure and operations of a potential Health IT Safety Collaborative. The report, also known as a roadmap, was published in July, 2015.

# Clinical Quality Improvement (CQI)

ONC is working to help providers use interoperable health IT and electronic HIE to drive improvements in care quality, safety, and value. Providers use health IT and HIE to identify high risk conditions, implement solutions to improve care quality and outcomes, and measure impact. Through such health IT-enabled improvement tools as clinical decision support (CDS) and quality measurement, providers and their patients benefit from up to date clinical best practices knowledge. CDS encompasses a variety of tools designed to enhance decision-making. Clinical quality measurement tools such as electronically specified clinical quality measures (eCQMs) allow providers to assess their performance in terms of clinical best practices and monitor health outcomes in more actionable timeframes than are possible without health IT. ONC provides subject matter expertise and technical assistance to federal programs that are working to improve clinical quality. Accomplishments include:

 Enhancing clinical quality measure (CQM) development and implementation processes, ensuring availability of health IT-enabled measures needed for the Centers for Medicare and Medicaid Services Electronic Health Record Incentive Programs and other quality-reporting and qualityincentive programs, in partnership with CMS.

- Increasing the availability and use of standards-based CDS that can help health care providers achieve performance goals for the Million Hearts initiative and other priority clinical topics such as HIV, Hepatitis C, Ebola, and immunizations. This work was done in close collaboration with the Centers for Disease Control and Prevention (CDC), CMS, and the Agency for Healthcare Research and Quality (AHRQ.)
- Established a Standards and Interoperability (S&I) Framework Initiative that is supporting
  progress toward harmonization and alignment of standards used to express clinical decision
  support and clinical quality measures for implementation in certified health IT. These standards
  are expected to help foster a robust, interoperable marketplace in which providers and
  consumers will be able to choose those quality improvement tools that most precisely and
  effectively meet their needs.

# **Funding History**

Fiscal Year	Amount
FY 2013	14,078,882
FY 2014	12,849,000
FY 2015	13,112,000
FY 2016 Enacted	13,019,000
FY 2017 President's Budget	28,209,000

# **Budget Request**

ONC requests \$28.2 million in FY 2017 for policy development and coordination activities, an increase of \$15.2 million above FY 2016 enacted. The request includes funding for 55 FTEs. Increased funding will foster innovation through the cross-Departmental initiative targeting prescription drug overdoses, 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. Additionally, ONC will continue to pursue efforts to address information blocking. Included within ONC's request are proposals to establish health IT governance certification, prohibit information blocking and associated business practices, require health IT transparency, and provide ONC authority to use contracts, grants, or cooperative agreements to establish a health it safety collaborative and provide adequate confidentiality protections.

This request supports Federal Health IT Strategic Plan 2015-2020 Goals 1: Expand Adoption of Health IT; 2: Advance Secure and Interoperable Health Information; 3: Strengthen Health Care Delivery; 4: Advance the Health and Well-Being of Individuals and Communities, and 5: Advance Research, Scientific Knowledge, and Innovation.

# Health IT Policy and Governance (\$11.8 million)

In FY 2017, ONC will continue to expose and discourage health information blocking by finalizing and aggressively implementing new ONC Certification Program rules, creating and promoting clear channels for reporting information blocking, and addressing provider information blocking in existing HHS programs. This is supported by ONC's proposal to prohibit information blocking where possible and associated business practices (Appendix II), which gives the Secretary of HHS the authority to establish program conditions and requirements for vendors of health IT certified under ONC programs to prevent unnecessary impediments to the use of certified health IT for the interoperable exchange of electronic health information. To support an interoperable, learning health system, ONC will identify the interoperability principles ("rules of the road") necessary for information to flow efficiently across

networks and will transition to a governance mechanism for health information exchange which will develop common policies and practices to advance interoperability goals across industry and government. This work is complemented by ONC's proposal to establish health IT governance certification (Appendix I), which will amend the PHS Act to specify that ONC may establish standards, implementation specifications, and certification criteria related to the business policies, practices, and behavior of heath IT entities. Taken together, these proposals allow ONC to establish guardrails around not only the technology itself, but how it is implemented.

ONC's Budget request also includes a legislative proposal to require health IT transparency (Appendix III), which will authorize the Secretary to require (through notice-and-comment rulemaking) that certified health IT vendors submit ongoing and detailed information to the National Coordinator concerning the costs, capabilities, limitations, and other performance characteristics of certified health IT.

ONC will continue working on the expansion of the Certification Program's regulatory guidance for health care providers – such as mental and behavioral health facilities – and will also continue to collaborate with its federal partners and interested stakeholders to align activities outlined in the updated Federal Health IT Strategic Plan 2015-2020. ONC will also convene a national working group on e-health and telemedicine to coordinate and collaborate with federal agencies regarding e-health needs, standards, federal goals, and federal efforts. This working group will promote interoperability by ensuring that ONC's federal partners are working together to increase e-health compatibility. Funding for ONC's two FACA committees, the Policy Committee and Standards Committee, is also included in this request.

# Cross Departmental Strategy: Prescription Drug Overdose Initiative (\$5.0 million)

In FY 2017, ONC will expand efforts to harmonize technical standards to support Prescription Drug Monitoring Program (PDMP) and Health IT interoperability. This funding will provide technical assistance to support PDMP-health IT integration and implement the ONC S&I Framework Initiative's "PDMP & HIT Integration Initiative Implementation Guide (IG)." This Budget request includes funding towards future work for the refinement, implementation, and dissemination of the ONC S&I Framework Initiative's "PDMP & HIT Integration (IG)."

Additionally, ONC will fund PDMP pilots and challenge awards to further high-impact innovation using health IT to improve clinical decision-making and prescribing practices. ONC will provide targeted technical assistance to help state PDMPs in need of assistance to achieve interoperability with health IT systems in an effort to increase providers' efficient and timely access to PDMP data. Also in FY 2017, ONC will support and lead efforts, with other HHS agencies, to further the adoption of electronic prescribing of controlled substances (EPCS) by identifying successful state practices and policies to inform a national, consistent approach for EPCS adoption and measurement across states; tracking trends in EPCS adoption (including enabled vs active); tracking the number of certified venders that are EPCS and their respective products; and, reporting on state level policies and challenges for implementing EPCS.

# Privacy and Security (\$3.8 million)

In FY 2017, ONC will continue to inspire consumer and provider confidence and trust in health IT by ensuring that electronic health information is private and secure wherever it is transmitted, maintained, or received, and that consumers have access to their health information when and where they need it for better health and smarter spending. Work on privacy and security will include:

- Development of Health IT Privacy and Security Policy, Standards, and Adoption Strategies: ONC will continue to engage with the FACAs, federal partners, the states, foreign countries, and other stakeholders to promote interoperability and coordinate, formulate, and prioritize privacy and security policies and standards by assessing policy gaps and weaknesses and developing appropriate policy or standards-based solutions.
- Safeguarding Health Information: ONC will continue to provide practical education on how the federal privacy and security law (HIPAA) supports interoperable exchange of health information and consumer access to their health information. ONC will also provide expert information on protection of health information in an electronic environment through the development of educational tools, resources, and standards for vendors, providers, consumers, and other stakeholders to ensure that health information technology and workflows are protected by adequate safeguards. Addressing health IT security issues allows patient health information to happen in a secure way, thus contributing to Precision Medicine, reducing information blocking, and promoting interoperability. To further the safe exchange of health information, ONC will support the creation and implementation of a health sector cyber threat information sharing and analysis organization (ISAO).
- *Patient and Provider Identity Management:* To further interoperability, ONC will continue its work on patient and provider identity management to assure that patients and providers are who they say they are when accessing and exchanging information electronically.
- Patient Control over Use and Disclosure of Protected Health Information (PHI): Patients have a right to view, download, and transmit their own health information under the HIPAA Privacy Rule and Meaningful Use Rule, but many patients are unaware of their rights. In order to fully realize the capabilities of electronic health information to attain better health, smarter spending, and better health care, ONC will continue to support the development of policies and standards for ensuring that patients can access their health information, and that the health care system takes advantage of advances in technology to enable patients to document a desire to disclose their health information where that documentation is required, such as when special laws other than HIPAA apply, or to supply data to support academic research and the Precision Medicine Initiative.

# Health IT Safety, Usability and Clinical Quality Improvement (\$7.6 million)

In FY 2017, ONC will work to support use of interoperable health IT by continuing to lay the foundation for and establishing a Health IT Safety Collaborative. Additionally, ONC will also continue to coordinate across federal partners and programs where interoperable health IT and health information exchange supports better care, smarter spending, and healthier people, with a focus on advancing: 1) the reliability of CQM data captured, calculated, and reported through certified health IT; 2) the availability and effective use of CDS; and 3) the ability to use data captured through routine clinical care to support the development and dissemination of new knowledge on care outcomes.

Health IT Safety Collaborative: The Health IT Safety Collaborative, funded at \$5.0 million, will
greatly improve HHS' ability to effectively coordinate implementation of the Health IT Safety
Plan. There is clear and emerging evidence that the broad scale implementation of health IT has
improved the general safety of healthcare but there are still best practices to be agreed upon
and more broadly and consistently implemented across the spectrum of healthcare providers
and entities. It is also becoming clear that there are a smaller number of unintended
consequences that are the result of health IT and that addressing these problems require the
participation of multiple stakeholders who play a role in promoting the safe implementation of
health IT. To address this, ONC will establish a Health IT Safety Collaborative. The Collaborative
and activities related to Collaborative development will generate substantial efficiencies by

enhancing coordination and alignment of activities by encouraging greater levels of private investment in health IT safety. Extending to software developers the same confidentiality protections afforded to providers under the Patient Safety and Quality Improvement Act of 2005 (PSQUIA, Pub. L. No: 109-41) will help ensure the participation of those developers. In 2017, Collaborative development will be informed by public/private stakeholder roadmap. As part of this initiative, ONC intends to conduct analysis to help prioritize Collaborative activities and to align those activities with broader patient safety goals, as well as the development of standards, guidance, best practices and tools to support Collaborative use and effectiveness. The Health IT Safety Collaborative will help ensure that approaches to health IT safety are properly implemented and evaluated, thereby promoting more effective and less burdensome regulation of health IT safety. This request is supported by ONC's proposal to provide ONC authority to use contracts, grants, or cooperative agreements to establish a Health IT Safety Collaborative and provide adequate confidentiality protections (Appendix IV).

