

**DEPARTMENT
of HEALTH
and HUMAN
SERVICES**

**Fiscal Year
2009**

Office of the National
Coordinator for Health
Information Technology

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

Introduction

The FY 2009 Congressional Justification is one of several documents that fulfill the Department of Health and Human Services' (HHS') performance planning and reporting requirements. HHS achieves full compliance with the Government Performance and Results Act of 1993 and Office of Management and Budget Circulars A-11 and A-136 through HHS agencies' FY 2009 Congressional Justifications and Online Performance Appendices, the Agency Financial Report and the HHS Performance Highlights. These documents can be found at <http://www.hhs.gov/budget/docbudget.htm> and <http://www.hhs.gov/afr/>.

The Performance Highlights briefly summarizes key past and planned performance and financial information. The Agency Financial Report provides fiscal and high-level performance results. The FY 2009 Department's Congressional Justifications fully integrate HHS' FY 2007 Annual Performance Report and FY 2009 Annual Performance Plan into its various volumes. The Congressional Justifications are supplemented by the Online Performance Appendices. Where the Justifications focus on key performance measures and summarize program results, the Appendices provide performance information that is more detailed for all HHS measures.

The Office of the National Coordinator for Health Information Technology Congressional Justification and Online Performance Appendix can be found at <http://www.hhs.gov/healthit/news/>.



I am pleased to present the Office of the National Coordinator for Health Information Technology (ONC) FY 2009 Congressional Justification. This budget request continues support for the President's and Secretary's priority initiatives and reflects the goals and objectives in the Department's FY 2007-2012 Strategic Plan. In addition, the PART process continues to be a critical tool for evaluating program effectiveness and developing budget and legislative strategies.

This justification includes the FY 2009 Annual Performance Plan and FY 2007 Annual Performance Report as required by the Government Performance and Results Act of 1993 (GPRA) along with a more direct link of the budget discussion with program performance. Performance measurement and reporting at ONC provide a set of measures and outcomes in two major areas – Standards and Architecture and Adoption – offering results-oriented information that enables ONC to demonstrate to stakeholders the Nation's progress in the access and use of electronic health information.

ONC's implementation of performance management has created a consistent framework for linking agency-wide goals with program priorities and targeting resources to make progress toward the goal that most Americans will have access to electronic health records by 2014. It has provided a shared vision of what needs to be accomplished with our partners and provides a consistent and effective way to measure our achievements and to strive for continued improvement.

Our FY 2009 budget request represents our efforts to sustain the important initiatives put forth in recent years.

Robert M. Kolodner, M.D.
National Coordinator for
Health Information Technology

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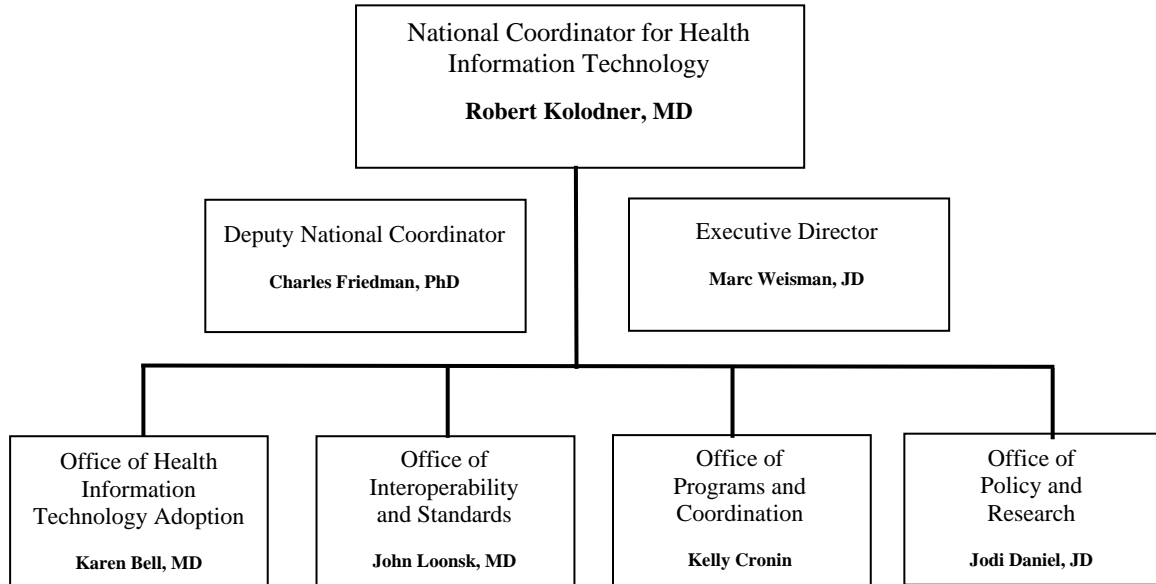
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ORGANIZATION CHART

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



EXECUTIVE SUMMARY

The Office of the National Coordinator for Health Information Technology (ONC), in the Office of the Secretary for the U.S. Department of Health and Human Services (HHS), is the principal Federal organization charged with coordination of national efforts related to the implementation and use of electronic health information exchange. Although computer technology has changed the way that Americans communicate and share information, for the most part medical data are still available to health care providers and patients only through paper and film records; millions of care providers and patients still face barriers to quality health care because of the lack of readily available health information. Coordinating the public and private-sector efforts to improve the quality of health and care through information technology is a key ONC role.

Vision

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

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.

