

**DEPARTMENT
of HEALTH
and HUMAN
SERVICES**

Fiscal Year

2011

Office of the National
Coordinator for Health
Information Technology

***Justification of
Estimates for
Appropriations Committees***

**OFFICE OF THE NATIONAL COORDINATOR FOR
HEALTH INFORMATION TECHNOLOGY**

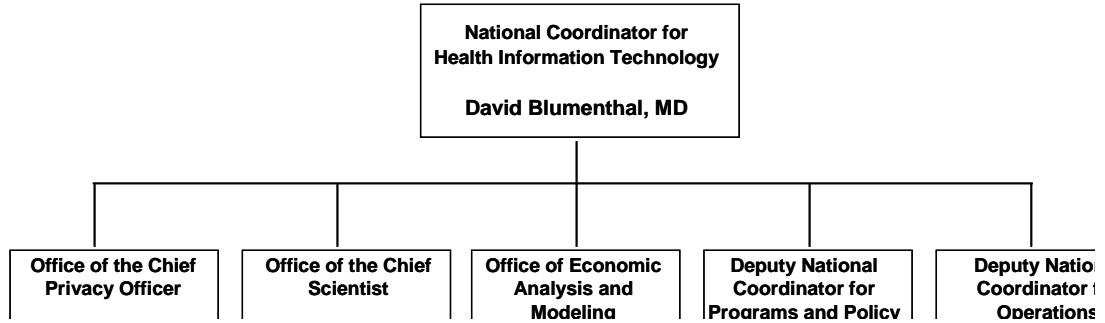
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Organization Chart

Department of Health and Human Services

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



Executive Summary

Introduction and Mission

ONC Vision

A Nation in which the health and well-being of individuals and communities are enabled by health information technology.

ONC Mission

ONC leads, coordinates, and stimulates public and private sector activities that promote the development, adoption, and use of health information technologies to achieve a healthier Nation.

Introduction

Health information technology (HIT) is a critical component of a modern health care delivery system. If successfully implemented, HIT will improve the quality, efficiency, and value of care delivered by enabling providers, consumers and policy makers to:

- Constantly produce new insights and evidence;
- Seamlessly apply real-time learning from the clinical experience;
- Monitor and manage the health of populations;
- Exchange health information across all points of service; and
- Make better health care decisions for individuals, communities and populations including populations with special needs.

The Office of the National Coordinator for Health Information Technology (ONC) is leading the federal government's efforts to support the thoughtful application of HIT through programs and policies designed to address the obstacles providers have faced in adopting and using HIT.

Though it has been in existence since 2004, ONC was permanently established by statute under the February 2009 American Reinvestment and Recovery Act, Title XIII – Health Information Technology (also cited as Health Information Technology for Economic and Clinical Health or HITECH Act). The HITECH Act was developed to support not only the adoption of HIT, but its meaningful use – an important concept that will promote the use of HIT to improve health outcomes and empower patients.

With its expanded role under HITECH, ONC has been developing programs, management and organizational structures to fulfill its new responsibilities. This budget document describes how ONC's FY 2011 budget request will support HITECH's implementation and the adoption and meaningful use of HIT.

FY 2011 Budget Overview

The FY 2011 Planning Level Budget Request for ONC is \$78,334,000 to support program activities and carry out American Recovery and Reinvestment Act (Recovery Act) responsibilities. This represents an increase of \$16,992,000 above the FY 2010 Omnibus level and includes a reduction in PHS Evaluation Funds of -\$19,011,000. This budget supports the implementation of the "*ONC-Coordinated Federal Health IT Strategic Plan*" and planned revision, and HHS Strategic Plan, Goal 1.3: improve health care quality, safety, cost and value.

Most importantly, it provides resources required to administer and manage the \$2 billion appropriated to ONC under the Recovery Act and ONC's responsibilities as legislated under the HITECH Act.

Program Increases:

Interoperability (+ \$12,820,000)

This increase includes additional funding for the Nationwide Health Information Network (NHIN) program and continued funding for further development of the conformance test bed being developed in coordination with NIST. It also includes a new initiative that addresses the need for specific mental health standards. The goal of this initiative is to ensure that standards and certification processes for the unique confidentiality rules that apply to both mental health and substance use disorder diagnosis and treatment are developed and incorporated into electronic health records (EHRs).

Privacy and Security (+ \$3,214,000)

This increase will provide resources for the new ONC Chief Privacy Officer, as required under HITECH. Also, this request builds on projects initiated with Recovery Act funding in FY 2010 to increase trust in electronic health information exchange: Cybersecurity programs will ensure that needed policies, technologies, practices, and guidelines are developed to improve health information security – a great concern for the general population. It also provides for continued support for guidance and regulation updates as required under HITECH.

Research and Evaluation (+ \$3,106,000)

This increase supports the work begun in FY 2010 under Recovery Act funds and is essential to continued program performance. Understanding and reporting the progress of and improvements in the HIT programs are requirements of HITECH and will support improvements in key program implementation.

Program Decreases:

Adoption (- \$1,894,000)

Funding is reduced from the FY 2010 level for Health Information Exchange interoperability support. The budget priority focuses on other state-level activities to enable adoption.

Operations (- \$254,000)

Funding is reduced for grants administration support. With the establishment of a permanent grants office in ONC, the cost of grants administration is decreased.

Public Health Evaluation Funds (- \$19,011,000)

No Public Health Evaluation Funds are included in this budget, resulting in a decrease of \$19,011,000 in PHS Evaluation Funds across all programs.

Discretionary All-Purpose Table

(Dollars in Thousands)

	FY 2009 Appropriation	FY 2009 Recovery Act	FY 2010 Appropriation	FY 2011 President's Budget Request
Budget Authority.....	\$43,552	\$2,000,000	\$42,331	\$78,334
PHS Evaluation Funds..	17,679	-	19,011	-
Total, Program Level....	\$61,231	\$2,000,000	\$61,342	\$78,334
FTE.....	31		75	120

The American Recovery and Reinvestment Act appropriated \$2 billion to ONC to implement the HITECH Act. Of these funds, HHS transferred \$20 million to the National Institute of Standards and Technology (NIST) as required under the Recovery Act.

Office of the National Coordinator for Health Information Technology
Summary of Recovery Act Obligations and Performance*
(dollars in millions)

ARRA Implementation Plan	FY 2009	FY 2010	FY 2011	FY 2009 – FY 2011
Program 1 - Subtitle D Enforcement	\$0.00	\$16.17	\$0.00	\$16.17
Program 2 - Regulations, Guidance and Studies	\$0.57	\$7.55	\$0.00	\$8.12
Program 3 - Grants to State and Qualified State-Designated Entities	\$0.00	\$564.00	\$0.00	\$564.00
Program 4 - HIT Research Center and Regional Extension Centers	\$0.00	\$648.00	\$0.00	\$648.00
Program 5 - Health IT Workforce	\$0.00	\$118.00	\$0.00	\$118.00
Program 6 - Beacon Communities	\$0.00	\$235.00	\$0.00	\$235.00
Program 7 - Omnibus Plan	\$0.00	\$282.21	\$32.93	\$315.14
Program 8 - Other Activities	\$0.00	\$30.50	\$0.00	\$30.50
Recovery Act required transfer to NIST	\$0.00	\$18.03	\$1.98	\$20.00
Total Obligations	\$0.57	\$1,919.46	\$34.91	\$1,954.93

*This table reflects additional information than what is included in the Budget Appendix.

By the end of FY 2011, HHS will show progress toward establishing the infrastructure necessary to encourage the adoption and meaningful use of HIT by establishing Regional Extension Centers in order to provide technical services to providers. The high priority performance goals below support this effort:

High Priority Performance Goals	FY 2010 Target	FY 2011 Target
By the end of FY 2011, establish the infrastructure necessary to encourage the adoption and meaningful use of HIT by:		
1. Establishing a network of 70 Regional Extension Centers by the end of FY 2010.	70	N/A
2. Registering 30,000 providers to receive services from Regional Extension Centers by end of FY 2010; 3. Registering 100,000 providers to receive services from Regional Extension Centers by end of FY 2011.	30,000	100,000
4. Achieving 20% adoption of EHRs among providers working with Regional Extension Centers by end of FY 2011.	N/A	20%

Data source:

Evaluation contractor will validate data reported by each Regional Extension Center grantee.

Budget Exhibits

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

Health Information Technology

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 ~~[\$42,331,000]~~\$78,334,000:

[Provided, That in addition to amounts provided herein, \$19,011,000 shall be available from amounts available under section 241 of the Public Health Service Act.] (Department of Health and Human Services Appropriations Act, 2010.)

Office of the National Coordinator for Health Information Technology

Amounts Available for Obligation

	FY 2009 Actual	FY 2010 Est.	FY 2011 PB
General Fund Discretionary Appropriation:			
Annual Appropriation.....	\$ 43,552,000	\$ 42,331,000	\$ 78,334,000
Subtotal, Adjusted Appropriation.....	\$ 43,552,000	\$ 42,331,000	\$ 78,334,000
<u>Recovery Act Appropriation (P.L. 111-5):</u>			
General Fund Appropriation.....	\$ 2,000,000,000	-	-
Total, Discretionary Appropriation.....	\$ 2,043,552,000	\$ 42,331,000	\$ 78,334,000
Discretionary Appropriation less ARRA.....	\$ 43,552,000	\$ 42,331,000	\$ 78,334,000
<u>Unobligated Balances:</u>			
Unobligated balance, Recovery Act start of year...	\$ 2,000,000,000	\$ 1,999,430,000	\$ 97,430,000
Unobligated balance, Recovery Act end of year...	\$ 1,999,430,000	\$ 97,430,000	\$ 44,490,000
Total Obligations.....	\$ 44,122,000	\$ 1,944,331,000	\$131,274,000
Obligations less ARRA.....	\$ 43,552,000	\$ 42,331,000	\$ 78,334,000

Office of the National Coordinator for Health Information Technology

Summary of Changes

2010	Total estimated budget authority.....	\$42,331,000
	(Obligations).....	-\$61,342,000
2011	Total estimated budget authority.....	\$78,334,000
	(Obligations).....	-\$78,334,000
	Net Change obligations.....	+\$16,992,000
	Net Change budget authority.....	+\$36,003,000

	FY 2011 Estimate	FY 2011 Estimate	Change from Base	Change from Base
	FTE	Budget Authority	FTE	Budget Authority
Increases:				
A. Built-in:	120		+45	
1. Cost of January 2011 Civilian Pay Raise of 2.1 percent		\$12,951,210		+4,717,180
2. Cost of January 2011 Commission Officer Pay Raise of 2.1 percent		\$250,000		+\$20,000
Subtotal, Built-in Increases.....	120	\$13,201,210	+45	+\$4,737,180
A. Program				
1. Interoperability		\$22,770,000		+\$12,820,000
[Including decrease in Evaluation Funds of]		[\$0]		-\$6,000,000
2. Privacy and Security		\$6,850,000		+\$3,214,000
[Including decrease in Evaluation Funds of]		[\$0]		-\$3,000,000
3. Research and Evaluation		\$6,701,000		+\$3,106,000
[Including decrease in Evaluation Funds of]		[\$0]		[\$0]
Subtotal, Program Increases.....		\$36,321,000		+\$19,140,000
Total Increases.....		\$49,522,210		\$23,877,180
Decreases:				
4. Adoption		\$4,439,000		-\$1,894,000
[Including decrease in Evaluation Funds of]		[\$0]		-\$4,011,000
5. Operations		\$24,372,790		-\$4,991,180
[Including decrease in Evaluation Funds of]		[\$0]		-\$6,000,000
6. [Total decrease PHS Evaluation Funds]		\$0		-\$19,011,000
Total Decreases.....		\$28,811,790		-\$6,885,180
Net Change.....	120	\$78,334,000	+45	+\$16,992,000