- Usability: ONC will work to support use of interoperable health IT by developing and implementing
  methods to assess the usability of health IT products including the features critical to participating in
  exchanging information to improve care delivery and coordination. ONC will develop and implement
  methods to assess the usability of health IT products including the features critical to participating in
  exchanging information to improve care delivery and coordination. ONC will create and disseminate
  usability guidance for purchasers of health IT, to assist them in making informed decisions about the
  interoperability of health IT products.
- Clinical Quality Improvement: ONC will continue using a strategic, collaborative approach to promote a robust, innovative marketplace for interoperable health IT measurement and improvement tools. Use of health information exchange, such as electronic reporting of quality measures, will help providers achieve and sustain transformational improvement in the quality and value of care.

# **Outputs and Outcomes Table**

Program/Measure	Most Recent Result / Target / Summary	FY 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
Consumer ^^^^				
Attitudes About Privacy & Security of EHRs				
1.F.2 Percent of Americans who strongly or somewhat agree that the privacy and security measures taken by providers establish reasonable protections for their electronic health	FY 2014: 80% Target: 82% (Below Target)	Not Set	Not Set	
records <sup>4</sup>	(			
Access to Electronic Health Information				
1.F.1 Percent of Americans who have been given electronic access to any	FY 2014: 38%	50%	60%	+10 Percentage
part of their health care record by their health care provider	Not Set			Points

Data Sources:

<sup>^</sup> 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.

<sup>^^</sup> Hospital measures: American Hospital Association (AHA) Information Technology (IT) Supplement to the AHA Annual Survey, which ONC partially funds through cooperative agreement.

<sup>^^^</sup> CMS EHR Incentive Program measures data are provided to ONC by the CMS EHR Incentive Programs. <sup>^^^</sup> 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.

<sup>&</sup>lt;sup>4</sup> Data are derived from a national survey. Year-to-year differences do not imply statistical significance. From 2013 to 2014 the percentage point difference is within the margin of error for the survey instrument. Data was not available for 2015.

# Standards, Interoperability, and Certification

Standards, Interoperability, and Certification	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 (+/-) FY 2016
Budget Authority	15,425	15,528	0	-15,528
PHS Evaluation Funds	0	0	24,135	+24,135
Total, Program Level	15,425	15,528	24,135	+8,607
FTE	26	40	40	0

# Budget Summary

# Authorizing Legislation:

Enabling Legislation Citation	PHS Act 42 U.S.C. 201
Enabling Legislation Status	Permanent
Authorization of Appropriations Citation	No Separate Authorization of Appropriations
Allocation Method	Direct Federal, Contract, Cooperative Agreement, Grant

# **Program Description and Accomplishments**

Advancing the interoperability of health information technology so that electronic health information can be used in support of payment and delivery system reform is a critical part of ONC's mission. An interoperable health IT infrastructure would ensure that the nation is given more transparency on the cost and quality of care. Electronic health information would provide all individuals, their families and their health care providers with consistent, secure and timely access to standardized health information that facilitates informed decision-making and effective health management, allows patients to be active partners in their care, bolsters clinical decision-making, and benefits the overall health of our population. The effective use of this health information supports improved models of care delivery, value-based purchasing, and scientific advancement.

Through investments in standards development and harmonization, ONC engages health care, technology, and standards stakeholders to accelerate industry consensus by focusing on core standards, principles, vocabularies, and technical components that will enable interoperable health IT. To maximize the impact of these investments, ONC convenes federal agencies and other partners to implement and advance Health Information Exchange (HIE) nationwide. ONC also provides direct technical and financial assistance to states and communities who have committed to developing interoperable health IT infrastructures that support national priorities. By providing reliable testing tools and data for the Certification Program, ONC is building trust in the health IT marketplace supporting providers' efforts to achieve interoperability, meaningful use, and the optimization of health IT.

### Standards and Technology

ONC makes strategic investments in standards harmonization, implementation guidance and pilots in order to accelerate industry progress in specific areas that require interoperability, and works with standards development organizations to develop and publish standards. ONC also administers the Health IT Certification program, which outlines the processes by which health IT developers can demonstrate that their health IT conforms to specific certification criteria and interoperability standards. These investments address interoperability requirements in support of clinical care, patient engagement, research, clinical quality improvement, privacy and security, and population health.

Standards-based technology enables health information to be consistently recorded and securely exchanged with another party. In the long term, coordinated standards-based innovation, combined with appropriate payment and care delivery policies, will reinforce the national health IT infrastructure, a foundational component for transforming health care and developing a learning health system. In coordination with the Health IT Standards Committee and federal partners, ONC engages a diverse community of stakeholders to rapidly advance the adoption of consensus-based standards to solve core interoperability issues of data capture and exchange.

ONC also invests resources to assist the stakeholder community to implement and test standards adopted through regulation. ONC funded the development of reference implementations and specific "companion guides" for standards to improve health IT developers' implementation consistency. In collaboration with National Institute of Standards and Technology (NIST) and the health IT community, ONC supports the development of testing tools, test procedures, and data that is ultimately used by Accredited Testing Labs (ATLs) to test health IT products to specific criteria. ONC strives to maintain an innovative health IT environment by continuing to support entrepreneurs, public health advocates, and developers as they seek to find ways to make health information more accessible and usable. ONC will continue to play a key role as a leader and convener of the health IT community as the industry as a whole works towards a health IT-enabled interoperable ecosystem.

#### Standards Coordination and Collaboration

Through structured coordination and collaboration, ONC helps accelerate health care stakeholder's ability to develop solutions to technical challenges posed by different interoperability needs. ONC focuses on ways to accelerate consensus and, where necessary, convenes broad communities together for the purposes of identifying and developing additional standards guidance. Each ONC-led activity tackles a critical interoperability challenge through processes that typically include an understanding the clinical uses in scope; identification and harmonization of existing technical specifications and implementation guidance; pilot projects; and mechanisms for feedback and testing of implementations, often in conjunction with ONC partners such as NIST. Accomplishments include:

- Publication of the 2016 Interoperability Standards Advisory, which provides a detailed list of the standards and implementation specifications that are best available to accomplish different interoperability goals.
- Awarded new cooperative agreements directly with standards development organizations (SDOs) to support the acceleration and development of additional best practice guidance, more specific implementation guidance, and evaluations of testing infrastructure capacity and the ability of SDOs to contribute to the measurement of standards adoption.
- Structured Data Capture (SDC) Initiative: This initiative is focused on standardization of how data is captured in an electronic heath record (EHR.) Ensuring that content and structure for incoming health information is standardized is crucial to data being available and usable for patient care, clinical research, patient centered outcomes research and public health. This initiative participated in the 2015 IHE Connect-a-thon, where there were 10 successful tests of the Integrating the Healthcare Enterprise (IHE) Profile by federal agencies including the Center for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and various health IT developers. A separate Health Level Seven International (HL7) SDC Fast Healthcare Interoperability Resource (FHIR) Profile was submitted for balloting and a virtual FHIR connect-a-thon was held in April 2015 to test the SDC Profile.
- Clinical Quality Framework (CQF) Initiative: This initiative joins together the standards that support clinical quality measurement and Clinical Decision Support (CDS) to support the delivery of evidence-

based care and its measurement. It harmonizes existing quality measure standards and extends the work of Health eDecisions (HeD) by focusing on shareable CDS artifacts that align with the data definitions of the quality measures. This standard was balloted in January 2015 and an implementation guide was balloted in May 2015 that describes how to use Contextual Query Language (CQL) in conjunction with Health Quality Measurement Format (HQMF) for quality measures.

Prescription Drug Monitoring Program (PDMP) & Health IT Integration Initiative: The purpose of this
initiative is to bring together the PDMP and health IT communities to standardize the data format,
and transport and security protocols to exchange patient controlled substance history information
between PDMPs and health IT systems (i.e., EHRs and HIEs). The initiative aims to enable integration
of PDMP data into the normal clinical workflow. The PDMP initiative has over a dozen on-going
pilots with several different organizations.

#### Standards Implementation and Testing Environment

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. The <u>Standards Implementation and Testing Environment</u> (SITE) provides conformance testing and validation tools for certain health IT functionality. SITE provides rapid 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. Accomplishments include:

- A variety of different health IT testing tools have been consolidated in SITE, which now includes nine technical "sandboxes" and additional specific test tools. It has also begun to serve as a central place through which other industry test tools can be accessed.
- Advanced Secure Transport Standards for Query based Exchange: Provided implementation support to enable developers' use of advanced technical standards for secure query based exchanges, including <u>Fast Health Interoperable Resources</u> (FHIR).
- Patient Matching: Implementation and testing support for enabling the use of patient matching standards and methods to enable patients to securely collect and link their data from multiple providers. This will improve patients' ability to use their entire health information in support of better health care.
- Consolidated Clinical Document Architecture (C-CDA): Created validators for validating systems capability to generate clinical content conformant to C-CDA Implementation Guide (IG) which is the critical for Transitions of Care, View, Download and Transmit and Clinical Office Visit Summaries. The tools added include C-CDA validators, reference C-CDA's, and negative tests for C-CDA.