As the coordinating office for national health information technology (health IT) activities, ONC provides leadership, program resources and services needed to guide nationwide implementation of interoperable health IT. ONC organizes its activities in four program areas:

- **Standards** – Software applications must ‘speak the same language’ to be able to work together. This involves creating, testing, and adopting interoperability standards that will allow systems across the health care market to move health information seamlessly. A technology certification process gives assurance that these accepted standards are appropriately incorporated in health IT products and systems. Multi-stakeholder collaboration that prioritizes standards development and advises the HHS Secretary on how to accelerate the development and adoption of health IT is currently accomplished through the American Health Information Community (AHIC). HHS is in the process of establishing a successor to AHIC as an independent public-private partnership organization by 2009 that will enable continuation of this highly collaborative process.
- **Privacy and Security** – Careful attention to privacy and security policies to guide evolving technology will help to build the high degree of public confidence and trust needed to achieve nationwide interoperable health IT. Ongoing work identifies disparate state policies and business practices to resolve variations that are barriers to health information exchange.
- **Architecture and Adoption** – The implementation of a Nationwide Health Information Network will provide the foundation for interoperable, secure and standards-based health information exchange. Demonstrating the value of electronic and personal health record systems and identifying enablers and barriers to their use and implementation will also advance adoption of health IT. Regularly assessing the adoption rate through surveys and studies will monitor progress toward the President’s goal that most Americans will have electronic health records by 2014.
- **Operations** – Required support for all activities and infrastructure necessary to sustain ONC including workforce, finance, administration, performance measurement, and strategic planning activities.

Overview of Budget Request

The FY 2009 President's Budget request for ONC is \$66,151,000 including \$48,000,000 in Public Health Evaluation Funds – an increase of \$5,590,000 over FY 2008. This budget supports the President's goal of most Americans having access to electronic health records by 2014, as well as the Secretary's Priorities to provide value-driven health care, information technology, and national preparedness in emergencies and disasters. If the Nation is to realize the benefits of a connected system and achieve the President's goal, the adoption of interoperable health IT systems must remain at the forefront and health IT must remain a national priority.

Program Increases:

Standards (+\$7,721,000).

This increase will maintain standards harmonization development and assurance necessary for IT systems to “speak the same language” to exchange data across different health care settings and will include specialty and special areas of health care delivery, as well as the additional review of previously established standards for any necessary updates. It will also expand the scope of technology certification processes for specialty areas (such as cardiovascular or child health) and special areas (such as emergency department or long term care) of health care. The goal of this program is to build on the successes of the current work to ensure that standards are quickly harmonized and deployed into health information technology products and mechanisms for health information exchange. This increase will provide support for a consolidated resource for Federal agencies as they transition to harmonized standards. Included is critical funding needed to support the American Health Information Community and a public-private successor in the private sector.

Architecture and Adoption (+\$6,848,000).

An increase for architecture and adoption will build on progress already achieved with the demonstrations of the trial implementations of a Nationwide Health Information Network begun in 2007, funding nine health information exchanges across the country. Additionally, these funds will support work needed to identify the best way to structure consumer-directed access to electronic medical data in a health information exchange.

Program Decreases:

Privacy and Security (-\$7,579,000).

The FY 2009 request continues to support projects to address barriers to exchanging health information electronically across states, territories and regions while maintaining and improving important privacy and security protections nationwide. Less funding is requested because during 2008, ONC plans to evaluate all ongoing work and determine which projects will be supported during FY 2009. ONC will continue to focus on these critical aspects of health information exchange.

Operations (-\$1,400,000)

Funding for Operations declines in FY 2009 as ONC anticipates economies through greater use of onboard Federal staff in lieu of contractor support.

Discretionary All-Purpose Table
Office of the National Coordinator for Health Information Technology
(Dollars in Thousands)

	FY 2007	FY 2008	FY 2009	Change from FY 2008 Enacted
	Actual	Enacted	Estimate	Enacted
Budget Authority.....	\$ 42,402	\$ 41,661	\$ 18,151	\$ (23,510)
PHS Evaluation Funds....	<u>18,900</u>	<u>18,900</u>	<u>48,000</u>	<u>29,100</u>
Total, Program Level....	\$ 61,302	\$ 60,561	\$ 66,151	\$ 5,590
FTE.....	23	28	28	-
<i>HCFAC Account</i>	<i>[\$490]</i>	<i>0</i>	<i>0</i>	<i>-</i>

Funding for the Health Care Fraud and Abuse Control (HCFAC) program is appropriated separately and is a non-add to ONC.

BUDGET EXHIBITS

Appropriation Language

For expenses necessary for the Office of the National Coordinator for Health Information Technology, including grants, contracts and cooperative agreements for the development and advancement of ~~an interoperable national~~ health information technology ~~infrastructure~~,

~~\$42,800,000~~**\$18,151,000**: *Provided*, That in addition to amounts provided herein,

~~\$18,900,000~~**\$48,000,000** shall be available from amounts available under section 241 of the Public Health Service Act ~~to carry out health information technology network development~~.

(Department of Health and Human Services Appropriations Act, 2009.)

Office of the National Coordinator for Health Information Technology
Amounts Available for Obligation

	FY 2007	FY 2008	FY 2009
<u>General Fund Discretionary Appropriation:</u>			
Annual appropriation.....	\$ 42,402,000	\$ 42,402,000	\$ 18,151,000
Rescission (PL 110-161).....		\$ (741,000)	
Subtotal, adjusted appropriation.....	\$ 42,402,000	\$ 41,661,000	\$ 18,151,000
 Total obligations.....	 \$ 42,398,000	 \$ 41,661,000	 \$ 18,151,000

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

2008

Total budget authority.....	\$ 41,661,000
(Obligations).....	\$(60,561,000)

2009

Total estimated budget authority.....	\$ 18,151,000
(Obligations).....	<u>\$(66,151,000)</u>

Net Change.....	\$(23,510,000)
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	<u>2009</u> <u>Estimate</u> <u>FTE</u>	<u>2009</u> <u>Estimate</u> <u>Program</u> <u>Level</u>	<u>Change</u> <u>from</u> <u>Base</u> <u>FTE</u>	<u>Change</u> <u>from Base</u> <u>Program</u> <u>Level</u>
Increases:				
A. Built-in:	28		0	
1. Cost of January 2009 Civilian Pay Raise of 2.9 percent.....		\$ 3,342,000		+\$ 96,000
2. Cost of January 2009 Commission..... Officer Pay Raise of 3.4 percent...		<u>\$ 112,000</u>		<u>+\$ 4,000</u>
Subtotal, Built-in Increases.....		\$ 3,454,000		+\$ 100,000
Increases:				
A. Program:				
1. Standards.....		\$21,500,000		+\$ 7,721,000
2. Architecture and Adoption.....		<u>\$26,033,000</u>		<u>+\$ 6,848,000</u>
Subtotal, Program Increases.....		\$47,533,000		+\$14,569,000
Total Increases.....		\$50,987,000		+\$14,669,000
Decreases:				
A. Program:				
1. Privacy and Security.....		\$10,568,000		\$ (7,579,000)
2. Operations.....		<u>\$ 4,596,000</u>	-	<u>\$ (1,500,000)</u>
Total, Program Decreases.....		\$15,164,000		\$ (9,079,000)
Net Change.....		\$66,151,000	0	+\$ 5,590,000