Office of the National Coordinator for Health Information Technology

Budget Authority by Activity

	FY 2009 Actual	FY 2010 Estimate	FY 2011 PB	FY 2011 PB
Health Information Technology				
Adoption BA.....	\$2,059	\$2,322	\$4,439	+\$2,117
[Evaluation Funds].....	[\$1,800]	[\$4,011]	[\$0]	-[\$4,011]
Total Adoption Program.....	[\$3,859]	[\$6,333]	[\$4,439]	-[\$1,894]
Interoperability BA.....	\$15,355	\$3,950	\$22,770	+\$18,820
[Evaluation Funds].....	[\$14,084]	[\$6,000]	[\$0]	-[\$6,000]
Total Interoperability Program.....	[\$29,439]	[\$9,950]	[\$22,770]	+[\$12,820]
Privacy and Security BA.....	\$1,706	\$636	\$6,850	+\$6,214
[Evaluation Funds].....	[\$0]	[\$3,000]	[\$0]	-[\$3,000]
Total Privacy and Security Program.....	[\$1,706]	[\$3,636]	[\$6,850]	+[\$3,214]
Research and Evaluation BA.....	\$2,518	\$3,595	\$6,701	+\$3,106
[Evaluation Funds].....	[\$1,551]	[\$0]	[\$0]	[\$0]
Total Research and Evaluation Program..	[\$4,069]	[\$3,595]	[\$6,701]	+[\$3,106]
Operations BA.....	\$21,914	\$31,828	\$37,574	+\$5,746
[Evaluation Funds].....	[\$244]	[\$6,000]	[\$0]	-[\$6,000]
Total Operations Program.....	[\$22,158]	[\$37,828]	[\$37,574]	-[\$254]
Total, Budget Authority	\$43,552	\$42,331	\$78,334	+\$36,003
Evaluation Funds	\$17,679	\$19,011	\$0	-\$19,011
Total Program Level	\$61,231	\$61,342	\$78,334	+\$16,992
FTE	31	75	120	+45

Office of the National Coordinator for Health Information Technology

Authorizing Legislation

	FY 2010 Amount Authorized	FY 2010 Appropriations Act	FY 2011 Amount Authorized	FY 2011 President's Budget
<u>Health Information Technology</u>		\$42,331,000		\$78,334,000
PHS Evaluation Funds (non-add)		[\$19,011,000]		[\$0]

Office of the National Coordinator for Health Information Technology

Appropriations History Table

	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
FY 2006				
Budget Authority.....	\$75,000,000	\$58,100,000	\$32,800,000	\$42,800,000
PHS Evaluation Funds.....	\$2,750,000	\$16,900,000	\$12,350,000	\$18,900,000
Rescission (PL 109-148).....				(\$428,000)
Transfer to CMS.....				(\$29,107)
Total.....	\$77,750,000	\$75,000,000	\$45,150,000	\$61,242,893
FY 2007				
Budget Authority.....	\$89,872,000	\$86,118,000	\$51,313,000	\$42,402,000
PHS Evaluation Funds.....	\$28,000,000	\$11,930,000	\$11,930,000	\$18,900,000
Total.....	\$117,872,000	\$98,048,000	\$63,243,000	\$61,302,000
FY 2008				
Budget Authority.....	\$89,872,000	\$13,302,000	\$43,000,000	\$42,402,000
PHS Evaluation Funds.....	\$28,000,000	\$48,000,000	\$28,000,000	\$18,900,000
Rescission (PL 110-161).....				(\$741,000)
Total.....	\$117,872,000	\$61,302,000	\$71,000,000	\$60,561,000
FY 2009				
Budget Authority.....	\$18,151,000	\$43,000,000	\$60,561,000	\$43,552,000
PHS Evaluation Funds.....	\$48,000,000	\$18,900,000	\$0	\$17,679,000
ARRA (PL 110-161).....				\$2,000,000,000
Total.....	\$66,151,000	\$61,900,000	\$60,561,000	\$2,061,231,000
FY 2010				
Budget Authority.....	\$42,331,000	\$0	\$42,331,000	\$42,331,000
PHS Evaluation Funds.....	\$19,011,000	\$61,342,000	\$19,011,000	\$19,011,000
Total.....	\$61,342,000	\$61,342,000	\$61,342,000	\$61,342,000
FY 2011				
Budget Authority.....	\$78,334,000			
PHS Evaluation Funds.....				\$0
Total.....	\$78,334,000			

Narrative By Activity

Authorizing Legislation: PHS Act 42 U.S.C. 201, as amended by TITLE XIII—Health Information Technology: Health Information Technology for Economic and Clinical Health Act (HITECH Act) in H.R.1, the American Recovery and Reinvestment Act of 2009.

Based on efforts to reorganize the office and programs to achieve the mission and the goals of HITECH, ONC modified the budget presentation to reflect priorities.

HHS and ONC priorities: HHS and ONC are working to achieve four basic priorities:

1. Define “meaningful use of HIT” in coordination with the Centers for Medicare and Medicaid Services (CMS);
2. Bolster public trust in electronic information systems by ensuring privacy and security;
3. Encourage and support the widespread adoption of HIT and the attainment of meaningful use through incentives and grant programs; and
4. Foster continued HIT innovation.

Regulatory activities: In December 2009, CMS, in close coordination with ONC, accomplished a major step toward the first priority through a notice of proposed rulemaking (NPRM) that will be finalized in 2010.

HHS was deliberate in defining meaningful use of HIT to advance five health care goals:

1. Improving the quality, safety, and efficiency of care while reducing disparities;
2. Engaging patients and families in their care;
3. Promoting public and population health;
4. Improving care coordination; and
5. Promoting the privacy and security of EHRs.

ONC and CMS accomplished a major step toward the second and third priorities by issuing an interim final rule (IFR) that adopts an initial set of standards, implementation specifications, and certification criteria for EHRs. A third regulatory action, creating a process for certifying EHRs, is in advance stages.

Taken together, these three regulations will form the basis for receiving incentive payments from Medicare and Medicaid. They also send a clear signal to providers to start taking steps to adopt and use EHRs in a meaningful manner, to vendors to start enhancing their products to make them capable of meaningful use, and to vendors, health care organizations and consumers concerning how personal health information must and can be kept private and secure.

Though regulation constitutes a vital tool to achieve HITECH’s goals, the thoughtful and judicious use of funds to support the adoption and meaningful use of HIT generally, and EHRs in particular, is also critical to the creation of a modern electronic health information system in the United States. Within ONC’s revised budget categories described below, this document discusses how ONC will use its FY 2011 budget to accomplish the four key priorities. Funds requested support programs that have two characteristics that distinguish them from ONC’s HITECH programs:

1. They represent ongoing activities of ONC that are vital to its mission, preceded HITECH, and will continue after Recover Act funds are exhausted.

2. They are vital to ONC's and HITECH purposes but are not specifically required under that legislation.

Adoption

The proportion of hospitals and health care professionals that have adopted EHRs remains small. HITECH was an historic, Federal effort to transform the Nation's HIT landscape by providing substantial Medicare and Medicaid incentives to reduce the financial barriers to adoption and use of EHRs.

In addition to the incentives, HITECH instructed HHS to undertake a series of grant programs that systematically address the obstacles that providers face in adopting and meaningfully using EHRs. In particular, HHS and ONC have allocated \$643 million to funding Health Information Technology Regional Extension Centers (RECs) and \$50 million to an Health Information Technology Research Center (HITRC), as well as \$118 million to training an improved and expanded HIT workforce. All mandated under HITECH, these programs will help to overcome technical and logistical obstacles faced by providers in adopting EHRs.

ONC's 2011 budget request supports the administration of these grant programs and provide oversight and accountability for their careful implementation. In addition, the request supports activities devoted to engaging consumers in the collection and use of electronic health information (a vital complement to and enabler of the effective use of EHRs) and developing information on the long-term consequences, including unintended effects, of the adoption and meaningful use of EHRs. Specifically, the FY 2011 request will enable ONC to:

- Support the operations of the HITECH grant programs;
- Continue ONC efforts to identify and take appropriate actions to mitigate unintended consequences resulting from increased adoption and use of EHRs;
- Identify ways to engage patients and families in their care through consumer e-health tools; and
- Track the adoption and use of EHRs across the Nation.

Interoperability

Interoperability is the ability of two or more systems to exchange information and to use the information that has been exchanged. This concept is fundamental to ONC's mission and necessary to attaining meaningful use of EHRs because, by statute, hospitals and health care professionals must exchange information to be considered meaningful users.

Using Recovery Act funds, ONC is funding several major programs focused on interoperability:

- Identifying existing or develop new standards for EHRs that enable those products to meet interoperability requirements under meaningful use;
- Developing certification criteria and a certification process to ensure that EHRs have incorporated the necessary standards and implementation specifications to support interoperability required under definitions of meaningful use;
- Providing the core set of needed publicly accessible specifications, tools and services for the NHIN; and
- Building the nationwide capability for health information exchange through the State Health Information Exchange grant program, a program specifically funded under the Recovery Act.

Complementing these HITECH programs, the FY 2011 budget request will enable ONC to:

- Administer and monitor its interoperability programs;
- Maintain ONC's historic and continuing responsibilities for identifying, developing and adopting standards, technical specifications, and certification criteria;
- Continue ONC's progress toward making publicly available a reference implementation of the NHIN for entities to use to exchange information with each other;
- Continue to pilot new NHIN standards and services; and
- Continue support of the Federal Health Architecture (FHA).

Privacy and Security

Privacy and security is the foundation upon which trust in electronic health information and participation in health information exchange will be built. If individuals and health care professionals do not believe that their health information will be protected and remain confidential, the Nation will not achieve the level of participation in health information exchange that is needed to improve individual and population health. Bolstering trust by ensuring privacy and security is fundamental to ONC's mission and a basic priority for ONC.

ONC's FY 2011 budget request will enable ONC to:

- Aggressively implement and enforce, in coordination with the Office for Civil Rights (OCR), new authorities and program related to privacy and security under HITECH;
- Provide hospitals and health care professionals with best practices and guidance on developing, implementing and maintaining organizational privacy and security policies;
- Identify opportunities to improve the current privacy and security legislation framework;
- Continue the security initiative started with Recovery Act funds; and
- Study medical identity theft and risk mitigation.

Research and Evaluation

Technologies continuously innovate and improve through research to identify new methods and approaches, creation of better products, and careful evaluation of current practices. By supporting research, innovation, analysis, and evaluation, ONC can accelerate the pace at which HIT is adopted and promotes the quality, safety, and efficiency of health care.

ONC is using Recovery Act funds to achieve some of its goals in the area of research and evaluation. Specifically, it has devoted \$60 million to its Strategic Health Information Technology Advanced Research Program (SHARP) and is using Recovery Act funds to carry out mandated studies under HITECH legislation.