#### Innovation

ONC leads efforts designed to encourage a vibrant health IT marketplace, where systems are interoperable and consumers have the ability to obtain "best-of-breed" solutions from among a plethora 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 through educational materials, live in-person training events, prize challenges and codeathons (live events that occur over the course of one or more days, bringing together developers, designers, innovators and entrepreneurs to build exciting new applications and tools,) and knowledge transfer. By engaging with vendors, startups, the venture capital community, incubators and accelerators, providers, and researchers at the leading edge of health IT, ONC is working to find the best ways to use health IT to meet the goals of better health, better care, and greater value. Accomplishments include:

- Collaborated with the HHS IDEA Lab and local startup incubator 1776 to host an Open Data Health Innovators Boot camp, bringing together open data managers from around HHS and focusing on how open data and health IT can reach underserved populations. Approximately 70 people attended.
- Collaborated with HHS IDEA Lab, United Kingdom (UK) Trade & Investment, and National Health Service (NHS) England to host a UK-US Startup Boot camp in June, with approximately 100 attendees and speakers representing UK and US startups that had successfully expanded their footprint to both countries, and a panel of Venture Capitalist's discussing the top market trends and advice for companies considering international expansion.
- The Market Research & Development Pilot Challenge awarded six innovator-pilot host site teams \$50,000 each to conduct six-month pilots testing new health information technologies with actual patients. These technologies included telehealth services in senior communities; preparation, education, and follow-up with patients pre- and post-surgery; information dissemination to prevent diabetes in low-income, non-English speaking communities; home health monitoring and intervention; real-time asthma monitoring of children; and remote monitoring and intervention in hypertension care. Following the pilot's conclusion, each team produced white papers or journal articles evaluating their technologies and the success of the pilots.

#### Certification

ONC administers the ONC Health IT Certification Program, which outlines the processes by which health IT developers can demonstrate that their health IT conforms to specific certification criteria and interoperability standards. Working cooperatively with NIST, Center for Medicare and Medicaid Services (CMS), CDC, and FDA the ONC Health IT Certification Program includes test methods that constitute testing procedures, data, and tools in accordance with the standards and certification criteria adopted by regulation. The ONC Health IT Certification Program as a whole provides comprehensive, 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 the health IT products certified through the ONC Health IT Certification Program. The CHPL is also used to generate a CMS EHR ID number that is representative of the Certified Electronic Health Record Technology (CEHRT) they used to demonstrate meaningful use under the Electronic Health Record Incentive Program. To date, there are over 1,400 health IT developers with over 2,000 unique products that have been certified against 2014 Edition Certification Criteria and over 1,900 unique products against the recently retired 2011 Edition. Accomplishments include:

- ONC, in collaboration with NIST, completed development and deployed the 2014 Edition Test Method for the adopted 2014 Edition certification criteria, which includes test procedures, test data, and test tools for use by ATLs. The 2014 Edition adheres to more rigorous conformance criteria than were used for the prior 2011 edition. ONC developed standardized test data for twice as many of the certification criteria compared to the previous edition and automated testing was improved for the 2014 Edition.
- ONC has adopted a new format for test procedures that is less prescriptive and more outcome-focused to encourage greater innovation the part of health IT developers. ONC also released <u>draft test</u> <u>procedures</u> for the first time concurrently with the release of the 2015 Edition NPRM. Now that the 2015 Edition certification final rule is published, the 2015 Edition Draft Final Test procedures are undergoing a public comment period in order to ultimately be finalized and approved by the National Coordinator.

• Developed Certification Companion Guides (CCG) that are intended to help health IT developers more quickly understand and interpret our regulatory requirements so that they can 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.

#### Federal Health Architecture

An E-Government Line of Business, the Federal Health Architecture (FHA) is a partnership among federal agencies, including the Office of Management and Budget (OMB), Department of Health and Human Services (HHS), Department of Defense (DoD), Department of Veterans Affairs (VA), and the Social Security Administration (SSA). On behalf of the federal partners, ONC acts as the managing partner for the FHA. Through the FHA, federal agencies have joined together to implement government-wide solutions to health IT that address agency business priorities while protecting citizen privacy. The FHA has successfully supported multiple federal partner priorities to address barriers to interoperability and identify potential solutions. The FHA serves the needs of more than 20 federal agencies in domains as diverse as military and veterans' health care, long-term care and disability services, research, and tribal health services. Accomplishments include:

- Released CONNECT 4.5 which continues to build upon and implement enhancements furthering CONNECT as an interoperability platform to securely exchange health information. Enhancements include additional logging and auditing capabilities were added to the previously released Nationwide Health Information Network (NwHIN) CAQH CORE X12 service. Additional improvements were made to testing both in rigor and automation. Supported the DoD, SSA, VA and CMS implementation teams working through deployment, operational and partner testing issues. Provided ongoing support to the open source community. Continued the maintenance of the open source wiki, website and ticketing support systems.
- Convened federal partners to review and provide input into the Interoperability Roadmap and the Federal Health IT Strategic Plan. Input from the Indian Health Service (IHS), CMS, DoD, SSA, VA, and other agencies were provided through FHA.
- The Directed Exchange Work Group Continues to assist the agencies in navigating the Electronic Healthcare Network Accreditation Commission (EHNAC), and DirectTrust landscape for accreditation and membership. Additionally, the group investigated what is needed for federal FHIR, exchange from a policy and security standpoint. The group also discussed recommendations to the Federal Public Key Infrastructure (PKI) Certificate Policy Work Group on what a federal health IT exchange certificate chain validation process would look like.

Fiscal Year	Amount
FY 2013	15,979,118
FY 2014	15,737,000
FY 2015	15,425,000
FY 2016 Enacted	15,528,000
FY 2017 President's Budget	24,135,000

#### Funding History

#### **Budget Request**

ONC requests \$24.1 million in FY 2017 to support standards, interoperability, and certification activities, an increase of \$8.6 million above FY 2016 enacted. The request includes funding for 40 FTEs. Increased funding will be used to advance interoperability among health IT systems to support clinical care, Precision Medicine, patient engagement, research, clinical quality improvement, privacy and security,

and population health. ONC will engage the public and private sectors to identify and fill gaps in current health IT infrastructure. ONC will also enhance standards, 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.

This request supports Federal Health IT Strategic Plan 2015-2020 Goals 1: Expand Adoption of Health IT; 2: Advance Secure and Interoperable Health Information; 3: Strengthen Health Care Delivery; 4: Advance the Health and Well-Being of Individuals and Communities, and 5: Advance Research, Scientific Knowledge, and Innovation.

#### Standards and Technology (\$23.0 million)

In FY 2017, ONC will continue to support collaborative, public-private initiatives through which accelerated and coordinated standards work can be accomplished. This funding and work is not only critical for ONC, but also for the many other HHS agencies with which we have collaborated in the past, including the Assistant Secretary for Planning and Evaluation (ASPE), the Substance Abuse and Mental Health Services Administration (SAMHSA), CMS, the Agency for Healthcare Research and Quality (AHRQ), CDC, and as well as DoD, VA, and other federal agencies with which ONC collaborates as part of the FHA.

In FY 2017, ONC's efforts will build upon recent accomplishments and ensure continued progress toward modernizing the nation's health IT infrastructure in order to support transformed, interoperable learning health care. ONC will address standards for interoperable health information technology, including support for work with SDOs and technology developers. Throughout FY 2017, ONC will continue work with industry to define best practices and provide guidance on the exchange and use of priority data elements. Additionally, ONC will make updates to existing interoperability testing tools to expand the breadth and depth of testing. In FY 2017, ONC's standards work will include:

- Summary care records: This standard is used most often for transitions of care. In FY 2017, ONC will continue coordinating with the industry to enable the consistent implementation of the standard for this purpose in order to enable interoperability.
- Medication-related standards: FY 2017 funding will be used to further improve the specificity, implementation, and use with which medication standards are applied. Medication standards include the consistent representation of drugs, medication instructions ("structured sig"), and medication transactions for refill, cancel, and medication history. The consistent use of medication standards also can support clinical decision support and drug-drug/drug-allergy interactions, one of the most often cited patient safety issues.
- Laboratory data exchange: ONC will continue coordinating in FY 2017 on a suite of laboratory standards for ordering, results, and lab service directories that require further implementation and testing by the field. The implementation of all of these standards can improve patient safety and provide efficiencies for health care providers.
- Continued implementation testing, pilots, and collaboration with industry stakeholders to advance
  patient matching, application programming interfaces, and semantic harmonization among
  identified priority data elements.

#### **Precision Medicine**

In FY 2017, ONC will fund standards coordination and development to advance the basis on which precision based medicine can be practiced. This \$5.0 million in funding will lay the ground work to achieve many of the milestones included in the Interoperability Roadmap's 6-year and 10-year milestones for how health IT can support a learning health system. ONC will engage industry

stakeholders to identify the standards, technology, and policy necessary to support big data analyses and Precision Medicine. Working closely with our many partners, ONC will aggressively pursue a portfolio of standards and technology initiatives that support Precision Medicine and protect user privacy, consistent with final revisions to the Common Rule, such as:

- The standardization and use with consent of patient-generated health data from non-clinical settings;
- The incorporation of genomic data into health IT with appropriate protections;
- Patient identity management and matching with consent to permit linked analyses; and,
- New platforms for clinical trial recruitment through the use of health IT.

#### Standards Implementation and Testing

In 2017, ONC will continue engaging the developer community through improvements to the technical implementation and testing environment that ONC has established to support a pre-certification/design and development testing environment that can link policy to real world and future state tools that support the market, providers, and consumers. ONC will provide implementation and testing support for the implementation of standards via this online environment adopted for ONC's Certification Program and Electronic Health Record Incentive Program Stages 2 and 3. It will also work toward the development of tools that providers will be able to use to test the health IT they acquire. These test tools help advance interoperability by allowing health IT developers to verify that their systems have implemented the standards correctly before they reach the marketplace.