Office of the National Coordinator for Health Information Technology

Program Level by Activity

(Dollars in thousands)

	2007	2008	2009
Health Information Technology			
Standards	\$ 10,963	\$ 13,779	\$ 21,500
Privacy and Security.....	10,568	18,147	10,568
Architecture and Adoption.....	29,465	19,185	26,033
Operations.....	<u>10,306</u>	<u>9,450</u>	<u>8,050</u>
	\$ 61,302	\$ 60,561	\$ 66,151
Total, Budget Authority	\$ 42,402	\$ 41,661	\$ 18,151
Evaluation Funds	<u>\$ 18,900</u>	<u>\$ 18,900</u>	<u>\$ 48,000</u>
Total Program Level	\$ 61,302	\$ 60,561	\$ 66,151
FTE	23	28	28

Office of the National Coordinator for Health Information Technology
Authorizing Legislation

	2008 Amount Authorized	2008 Budget Estimate	2009 Amount Authorized	2009 Budget Request
Health Information Technology		\$ 41,661,000		\$ 18,151,000
PHS Evaluation Funds (non-add)		[\$18,900,000]		[\$48,000,000]

Office of the National Coordinator for Health Information Technology
Appropriations History Table

	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
<u>FY 2006</u>				
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
<u>FY 2007</u>				
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
<u>FY 2008</u>				
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
<u>FY 2009</u>				
Budget Authority.....	\$ 18,151,000			
PHS Evaluation Funds.....	\$ 48,000,000			
Total.....	\$ 66,151,000			

NARRATIVE BY ACTIVITY

STANDARDS

	2007 Actual	2008 Enacted	2009 Estimate	FY 2009 + / - FY 2008
BA	\$ 10,963,000	\$ 12,279,000	\$ 4,500,000	\$ (7,779,000)
PHS Evaluation	-	1,500,000	17,000,000	15,500,000
TOTAL Program	\$ 10,963,000	\$ 13,779,000	\$ 21,500,000	\$ 7,721,000
Authorizing Legislation:				None
Allocation Method:			Contract, Cooperative Agreement	

Program Description and Accomplishments

The Standards program gathers the priorities from all stakeholders, including the government, and incorporates them into two related activities that will enable different health information technology systems to exchange data: 1) harmonization of data and technical standards and 2) certification of systems technologies and products that have incorporated these standards. These processes are key to the advancement of interoperability among systems engaged in health information exchange and the advancement of the widespread adoption of interoperable health information technologies.

Secure and reliable exchange of electronic health data and information is a complex challenge of huge magnitude. For each piece of information that needs to be exchanged, there needs to be standards for the type of data element, the transport of that element, the technical connection between software systems, and security of that data. At times, additional standards are necessary for the units of measure for the data, for what represents a high and low normal value, and more. Given the vast amount of data involved, the first step is one of prioritization, which has been accomplished through the American Health Information Community (AHIC) processes. Since it was established in 2005, the AHIC has made priority recommendations to the HHS Secretary by annually identifying the health-related activities where standardized data is needed. These priorities have then been used by ONC in an open, iterative process to develop Use Cases, which are detailed, real-life scenarios for each of these health-related activities that can be used to identify the necessary standards needs. This function of prioritizing health-related activities and needs will be transitioned by December 2008 from the AHIC to the AHIC Successor Organization. In FY 2009, ONC will continue to develop Use Cases for the priority recommendations made to HHS by the AHIC during FY 2008.

To assess the effectiveness of this program, ONC is developing ambitious targets with which to measure progress toward the goal of developing a unified set of standards to support requirements for broad health information exchange.

Standards Harmonization

The Healthcare Information Technology Standards Panel (HITSP) was established to be a multi-stakeholder, consensus-based body designed to provide the process where representatives from

all aspects of health care select and harmonize standards to support the Use Cases. At the close of 2007, the HITSP process successfully reviewed over 950 possible standards, harmonized them into 75 interoperability standards, including over 1,100 pages of specifications on exactly how those standards need to be used. In January 2008, harmonized standards from HITSP were approved by AHIC and accepted by the HHS Secretary for the second round of AHIC priorities: Emergency Responder Electronic Health Records, Consumer Access to Clinical Information, and Quality Reporting. The harmonized standards for Medication Management will soon be advanced by HITSP for similar approval and Secretarial acceptance.

Technology Certification

Providers and consumers must be able to have confidence that the electronic health information products and systems they use are secure, can maintain data confidentiality as directed by patients and consumers, can work with other systems to share information, and can perform a set of well-defined functions. ONC established the Certification Commission for Healthcare Information Technology (CCHIT) in 2005 to accomplish these goals. The CCHIT certifies provider-based ambulatory care electronic health records (EHRs) and inpatient EHRs through a public-private process that develops specific criteria for health IT systems and then rigorously evaluates them to determine that they truly meet the criteria for:

- Functionality – ensuring that the systems can support the activities and perform the functions for which they are intended
- Security – ensuring that systems can protect and maintain the confidentiality of data entrusted to them ; and
- Interoperability – ensuring that system can exchange information with other systems.

The CCHIT is now exploring how to certify health information networks, EHRs in specialty settings, and specific components of longitudinal personal health records.

The CCHIT assures that the products and services it certifies have incorporated the tested interoperability standards. This process will allow different certified EHRs used by physicians and other health care providers to freely exchange information as directed by their patients. In 2006, the first year, the total of number of certified ambulatory medical record products was 89. By the end of CY 2007, 98 ambulatory EHR products were certified representing more than 40 percent of the estimated ambulatory EHR product vendors.