ONC's FY 2011 budget request seeks support for several complementary programs related to research and evaluation:

- Support for the evaluation of programs specifically created to implement HITECH legislation;
- Ongoing collection and analysis of longitudinal data on the adoption of HIT and the evolution from adoption to meaningful use;
- Continuation of ongoing HITECH-required reports;
- Bolstering ONC's essential capacities for research, modeling, and analysis; and
- Monitoring emerging innovative technologies in the marketplace.

Operations

Based on the expanded role and responsibilities for ONC under HITECH, ONC required additional operational resources. ONC's request will enable it to:

- Support the additional staffing levels required for oversight of national grant programs and new regulatory responsibilities;
- Support increased administrative, financial and reporting requirements; and
- Support increased need for space and related infrastructure.

These major areas of activity are described on the following page, including accomplishments and the FY 2011 budget requests in greater detail.

Adoption

<i>(Dollars in thousands)</i>	FY 2009 Appropriation	FY 2009 ARRA	FY 2010 Appropriation	FY 2011 President's Budget Request	FY 2011 +/- FY 2010
BA	\$2,059	\$1,768,200	\$2,322	\$4,439	+ \$ 2,117
PHS Evaluation Funds	\$1,800	\$0	\$4,011	\$0	- \$ 4,011
Total Program Level	\$3,859	\$1,768,200	\$6,333	\$4,439	- \$ 1,894

Authorizing Legislation:

None

Allocation Method:

Contract, Grant, Cooperative Agreement

Program Description and Accomplishments

Over 80 percent of the \$2 billion in funds appropriated to ONC under the Recovery Act are directed toward state and community efforts to encourage adoption and support the attainment of meaningful use by hospitals and health care professionals. These constitute the major grant programs authorized by HITECH that are being conducted by ONC.

Grant Programs to Support the Attainment of Meaningful Use

Regional Extension Program

ONC established a grants program with Recovery Act funding to establish approximately 70 RECs. These centers will provide hospitals and clinicians with hands-on technical assistance in the selection, acquisition, implementation, and meaningful use of certified electronic health record systems. Additional assistance to health care providers will be provided through establishment of a Health Information Technology Research Center (HITRC). The HITRC will gather relevant information on effective practices from a wide variety of sources across the country and help the RECs collaborate with one another and with relevant stakeholders to identify and share best practices in EHR adoption, effective use, and provider support.

In August 2009, a Funding Opportunity Announcement (FOA) was released for the program and the first round of cooperative agreements are slated to be awarded by the end of January 2010; the second and final cycle of awards will be made by the end of March 2010.

A High Priority Performance Goal for HHS is to establish the infrastructure necessary to encourage the adoption and meaningful use of HIT. Measures for this goal focus on the largest Recovery Act investment in HIT infrastructure – the RECs. By the end of FY 2011, ONC aims to establish a network of approximately 70 RECs, register 100,000 providers for services, and achieve a 20 percent adoption of EHRs among providers by the end of FY 2011.

ONC plans to collect data from administrative and grants management records regarding the number of RECs established. Each REC will be required to plan and implement the outreach, education, and technical assistance programs necessary to meet the objective of assisting providers in its geographic service area to improve the quality and value of care they furnish by attaining or exceeding meaningful use criteria established by the Secretary. Each REC will report data on a routine basis including the number of providers with signed agreements to work with the REC, the number of providers who have purchased an EHR, the number of providers who have adopted an EHR and the number of providers who have become meaningful users of EHRs.

Workforce Training Program

In addition to ensuring that technical resources are available to hospitals and clinicians who are adopting HIT, the lack of a qualified health information professional workforce must be addressed. The Nation's current training capacity will not be adequate to produce the trained workforce that is needed to support progress to meaningful use of HIT. It is estimated that this training capacity must be increased to produce at least 50,000 additional, appropriately trained HIT workers by 2014. Accordingly, HITECH Subtitle C, §3016 requires that assistance to institutions of higher education be provided to establish or expand medical HIT education programs to ensure the rapid and effective utilization and development of health information technologies.

By the end of March 2010, awards for the creation of several programs that are aimed to support the education of health professionals, including curriculum development, competency exams, and training will be in place.

State Health Information Exchange Program

HITECH Subtitle C, §3013 required that a program be established to promote the electronic movement and use of health information among organizations. ONC established a substantial grant program that will provide funding to states and territories through cooperative agreements for planning, capacity building, and implementation activities that will enable health care providers across states to share health information at all points of service delivery. This state-based program targets developing the capacity for widespread and sustainable health information exchange to enable the meaningful use of EHRs and will mobilize clinical data needed for consumer engagement and health reform across all states.

These grants will help states to realize interoperable HIE where authorized health care providers and patients can access personal health information for prevention and care management and population level data is available for research and public health. The infrastructure necessary for widespread adoption of HIE will be developed over the next five years through the federally sponsored work on standards, certification, the NHIN, supporting governance mechanisms and federal, state and organizational policies.

The FOA for this program was also released in August 2009 and, starting in January 2010, awards will begin to be made to state-identified health information exchange organizations.

Beacon Communities Program

The Beacon Community grants program will demonstrate that interoperable HIT can have substantial, positive, short-term effects on the efficiency and quality of health care. This program will generate valuable lessons concerning how to achieve HIT-supported health system improvement, and increase momentum for the adoption and meaningful use of HIT. It will also demonstrate the feasibility of achieving the health care delivery system outcome and efficiency objectives for the meaningful use criteria for HIT incentive payments. Selected communities will demonstrate in CY 2012 the health system improvements that can be achieved nationwide in future years. This will be accomplished by selecting communities that are national leaders in HIT and information exchange. These communities will be able to demonstrate improved care coordination and performance monitoring by accelerating their capabilities through concentrated investment of federal resources. Consistent with ONC's desire and responsibility to coordinate HIT activities across the Federal government, the Beacon Community program is closely aligned with the Department of Defense (DoD) and the Department of Veterans Affairs (VA) Virtual Lifetime Electronic Record (VLER) initiative and ongoing HIT work at the Health Resources and Services Administration (HRSA) in support of federally qualified community health centers.

By the end of March 2010, up to 15 awards will be made to communities across the country in which clinicians, hospitals and consumers show how the meaningful use of EHRs can achieve measurable improvement in the quality and efficiency of health services or public health outcomes in a given geographic area.

These critical HITECH grant programs are supported through the Adoption program, as well as through program staff positions, consultant contracts, and grants management support described under Operations.

Additional Activities to Support the Attainment of Meaningful Use

In addition to these grant programs focused on supporting hospitals and health care professionals, ONC is supporting targeted Recovery Act funded activities to address specific meaningful use health care goals:

- **Consumer e-Health Tools** – ONC will identify and describe consumer perspectives on consumer e-health tools, including patient decision aids. This information will assist physicians and hospitals to more effectively achieve meaningful use of certified EHR technology, specifically those objectives related to engaging patients and families in their health care and managing chronic conditions. To become meaningful users, providers must increasingly share and exchange data with their patients, and will eventually have to interact seamlessly with personal health records (PHRs).
- **Provider Workflow Relative to Meaningful Use Criteria** – This project will extend beyond the availability of Recovery Act funds and represents a core, ongoing activity of ONC. Specifically, ONC will design and implement a longitudinal cohort study of a sample of physicians who will be tracked over an extended period of time to measure how they respond to the adoption and meaningful use of EHRs.
- **Unintended Consequences in Health Information Exchange** – As the number of providers that use EHRs and engage in electronic health information exchange grows in response to incentives, ONC anticipates that there will be unintended consequences. These include identifying quality and safety issues, liability issues, ethics issues and other unintended consequences.

ONC is also supporting Federal and private sector collaboration to further adoption and use of EHRs, including:

- **Health Information Technology Policy Committee** - As required by HITECH Subtitle A, Part 1 §3002, in 2009, ONC chartered the HIT Policy Committee, a FACA Committee, to make policy recommendations to the National Coordinator relating, but not limited to, defining meaningful use criteria for the CMS incentives program under HITECH, the protection of the privacy of health information and promotion of security in a qualified EHR, utilization of a certified EHR for each person in the United States, the use of certified EHRs to improve the quality of health care, the use of electronic systems to ensure the comprehensive collection of patient demographics and the implementation of a nationwide HIT infrastructure and implementation of the Federal HIT Strategic Plan, among other things. These activities are well under way and the Committee and its work groups meet on a regular basis and have provided valuable insight and recommendations to the National Coordinator.

Federal coordination is another important strategy in increasing adoption and meaningful use of HIT. ONC's coordination role preceded and will extend beyond HITECH activities. ONC collaborates with multiple Federal entities to further the goal of advancing and adopting interoperable EHRs and health information exchange. Some examples include:

- ONC is collaborating with CMS to define meaningful use of an EHR and create an executable payment incentive program. This work, begun in FY 2009 with Recovery Act funds, will inform the incentives program for HIT adoption that will be conducted by CMS.
- Working in close collaboration with HRSA, the Centers for Disease Control and Prevention (CDC), the National Library of Medicine (NLM), the National Science Foundation (NSF) and others, ONC is crafting a program to increase the HIT workforce as prescribed in HITECH.
- ONC is coordinating closely with AHRQ to leverage contracts that support the establishment of health information exchange organizations and to document the benefits of EHRs on health care quality and efficiency.
- ONC is working closely with DoD, VA, and HRSA in funding the Beacon Community initiative.

Federal policy coordination involves a broad array of policy activities across HHS and other Executive Branch agencies. Specific areas are described below.

Increase the alignment of Federal regulations, where possible, and Federal HIT policies to ensure:

- Improved HIT policy coordination across the Federal government;
- Increased Federal and state policy consistency and understanding through efforts to communicate Federal policy and reduce confusion about its implications for States and localities;
- Facilitation of provider adoption and attainment of meaningful use by reducing obstacles to health information exchange created by conflicting Federal policies and programs.

Efforts to date include working with:

- the Internal Revenue Service on: (1) hospital tax-exempt status and Stark and Anti-kickback, and (2) Health Information Organizations and tax-exempt status;
- CMS on Clinical Laboratory Improvement Amendments (CLIA);
- Drug Enforcement Agency on e-Prescription regulations; and
- OCR and CMS on HIPAA-related activities.

Additional work includes ONC's continued support of the development of Clinical Decision Support (CDS) as a vital way to use HIT to improve the quality and safety of care provided in the US. Clinical decision support is a term that encompasses a wide variety of tools and technologies that have in common the presentation of computer-mediated information - intelligently filtered at appropriate times - to enhance and inform decisions related to health and health care. Simply put, CDS can make clinicians, hospitals, and patients better at using health information to make good health care decisions. ONC had an extensive CDS program prior to HITECH, in collaboration with multiple other federal agencies, and believes that work on CDS constitutes a core ONC activity that must continue well into the future.

State Coordination

ONC has long worked with states to help them support the adoption and use of EHRs, and proposes to build on these previous efforts. States play a critical role in ONC's strategy to support

hospitals and health care professionals in attaining meaningful use and encouraging widespread health information exchange. Efforts to coordinate with states (in addition to the State Health Information Exchange Program) include:

- State Alliance for e-Health – Under ONC leadership, significant progress continues through the State Alliance for e-Health (State Alliance), which provides the Federal government the ability to communicate and coordinate with state governments on policy issues that include privacy and security. The State Alliance is a consensus-based, executive-level body of state elected and appointed officials (in all levels of state government), formed to address the unique role that states can play in facilitating electronic health information exchange. By design, the State Alliance supports populations of all states and territories – which include minorities, children and other vulnerable populations, under-served communities, providers, public and private programs, and others. The State Alliance explores solutions to programmatic and legal issues.