#### Health Information Exchange

In FY 2017, ONC will strive for the health care delivery system to achieve the same steep adoption curve for standards-based exchange that has occurred for EHRs. ONC will continue to leverage the lessons, insights and tools developed during the past seven years to support nationwide interoperability and meaningful use. Additionally, ONC will build upon the existing health IT infrastructure across the system by filling service gaps, especially in underserved areas, enhancing standards and ensuring that the infrastructure of our nation's health data supports access, equity, and sustainable sharing of health information nationwide. ONC will continue expanding strategic relationships with states, communities and the private sector to support health information exchange implementation and adoption efforts that enabled health transformation initiatives. Additionally, ONC will conduct robust "real world" pilots and other collaborative demonstrations of the standards to identify unforeseen weaknesses and provide feedback to the standards development process before standards get integrated into health IT certification.

#### Certification

In FY 2017, ONC will continue to enhance the Health IT Certification Program, which will result in improved efficiency for health IT developers as well as more rigorous testing requirements, which will provide greater assurance relative to product functionality. This funding will support the ongoing maintenance of standards conformance test tools, implementation guides, and user guides to enhance the interoperability of health IT, and support new certification and testing functionality required to fulfill the growing number of federal programs relying on ONC's certification program. ONC will continue to refine and enhance (in coordination with NIST) 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 certification program is expected to broaden its support in some areas to cover certain health information exchange functionality and other capabilities that are used by specific types of service providers. This includes developing certification criteria and associated testing tools to support alternative payment models as described in the Medicare Access and CHIP Reauthorization Act

(MACRA) legislation, as well as support for other Federal programs looking to leverage ONC's certification. Enhancing testing tools and test methods with a greater focus toward interoperability in addition to basic standards conformance will help ensure certified products interoperate and provide individuals and health care providers with the functionality needed to coordinate care and implement care delivery transformation. The program will continue its monitoring 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.

#### Science and Innovation

In FY 2017, ONC will continue to coordinate federal efforts to accelerate progress toward a vibrant health IT marketplace with interoperable solutions for providers and consumers from which to choose. These outreach programs serve three purposes, focusing on receiving feedback from implementers on the ground. Through these programs, ONC is able to:

- Quickly gauge consumer and developer interest through collaborative outreach, allowing ONC to target our approach;
- Accelerate consensus on interoperable solutions using open codeathons and challenges that bring developers together to quickly converge on shared solutions; and,
- Understand where ONC efforts should end and the private sector should take over.

In FY 2017, ONC will hold approximately four Innovation Challenges focusing on interoperability, and additional outreach programs such as code-a-thons and webinars.

#### Federal Health Architecture (\$1.2 million)

In FY 2017, ONC will continue to act as the managing partner of the FHA. The request, required by OMB, will ensure continued coordination and alignment HHS-wide in support of the FHA. The FHA will continue to support multiple federal partners, including the VA and DoD, by addressing barriers to interoperability and identifying potential solutions. This includes continuing to work with the DoD Healthcare Management System Modernization Program on modernizing the military health system and making it interoperable with Department of Veterans Affairs and private provider electronic health records. ONC will also work with the DoD and the VA to identify and pilot potential shared service opportunities.

#### **Outputs and Outcomes**

	Most Recent Result / Target	FY 2016	FY 2017	FY 2017 +/- FY
Program/Measure	/ Summary	Target	Target	2016
Health Information Exchange: Capability				
Office-Based Professionals ^				
1.E.5 Percent of physicians with capability	FY 2014: 47%	Not Set	Not Set	
for patients to view online, download, or				
transmit information from their medical	(Historical)			
record ^^				
Non-Federal Acute Care Hospitals **				
1. E.9 Percent of non-federal acute care	FY 2014: 64%	Not Set	Discontinue	
hospitals with capability for patients to	( <b>-</b> 11 )			
view online, download, <i>and</i> transmit information from their medical record <sup>5</sup> ^^	(Baseline)			
Health Information Exchange: Activity				
Office-Based Professionals ^				
1.E.3 Percent of office-based physicians	FY 2014: 42%	60%	Discontinue	
who are electronically sharing any patient	FT 2014. 4270	00%	Discontinue	
health information with other providers	(Historical)			
1.E.4 Percent of office-based physicians	FY 2014: 26%	25%	40%	+15Percent
who are electronically sharing patient	112014.2070	2370	4070	age Points
information with any providers outside	Target: 40%			uge i onito
their organization	Turget. 40/0			
, , , , , , , , , , , , , , , , , , ,	(Target Not Met			
	But Improved)			
Non-Federal Acute Care Hospitals ^^				
1. E.7 Percent of non-federal acute care	FY 2014: 76%	80%	85%	+5
hospitals that are electronically				Percentage
exchanging patient health information	Target: 75%			Points
with any providers outside their	(Target Exceeded)			
organization				
1.E.10 Percent of non-federal acute care	FY 2014: 69%	Not Set	Discontinue	
hospitals that are electronically sharing any patient health information with	Targat: 60%			
ambulatory providers that are outside	Target: 60% (Target Exceeded)			
their organization	(Target Exceeded)			
Health Information Exchange:				
Interoperability				
Office-Based Professionals ^				
1.E.6 Percent of office-based physicians	FY 2013: 42%	Not Set	Not Set	
who are electronically sharing patient				
information using a Summary Care	(Baseline)			
Record <sup>6</sup>				

<sup>&</sup>lt;sup>5</sup> ONC revised this measure from "view, download <u>or</u> transmit" to "view, download, *and* transmit". The change rationale is to improve alignment with the CMS EHR Incentive Programs' related requirements. Accordingly the 2013 baseline (was 41%) has been updated. Using the prior measurement statement the 2014 actual would have been 91%. The previous FY 2014 target was 55%.

<sup>&</sup>lt;sup>6</sup> A FY 2014 estimate is not available for this measure due to inability to calculate a reliable national estimate for the measure considering survey response patterns.

Program/Measure	Most Recent Result / Target / Summary	FY 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
1.E.11 Percent of office-based physicians who can easily integrate (e.g. without manual entry) health information received electronically into their EHR.	Baseline expected February 2016	Not Set	Not Set	
Non-Federal Acute Care Hospitals ^^				
1.E.8 Percent of non-federal acute care hospitals that are electronically sharing clinical/summary care records with any providers outside their organization	FY 2014: 64% Target: 65% (Target Not Met	Not Set	Discontinue	
1.E.12 Percent of non-federal acute care	But Improved) FY 2014: 40%	45%	50%	+15
hospitals that can easily integrate (e.g. without manual entry) health information received electronically into their EHR.	(Baseline)	4370	50%	percentage points

Data Sources:

^ 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.

^^ Hospital measures: American Hospital Association (AHA) Information Technology (IT) Supplement to the AHA Annual Survey, which ONC partially funds through cooperative agreement.

^^^CMS EHR Incentive Program measures data are provided to ONC by the CMS EHR Incentive Programs.

#### Adoption and Meaningful Use

Adoption and Meaningful Use	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 (+/-) FY 2016
Budget Authority	10,524	10,514	0	-10,514
PHS Evaluation Funds	0	0	11,523	+11,523
Total, Program Level	10,524	10,514	11,523	+1,010
FTE	42	50	50	0

## Budget Summary

#### Authorizing Legislation:

Enabling Legislation Citation	PHS Act 42 U.S.C. 201
Enabling Legislation Status	Permanent
Authorization of Appropriations Citation	No Separate Authorization of Appropriations
Allocation Method	Direct Federal, Contract, Cooperative Agreement, Grant

#### **Program Description and Accomplishments**

Advancing a patient-centered health system requires a fundamental transformation in how we pay for and deliver care. Prior to the Health Information Technology for Economic and Clinical Health (HITECH) Act, significant barriers — such as lack of financing, gaps in a trained workforce, and difficulties integrating health IT tools with traditional provider workflows — threatened to slow adoption of electronic health record (EHR) systems and prevent their use. With more than 72 percent of eligible health care professionals and 99 percent of eligible hospitals in the nation adopting certified EHR technology, ONC has made substantial progress towards overcoming these barriers. Through strategic investments, effective leadership, and direct engagement with the health IT community, ONC has developed a nationwide network of organizations that are focused on supporting individual providers and consumers to adopt and meaningfully use health IT. Through innovative techniques, ONC diffuses best practices and resources such as guides, training, and technical assistance to these organizations.

Through ONC's adoption and meaningful use efforts, ONC engages consumers and patients; monitors and evaluates economic data and market trends concerning the adoption, meaningful use, and optimization of health IT, as well as the collection, use, and sharing of health information. Furthermore, ONC engages providers, consumers, and other stakeholders to increase awareness of the benefits of health IT and ONC's programs, which can help them adopt and meaningfully use interoperable health IT tools and to improve health outcomes and transform the way healthcare is delivered.

#### Provider Adoption and Optimization Support

ONC designs and implements a variety of methods to accelerate and support providers' ability to collect, share and use health data. ONC also works directly with health care providers to identify barriers to adoption of adoption and use of health IT and develop strategies to mitigate those barriers. ONC provides a full range of services and technical assistance to meet the challenges of utilizing, optimizing and meaningfully using health IT tools, including EHR systems. In particular, ONC convenes providers, shares best practices nationally through its National Learning Consortium (NLC), and monitors their progress with a robust web-based customer relationship management (CRM) tool. When these services

and technical assistance programs are coordinated with patient engagement efforts to affect a change in behavior, favorable impacts on health status and reduced costs are achieved.