These products offer health care providers more certainty about viability and components of their health IT investments, thus advancing adoption of EHRs and moving toward interoperability. Likewise, inpatient EHR products are quickly adapting to the certification process. In November 2007, CCHIT announced 6 inpatient EHR vendors received certification representing 25 percent of the vendors in that market space. While the certifying body itself is creating a self-sustaining business model for existing certification criteria, continued ONC support will be needed to expand the certification process in other areas such as long-term care, behavioral health care and special populations.

CCHIT closely coordinates its work with HITSP and the Nationwide Health Information Network to integrate all standards and specifications necessary for secure, reliable, patient-controlled exchange of health information.

To ensure that software developers have adequate time to implement recognized standards in their software, which is a key component of the interoperability certification criteria, the HHS Secretary has established a two step process for recognition of interoperability standards. First, the Secretary publicly “accepts” standards recommended to him by the AHIC and then, one year after “acceptance,” the Secretary commits to formal “recognition” of these standards. The intervening year between “acceptance” and “recognition” of interoperability standards allows software developers time to test the standards within their systems and allows the HITSP to refine the guidance for how the standards need to be implemented based on feedback from these tests.

Forty-eight (48) interoperability standards for medical history, laboratory result reporting, and biosurveillance were publicly recognized by the Secretary in January, 2008. Four (4) additional interoperability standards are expected to be recognized in June, 2008. These standards will be included in ambulatory and inpatient EHR product certifications beginning in mid-2008. Additionally, it is anticipated that the Federal Government will require all federal health care delivery systems that support direct patient care to use these standards in their new and upgraded health-related software systems for exchanging information with external systems. Federal agency adoption plans are being developed for incorporating interoperability capabilities into their software systems using these standards.

American Health Information Community

The American Health Information Community (AHIC) is an advisory body to the HHS Secretary. This Federal Advisory Committee Act (FACA)-governed body and its workgroups have been instrumental in developing recommendations to HHS in all areas of health IT that are necessary for moving the health IT agenda forward. AHIC is made up of representatives from across the Nation and includes leaders from the federal government, employers concerned with the high cost of health care, members of the health care sector and consumer advocates. AHIC meets eight times each year. In addition, there are seven workgroups that meet monthly to engage all interested stakeholders in making recommendations to the Secretary about all aspects of the health IT agenda. These workgroups focus on population health, chronic care, consumer empowerment, and electronic health records, privacy and security, quality measurement and improvement, and personalized health care. In 2007, there were 163 volunteers that worked approximately 9,340 hours, including 54 participants from federal entities outside of ONC. This amount of effort demonstrates the program’s momentum.

HHS is in the process of transitioning the collaborative functions related to all non-policy areas of interoperability – to a successor organization (AHIC 2.0), which will be an independent, sustainable public-private partnership focused on achieving health information interoperability. The existing AHIC will continue to function until December 2008, when the transition of the collaborative functions will be complete. To ensure a smooth transition without slowing down, AHIC is continuing as a FACA body until its charter is dissolved in December 2008. The mandated activities of a FACA body require support for the remaining meetings, reports, transcriptions and other public disclosures and announcements required by this Act.

The AHIC Successor Organization

The AHIC successor organization cooperative agreement was awarded in January 2008 and, as

noted above, will be an independent, sustainable public-private partnership that brings together the best attributes of public and private entities and involves representation from all health- and health care-related sectors, including the federal government. With the specific organizational details being determined in FY 2008 by a broad spectrum of health care stakeholders, the new entity will develop a unified approach among all sectors for achieving health information interoperability nationwide to enable improved quality, safety, and efficiency of health care in the U.S. Given the competitive nature of the health care industry, widespread exchange of health care information requires a level of trust among the participants that has never been achieved previously (in addition to issues related to privacy policies and to security of the systems and networks). A governance body is needed, comprised of multiple stakeholders representing the competing interests and organized in a manner that ensures that all are represented and that equitable decisions are made that are perceived by all to be trustworthy and fair, such that no special interest or group of special interests dominates or can force its will on the other sectors. AHIC 2.0 will recruit broad-based membership from all stakeholder communities to ensure balanced representation while having stronger private-sector leadership.

Funding will ensure the new entity is given the time needed to firmly establish its organization and infrastructure, including a sustainable business plan. In addition to Federal funding for the initial start-up, the entity is expected to obtain financial contributions from the private sector to support the operations of the organization.

AHIC 2.0 is expected to become self-sustaining after FY 2009. ONC staff will continue to actively coordinate across the relevant Federal departments and agencies to ensure that the federal representatives to AHIC 2.0 are fully engaged and informed to be able to speak on behalf of the broad federal interests.

Other Federal Efforts

The Federal government is actively involved as a major stakeholder in the health care industry and there are many Federal efforts utilizing the results of ONC-sponsored work as the government moves to implementing adopted standards and certified products within federal health care systems. Executive Order 13410, issued on August 22, 2006, requires that HHS and all federal agencies ensure that internal programs and external contracts implement relevant HHS-recognized interoperability standards. This requirement applies to the implementation, acquisition and upgrade of health information technology systems consistent with the Executive Order. The Federal Health Architecture, an e-Gov initiative that involves all federal entities with a health care practice, provides federal expertise and experience as a coordinated voice, reviewing standards recommendations produced through the HITSP process and then works with and across agencies toward implementation of these standards. These activities include coordination of federal participation in health care-related Standard Development Organization activities, communication, and collaboration on National Health IT Standards.

Other Federal entities are collaborating with ONC to further the goal of incorporating standards and certified EHR systems and services. Some examples include:

- CMS: EHR Adoption Demonstration - On October 30, 2007, CMS announced a new demonstration project which will provide financial incentives for physician practices to improve the quality and efficiency of services through adoption of certified EHR systems.
- In 2005, CMS published a final rule setting three “foundation” eRx standards. These standards cover transactions between prescribers and dispensers, eligibility and benefit queries and responses, and eligibility queries between dispensers and Part D Plans. The rule became effective January 1, 2006. In 2006, CMS initiated pilot projects to test six expanded eRx standards including formulary history, medication history, fill status notification, structured and codified patient instructions, clinical drug terminology, and prior authorization messages.
- The National Library of Medicine (NLM) is leading an effort with a broad constituency of health care stakeholders to target clinical vocabularies for use in the U.S., and make them generally available at low or no cost through the NLM Unified Medical Language System Metathesaurus. NLM also coordinates feedback on how to improve standard clinical vocabularies to promote their use as a critical tool to improve health care quality, optimize public health surveillance, and facilitate clinical research. NLM coordinates their data standards activities, which are related to terminologies and vocabularies, with ONC.