In 2009, an important accomplishment was the convening of bi-monthly learning network meetings with key state government individuals involved in HIT/HIE and appointed by the Governors, and the state guide to support their work. This effort leveraged state interest in HITECH planning and implementation grants to further the goal of states in meeting the intent of meaningful use with an emphasis on public trust through privacy and security, and information exchange across state lines.

During 2009, the State Alliance also convened representatives of 20 state medical boards with a goal of defining a path to licensure portability, which resulted in a summary document, the *State Alliance for e-Health Licensure Portability Summit*. This document continues to serve as a tool to promote license portability among state medical boards.

In 2010, the contract for the work of the State Alliance will be renewed. Plans for 2010 will focus on supporting state governments as they continue to implement their HITECH grants to promote exchange and meaningful use, as well as address state leadership, policy and planning relative to state barriers to exchange (laws, policies, etc.).

- State Health Policy Consortium – The State Health Policy Consortium, to be initiated in 2010, builds on the momentum created by the Health Information Security and Privacy Collaboration (HISPC) and leverages the state government and ‘grass roots-level’ expertise. It will continue to support other ONC efforts, such as the grants to states or state-designated entities and the work being done by the State Alliance for e-Health by:
 - Expanding state government and “grass roots-level” involvement in the harmonization and/or standardization of state policies that will facilitate health information exchange.
 - Convening select states or groups within states to collaborate around specific policy issues identified by ONC, including privacy and security.

Funding History

FY 2006	\$	3,600,000
FY 2007	\$	4,225,000
FY 2008	\$	1,320,000
FY 2009	\$	3,859,000
FY 2010*	\$	6,333,000

*FY 2010 Funding supplemented with Recovery Act funds.

Budget Request

The FY 2011 request for Adoption is \$4,439,000; a decrease of \$1,894,000 from the FY 2010 Omnibus level. This funding level supports implementation, continuation and oversight of HITECH activities.

Funding to continue work related to clinical decision support to address key functional aspects of HIT for which it is commonly understood that technology performance will have to improve and open problems addressed in order to reach the goal of meaningful use by 2014. Work in this area to date has emphasized clinical decision support but will be expanding to include usability and human-computer interactions.

As the number of providers that use EHRs and engage in electronic health information exchange grows in response to Medicare and Medicaid incentive payments and ONC initiatives, ONC anticipates that there will be unintended consequences. These include identifying quality and safety issues, liability issues, ethics issues and other unintended consequences of HIE. In FY 2011, ONC will manage a panel on unintended consequences to identify and address issues that arise as a consequence of changes in the HIT market and health information exchange.

Funding will continue to support the identification of consumer perspectives on consumer e-health tools and the development of patient decision aids. As in 2010, this information will assist physicians and hospitals to more effectively achieve meaningful use of certified EHR technology as the criteria becomes more demanding, specifically those objectives related to engaging patients and families in their health care and managing chronic conditions.

Also critical is continuation of the support for the State Alliance for e-Health. Plans for 2011 will continue to focus on supporting state governments as they implement their HITECH grants, while promoting exchange and focusing on state barriers to exchange (laws, policies, etc.). Work will continue through regional efforts to facilitate inter-state exchange and to capitalize on already established relationships to mobilize states that do not clearly see the benefits of engaging in HIT/HIE or are not as skilled in doing so. Emphasis will also be given to developing inter-state compacts and/or uniform state laws to facilitate information exchange across state borders. The State Alliance will be required to work with other organizations that can support their goals such as the National Conference of Commissioners on Uniform State Laws, the National Conference of State Legislatures, the Association of State and Territorial Health Organizations, the National Governors Association, and the National Academy for State Health Policy.

Work will include continued collaborations with CMS on future modifications of meaningful use, FDA relative to EHRs being categorized as medical devices, OCR relative to HIPAA guidance (as discussed in the privacy and security section), the Federal Trade Commission (FTC) on consumer protections, and continued work with CMS on the Clinical Laboratory Improvement Amendments (CLIA).

HITECH mandates that ONC carry out a number of programs that will further adoption of HIT with the goal of meaningful use beginning in 2011. Included are:

HITECH Sections: 3001(c)(5), 3001(c)(8) and 3004 requires the development of (1) regulations and associated guidance needed to adopt standards, and certification criteria, and (2) guidance or a regulation for a process to recognize certification bodies. The process for

developing standards and certification criteria and recognizing certification bodies will change to support meaningful use. It is likely that regulations and guidance will have to be developed annually to support these changes.

These funds support the HIT Policy Committee, a public-private FACA that provides advice to the National Coordinator with a focus on achieving health information interoperability and full participation of stakeholders in the adoption of a nationwide HIT infrastructure that allows for the electronic use and exchange of health information.

Adoption resources will continue the work to implement HITECH responsibilities through collaboration with other HHS entities and while coordinating across the public and private sectors.

By the end of FY 2011, HHS will show progress toward establishing the infrastructure necessary to encourage the adoption and meaningful use of HIT by establishing Regional Extension Centers in order to provide technical services to providers. The high priority performance goals below support this effort:

High Priority Performance Goals	FY 2010 Target	FY 2011 Target
By the end of FY 2011, establish the infrastructure necessary to encourage the adoption and meaningful use of HIT by:		
1. Establishing a network of 70 Regional Extension Centers by the end of FY 2010.	70	N/A
2. Registering 30,000 providers to receive services from Regional Extension Centers by end of FY 2010; 3. Registering 100,000 providers to receive services from Regional Extension Centers by end of FY 2011.	30,000	100,000
4. Achieving 20% adoption of EHRs among providers working with Regional Extension Centers by end of FY 2011.	N/A	20%

Data source:

Evaluation contractor will validate data reported by each Regional Extension Center grantee.

Interoperability

<i>(Dollars in thousands)</i>	FY 2009 Appropriation	FY 2009 ARRA	FY 2010 Appropriation	FY 2011 President's Budget Request	FY 2011 +/- FY 2010
BA	\$15,355	\$84,300	\$3,950	\$22,770	+ \$ 18,820
PHS Evaluation Funds	\$14,084	\$0	\$6,000	\$0	- \$ 6,000
Total Program Level	\$29,439	\$84,300	\$9,950	\$22,770	+ \$ 12,820

Authorizing Legislation:

None

Allocation Method:

Contract, Cooperative Agreement

Program Description and Accomplishments

Funding for interoperability activities supports work to enable health information to be captured and exchanged among HIT systems – whether small physician practices or large hospital systems. The funding is allocated among several components necessary to achieve exchange of health information among different entities and organizations. These elements allow ONC to:

- Identify existing or develop new standards and implementation specifications for EHRs;
- Develop and maintain certification criteria and a certification process;
- Provide a core set of needed publicly accessible specifications, tools and services for the NHIN; and
- Coordinate Federal participation in health information exchange (i.e., the Federal Health Architecture).

This funding addresses the need to:

- Maintain ONC’s historic and continuing responsibilities for identifying, developing and adopting standards, technical specifications, and certification criteria;
- Continue ONC’s progress toward making publicly available a reference implementation of the NHIN for entities to use to exchange information with each other;
- Continue to pilot new NHIN standards and services; and
- Continue support of the Federal Health Architecture (FHA).

Moreover, the availability of standards and certification criteria supporting meaningful use is critical to achieving the goals of the HITECH legislation. The meaningful use requirements progress from a focus on data collection to an increasing requirement for improved processes of care, better care coordination, and demonstration of improved outcomes. This progression of meaningful use depends fundamentally on improving the interoperability of EHRs and actual information exchange.

Standards and Certification

Ongoing standards and certification efforts by ONC are focused on aligning the set of adopted standards, implementation specifications, and certification criteria with the progressively more demanding meaningful use requirements. Meaningful use requirements will be established through regulation by CMS, in close coordination with ONC. ONC, in turn, is working closely with CMS to align standards and certification with meaningful use requirements. ONC will also leverage the work and expertise of the NLM in developing standardized terminologies. The RxNorm terminology is an example of a standardized terminology developed by the NLM. ONC

will adopt a set of standards, implementation specifications, and certification criteria through regulation.

Incorporation of these standards and implementation specifications will advance interoperability among systems engaged in health information exchange and widespread adoption of interoperable health information technologies. On December 30, 2009 an interim final rule was put on display by the Federal Register that described the initial set of standards, implementation specifications and certification criteria for HIT adopted by the HHS Secretary. A subsequent final rule will be published in 2010.

Under HITECH, federal agencies that are engaged in health care delivery and health information exchange are required to incorporate this set of adopted standards and implementation specification into their systems. Hospitals and health care professionals in the private sector are required to use EHRs that are certified to meet the adopted set of standards and implementation specifications in order to receive the incentive payments from Medicare and Medicaid.

In furtherance of these activities during 2010, ONC will refine the initial work begun in 2009 to support EHR meaningful use for implementation in 2011. ONC will:

- Support the new standards areas and recommendations of the HIT Policy Committee and the HIT Standards Committee established pursuant to HITECH;
- Identify and address the overlaps among standards supporting meaningful use;
- Harmonize inconsistencies in the meaningful use standards across standards development organizations, such as aiming for the same coding systems for demographic data and clinical information;
- Engage stakeholders in the standards development processes;
- Support the development and continued use of tools that enable standards users to more effectively identify and integrate meaningful use standards and their components into their work.

The HIT Standards Committee, a Federal Advisory Committee Act (FACA) body, is a public-private enterprise focused on supporting the goals of HITECH through the development of necessary standards, implementation specifications and certification criteria. The HIT Standards Committee makes recommendations to the National Coordinator in accordance with policies developed by the HIT Policy Committee (discussed further in the Adoption section). ONC staff will continue to actively coordinate across the relevant Federal departments and agencies to ensure that the Federal representation on the HIT Standards Committee is fully engaged and informed to speak on behalf of broad Federal interests.

The EHR certification process will be established through HHS regulation in 2010. This new certification process will be in accordance with the requirements of HITECH and provide confidence to the market that certified EHRs have the necessary functionality to support hospitals and health care professionals in meeting the meaningful use requirements. ONC is collaborating with NIST to develop and apply tests of the conformance of EHRs to the standards and other capabilities needed for meaningful use functions and implement the initial phase of the new certification program.

Nationwide Health Information Network (NHIN)

The NHIN is a collection of standards, protocols, legal agreements, specifications, and services that enables the secure exchange of health information over the Internet. The NHIN is a key

component of the nationwide HIT strategy and will provide a common platform for health information exchange across diverse entities, within communities and across the country, helping to achieve the goals of the HITECH Act. The NHIN is a critical part of meeting ONC's mission and achieving established priorities. It will enable health information to follow the consumer, be available for clinical decision making, and support appropriate use of health care information beyond direct patient care so as to improve public health. This level of broad health information exchange is necessary to achieve established health outcome goals.

The NHIN is evolving to meet the emerging needs of those wishing to exchange health information securely over the Internet. The desired outcome is to promote a more effective marketplace, greater competition, and increased choice through accessibility to accurate information on health care costs, quality, and outcomes.