#### National Learning Consortium (NLC)

The NLC uses HealthIT.gov as the primary method of educating and disseminating nationwide best practices and solutions to common challenges that providers and consumers face related to adoption and use of health IT. In 2014, over 1,000,000 visitors accessed healthit.gov and over 23,000 health IT tools and resources were downloaded. Through Communities of Practice (CoP) and the Health IT Fellows program, individuals share stories from the perspective of health care providers, office staff, and administrators on how they have leveraged health IT to deliver better care, improve health and reduce costs. CoPs and other similar groups bring together over 6,600 health IT implementers and ONC technical experts as they identify issues and discover solutions to common pressing challenges. They address topics such as delivery system reform, implementation and project management, workflow redesign, vendor selection and management, meaningful use, privacy and security, workforce issues, and public health. The NLC provides a virtual platform to disseminate hundreds of best practice guides and tools to the broader health IT community. Accomplishments include:

- Providers reported challenges on Certified Electronic Health Record Technology (CEHRT,) the Electronic Health Record Incentive Program, and health IT enabled delivery system reform impacting providers across all practice settings. To address these challenges via NLC resources, trainings and tools were tested, revised, and disseminated among all Regional Extension Centers (RECs,) then made available on <u>HealthIT.gov.</u>
- Providers also reported challenges in completing the Security Risk Analysis (SRA) and mitigating
  findings that could put patient data privacy or security at risk. In partnership with ONC's Office of the
  Chief Privacy Officer and HHS Office for Civil Rights (OCR), and in conjunction with the NLC and
  Privacy and Security Community of Practice, resources, trainings and tools were tested, revised, and
  disseminated among all RECs, then made available on <u>HealthIT.gov.</u>
- <u>Additional resources</u> have been developed on topics such as Change Management, Vendor Selection and Management, Health Workforce Issues, Workflow Redesign, Health Information Exchange, Rural Health, Consumer Engagement and Public Health.

#### Customer Relationship Management (CRM) Tool

The CRM is a nimble, cloud-based business intelligence tool that serves approximately 740 users at ONC, partner organizations and grantees. A large number of users throughout the United States are "on the ground" helping health care providers adopt, use, and optimize their interoperable health IT systems by entering near real-time data into the system. This helps to inform ONC about the adoption and appropriate use of EHR technology. To assist ONC programs with data analytics and situational awareness, the CRM data set is merged regularly with several other data sources. Combined with ONC's internal analytical capacity, this data provides feedback that goes beyond the realm of anecdotal evidence and can be turned into concrete lessons learned that are used to focus policy and program efforts. Accomplishments include:

- Leveraging more than 11 million data elements from over 158,000 providers currently enrolled with RECs, ONC uses CRM data to identify barriers and best practices to health IT adoption and meaningful use. Approximately half of all primary care providers in the U.S. are represented in the CRM tool.
- Expanding the use of CRM to federal partners working with the Health Resources and Services Administration (HRSA) and Centers for Medicare and Medicaid Services (CMS), deploying the CRM tool to track the progress of over 990 (over 80 percent) of the approximately 1,200 Federally Qualified Health Centers in achieving Meaningful Use, and incorporated data from the Electronic

Health Record Incentive Programs to allow for better analysis of how providers are moving through the Electronic Health Record Incentive Program. For instance, ONC is able to identify providers who are registered for the Electronic Health Record Incentive Program who are working with an REC but who have not achieved Meaningful Use. This information can be used to target outreach and technical assistance.

#### Regional Extension Center (REC)

The <u>REC Program</u> is an ONC Recovery Act-funded grant program whose primary mission is to provide onthe-ground technical assistance to individual and small health care provider practices, critical access hospitals, community health centers, and other underserved settings that require assistance with implementing and maintaining EHRs. RECs assist in transforming physician practices to achieve specific, measured clinical, quality, safety, and cost outcomes. There are 62 federally funded RECs that support over 158,000 providers in practice transformation and change management activities to achieve these outcomes. An October 2013 Government Accountability Office (GAO) report found that Medicare providers working with an ONC regional extension center were over 1.9 times more likely to receive an EHR incentive payment than those who were not partnered with an extension center. With over five years of building this level of trust, ONC funded programs have become an essential community asset serving solo, small group and underserved settings. Leveraging this existing, nationwide infrastructure, RECs are poised to further build physician practice competencies and spread best practices necessary to manage the health and health care of patients in every state and territory in the nation. Accomplishments include:

- Actively working with <u>over 158,000 providers</u> (including over 47 percent of all primary care providers in the country and 13,000 specialists) in over 24,000 small practices, including 83 percent of Federally Qualified Health Centers and 81 percent of the nation's Critical Access Hospitals (CAHs).<sup>7</sup> This far surpasses the initial program goal of partnering with 100,000 primary care providers.
- As of October 2015, over 93 percent of primary care providers working with an REC adopted an EHR system and over 74 percent of these providers are demonstrating Meaningful Use through ONC supported programs.<sup>8</sup> This support resulted in over 100 million patients having access to electronic prescriptions, resulting in reduced medication related errors; patient visit summaries, allowing patients to more fully understand and participate in their health; and evidence-based care recommendations based on quality measures and indicators.

#### Consumer eHealth

ONC advances Consumer eHealth by coordinating with federal partners and private sector supporters to empower individuals with the information and tools they need to improve their own health and health care experience; to partner with their care team; and to influence health system transformation. ONC leads a national strategy for advancing Consumer eHealth based on three key premises: (1) Health care entities underuse and sometimes undervalue people and their caregivers as team members managing both wellness and illness; (2) Access to information and digital technologies can activate people and

<sup>&</sup>lt;sup>7</sup> Customer Relationship Management (CRM) Tool, maintained by ONC, data as of November 12, 2015. CMS Data as of June 30, 2015. Hospital denominators based on national CAH database maintained by The Flex Monitoring Team, and the Small Hospital Improvement Program (SHIP) maintained by Health Resources and Services Administration (HRSA); Provider denominators obtained from the SK&A Office-based Providers Database, Q4, 2011.

<sup>&</sup>lt;sup>8</sup> Customer Relationship Management (CRM) Tool, maintained by ONC, data as of November 12, 2015. CMS Data as of June 30, 2015.

their caregivers to be more informed and engaged in preventing and managing illness and injury, and in living healthy, productive lives; and (3) When people participate in managing their health and interactions with the health care system, they achieve better health and receive better health care at lower costs. ONC's Consumer eHealth work streams include evolving and enhancing the Blue Button Initiative to build consumer awareness and allow patients to access and use data in a meaningful way; convening diverse stakeholders, influencing policy and standards, building public-private partnerships, supporting providers, showing how patient-generated health data is being used, and catalyzing innovation in the development of apps and tools. Accomplishments include:

- Increased consumers' ability to access their health information online from a variety of sources. ONC worked with the White House to bring <u>eight of the nation's leading pharmacies and associations into</u> <u>the Blue Button Initiative</u>. These pharmacy chains will provide patients with easy and secure access to their own pharmacy prescription history.
- Expanded the ability of consumers to take action with their health data by releasing and continuing to evolve <u>Blue Button+ technical guidelines</u> to help organizations that hold patient data to release it in a structured way consistent with Electronic Health Record Incentive Program Stage 2 requirements.

#### Planning, Evaluation and Monitoring

ONC develops the Federal Health IT Strategic Plan. This Plan reflects the collective efforts of over 35 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. ONC uses economic analysis and modeling to describe and understand the factors driving the adoption and meaningful use of health IT, including the costs and benefits of health IT implementation. Studies and reports generated from these activities inform policies and decisions not only within ONC, but also by Congress, the White House, other federal agencies, state and local governments, and the private sector. ONC uses statistical methods to analyze data from numerous internal and external sources in order to provide accurate and reliable information. To ensure that up-to-date data is available, ONC sponsors and advises the development of health IT data elements for a number of surveys including the American Hospital Association Information Technology Supplement, the National Electronic Health Records Survey, and the Health Information National Trends Survey. Further, ONC uses data from internal operations, Recovery Act Programs, the CRM Tool, and the Electronic Health Record Incentive Program. Accomplishments include:

- Published <u>The Federal Health IT Strategic Plan 2015 2020</u>, representing the collaborative efforts across the federal government, with more than 35 federal entities contributing to its development. In May 2014, ONC established the Federal Health IT Advisory 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 inaugural task of this body was to coordinate and prioritize strategies and define implementation accountabilities to update the federal health IT strategy.
- Published analyses of progress toward the use of health IT to improve the health and health care of all Americans and barriers to the use of health IT, including: a <u>Congressional Report on Health IT</u> <u>Adoption</u>; <u>ONC Data Briefs</u> and <u>Quick Stats</u>; and regular reports to ONC's Health IT FACAs. Conducted <u>program evaluations</u> of HITECH programs to assess contextual factors, implementation approaches, and effectiveness and impacts of program interventions.
- Published a measurement and evaluation strategy for the Nationwide Interoperability Roadmap, establishing national measures to evaluate progress toward a nationwide interoperable electronic health information infrastructure.

• Expanded capabilities of the public <u>Health IT Dashboard web site</u>. This innovative platform provides ONC, its stakeholders, and the American public with access to thousands of data points presented as user-interactive graphs and maps.

#### Stakeholder Outreach and Engagement

ONC maintains a coordinated public affairs and communications strategy to reach decision-makers, and key public and private stakeholders including but not limited to consumers; clinicians, payers; local, state and federal policymakers and regulators; developers; public health community; and scientific community. Core communications functions include strategic communications planning and implementation, stakeholder engagement, media engagement, brand and content management, and legislative and public affairs. In addition, ONC supports its various programs and initiatives by coordinating announcements, developing messaging, and other support materials, including specific content posted on HealthIT.gov to help key audiences including eligible providers, consumers, health IT developers and innovators, policymakers and researchers learn about the use of health IT. Accomplishments include:

- Coordinated the publication of <u>The Federal Health IT Strategic Plan 2015 2020</u> which was released in September 2015. This plan was developed in collaboration with private industry and was supported by extensive stakeholder outreach, education, and informational activities and resources.
- Issued a call-to-action for a nationwide interoperable health IT infrastructure through the development and dissemination of a vision paper, <u>Connecting Health and Care for the Nation: A 10 year Vision to Achieve and Interoperable Health IT Infrastructure</u>. ONC also completed the first deliverable in the Roadmap with the issuance of the <u>draft 2015 Interoperability Standards Advisory</u>. These documents were developed in collaboration with federal government and private industry stakeholders and was supported by extensive stakeholder outreach, education, and informational activities and resources.
- Coordinated on delivery system reform initiative messaging and rollout in coordination with HHS
  Immediate Office of the Secretary and other HHS operating divisions and staff divisions to set a path
  to achieving better care, smarter spending of health care dollars, leading to a healthier nation with
  information sharing as a critical component. This was done in collaboration with federal government
  and private industry stakeholders and was supported by extensive stakeholder outreach, education,
  and informational activities and resources.