Funding History

FY 2004	NA
FY 2005	NA
FY 2006	\$ 9,480,000
FY 2007	\$ 10,963,000
FY 2008	\$ 13,779,000

Budget Request

The FY 2009 Budget Request is \$21,500,000, an increase of +\$7,721,000 from FY 2008. The development and implementation of standards in health information technology is critical to enabling an interoperable, secure capability for health information exchange. This request includes:

- Funding for Standards Harmonization to continue the contracted work of the Healthcare Information Technology Standards Panel (HITSP). In FY 2009, HITSP will provide the harmonized standards to address the areas prioritized by the AHIC and recommended to the HHS Secretary in 2008. HITSP will also fill the gaps identified in prior rounds of standards harmonization and maintain and update existing standards as technology continues to evolve. Additional emphasis will be placed on solidifying the processes required to transfer the standards-setting process to the private sector.

- Continued funding for Certification to support the next phase of a technology certification contract that will (1) update the existing criteria to incorporate the standards (just accepted in January 2008) that will be recognized by the HHS Secretary in early FY 2009 and (2) build upon FY 2008 efforts and advance them in several critical areas. The increased scope for certification efforts will meet the accelerated timeline for certification of specialty area products as well as aspects of personal health records. Other areas to be advanced include: long-term care, additional specialty areas, and a variety of different network certification needs. Progress has been made in developing a self-sustaining business model for the certification of ambulatory and inpatient provider-based EHRs. It is anticipated that a similar self-sustaining business model will be developed after the certification criteria are developed for these expanded certification processes.
- Funding through a memorandum of understanding with the National Institute of Standards and Technology, to provide technical program expertise for conformance testing infrastructure as well as provide advice to the testing activities implemented by CCHIT. These activities include engaging these technologies to support the secure exchange of interoperable information among the private sector and regional, state, and Federal entities.
- A Memorandum of Understanding with the National Library of Medicine to support the increasingly important effort both to make federal standards work related to terminologies and vocabularies available across the government and to coordinate and map between and among existing standards during 2009. This initiative is critical to ensuring that federal terminologies and vocabularies work is readily available for national needs. There is a need for resources to support collaborative activities across the National Library of Medicine, the Food and Drug Administration, and the Department of Veterans Affairs in the development, testing, and dissemination of well-maintained terminologies and vocabularies and to fill similar standards gaps where there is a unique federal role. Funding is needed in support of these federal efforts to advance the implementation of the national health IT agenda, including achievement of commensurate quality and efficiency outcomes, all of which will move the federal government toward interoperability of health care information.
- Funds to continue support for the FACA requirements of the AHIC as its charter sunsets.
- This request also funds the second year of a cooperative agreement with the AHIC 2.0 successor organization – an independent, sustainable public-private partnership focused on achieving health information interoperability. Because health information technology adoption is an incredibly complex undertaking, input from both the public and private sectors must be obtained and considered. These funds will support start-up operations to transition the collaborative functions of the current AHIC interoperability initiatives – except for privacy and security policies – and to coordinate the federal government’s participation.

The FY 2009 Request for Standards will fund critical efforts building on the extensive progress already made in the areas of standards harmonization and certification of EHR products and continue to provide a critical advisory function through the public/private partnership of the AHIC and AHIC successor organization.

ONC received a PART review in 2006, and received a Results Not Demonstrated rating. This was not unexpected with the office having been established just eight months earlier in August 2005. As a result of the PART review, ONC is taking actions to continue to develop milestones and targets for the annual measures, which will produce tangible outcomes and results. ONC has initiated development of a Health IT Strategic Plan and is identifying program/office priorities to achieve over the shorter-term (two years). These priorities will have outcome-oriented results and show clear links to the program's resources and overall mission.

Outcomes Table

#	Key Outcomes	FY 2004 Actual	FY 2005 Actual	FY 2006 Target	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2009 Target	Out- Year Target
Long-Term Objective 1: Increase adoption of Electronic Health Records (EHRs)										
1.3.5	Develop a unified set of standards to support requirements for broad health information exchange	N/A	N/A	Under Development						

PRIVACY AND SECURITY

	2007 Actual	2008 Enacted	2009 Estimate	FY 2009 + / - FY 2008
BA	\$ 8,343,000	\$ 3,897,000	\$ 2,568,000	\$ (1,329,000)
PHS Evaluation	2,225,000	14,250,000	8,000,000	(6,250,000)
TOTAL Program	\$ 10,568,000	\$ 18,147,000	\$ 10,568,000	\$ (7,579,000)
Authorizing Legislation:				None
Allocation Method:				Contract

Program Description and Accomplishments

The Privacy and Security Program provides leadership to federal, state and local governments and the private sector to ensure that health information is exchanged in a manner that is appropriately confidential, private and secure. These basic assurances are important components to the success of health IT adoption. As a foundational document and a supplement to existing laws that protect health information, a Nationwide Health Information Technology Confidentiality, Privacy and Security Framework, begun in 2007, will be the result of a federal-led effort involving stakeholders community-wide and will serve to increase trust among consumers and users of electronic individual health information and to govern all efforts to advance electronic health information exchange. HHS reviewed various international, national and private-sector confidentiality, privacy and security principles that focused on individual health information in an electronic environment, although not all principles were specific to electronic health information exchange. While there was some variation, many of the same confidentiality, privacy, and security concepts appeared in most of these principles. Common themes and salient concepts were extracted and are being used as the basis for developing a nationwide health information confidentiality privacy and security framework. In 2009, the Framework will be reviewed and updated.