The HIT Policy Committee formed a workgroup to offer recommendations on creating a policy and technical framework that allows the Internet to be used for the secure and standards-based exchange of health information, in a way that is open to all and fosters innovation. ONC will consider the recommendations of the HIT Policy Committee as it moves forward. ONC is working to establish an incremental approach for the NHIN that will generate immediate value (e.g., enable providers to achieve meaningful use) while creating the components that will be needed for more advanced information exchange (e.g., broadcast query).

One important part of ONC's NHIN strategy is to provide a reference implementation of the NHIN for entities to use to exchange information with each other. A reference implementation is a working software application that meets all the specification criteria for exchanging health information. It is both a quality check of the standards and implementation specifications and a template that federal and private partners can use to develop their own software. The CONNECT project supports such a reference implementation. CONNECT is a Federal Health Architecture (see discussion below) initiative to develop a federal software solution to link federal systems to the NHIN. CONNECT was built in open source and has now been made available to the health care industry at large. The CONNECT initiative takes the NHIN specifications and creates a production-ready open-source software solution that can be adopted by both federal and private entities. CONNECT provides a full software instantiation of the NHIN specifications and services. ONC will continue to support the CONNECT efforts with this funding.

HITECH Subtitle A, Part 1 §3001(c)(8) specifies that ONC has the responsibility to establish a governance mechanism for the NHIN. To discharge this responsibility, ONC will publish a notice of proposed rulemaking in 2010 after gathering input from a wide array of sources. Establishing a governance mechanism is critical to the success of the NHIN and of achieving ONC's mission and the goals of HITECH.

Federal Health Architecture (FHA)

The Federal Health Architecture (FHA) is a partnership among Federal agencies, ONC, and the Office of Management Budget (OMB). The Department of Health and Human Services (HHS), through ONC, is the Managing Partner. The DoD and the VA serve as Lead Partners. The Lead Partners provide program funding annually. In addition, more than 20 agencies, all with health-related responsibilities, contribute time and expertise to participate in specific FHA activities. Through this group, a collaborative Federal voice informs the development of the NHIN from the government's perspective and provides a venue for implementing and deploying a Federal version of the architecture that will allow data exchange with all entities across the Nation.

HHS Agencies:

- Administration for Children and Families
- Administration on Aging
- Agency for Healthcare Research and Quality
- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services
- Food and Drug Administration
- Federal Occupation Health
- Health Resources & Services Administration
- Indian Health Service
- National Institutes of Health
- Substance Abuse and Mental Health Administration

Non HHS Agencies:

- Department of Agriculture
- Department of Defense
- Department of Energy
- Department of Homeland Security
- Department of Justice
- Department of Labor
- Department of State
- Department of Transportation
- Department of Veterans Affairs
- Environmental Protection Agency
- National Aeronautics and Space Administration
- Office of Personnel Management
- Social Security Administration

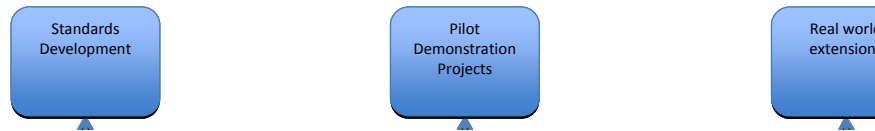
Recovery Act Activities

ONC is working closely with the National Institute for Standards and Technology (NIST), to develop an effective set of standards testing, conformance testing and interoperability testing components for EHRs with funding under the Recovery Act. The resulting HIT standards testing and evaluation infrastructure will support effective industry consensus standards development processes and will provide the U.S. HIT industry and federal activities with robust conformance and interoperability testing capabilities. Deployment of these technologies will promote interoperable HIT adoption.

To continue the work begun in 2009 with Recovery Act funds, ONC is working with NIST to provide the testing and certification processes as required by HITECH Subtitle A, Part 1 §3001(c)(5). These activities will continue collaboration toward incorporating more stringent requirements in standards that will meet meaningful use goals in 2012 and future years.

Recovery Act funds will also support the development of the standards, tools, policies, governance, interoperability framework, and technical infrastructure to support the NHIN and create standards-based interoperability for health information. The interoperability framework will develop standards and software to support data exchange.

The diagram below illustrates how the standards development tasks relate to one another. Ultimately, the data standards and software developed as part of this process will support NHIN software development and data standards. Each box corresponds to an activity further described on the following pages.



Standards development activities will develop a robust process based on federal best practices.

- *Use case development and functional requirements for interoperability* – Standards and software developers require precise functional requirements and use cases to document the real-world challenges that must be addressed. Standardizing documentation of functional requirements and use cases is a critical step in streamlining the development process. Working closely with consumers, providers, government organizations and other stakeholders, ONC will identify use cases (specific operational scenarios), prioritize them through a governance process, and create explicit, unambiguous documentation of the use cases, functional requirements and technical specifications for interoperability.
- *Harmonization of standards* – The harmonization process integrates different views of health care information into a consistent view. For example, one use case may need patient demographic information (Age, Sex, Address), while another may describe similar demographic information in a different way (Date of Birth, Gender, City/State). These descriptions will need to be harmonized and produce an inclusive, consistent view of the interoperability requirements. This process will include merging related concepts, adding new concepts, and mapping concepts from one view of health care information into another view.
- *Standards Development* – Modification or extension of existing standards or the development of new standards to support use case development.
- *Tools and Standards Repository* – To accelerate the development, use, maintenance and adoption of interoperability standards across the health care industry, and to spur innovation, ONC will develop tools to facilitate the entire standards lifecycle and maximize re-use of concepts and components – from standardized use case development, to harmonization, and software developer access to standards, including tools and a repository for browsing, selecting, and implementing appropriate standards.
- *Interoperability Specifications* – ONC will contract for the full specification of priority use cases (for data, services, vocabularies and value sets), which will enable the testing and validation of these standards within the NHIN architecture. This work will develop an interoperability specification that is independent of a specific software architecture (a platform-independent model, or PIM) and also an interoperability specification that is specific to the NHIN architecture (a platform-specific model, or PSM). Federal agencies that have different software requirements can use the PIM to develop interoperable software that can exchange data with

NHIN. States, companies, or NHIN partners can use the PSM to develop new applications that conform to the NHIN interoperability specification.

- *Reference Implementation* – A reference implementation is the fully ‘instantiated’ software solution that is analyzed to be compliant with the standards and serves as a “reference” to other software developers of what an interoperable solution looks like. Fully documented, a reference implementation defines a well-understood solution to the use case, and provides other developers an opportunity to see and interact with a working model of the technology solution. The reference implementation will be accessible as a public resource with compiled code, source code and supporting documentation. The reference implementation will be accessible to software developers through the Tools and Standards Repository activities.
- *Integration Testing* – Testing is an important part of validating that any technology solution satisfies the goals of interoperability. Integration testing evaluates how a particular system integrates with existing technology solutions. NIST will provide tools to test a particular implementation for conformance to a set of standards specification. ONC will contract for the development of an integration testing “harness” that will test how a particular component that has satisfied conformance testing requirements integrates into the reference implementation.
- *Certification* – ONC will work with NIST and other stakeholders to develop a robust certification process that includes:
 - Developing a process for certifying HIT, including PHR and EHR technology;
 - Establishing technical requirements; and
 - Maintaining the master list of all Certified EHR Technology Products. This list will be readily available for providers and purchasers of EHR technology products to meet this meaningful use requirement.
- *Real World Extensions: Interim Governance, NHIN Demonstrations and Pilots* – ONC will contract for limited, but real world demonstration pilots. These activities provide the necessary implementation feedback of problems, risks, and lessons learned to standards harmonization and specifications refinement processes. This is the final step of feedback to the standards development process, and will provide real world vetting for the standards activities.
- *NHIN Operations and Infrastructure* – To support the ongoing demonstrations and production pilots of health information exchange across a trusted network, ONC will fund:
 - Coordinating and managing the addition of new participants onto the NHIN, ensuring that technical and organizational processes are followed;
 - Standing up, administering and operating the NHIN digital certificates and operational and services registries;
 - Providing NHIN network support functions for the network (help desk);
 - Providing basic network monitoring services;
 - Sponsoring network penetration studies to ensure security of the network; and
 - Providing collaboration tools to elicit and share implementation lessons learned.

Performance Measurement

To assess the effectiveness of this program, ONC is developing new performance measures with ambitious targets to gauge Federal progress toward the goal of enabling meaningful use through implementation of required standards in Federal and commercial systems.

Funding History

FY 2006	\$	31,880,000
FY 2007	\$	33,963,000
FY 2008	\$	26,327,000
FY 2009	\$	29,439,000
FY 2010*	\$	9,950,000

*FY 2010 funding supplemented with Recovery Act Funds.

Budget Request

The FY 2011 planning level budget for Interoperability is \$22,770,000. It is an increase of \$12,820,000 over the FY 2010 Omnibus and supports implementation of HITECH requirements.

Standards (\$7.3M, +\$4.7M from FY 2010)

Funds for the management of the HIT Standards Committee, a public-private FACA required in HITECH Subtitle A, Part 1 §3003 that provides advice to the National Coordinator with a focus on achieving health information interoperability. Because implementation of HIT is an incredibly complex undertaking, the FACA will solicit and consider input from both the public and private sectors. These funds will ensure compliance with all FACA requirements for this.

The development and implementation of standards in HIT are critical to enabling an interoperable, secure capability for health information exchange and for reaching the goal of meaningful use. Funding will support further development and harmonization of standards necessary to support the evolving definition of meaningful use as it changes between 2011 and 2013 to incorporate additional EHR functions. Since those changes are not currently known, the program must be anticipatory and flexible.

Federal Health Architecture is incrementally funded, which allows for discussions to occur with existing funding partners, as well as opportunity to seek out additional partners to secure future funding if required and approved. FHA is not building a health information exchange system but rather helping to architect solutions. The operations and maintenance costs for the program are less than might be expected for such a large undertaking and these costs will be absorbed by the participating agencies. FHA partners reevaluate the lifecycle costs yearly during strategy planning to identify the next year's work plan. ONC is participating with the HHS CIO Office as the lead partner for FHA.

Nationwide Health Information Network (\$11.5M, +\$4.1M from FY 2010)

FY 2011 funding is requested to support ongoing activities to implement the established incremental approach for the NHIN that will generate immediate value in enabling hospitals and health care professionals to achieve meaningful use and create the components that will be needed for more advanced information exchange in the coming years.

Funding that supports ongoing NHIN governance activities will continue. As a requirement of HITECH Subtitle A, Part 1 §3001(c)(8), the NHIN governance mechanism will continue to be developed and implemented.

Funding will support the cooperative agreement activities for the Recovery Act-funded state and state-designated entities for planning, capacity building, and implementation activities is essential to ensure appropriate management and oversight of this large investment of funds. Activities will include providing for contracted subject matter expertise, oversight and costs associated with business (non-programmatic) award, management and administration of the cooperative agreements.

Mental Health and Substance Abuse (\$4.0M, +\$4.0M from FY 2010)

Through a collaboration among ONC, the Substance Abuse and Mental Health Services Administration (SAMHSA) and State substance abuse and mental health agencies, this funding supports the planning, development, and/or initial implementation of interoperable state agency data systems that meet federal data standards, and will assist mental health and substance abuse (MHA/SA) providers in the adoption of certified HIT, primarily EHR systems. Additionally, it supports more cost effective development and deployment of interoperable EHRs by means of software re-use (versus repeated re-invention). The overall goal is to integrate substance abuse and mental health prevention and treatment into the larger primary care delivery system HIT framework and within the larger universe of Medicaid and other safety net services. This effort will also demonstrate and deploy state-of-the-art, privacy protection technology, based upon new standards. It recognizes that there are unique confidentiality rules that apply to both mental health and substance use disorder diagnosis and treatment.