Fiscal Year	Amount
FY 2013	9,413,000
FY 2014	11,170,000
FY 2015	10,524,000
FY 2016 Enacted	10,514,000
FY 2017 President's Budget	11,523,000

#### **Funding History**

#### Budget Request

ONC requests \$11.5 million in FY 2017 for activities relating to the adoption and meaningful use of health IT, an increase of \$1.0 million above FY 2016 enacted. The request includes funding for 50 FTEs. Increased funding supports gathering data and evaluating progress toward achieving interoperability, which is required under the Medicare Access and CHIP Reauthorization Act (MACRA) legislation.

In 2016, ONC will continue its core work supporting a national support network of implementers to support the appropriate collection, use, and sharing of data. ONC will continue consumer engagement efforts by leveraging existing consumer organizations and through direct outreach efforts. Supporting these efforts are analytical, performance, and communication services that work throughout ONC to assess the current market, measure program outcomes, and provide a framework for disseminating technical materials to the widest audience.

This request supports Federal Health IT Strategic Plan 2015-2020 Goals 1: Advance Person-Centered and Self-Managed Health; 2: Transform Health Care Delivery and Community Health; 3: Foster Research, Scientific Knowledge, and Innovation; 4: Enhance Nation's Health IT Infrastructure

#### Provider Adoption Support and Consumer e-Health (\$5.1 million)

In FY 2017, ONC will continue to support provider adoption through innovative means by addressing critical barriers to the collection, sharing and use of health information. These innovative means include pilot programs, communities of practice, and other peer learning collaboratives, along with the development of impactful tools and resources. ONC will continue to support the NLC, Health IT Vanguards, and CRM tool. Through these tools, ONC will continue convening providers to develop, share, and spread innovative best practices, support workforce needs, and provide national provider-level situational awareness. In FY 2017, ONC will work to allow EHRs to be linked with other alternative payment models, which will advance value-based payments and continue to encourage market transparency. The request supports a strong national network of organizations working to assist over 150,000 providers, including over 44 percent of the country's total primary care providers, to meaningfully use health IT. The network is also working with over 80 percent of HRSA-funded federally qualified health centers (FQHCs) and over 50 percent of the practices enrolled in the Center for Medicare and Medicaid Innovation (CMMI) Comprehensive Primary Care initiative (CPCi).

To support ONC's Consumer e-Health program, ONC will convene stakeholders, identify barriers, and develop strategies so consumers can electronically send, receive, find and use their health information. ONC will focus on supporting consumer access to electronic health information, enabling the development of interoperable mobile and other tools that help consumers to use their health information effectively, and increasing consumer awareness of and demand for digital health information and tools. In FY 2017 ONC will support providers in their efforts to engage and share data with patients as required by the Electronic Health Record Incentive Program, and, via the Blue Button Pledge Program, support other organizations such as pharmacies, labs, and health insurance companies in data sharing via contract based pilot programs, community collaboratives, and/or challenge grants. ONC will continue to evolve a portfolio of recommended national standards for structured health data sharing in order to encourage the technology developer community to build useful tools, and will work with federal partners and the private sector on an ongoing consumer education and awareness campaign. ONC will also continue enhancing the resources to help consumers better locate their health data to their doctors.

#### Planning, Evaluation and Monitoring (\$4.0 million)

In FY 2017, ONC will gather data and evaluate nationwide and ONC progress at achieving health information interoperability, as required under MACRA. In doing so, ONC will oversee a portfolio of surveys designed to follow health care provider and consumer patterns of health IT adoption and use. ONC's consumer survey will measure the extent to which Americans have access to their essential health information in a format that allows them to better manage their health; how consumers are

using their health information; the impact their providers' use of EHRs and exchange is having on them; how consumer mediated exchange is evolving as a means to reduce ineffective and potentially costly health data silos; the extent of consumer confidence and trust in health IT, including the privacy, security and confidentiality of their data, as well as how they are informed of their rights and use of their health information. Additionally, ONC will maintain the Health IT Dashboard as an open government a tool for synthesizing and communicating the results of ONC analyses.

#### Provider and Consumer Engagement and Outreach (\$2.5 million)

In FY 2017, ONC's communications activities will provide policy-focused content development, stakeholder outreach and dissemination support to meet the health IT policy information needs of audiences, in keeping with the vision, mission, and goals of ONC. In addition to partnering and informing stakeholders across the care continuum, ONC will continue to use traditional and social media to educate and inform consumers, providers, developers and decision makers. Funding for stakeholder engagement, content development, traditional and social media monitoring tools as well as HealthIT.gov operations and Section 508 remediation is included in the request.

#### Outputs and Outcomes Table

	Most Recent			
Program/Measure	Result / Target / Summary	FY 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
Provider Adoption of Electronic Health Records				
Office-Based Professionals ^				
1.A.1 Percent of office-based physicians who have adopted electronic health records (basic) <sup>9</sup>	FY 2014: 51% Target: 60%	60%	65%	+5 percentage points
	(Target Not Met but Improved)			
1.A.2 Increase the percent of office-based primary care physicians who have adopted electronic health records (basic)	FY 2014: 56% Target: 65%	70%	75%	+5 percentage points
	(Target Not Met but Improved)			
Non-Federal Acute Care Hospitals ^^				
1.A.3 Percent of non-federal acute care hospitals that have adopted electronic health records (basic)	FY 2014: 76% Target: 65%	80%	85%	+5 percentage points
	(Target Met)			
CMS EHR Incentive Programs ^^^				
Stage 1				

<sup>&</sup>lt;sup>9</sup> National Electronic Health Records Survey (NEHRS) formerly entitled NAMCS Electronic Medical Records Supplement. Most recent results are from 2013 and 2014 survey results are expected in March 2015.

Program/Measure	Most Recent Result / Target / Summary	FY 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
1.B.1 Percent of eligible hospitals receiving meaningful use incentive payments	FY 2014: 94% Target: 85%	97%	Discontinue	
	(Target Exceeded)			
1.B.2 Percent of eligible professionals receiving meaningful use incentive payments	FY 2014: 74% Target: 65% (Target Met)	85%	Discontinue	
1.B.4 Increase the number of eligible professionals who receive an incentive payment from the CMS Medicare and Medicaid EHR Incentive Programs for the successful adoption or meaningful use of certified EHR technology	FY 2014: 414,914 Target: 375,000 (Target Met)	455,000	Discontinue	

Data Sources:

^ 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.

^^ Hospital measures: American Hospital Association (AHA) Information Technology (IT) Supplement to the AHA Annual Survey, which ONC partially funds through cooperative agreement.

^^^ CMS EHR Incentive Program measures data are provided to ONC by the CMS EHR Incentive Programs.

#### **Agency-wide Support**

#### **Budget Summary**

Agency-wide Support	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 (+/-) FY 2016
Budget Authority	21,306	21,306	0	-21,306
PHS Evaluation Funds	0	0	18,133	+18,133
Total, Program Level	21,306	21,306	18,133	-3,173
FTE	55	55	55	0

(Dollars in Thousands)

#### Authorizing Legislation:

Enabling Legislation Citation	PHS Act 42 U.S.C. 201
	Permanent
	No Separate Authorization of Appropriations
Allocation Method	Direct Federal, Contract, Cooperative Agreement, Grant

#### **Program Description and Accomplishments**

ONC launched a number of crosscutting efforts to improve customer service, enhance management controls, and increase efficiency in its program support partnership activities:

- 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 systems and data management capability and manages nimble procurement and grants training programs to ensure proper stewardship of federal funds.
- Program Oversight: 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.
- Human Capital: ONC's human capital experts provide leadership, oversight, and guidance to ONC in hiring a talented workforce. ONC optimizes its strong and high-performing organization through strategic workforce planning, innovative recruitment and retention strategies, including those for students and Veterans, and professional development planning.
- Budget and Operational Services: ONC's Budget and Operational Services functions include budget formulation and execution and space and facilities management. 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 are yielding positive results and improved value. Finally, ONC moved into a consolidated facility in FY 2015.

Fiscal Year	Amount
FY 2013	20,896,000
FY 2014	20,611,000
FY 2015	21,306,000
FY 2016 Enacted	21,306,000
FY 2017 President's Budget	18,133,000

#### **Funding History**

#### **Budget Request**

ONC requests \$18.1 million in FY 2017 for activities related to agency wide support, a decrease of \$3.2 million below FY 2016 enacted. The request includes funding for 55 FTEs. ONC has been actively working to reduce agency-wide support costs and will continue to realize savings from improved efficiencies and in-sourcing.

This request includes funding for critical central costs such as information technology, space, human capital, acquisition, and other shared services. These shared services, which are not attributed to a specific office, but rather are used by ONC as a whole, include financial and grants management systems, as well as contract management fees and legal counsel. This request also funds the personnel costs for the Immediate Office of the National Coordinator.

By providing ONC's offices and programs with essential agency-wide support services, this request supports Federal Health IT Strategic Plan 2015-2020 Goals 1: Expand Adoption of Health IT; 2: Advance Secure and Interoperable Health Information; 3: Strengthen Health Care Delivery; 4: Advance the Health and Well-Being of Individuals and Communities, and 5: Advance Research, Scientific Knowledge, and Innovation.