State and Regional Policies for Electronic Health Information Exchange

Reaching the President's goal and Secretary's priority for health IT adoption requires addressing the privacy and security concerns related to health information exchange. Under ONC leadership, significant progress has been made both through the Health Information Security and Privacy Collaboration (HISPC) and the State Alliance for e-Health (State Alliance), which provide the Federal government the ability to communicate and coordinate with multiple state governments. These collaborative initiatives address issues that have direct benefit to U.S. citizens, and cannot be resolved at the Federal level alone. It is important that HHS engage the States to recommend and develop solutions for:

- variability in state privacy and security laws, which pose challenges to the transmission of electronic health information across state borders;
- variances in state licensure laws and processes that directly impede telemedicine, which is particularly essential to providing treatment to underserved areas;

- processes for involving state Medicaid and public health programs in electronic exchange of health information that will promote more comprehensive information for public health and emergency preparedness; and consumer and provider education.

With representatives from 45 states and territories and approximately 4,000 people engaged in privacy and security discussions at the state level, the work of the HISPC brings collaborative, replicable solutions to critical issues and has expanded the base of informed stakeholders who will promote interstate interoperability for health information exchange. These efforts are expected to inform the Nationwide Health Information Network trial implementations, as well as the State Alliance work in 2009 to garner state government support. These multi-state collaboratives are currently working to:

- develop model inter-organizational agreements, such as data sharing agreements, that will facilitate electronic health information exchange (8 jurisdictions);
- identify, analyze and recommend possible solutions for variations in consent data elements required for electronic health information exchange (12 jurisdictions);
- recommend approaches for obtaining patient consent for the release of information (4 jurisdictions);
- advance recommendations for business and operational security policies and practices that can be tied to already proposed technology standards (10 jurisdictions);
- increase consumer engagement in electronic health information exchange through the development of a toolkit to educate consumers in the privacy and security of their health records (8 jurisdictions);
- develop tools and techniques to enhance provider awareness and adoption of health IT and involvement in electronic health information exchange (8 jurisdictions); and
- develop a legislative template, with a common taxonomy, which will allow states to analyze their privacy and security laws and promote consensus to advance electronic health information exchange (8 jurisdictions).

The State Alliance for e-Health is a state legislative/executive-level advisory body that is identifying and assessing consensus-based approaches to resolve state-level health IT issues that pose challenges to interoperable exchange of electronic health information. After conducting an analysis of major issues that all states should consider as they engage in electronic health information exchange activities within their states and across states, they made recommendations:

1. relative to States' recognition of certified EHRs and network components;
2. encouraging States to facilitate the alignment of interstate privacy protections;
3. regarding harmonizing licensure applications and facilitating the use of electronic licensure applications and a common credentials verification organization;
4. relative to the coordination and finance mechanisms of state government-based electronic exchange of health information implementation activities and electronic health information exchange; and
5. regarding state Medicaid agencies and health IT and health information exchange.

The State Alliance is accepting additional recommendations from its taskforces in January 2008 and will publish a report that will include its recommendations in spring 2008. It is anticipated that these recommendations will strategically influence state change-agents furthering the progress being made toward interoperable health information exchange.

By FY 2009, the State Alliance will have disseminated two reports. The first, *Report to the Nation – Critical Pathways for States*, will include recommendations regarding privacy and security of electronic health information, health care practice and integration of state programs into health information exchange. The follow-up report, the *State Leadership Guide*, will address some of the issues that are relevant and essential but for which there are no ‘best practices’ and will offer additional tools and content related to possible mechanisms states might explore.

A major goal for the State Alliance is to work toward self-sustainment. This project is critical to meeting the President’s goal of most Americans having access to EHRs by 2014 with the developed interrelationship of federal and state laws and programs.

Other Federal Efforts:

All privacy and security efforts must support the development and implementation of appropriate policies, practices, and standards for electronic health information exchange. In addition to the activities described above, ONC provides support to the Confidentiality, Privacy, and Security Workgroup of the AHIC. This workgroup makes policy recommendations to the AHIC regarding health IT and health information exchange.

In addition, since 2006, ONC has been leading the Interagency Health Information Technology Policy Council, which involves representation from across the federal government. Through this group, representatives from more than 20 Federal departments and agencies regularly interact and exchange information about Federal health IT activities and examine collaborative approaches to implementing health IT policy.

Funding History

FY 2004	NA
FY 2005	NA
FY 2006	\$ 13,921,000
FY 2007	\$ 10,568,000
FY 2008	\$ 18,147,000

Budget Request

The FY 2009 Request is \$10,568,000, a decrease of -\$7,579,000 from FY 2008. These funds are critical to continue the contracted support of the implementation of regional, State and multi-State solutions to identified barriers to exchange of electronic health information and, where appropriate, align State and health information exchange efforts with the work of the Nationwide Health Information Network. The increased effort during FY 2008 will complete some collaborative projects described above. In FY 2008, activities that, in previous years had been funded with shared resources, were fully funded by ONC. Less funding is requested in FY 2009 because during 2008, ONC plans to evaluate all continuing work and determine which projects will be supported during FY 2009. ONC will continue to focus on these critical aspects for exchange of health information.

ARCHITECTURE AND ADOPTION

	2007 Actual	2008 Enacted	2009 Estimate	FY 2009 + / - FY 2008
BA	\$ 12,790,000	\$ 16,035,000	\$ 3,033,000	\$(13,002,000)
PHS Evaluation	16,675,000	3,150,000	23,000,000	19,850,000
TOTAL Program	\$ 29,465,000	\$ 19,185,000	\$ 26,033,000	\$ 6,848,000
Authorizing Legislation:				None
Allocation Method:				Contract

Program Description and Accomplishments

Architecture and Adoption provides coordination and leadership for activities that are moving the Nation toward adoption of a nationwide solution that supports the creation, use, and exchange of reliable and secure electronic health information to better coordinate care among providers, engage individuals in their own health maintenance and management, and meet the needs of research, public health, biomedical research, quality improvement, and emergency preparedness and other related community and population health efforts. ONC is working toward the President's goal of most Americans having access to EHRs by 2014 by focusing on a number of non-technical barriers and enablers while developing and demonstrating an information technology architecture that will allow interoperable exchange of electronic health information.