ONC FY 2011 OMB Circular A-11, Exhibit 300: Capital Asset Plan and Business Case Summaries can be found at <http://it.usaspending.gov/> .

Privacy and Security

<i>(Dollars in thousands)</i>	FY 2009 Appropriation	FY 2009 ARRA	FY 2010 Appropriation	FY 2011 President's Budget Request	FY 2011 +/- FY 2010
BA	\$1,706	\$35,100	\$636	\$6,850	+ \$ 6,214
PHS Evaluation Funds	\$0	\$0	\$3,000	\$0	- \$ 3,000
Total Program Level	\$1,706	\$35,100	\$3,636	\$6,850	+ \$ 3,214

Authorizing Legislation:
Allocation Method:

None
Contract, Cooperative Agreement, Grant

Program Description and Accomplishments

Efforts to increase health information exchange will not reach their potential unless individuals and health care professionals are confident that personal health information will be private and secure. This includes both information in EHRs and information moving through the health care system. For this reason, ONC is taking proactive steps to assure that privacy and security are addressed in every phase of the development, implementation and adoption of policies and technical standards that will form the foundation and infrastructure for HIT and health information exchange.

ONC's strategy for bolstering public trust in electronic information systems through a comprehensive approach to privacy and security includes two major components:

1. ONC will aggressively implement and enforce, in coordination with OCR, the multiple new authorities and programs related to privacy and security under HITECH;
2. ONC will identify and take actions to address gaps and issues in current privacy and security laws and guidance.

ONC's FY 2011 budget request addresses the need to:

- Provide hospitals and health care professionals with best practices and guidance on developing, implementing and maintaining organizational privacy and security policies;
- Implement and provide guidance regarding new privacy and security regulations;
- Identify gaps in current privacy and security legislation and guidance;
- Continue a security initiative started with Recovery Act funds; and
- Gain a better understanding of issues related to medical identity theft and risk mitigation.

Privacy and Security Framework

To increase public trust in electronic health information exchange and to ensure the safe and secure encryption of health information, ONC continues to work with other HHS agencies to develop a nationwide privacy and security framework for electronic exchange of individually identifiable health information. Work to date has resulted in a Privacy and Security Framework that establishes a set of principles for privacy and security to guide policy and technical development across the Federal government, state governments, and the private sector. This document also includes a tool box comprised of HIPAA guidance related to the principles, a draft personal health record privacy notice, and security guidance for small practices.

ONC now needs to provide more detailed guidance to hospitals and health care professionals with best practices and guidance on developing, implementing and maintaining organizational privacy

and security policies. To provide more useful guidance as states and the private sector organizations begin to develop and implement plans for health information exchange, ONC will develop implementation guidance and activities to help entities put these principles into operation consistent with HITECH and meaningful use as defined for 2011. This is also a critical step to inform federal policy initiatives in other areas such as NHIN governance, and to inform technology development, including standards and products to assure policy is integrated into technology. ONC will leverage its Regional Extension Program to get these best practices and guidance on privacy and security out to hospitals and health care professionals.

Building on HITECH Regulatory Authorities

HITECH provides new regulatory authorities to HHS for privacy and security. ONC will support, in close coordination with OCR, to continue activities to develop HIPAA amendments and tools. It will also support continuing the development of guidance regarding breach notification and technical security safeguards.

Using Recovery Act funding, ONC will conduct a study regarding privacy and security for non-HIPAA covered entities, which is required under HITECH Subtitle D, Part 2 §13424(b). This study and subsequent report to Congress on privacy and security requirements for entities that are not HIPAA covered entities or business associates will be developed in conjunction with OCR and the Federal Trade Commission, and provided to Congress by February 17, 2010. ONC's FY 2011 budget request will allow ONC to continue follow-up actions to address identified gaps, overlaps and inconsistencies in privacy and security protections, with a particular focus on those entities not currently covered by existing federal law.

Cybersecurity

Using Recovery Act funds, ONC will launch a cybersecurity initiative in FY 2010. This funding will enable ONC to continue critical work to protect electronic health information. Increased adoption of HIT, combined with increased health information interconnections will create a novel information environment, with risks as well as opportunities. All of the multiple, independent entities that belong to this information "ecosystem" are governed by diverse legal and regulatory authorities, and each has its own unique mission and vision. Because the health information ecosystem has no exact analog in other sectors, the nature and the impact of information security vulnerabilities is not yet well understood; information on vulnerabilities and breaches is anecdotal. ONC views work on cybersecurity as a core, ongoing ONC requirement that will extend beyond the Recovery Act funding.

Funding of Recovery Act Activities

ONC is working closely with OCR and SAMHSA to implement required HITECH changes to the HIPAA privacy and security rules; conduct audits to ensure covered entities and business associates are complying with HIPAA and HITECH privacy and security requirements; and conduct studies and draft regulations, guidance, and reports that HITECH requires the Department to complete by specific deadlines.

HITECH Subtitle A, Part 1 §3001(e) requires establishing a Chief Privacy Officer (CPO) position. This position will shortly be filled and with supporting resources will advise the National Coordinator on privacy, security, and data stewardship of electronic health information and coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information. Since the CPO position and

related activities will exist without time limitation, funds will support these through the FY 2011 budget request.

In addition to the activities highlighted above, ONC is conducting the following privacy and security activities focused on consumers:

- *Consumer Permissions* - ONC will identify current trends and best practices with respect to consumer permissions employed by different models of electronic health information exchange to gain consumer trust through providing consumers with choice(s) in how their health information is exchanged electronically. These models included health information organizations, PHRs, health record banks, and integrated delivery systems or networks. Recommendations will inform policy development relative to consumer permissions.
- *On-line Dispute Resolution* - In close coordination with the National Science Foundation, ONC will plan to oversee demonstrations to test and determine the utility and scalability of on-line dispute resolution facilitated by EHRs, with secure portals for patient access, in a variety of health care settings.

Funding History

FY 2006	\$	13,921,000
FY 2007	\$	8,343,000
FY 2008	\$	15,932,000
FY 2009	\$	1,706,000
FY 2010*	\$	3,636,000

*FY 2010 Funding supplemented with Recovery Act funds.

Budget Request

The FY 2011 request for Privacy and Security is \$6,850,000. This is an increase of \$3,214,000 above the FY 2010 Omnibus and supports implementation and oversight of HITECH requirements.

Privacy (\$3.0M, +\$0.6M from FY 2010)

Funding is included for the Chief Privacy Officer, as required by HITECH Subtitle A, Part 1 §3001(e), who will advise the National Coordinator on privacy, security, and data stewardship of electronic health information and coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information. The office, established during FY 2009, will continue to support initiatives important to securing health information during electronic exchange.

In 2011, one or more contracts will be funded to continue ONC's on-going work on identifying gaps in HIPAA privacy and security statutes, translate those gaps into policy options, present those options to the HIT Policy Committee and its Privacy and Security Workgroup, support the deliberations of those groups, and translate their recommendations into policy and guidance from ONC.

Beginning in 2010, ONC will convene a new Federal HIT Interagency Security Advisory Panel. The purpose of the Security Advisory Panel is to learn from the expertise of the most sophisticated federal agencies concerning approaches and options to improving the security of health information. The Advisory Panel will be chaired by the Director of Programs and Policy.

Several Privacy and Security and Policy activities begun in FY 2009 are mandated in HITECH and, although previously funded through Recovery Act dollars, must be continued annually. These activities include:

- *Guidance and tools to support HIPAA modifications:* HITECH Subtitle D, Part 2 §13421(b) allows for the amendment of HIPAA to make it consistent with the Recovery Act, which will be accomplished in FY 2010. Guidance and tools will need to be developed in conjunction with OCR in 2011 to support those changes. For example, the current draft of the Privacy and Security Framework includes a tool box with HIPAA guidance that is cross-walked to the privacy and security principles. This tool box will now need to be revised consistent with HITECH and meaningful use. The measure of success of the project will be in terms of the numbers of questions received about the areas of HIPAA added by HITECH before and after the guidance is issued.
- *Breach Notification Guidance:* HITECH Subtitle D, Part 2 §13402(h)(2) requires that annual guidance be issued specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals (as it relates to breach notification). Initial guidance was developed in conjunction with OCR and issued on April 17, 2009. After receiving and incorporating comments on the initial guidance, it will be updated on April 17, 2010.

The April 17, 2011 guidance is anticipated to build on the guidance issued in 2010 by incorporating advancements in technology and any new policy development. This guidance will be targeted to specific aspects of meaningful use including public trust, exchange and public health that have raised the most questions by stakeholders. Again, draft updated guidance will be vetted among a diverse set of stakeholders in order to achieve the right balance of guidance.

- *Security Guidance:* HITECH Subtitle D, Part 2 §13401(c) requires that annual guidance is issued relative to technical safeguards to carry out security beginning in 2009. Such guidance was issued in conjunction with OCR in 2009 and will be again in 2010 and 2011. The additional guidance will build on the work of the previous year, incorporating advances in technology and new policy development particularly as it relates to meaningful use and will be developed in conjunction with OCR and the Chief Technology Officer, as appropriate. Draft guidance will be vetted by a diverse set of stakeholders, including the security community, to enhance successful communication and increase the usefulness of the assistance.
- *Privacy and Security Requirements for non-HIPAA covered entities;* HITECH Subtitle D, Part 2 §13424(b) requires that a study be conducted and a report be developed and issued to Congress on privacy and security requirements for entities that are not HIPAA covered entities or business associates as of the date of enactment of the Recovery Act. This study and report will be developed in conjunction with OCR and the Federal Trade Commission, and provided to Congress by February 17, 2010.

Security (\$3.9M, +\$2.6M from FY 2010)

Cybersecurity activities in FY 2011 will focus on understanding and mitigating data breaches, developing an incidence response program and providing education and outreach relative to

enhancing HIT/HIE security. ONC will analyze data breach information collected by OCR in 2009 to identify patterns and causes with the goal of understanding how and why breaches occur so that preventive measures can be developed. ONC will contract for the development of a database and analytical tools to implement this program. A critical gap ONC has identified is the lack of either a public or private incident response program that provides means to collect and analyze cybersecurity incidents (e.g., hacking). ONC will contract for a feasibility study and pilot implementation of a healthcare incident response program. Finally, ONC will focus on communications, education, and outreach programs that promote HIT security and cybersecurity through the dissemination of security updates.

ONC continues to provide leadership in two areas related to privacy and security in electronic health information exchange – using HIT - to minimize fraud and abuse and support cost containment efforts. FY 2011 funds will allow ONC to continue its efforts to find ways that HIT can minimize the negative impacts in these two areas.

The Privacy and Security initiative will continue the work as required under HITECH through collaboration with other HHS entities and while coordinating across the governments – both at the Federal and State levels.