### SUPPORTING EXHIBITS

## **Crosswalk of Budget Activity by Office**

(Dollars in Thousands)

Detail	FY 2015 E	nacted	FY 2016	FY 2016 Enacted		FY 2017 Request	
Detail	FTE	\$	FTE	\$	FTE	\$	
Policy Development & Coordination							
Office of Policy	15	5,617	23	6,410	23	16,244	
Office of the Chief Privacy Officer	9	3,928	13	2,913	13	3,825	
Office of Clinical Quality and Safety	9	2,469	13	2,832	13	7,553	
Office of Care Transformation	4	1,098	6	864	6	587	
Total, Policy Development & Coordination	37	13,112	55	13,019	55	28,209	
Standards, Interoperability, & Certif	cation						
Office of Standards and Technology	24	14,266	34	14,281	34	22,962	
Office of the Chief Scientist	2	1,159	6	1,247	6	1,173	
Total, Standards, Interoperability, & Certification	26	15,425	40	15,528	40	24,135	
Adoption & Meaningful Use							
Office of Programs	26	5,102	29	4,691	29	5,102	
Office of Planning, Evaluation and Analysis	9	2,961	14	3,446	14	3,960	
Office of Public Affairs and Communications	7	2,461	7	2,377	7	2,461	
Total, Adoption & Meaningful Use	42	10,524	50	10,514	50	11,523	
Agency-Wide Support							
Agency-Wide Support	55	21,306	55	21,306	55	18,133	
Total, Agency-Wide Support	55	21,306	55	21,306	55	18,133	
Total, Program Level	185	60,367	200	60,367	200	82,000	

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

Object Class Code	Description	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
11.1	Full-time permanent	14,613	17,906	18,125
11.3	Other than full-time permanent	1,937	3,038	3,076
11.5	Other personnel compensation	548	554	561
11.7	Military personnel	157	238	241
Subtotal	Personnel Compensation	17,255	21,736	22,002
12.1	Civilian personnel benefits	5,073	6,377	6,455
12.2	Military benefits	68	103	104
13	Benefits for former personnel	0	0	0
Total	Pay Costs	22,396	28,216	28,562
21	Travel and transportation of persons	317	382	382
22	Transportation of things	17	0	0
23.1	Rental payments to GSA	2,825	3,786	3,786
23.3	Communications, utilities, and misc. charges	588	588	588
24	Printing and reproduction	131	131	131
25.1	Advisory and assistance services	585	585	585
25.2	Other services from non-Federal sources	16,951	12,943	27,410
25.3	Other goods and services from Federal sources	13,054	11,234	18,054
25.4	Operation and maintenance of facilities	254	254	254
25.5	Research and development contracts	0	0	0
25.6	Medical care	45	45	45
25.7	Operation and maintenance of equipment	15	15	15
25.8	Subsistence and support of persons	536	536	536
26	Supplies and materials	275	275	275
31	Equipment	177	177	177
32	Land and Structures	0	0	0
41	Grants, subsidies, and contributions	2,200	1,200	1,200
42	Insurance claims and indemnities	0	0	0
44	Refunds	0	0	0
Total	Non-Pay Costs	37,971	32,151	53,438
Total	Total by Object Class	60,367	60,367	82,000

# Budget Authority By Object Class - Direct (Dollars in Thousands)

Object Class Code	Description	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
11.1	Full-time permanent	14,613	17,906	0
11.3	Other than full-time permanent	1,937	3,038	0
11.5	Other personnel compensation	548	554	0
11.7	Military personnel	157	238	0
Subtotal	Personnel Compensation	17,255	21,736	0
12.1	Civilian personnel benefits	5,073	6,377	0
12.2	Military benefits	68	103	0
13	Benefits for former personnel	0	0	0
Total	Pay Costs	22,396	28,216	0
21	Travel and transportation of persons	317	382	0
22	Transportation of things	17	0	0
23.1	Rental payments to GSA	2,825	3,786	0
23.3	Communications, utilities, and misc. charges	588	588	0
24	Printing and reproduction	131	131	0
25.1	Advisory and assistance services	585	585	0
25.2	Other services from non-Federal sources	16,951	12,943	0
25.3	Other goods and services from Federal sources	13,054	11,234	0
25.4	Operation and maintenance of facilities	254	254	0
25.5	Research and development contracts	0	0	0
25.6	Medical care	45	45	0
25.7	Operation and maintenance of equipment	15	15	0
25.8	Subsistence and support of persons	536	536	0
26	Supplies and materials	275	275	0
31	Equipment	177	177	0
32	Land and Structures	0	0	0
41	Grants, subsidies, and contributions	2,200	1,200	0
42	Insurance claims and indemnities	0	0	0
44	Refunds	0	0	0
Total	Non-Pay Costs	37,971	32,151	0
Total	Total by Object Class	60,367	60,367	0

## Budget Authority By Object Class - Reimbursable (Dollars in Thousands)

Object Class Code	Description	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
11.1	Full-time permanent	0	0	18,125
11.3	Other than full-time permanent	0	0	3,076
11.5	Other personnel compensation	0	0	561
11.7	Military personnel	0	0	241
Subtotal	Personnel Compensation	0	0	22,002
12.1	Civilian personnel benefits	0	0	6,455
12.2	Military benefits	0	0	104
13	Benefits for former personnel	0	0	0
Total	Pay Costs	0	0	28,562
21	Travel and transportation of persons	0	0	382
22	Transportation of things	0	0	0
23.1	Rental payments to GSA	0	0	3,786
23.3	Communications, utilities, and misc. charges	0	0	588
24	Printing and reproduction	0	0	131
25.1	Advisory and assistance services	0	0	585
25.2	Other services from non-Federal sources	0	0	27,410
25.3	Other goods and services from Federal sources	0	0	18,054
25.4	Operation and maintenance of facilities	0	0	254
25.5	Research and development contracts	0	0	0
25.6	Medical care	0	0	45
25.7	Operation and maintenance of equipment	0	0	15
25.8	Subsistence and support of persons	0	0	536
26	Supplies and materials	0	0	275
31	Equipment	0	0	177
32	Land and Structures	0	0	0
41	Grants, subsidies, and contributions	0	0	1,200
42	Insurance claims and indemnities	0	0	0
44	Refunds	0	0	0
Total	Non-Pay Costs	0	0	53,438
Total	Total by Object Class	0	0	82,000

## Salary & Expenses

(Dollars in Thousands)

Object Class Code	Description	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
11.1	Full-time permanent	14,613	17,906	18,125
11.3	Other than full-time permanent	1,937	3,038	3,076
11.5	Other personnel compensation	548	554	561
11.7	Military personnel	157	238	241
Subtotal	Personnel Compensation	17,255	21,736	22,002
12.1	Civilian personnel benefits	5,073	6,377	6,455
12.2	Military benefits	68	103	104
13	Benefits for former personnel	0	0	0
Total	Pay Costs	22,396	28,216	28,562
21	Travel and transportation of persons	317	382	382
22	Transportation of things	17	0	0
23.3	Communications, utilities, and misc. charges	588	588	588
24	Printing and reproduction	131	131	131
25.1	Advisory and assistance services	585	585	585
25.2	Other services from non- Federal sources	16,951	12,943	27,410
25.3	Other goods and services from Federal sources	13,054	11,234	18,054
25.4	Operation and maintenance of facilities	254	254	254
25.5	Research and development contracts	0	0	0
25.6	Medical care	45	45	45
25.7	Operation and maintenance of equipment	15	15	15
25.8	Subsistence and support of persons	536	536	536
Subtotal	Other Contractual Services	32,494	26,713	48,000
26	Supplies and materials	275	275	275
Total	Non-Pay Costs	32,769	26,988	48,275
Total	Salary and Expenses	55,165	55,204	76,837
23.1	Rental payments to GSA	2,825	3,786	3,786
Total	Salaries, Expenses, and Rent	57,990	58,990	80,623

## Detail Of Full-Time Equivalent (FTE) Employment

Detail	FY 2015 Civilian	FY 2015 Military	FY 2015 Total	FY 2016 Civilian	FY 2016 Military	FY 2016 Total	FY 2017 Civilian	FY 2017 Military	FY 2017 Total
Direct	158	2	160	198	2	200	198	2	200
Reimbursable									
Total FTE	158	2	160	198	2	200	198	2	200

#### Average GS Grade

	Grade:	Step:
FY 2013	13	5
FY 2014	13	6
FY 2015	13	8
FY 2016	13	6
FY 2017	13	6

## **Detail Of Positions**

Deteil	FY 2015	FY 2016	FY 2017
Detail	Actual	Enacted	President's Budget
Executive level	0	0	0
Total - Exec. Level Salaries	0	0	0
SES	7	7	7
Total - SES Salaries	1,219,460	1,236,532	1,251,680
Total - ES Salary	1,219,460	1,236,532	1,251,680
GS-15	49	50	50
GS-14	45	54	54
GS-13	43	55	55
GS-12	11	24	24
GS-11	5	15	15
GS-10		1	1
GS-9	8	2	2
GS-8			
GS-7			
GS-6			
GS-5	1	1	1
GS-4			
GS-3			
GS-2			
GS-1			
Subtotal	162	202	202
Total, GS Salary	18,357,798	21,768,289	22,034,950
Commissioned Corps	2	2	2
Total, Commissioned Corps Salary	157,000	226,823	229,601
<b>Total Positions</b>	171	211	211
Total FTE	160	200	200