Architecture

Today's health information environment is fragmented with different systems unable to communicate with each other to transmit data in a consistent, safe and secure way. Development of a technological roadmap – or architecture – that can support true interoperability across state and organizational lines is critical to achieving the goal of a safer, more effective, efficient and coordinated person-centric health care system. In addition, successful adoption of health information technologies, which can generate and use electronic health information, is inextricably linked to success in meeting this goal.

One of the goals of ONC is to interconnect health care providers so that they can better coordinate care through secure and reliable exchange of health information. Building on the work of the Standards Program, ONC is leading activities to establish a minimum set of information exchange standards that can be adopted by any entity engaged in exchanging electronic health information. This minimal set of standards and services is the architectural basis of the Nationwide Health Information Network (NHIN). Entities that use this architecture of standards and services will be able to exchange health information with other entities that also use them. In order to be able to scale beyond a small number of entities, the networking activities will need governance and oversight functions in the future. Discussion will be occurring in FY 2008 and early FY 2009, in conjunction with the establishment of AHIC 2.0, to establish these functions to be provided by AHIC 2.0 as multiple entities begin using the NHIN architecture of standards and services for daily operations.

ONC has awarded contracts over the past three years that have developed and demonstrated how existing technologies can be leveraged to allow interoperability among organizations that had previously created distinct and separate ways of exchanging data within each organization.

Nationwide Health Information Network Trial Implementations

Based on public input through a request for information published in June 2005, ONC received more than 500 comments expressing options, recommendations and issues regarding the creation and operation of a nationwide health information network. The resulting report (<http://www.hhs.gov/healthit/rfisummaryreport.pdf>) informed the basic approach to developing this capability and the subsequent request for proposals that was issued in June 2005. This evolution has progressed through the following activities:

1. Developing pilots to connect health information exchanges in different parts of the country – the Nationwide Health Information Network prototype architectures.
 - a. Four contracts were awarded in FY 2006 to develop prototype IT ‘blueprints’ or architectures with functional requirements, as well as security and business models for health information exchange.
 - b. Through three subsequent public forums, the information gained from the resulting four prototypes was shared and commented on by participants. Through these meetings: a list of functional requirements that framed the development of the NHIN was developed; the need to ensure security and protect confidentiality of data was discussed, including policy and practicality implications developed clarity on architecture approaches; demonstrations of health information exchanges were given; and experiences from state and regional health information exchanges as they implement and test them were shared. Two additional forums are planned for 2008.
2. Advancing the prototype architectures work in FY 2007, nine contracts were awarded to form the NHIN Cooperative for NHIN Trial Implementations. Subsequently, a tenth health information exchange participant group – made up of the Indian Health Service, Department of Defense and Department of Veterans Affairs – was formed to bring a Federal presence to the Cooperative.
 - a. The Cooperative involves public and private health information exchange organizations across the country that can move health-related data among entities within a state, a region or a non-geographic participant group.
 - b. The goal of the Cooperative is to demonstrate on-site, interoperable and secure health information exchange based on common specifications. There are four core services that are included: 1) delivery of data across the involved health information exchanges that include a summary patient record; 2) the ability to look up and retrieve data across the exchanges from EHRs and personal health records; 3) the ability for consumers to decide whether they want to participate in electronic exchange of their data and to whom they want to give access; and 4) supporting the delivery of data for population health uses, such as emergency response.
3. Adding specific scenarios to the existing successful demonstrations, including one coordinated with and supported by contracts issued by the Centers for Disease Control and Prevention (CDC).

- a. Sites will demonstrate information exchange in specific areas (based on the priorities recommended by the AHIC to the HHS Secretary), such as reporting laboratory test result data to the clinician who ordered the test through secure data delivery, while limiting access to only the appropriate health care provider and notifying the recipient of the information's availability.
- b. Other priority areas to demonstrate information exchange include: medication management, emergency responder EHRs, biosurveillance (with CDC funding), consumer registration and medication history, consumer access to clinical information, and quality information data exchange.

Consumer Permissions and Access to Information

One important aspect of privacy and security that needs to be addressed is identifying the best way to structure consumer permissions in health information – that is, the manner and degree to which consumers can elect to share their health information – which is one important aspect of ensuring the privacy and security of their health information. Based on recommendations from the National Committee on Vital and Health Statistics (NCVHS), this project is critical to gain consumer trust in electronic health information exchange.

This study will focus on how health information exchanges (geographical or non-jurisdictional) have implemented a health information technology that allows individual choice for participation in an exchange, as well as how much information will be accessed through the health information exchange. Once that base-line is established, the study will involve collaboration with numerous stakeholders to develop consensus on how best to obtain consumer trust while not overburdening the industry. The expected results will be published in 2009 and describe the current and upcoming landscape regarding the manner in which consumer permissions are being handled, marketed, or developed within health information exchanges and highlight best practices.

With an interoperable network, the need to limit and compartmentalize access is critical. This will ensure that the correct permissions are available to only those individuals that the patient wants to have access and then only to information related to the request. However, there could be emergency situations requiring that the context allow for other, qualified health care professionals have access to a record. ONC will propose a draft and facilitate a process to reach widespread agreement on the concept of different contexts that would protect the privacy of individuals by preventing unnecessary information from being disclosed while allowing for appropriate access in the event of an emergency. For example, it would allow for an employer to request only information that they should, by law, be able to view while the Emergency Room doctor would be able to view everything related to the current urgent care of the patient.

ONC work will examine and propose appropriate role classifications for access to EHRs and networks (e.g., who would have access to which part of a patient's health information) as well as the application of contextual access criteria to EHRs that will enable limiting disclosures beyond the health care setting to be relevant to the request.

Adoption

ONC is also focusing on the non-technical issues related to adoption of interoperable EHRs. A number of activities have been undertaken to achieve the President's goal of most Americans having access to EHRs by 2014.