Research and Evaluation

<i>(Dollars in thousands)</i>	FY 2009 Appropriation	FY 2009 ARRA	FY 2010 Appropriation	FY 2011 President's Budget Request	FY 2011 +/- FY 2010
BA	\$2,518	\$93,300	\$3,595	\$6,701	+ \$ 3,106
PHS Evaluation Funds	\$1,551	\$0	\$0	\$0	\$ 0
Total Program Level	\$4,069	\$93,300	\$3,595	\$6,701	+ \$ 3,106

Authorizing Legislation:
Allocation Method:

None
Contract, Grant, Cooperative Agreement

Program Description and Accomplishments

ONC's Research and Evaluation activities include measuring the success of programs funded under the Recovery Act, supporting innovation in HIT, and other ongoing ONC efforts to further adoption and meaningful use of HIT. Important efforts to support HIT research and innovation will also be continued in FY 2011 using Recovery Act funds, as will ONC's evaluations of all of its major initiatives. The specific HITECH programs to address these goals are described below.

The following funded activities will play a critical role in bringing information to bear on management decisions as HITECH programs are implemented:

- Support for the ONC innovation research agenda and continue innovation tracking;
- Development of ONC's capacity for analysis, modeling and internal research on the value of HIT; and
- Continuation and augmentation of our evaluation and adoption monitoring activities.

Evaluation, Monitoring and Analysis

ONC recognizes that effectively measuring progress and evaluating success is critical to implementing and managing ONC's program and meeting set goals. This includes both measuring the progress of individual programs and studying the collective impact of these efforts toward achieving ONC's mission. Independent evaluations of ONC's major initiatives will be conducted to ensure the effective and efficient use of Recovery Act dollars to accomplish the goal of widespread adoption and use of HIT. In addition, ONC has and will continue to support surveys and studies that elucidate progress towards the adoption and meaningful use of EHRs. These programs are intended to outlast Recovery Act funds, so ONC has built them into the ongoing annual budget request.

Finally, to support policy development, program design, and the analysis of evaluation data, it is important that ONC have internal modeling and analysis resources. Economic and behavioral models will be used to describe and understand the factors driving the adoption, meaningful use, interoperability of EHRs, and information exchange. They will also help to better inform the value delivered by ONC programs and communicate that information to key audiences.

Funding of work mandated by or related to Recovery Act Activities

Evaluation, Studies, Performance Monitoring, and Strategic Plan

Independent evaluations will be conducted to assess the effective use of the \$2 billion of Recovery Act funds appropriated to ONC for discretionary programs under the HITECH Act to promote widespread adoption and use of HIT in the following five categories:

- An overall, summative evaluation (“Global Evaluation”) to determine the combined success of the Recovery Act programs and activities in achieving HITECH goals, and illuminate the contribution of each component program;
- Individual evaluations of four specific programs funded by Recovery Act (“component evaluations”) that will measure the effectiveness of each individual program in meeting stated goals;
- Reports and studies that are required under Title XIII of the HITECH Act; and
- Revision of the Federal Health IT Strategic Plan and development of relevant metrics and tools necessary to track overall performance toward the HITECH goals.

Recovery Act funding will also establish a performance management dashboard to assist ONC in monitoring HITECH programs and grantees, in assessing overall progress towards the goals outlined in the HITECH Act.

Research, Development and Innovation

The overall goal of these HITECH activities is to support research and development of HIT innovations that will accelerate the transformational improvement of U.S. health care to a high-performance, 21st-century system that supports the health of individuals and of the population as a whole.

- *Strategic Health IT Advanced Research Projects (SHARP)* – This activity will fund research projects focused on areas where breakthrough improvements can greatly enhance the transformational effects of HIT and address well-documented problems that have impeded adoption and the pathway to meaningful use. The four focus areas for the SHARP awardees will be: security of HIT; patient-centered cognitive support; health care application and network platform architectures; and secondary use of EHR data.
- *Support for HIT Innovation* – Without adequate innovation research and investment, a nation risks failing to keep up with the most effective techniques to leverage health care information to improve safety, quality, and outcomes of health care while providing a more efficient health care system through reduced clinical and administrative costs. Specifically, this initiative seeks to identify HIT innovations which have value within health care, but for which there is currently not an available market.

Performance Measurement

Since 2008, ONC has collected data on physician adoption rate of EHRs and started collecting data on non-federal hospital adoption of EHRs in 2009. Further refinement of adoption measures, for both hospitals and providers, is ongoing and should be completed this spring. Such measures will monitor the progress of EHR adoption.

The success of programs designed to increase adoption will collectively move the Nation closer to a transformed health system that makes health information available and actionable for individuals and health care professionals.

Funding History

FY 2006	\$	2,000,000
FY 2007	\$	1,000,000
FY 2008	\$	3,675,000
FY 2009	\$	4,069,000
FY 2010*	\$	3,595,000

*FY 2010 Funding supplemented with Recovery Act funds.

Budget Request

The FY 2011 request for Research and Evaluation is \$6,701,000; an increase of \$3,106,000 above the FY 2010 Omnibus level. This funding level supports implementation, continuation and oversight of HITECH activities.

Adoption Surveys (\$3.2M, +\$1.7M from FY 2010)

ONC contracts two national surveys – one of physicians’ offices and the other of hospitals – to assess the current state of HIT adoption and investigate approaches that might accelerate HIT adoption in a cost-effective manner. Through a Memorandum of Understanding, the CDC will continue surveying physicians to measure the adoption rate of EHRs in physician offices and will increase the survey sample size more than 10,300 physicians – a more than five-fold increase. Funds will also support continuation of contracted analyses of hospital adoption rates through established surveys. In addition, funding will be allocated for a national-level tracking survey and for studies of the barriers to and costs and benefits of the adoption and meaningful use of HIT.

Evaluation and Reports (\$3.5M, +\$1.4M from FY 2010)

Understanding and reporting the progress and improvements in the HIT programs are requirements of HITECH and continued support will assure ongoing evaluation and dissemination of information about key program components. ONC will produce reports, data, and analyses that facilitate progress towards meaningful use, information exchange, and the use of HIT to transform the delivery system through a better understanding of key elements necessary to achieve those goals. These initiatives will also help ONC monitor progress toward achieving the objectives of the revised HIT strategic plan and provide audiences, including the Congress and ONC’s stakeholders, with updates on ONC programs.

Operations

<i>(Dollars in thousands)</i>	FY 2009 Appropriation	FY 2009 ARRA	FY 2010 Appropriation	FY 2011 President's Budget Request	FY 2011 +/- FY 2010
BA	\$21,914	\$19,100	\$31,828	\$37,574	+ \$ 5,746
PHS Evaluation Funds	\$244	\$0	\$6,000	\$0	- \$ 6,000
Total Program Level	\$22,158	\$19,100	\$37,828	\$37,574	- \$ 254
FTE	31	0	75	120	+45

Authorizing Legislation:
Allocation Method:

None
Contract

Program Description and Accomplishments

ONC operates as a Staff Division within the Office of the Secretary and provides continuing leadership for the development and nationwide implementation of interoperable HIT to improve the quality and efficiency of health care. The Recovery Act initiated significant new ONC programs and activities in order to enable health care providers to adopt and meaningfully use HIT.

To effectively meet the requirements of HITECH, and to provide the structure needed for developing and overseeing programs and regulations to successfully accomplish the mandates of the Recovery Act and the goals of the Administration, ONC is increasing Federal staffing levels in FY 2010. Term and permanent positions will be established to provide sound, Federal oversight to new programs and responsibilities, including grants oversight. Term positions will be established for up to four years to develop and oversee programs, such as the new grants programs, that are for a limited time. Permanent staff will be recruited for new responsibilities that are long-term in nature. ONC will also use other hiring mechanisms approved under the Recovery Act including Schedule A and details, as provided in HITECH Subtitle A, Part 1 §3001(d); and Intergovernmental Personnel Act Mobility Program (IPA) appointments. The use of Federal staff rather than contract staff will allow some cost savings that can be utilized to ensure appropriate oversight.

Operations funding includes direct support for new HITECH grant programs and coordination activities including personnel compensation, facilities and systems support, travel, and associated program support costs. The increased need for space and related infrastructure (such as furniture, computers, equipment and supplies) will accommodate new staff while moving contractor support off-site. Memoranda of Understanding, Inter-Agency Agreements and contracts will be completed in support of ONC administrative, financial, logistical and planning activities.

ONC is launching a comprehensive communications initiative in FY 2010 that will support all components of adoption and meaningful use through the timely dissemination of information through a wide array of tools including, but not limited to, blogs, e-mail alerts, and postings to websites. ONC is collaborating with CMS, OCR and other partners to implement the communications and outreach activities needed to promote acceptance of the broader goals and to support the specific programs and policies of HITECH. These communication activities are essential components of a powerful change management strategy. ONC will focus on informing patients, providers, and caregivers about the benefits of EHRs and providers as well as increasing their knowledge of protections for privacy and security of personal health information. These

activities are very closely coordinated with CMS provider communications focusing on the incentives program for meaningful use. They will be jointly led by ONC and OCR. OCR's involvement relates to its mandate to educate the public on uses of and safeguards for protected health information, and overseen by the interagency HITECH Communications Workgroup - chaired by ONC.

Funding History

FY 2006	\$ 10,299,000
FY 2007	\$ 13,771,000
FY 2008	\$ 13,307,000
FY 2009	\$ 22,158,000
FY 2010*	\$ 37,828,000

*FY 2010 Funding for Communications and Outreach is supplemented with Recovery Act funds.

Budget Request

The FY 2011 budget for Operations is \$37,574,000 to fund increased service levels. This request is a decrease of \$254,000 from the FY 2010 Omnibus level. Continued funding at this level will provide necessary federal stewardship to support the \$2 billion Recovery Act investment in HIT.

Operating Expenses (\$32.4M, -\$4.1M from FY 2010)

The role and nature of ONC has changed significantly since the passage of HITECH – from a policy-oriented staff division to an operational entity charged with implementation and oversight of \$2 billion in grants and procurements. While the Recovery Act provided program funding for non-federal entities, it did not provide funding for administration of these important grant programs. The ONC budget requests resources to provide appropriate grants administration and oversight. To operate these new programs, ONC needs to expand and redirect the workforce from a policy focus to program operations and oversight. The budget reflects increased costs for staffing, rent and operating costs associated with ONC's significantly increased responsibilities to support HIT implementation. ONC anticipates some cost savings through the planned increases in federal staff, which are estimated to be a lower cost than contractor support. This funding will allow ONC to support and manage its programs toward achievement of the national HIT agenda, while improving office operations to allow ONC to prudently oversee and coordinate ongoing programs and Recovery Act activities.

Communications and Outreach (\$5.2M, +\$3.9M from FY 2010)

Funding is required to maintain the multi-faceted communication and outreach program to health care stakeholders, including consumers. This effort is essential to build knowledge of the benefits of the meaningful use of HIT, the protections that will accompany such use, and specific opportunities for advancing HIT implementation through Recovery Act programs. The planned work is closely coordinated with CMS, OCR and FTC, as appropriate, and will be performed under a competitive contract. It will include the requirements of Subpart D, Part 1§12403(a): that a multi-faceted national education campaign be initiated and maintained to educate individuals about the potential uses of their protected health information, the effects of such uses, and the rights of individuals with respect to such uses. The program is to incorporate a variety of languages and present information in a clear and understandable manner. To achieve the communication goals a sustained approach is essential.

Public Health Service Act Evaluation Funds

ONC's program level budget includes \$0 of Public Health Service (PHS) Act Evaluation Funds. It is a decrease of \$19,011,000 from the FY 2010 Omnibus level.