## FY 2017 Budget By HHS Strategic Goal (Dollars in Millions)

HHS Strategic Goals	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
1.Strengthen Health Care	42.923	42.471	60.601
<b>1.A Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured</b>			
1.B Improve health care quality and patient safety	9.131	9.434	15.686
1.C Emphasize primary and preventive care, linked with community prevention services			
1.D Reduce the growth of health care costs while promoting high-value, effective care	22.028	21.746	31.681
1.E Ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations			
1.F Improve health care and population health through meaningful use of health information technology	11.764	11.291	13.234
2. Advance Scientific Knowledge and Innovation	17.444	17.896	21.399
2.A Accelerate the process of scientific discovery to improve health			
2.B Foster and apply innovative solutions to health, public health, and human services challenges	7.821	7.848	9.306
2.C Advance the regulatory sciences to enhance food safety, improve medical product development, and support tobacco regulation			
2.D Increase our understanding of what works in public health and human services practice	9.623	10.048	12.093
2.E Improve laboratory, surveillance, and epidemiology capacity			
3. Advance the Health, Safety and Well-Being of the American People			
<b>3.A Promote the safety, well-being, resilience, and healthy development of children and youth</b>			
3.B Promote economic and social well-being for individuals, families, and communities			
3.C Improve the accessibility and quality of supportive services for people with disabilities and older adults			
3.D Promote prevention and wellness across the life span			
3.E Reduce the occurrence of infectious diseases			
<b>3.F</b> Protect Americans' health and safety during emergencies, and foster resilience to withstand and respond to emergencies			
4. Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs			
4.A Strengthen program integrity and responsible stewardship by reducing improper payments, fighting fraud, and integrating financial, performance, and risk management			
4.B Enhance access to and use of data to improve HHS programs and to support improvements in the health and well-being of the American people			
4.C Invest in the HHS workforce to help meet America's health and human services needs			
4.D Improve HHS environmental, energy, and economic performance to promote sustainability			
TOTAL	60.367	60.367	82.000

Physicians' Comparability Allowance			FY 2016 (Estimates)	FY 2017 (Estimates)
1) Number of Physicians R	1) Number of Physicians Receiving PCAs			5
2) Number of Physicians w	ith One-Year PCA Agreements	0	0	0
3) Number of Physicians w	ith Multi-Year PCA Agreements	5	5	5
4) Average Annual PCA Phy	4) Average Annual PCA Physician Pay (without PCA payment)			\$155,500
5) Average Annual PCA Pay	/ment	\$13,000	\$13,000	\$13,000
	Category I Clinical Position	0	0	0
	Category II Research Position	0	0	0
6) Number of Physicians	Category III Occupational Health	0	0	0
Receiving PCAs by Category (non-add)	Category IV-A Disability Evaluation	0	0	0
	Category IV-B Health and Medical Admin.	5	5	5

### **Physicians' Comparability Allowance**

In 2015 and 2016, ONC needed physicians with strong medical backgrounds to work in engaging 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.

#### APPENDIX I: ESTABLISH HEALTH IT GOVERNANCE CERTIFICATION

The Budget proposes to amend Section 3001(c)(5) and Section 3004 of the PHS Act to specify that ONC may establish standards, implementation specifications, and certification criteria related to the business policies, practices, and behavior of heath IT entities. Nationwide interoperability, reliability, and transparency cannot be accomplished through technical requirements alone. These proposed changes are complementary with ONC's other proposals to clarify ONC's authority to address health IT safety and information blocking.

These clarifications would unambiguously allow ONC to establish and enforce Rules of the Road (i.e., organization business and operational requirements) related to the electronic exchange of health information that would define and outline the basic expectations of exchange participants, including, for example, health IT developers, and health information exchange services.

### APPENDIX II: PROHIBIT INFORMATION BLOCKING AND ASSOCIATED BUSINESS PRACTICES

ONC proposes to prohibit and prescribe penalties for "information blocking" (knowingly and unreasonably interfering with the exchange or use of electronic health information) by any provider or supplier participating in a federal health care program; by any provider or supplier in connection with items or services furnished under such a program; and by any vendor of health IT certified under programs recognized by the National Coordinator under Section 3001(c)(5) of the PHS Act. This proposal would also strengthen conditions and requirements of ONC programs to address information blocking as well as other business practices that impede the use of certified health IT for the interoperable exchange of electronic health information.

This proposal is needed because evidence and experience suggest that persons and entities are engaging in information blocking<sup>10</sup>; and because current law does not directly prohibit or provide an effective means to investigate and address these practices, even though they undermine efforts across HHS to promote the use of information and technology to transform the nation's health and health care delivery system.

The proposal would solve this problem through a coordinated approach to administration and enforcement that builds on and strengthens the existing roles and competencies of ONC and the HHS Office of Inspector General (OIG). The proposal would explicitly prohibit information blocking by health IT vendors and by health care providers and suppliers. Further, it would authorize the Secretary to adopt related conditions and requirements for vendors of health IT certified under ONC programs and to require vendors to periodically attest to compliance.

Under the proposal, OIG would be given explicit authority to investigate suspected information blocking (by providers, suppliers, or health IT vendors) as well as false attestations to the National Coordinator. OIG would be authorized to impose appropriate administrative sanctions for these offenses, which would include civil money penalties and, for health care providers and suppliers, permissive exclusion from federal health care programs.

With respect to information blocking and false attestations by a health IT vendor, a key feature of the proposed enforcement framework is the requirement that the National Coordinator terminate the certification of the vendor's health IT prospectively while ensuring that existing providers and users who rely on the technology's certification to meet program and other requirements are not adversely affected.

The proposal also includes protections for persons who report information blocking and other conduct described above. Health IT vendors may prohibit the reporting or sharing of this information by requiring and aggressively enforcing broad non-disclosure provisions in their software licensing agreements. These contractual non-disclosure provisions may also require health care providers to discipline their employees for reporting or discussing information blocking and other practices that would be prohibited under this proposal. The proposal would create a civil right of action for aggrieved persons (as, for example, Section 806 of the Sarbanes-Oxley Act). The right of action would enable

<sup>&</sup>lt;sup>10</sup> See ONC, <u>Report to Congress on Health Information Blocking</u> (2015).

employees of health care providers, health care suppliers, and health IT vendors to report information blocking and other prohibited practices without fear of retaliation or reprisal.

## OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH IT APPENDIX III: REQUIRE HEALTH IT TRANSPARENCY

This proposal would authorize the Secretary to require (through notice-and-comment rulemaking) that certified health IT vendors submit ongoing and detailed information to the National Coordinator concerning the costs, capabilities, limitations, and other performance characteristics of certified health IT. It would authorize the Secretary to specify the information that must be disclosed, which should extend to detailed information about prices, technical specifications, and contractual terms and restrictions. It would also authorize the National Coordinator to publish such information—subject to appropriate safeguards for intellectual property and competitively sensitive information—to enable persons or entities who purchase or license certified health IT to meaningfully compare and assess products and services.

This proposal would require, as a condition of participation in certification programs recognized by the National Coordinator under Section 3001(c)(5) of the PHS Act, that vendors or entities offering health IT certified under such programs provide an attestation to the National Coordinator that they have submitted all required information and that they have not taken any action to prevent or discourage customers or users from sharing information about the costs, capabilities, limitations, and other performance characteristics of certified health IT.

This proposal is needed to address the lack of transparency in health IT products and services, which stakeholders ranging from industry associations to Congress have identified as a serious problem that impairs the efficient functioning of health IT markets. Providers who lack access to basic information about the costs, limitations, and trade-offs of competing health IT products and services cannot effectively compare solutions and select those that meet their needs, including capabilities that will enable them to participate in new care delivery and payment models that leverage health information exchange and analytics. In addition, they are more likely to become "locked in" to technologies, which diminishes incentives and opportunities for health IT vendors to improve their technologies and compete to deliver more innovative, more advanced, and less expensive products and services that meet the needs of providers, patients, and the health care system.

These problems are exacerbated by the practices of some health IT vendors, who may prohibit the reporting or sharing of information about their products—including screenshots and other information about the *safety of those products*—by requiring and aggressively enforcing broad non-disclosure provisions in their software licensing agreements. These provisions may also require providers to discipline their employees for reporting or discussing information blocking and other practices that would be prohibited under this proposal.

The proposal would provide clear authority for ONC to obtain and publish information about certified health IT products and services in a format that would enable persons who purchase or license such technology to meaningfully compare and assess products and services. It would also address contractual restrictions and other business practices that are preventing customers from discussing and sharing their experiences and information about the costs, capabilities, limitations, and other performance characteristics of certified health IT, including the sharing of screenshots for purposes reasonably related to improving consumer awareness and access to information or promoting patient safety and other research.

### APPENDIX IV: PROVIDE ONC AUTHORITY TO USE CONTRACTS, GRANTS, OR COOPERATIVE AGREEMENTS TO ESTABLISH A HEALTH IT SAFETY COLLABORATIVE AND PROVIDE ADEQUATE CONFIDENTIALITY PROTECTIONS

This proposal builds upon requests in previous budgets and gives ONC explicit statutory authority to use contracts, grants, or cooperative agreements to establish a Health IT Safety Collaborative, which could:

- support and develop targeted solutions to health IT-related safety issues identified through evidence;
- disseminate, pilot test, and evaluate solutions;
- strengthen and augment existing ways to identify and classify health IT-related safety events;
- identify ways to encourage better reporting of health IT-related safety events;
- identify and share advances in automated safety tools for adverse event detection and health IT-related safety improvements;
- produce reports summarizing current evidence of health IT safety;
- target examinations of specific issues and identify approaches to addressing issues;
- serve as a clearinghouse for health IT safety solutions, evidence reports and best practices; and,
- develop new educational resources and training materials to build health IT-related competencies.

This proposal would establish confidentiality protections for health IT for developers and vendors who report health-IT-related safety concerns to Patient Safety Organizations (PSOs) similar to the current statutory confidentiality protections for clinicians and hospitals who report health-care-related safety concerns to PSOs.

ONC could take many of the actions specified above within existing authorities, but this proposal would allow ONC to conduct this activity through grants or cooperative agreements and allow ONC to protect proprietary information and data provided within the collaborative.

There is clear and emerging evidence that the broad scale implementation of health IT has augmented the general safety of healthcare but there are still best practices to be agreed upon and more broadly and consistently implemented across the spectrum of healthcare providers and entities. It also appears there may be a smaller number of unintended consequences that are the result of health IT and that addressing these problems requires the participation of multiple stakeholders to promote the safe implementation of health IT. In response to clinician concerns about health IT usability and the apparent lack of user centered and safety enhanced design in the software and as a consequence of its implementation, the Safety Collaborative is intended to focus on improving the usability of health IT and reducing the likelihood of any errors or safety concerns.