Supplementary Tables

Office of the National Coordinator for Health Information Technology

Budget Authority by Object

	2010 Estimate	2011 Estimate	Increase or Decrease
<u>Personnel compensation:</u>			
Full-time permanent (11.1).....	8,234,030	12,951,210	4,717,180
Other than full-time permanent (11.3).....	-	-	-
Other personnel compensation (11.5).....	-	-	-
Military personnel (11.7).....	230,000	250,000	20,000
Special personnel services payments (11.8).....			
Subtotal personnel compensation.....	8,464,030	13,201,210	4,737,180
Civilian benefits (12.1).....	1,976,167	3,108,290	1,132,123
Military benefits (12.2).....	115,000	125,000	10,000
Benefits to former personnel (13.0).....			
Total Pay Costs.....	10,555,197	16,434,500	5,879,303
Travel and transportation of persons (21.0).....	1,084,500	712,000	(372,500)
Transportation of things (22.0).....	15,000	15,000	-
Rental payments to GSA (23.1).....	5,600,000	6,000,000	400,000
Communication, utilities, and misc. charges (23.3)..	1,000,000	800,000	(200,000)
Printing and reproduction (24.0).....	300,000	200,000	(100,000)
<u>Other Contractual Services:</u>			
Advisory and assistance services (25.1).....	7,804,803	3,537,000	(4,267,803)
Other services (25.2).....	7,476,500	39,380,500	31,904,000
Purchase of goods and services from government accounts (25.3).....	6,795,000	9,585,000	2,790,000
Operation and maintenance of facilities (25.4).....	1,500,000	1,545,000	45,000
Research and Development Contracts (25.5).....			-
Medical care (25.6).....			-
Operation and maintenance of equipment (25.7)..	-		-
Subsistence and support of persons (25.8).....			
Subtotal Other Contractual Services.....	23,576,303	54,047,500	30,471,197
Supplies and materials (26.0).....	50,000	50,000	-
Equipment (31.0).....	150,000	75,000	(75,000)
Land and Structures (32.0).....			
Investments and Loans (33.0).....			
Grants, subsidies, and contributions (41.0).....			
Interest and dividends (43.0).....			
Refunds (44.0).....			
Total Non-Pay Costs.....	31,775,803	61,899,500	30,123,697
Total Budget Authority by Object Class.....	42,311,000	78,334,000	36,003,000

Office of the National Coordinator for Health Information Technology

Salaries and Expenses

	2010 Estimate	2011 Estimate	Increase or Decrease
<u>Personnel compensation:</u>			
Full-time permanent (11.1).....	8,234,030	12,951,210	4,717,180
Other than full-time permanent (11.3).....	-	-	-
Other personnel compensation (11.5).....	-	-	-
Military personnel (11.7).....	230,000	250,000	20,000
Special personnel services payments (11.8).....			
Subtotal personnel compensation.....	8,464,030	13,201,210	4,737,180
Civilian benefits (12.1).....	1,976,167	3,108,290	1,132,123
Military benefits (12.2).....	115,000	125,000	10,000
Benefits to former personnel (13.0).....			
Total Pay Costs.....	10,555,197	16,434,500	5,879,303
Travel and transportation of persons (21.0).....	1,084,500	712,000	(372,500)
Transportation of things (22.0).....	15,000	15,000	-
Rental payments to Others GSA (23.1).....			
Communication, utilities, and misc. charges (23.3)..	1,000,000	800,000	(200,000)
Printing and reproduction (24.0).....	300,000	200,000	(100,000)
<u>Other Contractual Services:</u>			
Advisory and assistance services (25.1).....	7,804,803	3,537,000	(4,267,803)
Other services (25.2).....	7,476,500	39,380,500	31,904,000
Purchase of goods and services from government accounts (25.3).....	6,795,000	9,585,000	2,790,000
Operation and maintenance of facilities (25.4).....	1,500,000	1,545,000	45,000
Research and Development Contracts (25.5).....			-
Medical care (25.6).....			-
Operation and maintenance of equipment (25.7)..	-		-
Subsistence and support of persons (25.8).....			
Subtotal Other Contractual Services.....	23,576,303	54,047,500	30,471,197
Supplies and materials (26.0).....	50,000	50,000	-
Total Non-Pay Costs.....	31,775,803	61,899,500	30,123,697
Total Salary and Expense.....	36,581,000	72,259,000	35,678,000
Direct FTE.....	75	120	45

Office of the National Coordinator for Health Information Technology

Detail of Full Time Equivalent (FTE)

	2009 Actual Civilian	2009 Actual Military	2009 Actual Total	2010 Est. Civilian	2010 Est. Military	2010 Est. Total	2011 Est. Civilian	2011 Est. Military	2011 Est. Total
Health Information Technology									
ONC FTE Total.....	30	1	31	73	2	75	118	2	120

Increase of 45 FTE in 2010 due to addition of permanent and term staff to support Recovery Act activities

Average GS Grade

FY 2006.....	12.9
FY 2007.....	12.8
FY 2008.....	13.2
FY 2009.....	13.2
FY 2010.....	13.3
FY 2011.....	13.6

Office of the National Coordinator for Health Information Technology

Detail of Positions

	2009 Actual	2010 Estimate	2011 Estimate
SES	\$1,062,318	\$1,355,571	\$1,687,757
Total – ES Salary	\$1,062,318	\$1,355,571	\$1,687,757
GS-15.....	\$1,874,414	\$3,101,794	\$4,604,163
GS-14.....	\$965,371	\$1,944,750	\$3,314,323
GS-13.....	\$284,090	\$889,960	\$1,577,418
GS-12.....	\$65,447	\$379,806	\$295,742
GS-11.....		\$124,087	\$1,222,452
GS-10.....			
GS-9.....	\$80,982	\$668,062	\$499,355
GS-8.....			
GS-7.....			
GS-6.....			
GS-5.....			
GS-4.....			
GS-3.....			
GS-2.....			
GS-1.....			
Total – GS Salary	\$3,270,304	\$7,108,459	\$11,513,453
Average ES level.....			
Average ES salary.....	\$199,328	\$169,446	\$187,529
Average GS grade.....	13.2	13.3	13.6
Average GS salary.....	\$126,307	\$94,981	\$101,860
Average CO salary.....	\$100,000	\$112,000	\$112,000

Federal Health Architecture Program

The Federal Health Architecture (FHA) is an ongoing initiative that is a partnership among all Federal entities with a health care practice. HHS is the Managing Partner, together with the Department of Defense (DoD) and the Department of Veterans Affairs (VA) serving as Lead Partners. FHA provides Federal expertise and experience as a coordinated voice, reviewing standards recommendations produced through the standards process, and then works with and across agencies toward implementation of these standards. These activities include coordination of Federal participation in health care-related standards development organization activities, communication, and collaboration on national health information technology (HIT) standards. The Federal Government also requires all Federal health care delivery systems that support direct patient care to implement recognized standards in new and upgraded health-related technology systems for exchanging information with external systems.

FHA was initiated in July 2003 and is governed by principles that focus on achieving the vision of interoperable health information in support of the agency business priorities, Federal mandates and the national HIT agenda to enable better care, increase efficiency and improve population health. FHA's priorities are driven by federal agency value propositions related to identifying needs for secure, interoperable health information exchanges, architecting solutions, planning HIT investments, developing and implementing solutions, and measuring progress. These activities support the requirements of the HITECH Act as discussed in Sec. 3011 (a) (1) to develop health information technology architecture that will support the nationwide electronic exchange and use of health information in a secure, private, and accurate manner. FHA demonstrates the value of each task or activity and ensures that every undertaking is stakeholder-driven. This ensures alignment of FHA objectives, deliverables and timeframes to agency priorities and mandates.

In FY 2009, FHA carried out the operational activities to realize its 2007 strategy and goals of five initiatives and further refined initiative goals to support federal agency priorities.

- 1) CONNECT is a software solution that organizations can use to securely link their existing HIT systems into the NHIN. More than 20 federal agencies collaborated to build CONNECT through the FHA. The CONNECT solution enables secure and interoperable electronic health information exchanges with other NHIN-participating organizations, including federal agencies, state, tribal and local-level health organizations, and healthcare participants in the private sector. CONNECT was jointly developed with the Lead Partners and used during NHIN demonstration projects in September and December, 2008 by DoD, VA, Social Security Administration (SSA), Centers for Disease Control (CDC), Indian Health Service (IHS) and the National Cancer Institute (NCI). The health information exchange solution (CONNECT) was advanced into limited production by SSA and a private sector health information exchange organization in Virginia in February, 2009, and released as publicly available, open-source software April, 2009.
- 2) Federal Adoption of Standards for Health Information Technology (FAST) evolved into the Federal Health Information Technology Standards Organization Participation (FHITSOP) to provide a working environment from where the one voice to represent the federal perspective to Standards Development Organizations (SDO) could be developed.

- 3) Federal Health Information Technology Planning and Reporting (FHIPR) created an investment guide and reporting capabilities together with support in work groups that assured successful investments and outcome measurements for participating agencies. The guide and reporting capabilities reached the goal of providing support and guidance for health information exchange-specific investments to agencies for the purposes of planning investments and reporting outcomes.
- 4) Federal Health Interoperability Sharing Environment (FHISE) is a knowledge base and tool set that provides information to help guide program managers and enterprise architects in identifying, creating, and/or implementing products that have been created and made available by others while carrying out the national HIT agenda. The knowledgebase and end user tools were released at the end of July, 2009 and updated in September, 2009. In the fall of 2009, FHIPR and FHISE work groups merged and provided guidance to OMB on the creation of harmonized segments for the health domain. Our work efforts resulted in six health segments that agencies will align with investments in the upcoming fiscal year. Additional work commenced on the creation of a citizen centric information driven framework to address federal, state, local and private business challenges.
- 5) Federal Security Strategy (FSS) has produced a document that helps federal agencies, state, local, and tribal governments as well as private entities, identify the Federal Information Security Management (FISMA) and Health Insurance Portability and Accountability Act (HIPAA) implementation considerations for nationwide health information sharing. Additional project planning is underway to support federal agencies in working together to achieve a policy that supports their security missions as they relate to health information exchanges.

These initiatives provide for information dissemination and support and guidance across federal agencies. Each of the initiatives is designed to support the President's health information technology initiative.

Schedule risk is managed throughout the entire lifecycle of each initiative for the program. FHA has a risk mitigation plan that is available upon request. In addition, FHA has developed an operational plan that outlines the following years' deliverables as well as a strategic plan for adjusting the direction of the program as a whole when needed. The identified tasks have been prioritized by the FHA Leadership Council. As part of the operational planning efforts, project charters, project plans, and project cost estimates are developed for tracking purposes. Changes in scope undergo an impact analysis including cost and appropriateness by the Leadership Council prior to moving forward.

FHA is incrementally funded, which allows for discussions to occur with existing funding partners, as well as the opportunity to seek out additional partners to secure future funding if required and approved. FHA is not building a health information exchange system but rather helping to architect solutions. The operations and maintenance costs for the program are less than might be expected for such a large undertaking and these costs will be absorbed by the participating agencies. FHA partners reevaluate the lifecycle costs yearly during strategy planning to identify the next year's work plan.

Federal Health Architecture Program Funding

Justification of Estimates for Appropriations Committees

	2009 Actual	2010 Estimate	2011 Estimate
Department of Health & Human Services.....	3.662	3.538	3.538
Department of Veterans Affairs.....	1.936	2.013	2.094
Department of Defense.....	1.936	2.013	2.094
Total.....	7.534	7.564	7.726