1. A standardized methodology has been established for measuring the rate of EHR adoption in both the ambulatory and inpatient care settings.
2. Annual surveys to measure EHR adoption in outpatient care settings are in place. Additional survey instruments are being developed to measure the rate of adoption in inpatient or hospital settings and will be deployed in 2008.
3. The vendor community has embraced a highly visible and rigorous certification process for ambulatory and outpatient EHRs, currently overseen by the Commission for Certification of Healthcare Information Technology and described in the Standards Program narrative. The ambulatory EHR certification process, which certified its first products in 2006, now enables physician practices to invest in health IT products with confidence, knowing that they have been tested and shown to perform a core set of functions, have incorporated specific criteria for security, and are interoperable with respect to key clinical information. The first hospital – or inpatient – EHR systems were certified in 2007. The Commission is now focusing on developing certification criteria for specialty EHRs, personal health records and network systems.
4. A methodology to measure the value of specific types of health information exchange was developed.
5. A number of secure messaging pilots are being implemented, which will assess the effect of different forms of reimbursement for clinician time and expertise on patient care and outcomes.
6. A consensus process was established to develop a consistent ontology or precise utilization of words as descriptors of entities with respect to health information terminologies and contexts. Payers, legislators, vendors, policy-makers, providers all use health information terms indiscriminately, confusing the public and increasing the risk of unsuccessful investments.

ONC also engages the private sector to encourage innovative practices related to health information technology adoption. Examples include: working with malpractice insurers to offer credits toward malpractice premiums for use of certified EHRs; collaborating with local medical societies and others in their efforts to purchase and implement EHRs; engaging local commercial health insurers when developing secure messaging pilots; and working with the community of the disabled in developing a personal health record focused on the unique needs of this population.

Through three performance measures (1.3.1, 1.3.2 and 1.3.4 in the Outcomes Table), ONC monitors its progress toward the ultimate goal of most American having access to interoperable EHRs by 2014. These measures were established through the FY 2006 Program Assessment Rating Tool (PART) process with reported baselines and goals set in 2007. The key performance measure for ONC is to increase physician adoption of EHRs with a long-term goal of more than 50 percent in 2014. The most recent survey results are reporting lower adoption rates than anticipated and analyses of possible adoption barriers are currently underway.

The results of the 2007 outpatient adoption survey indicate that 14 percent of physicians have adopted minimally functional EHRs. While this is lower than the anticipated rate of 18 percent in 2007, it does represent a significant increase. The new availability of EHRs that are certified for specific functionalities and security addresses one of the key concerns that physicians have had when making their investments. The Centers for Disease Control and Prevention (CDC), is measuring the adoption rate of EHRs in physician offices and inpatient hospitals through established surveys. CDC has expanded the sample size of its National Ambulatory Medical Care Survey (NAMC) to measure the adoption rate of EHRs by physicians. CDC will increase the sampling framework to measure the adoption rate among small and rural physician practices by adding mailed survey questionnaires to an additional 10,000 physicians.

Current surveys for measuring health IT adoption in the hospital setting have published adoption rates ranging from 10 percent to 70 percent, as the result of differing definitions of "adoption" and varying survey designs. A standardized survey methodology to assess health IT adoption among hospitals has been developed and field tested in for deployment in FY 2008. Analysis and reporting of the data generated from this survey instrument, which will be the "gold standard" against which the effectiveness of programs developed to improve adoption can be evaluated, will be conducted during FY 2009. The collection of this data will enable ONC to begin reporting a national rate of hospital adoption of EHRs.

An additional measure (1.3.7 in the Outcomes Table) will provide information about the cost of adopting certified EHRs. This efficiency measure was established in FY 2008 and targets are currently being developed. This measure will indicate the per physician cost by dividing the costs of certification by the number of physicians who are adopting certified EHRs as reported through the annual adoption survey. The information could inform the adoption rate results as the cost of adoption has been identified as one of the barriers that need to be addressed.

The demonstration projects that ONC initiated during 2008 to demonstrate and measure the value of secure messaging in four geographically distributed areas will yield at least one year's worth of data resulting in methodologically sound information with respect to outcome assessment and to demonstrate value. Data generated will be analyzed with a report published in 2009. This report will inform areas in policy and aspects of the Nationwide Health Information Network that would require modification to increase the potential for physician adoption of EHRs.

Other Federal Efforts:

Other Federal entities are collaborating with ONC to further the goal of advancing and adopting interoperable EHRs and health information exchange. Some examples include:

- CDC is awarding contracts to include interoperable biosurveillance information in health information exchange.
- CDC will incorporate the standardized methodology for measuring EHRs to its annual National Center for Health Statistics' National Ambulatory Medical Care Survey questions that were collaboratively added to the FY 2008 survey.
- Leading the work of the Federal Health Architecture Program, an eGov initiative that involves representation from across the federal government of all organizations that engage in health care activities. Through this group, a collaborative Federal voice informs the development of the Nationwide Health Information Network 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.

- To further the adoption of health IT, the CMS budget includes funding for a demonstration project providing financial incentives for physician practices to adopt certified EHR systems to improve the quality and efficiency of services.
- The Internal Revenue Service, after working closely with ONC, provided guidance to non-profit hospitals and other institutions that their non-profit status would not be threatened when exercising Stark Amendment and Anti-Kickback relief.
- Coordinating closely with the 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.
- Coordinating closely with the Office of Personnel Management to implement Executive Order 13410, issued August 22, 2006, to advance quality and efficient health care in federal government. ONC worked with OPM to develop contract language for inclusion in their federal health care contracts to advance the use of the HITSP standards and to advance quality and efficiency in care.
- As a result of a recommendation made by the AHIC in 2006, ONC has been working with the Federal Communications Commission to fund a Rural Health Care Pilot Program that would expand access to health care to America's rural and underserved communities through the creation of broadband telehealth networks in 42 states and 3 U.S. territories. This will bring added value to physicians interested in adopting EHRs.

Funding History

FY 2004	NA
FY 2005	NA
FY 2006	\$ 29,500,000
FY 2007	\$ 29,465,000
FY 2008	\$ 19,185,000

Budget Request:

The FY 2009 Request for Architecture and Adoption is \$26,033,000; an increase of +\$6,848,000 over FY 2008. This request includes:

- Funding to broaden and sustain the existing capabilities of the Nationwide Health Information Network Cooperative and particularly increase capabilities across integrated delivery systems and specialty networks. Included is the continuation of core services work for nine sites funded in 2007 and 2008. Continuing the work of all nine sites is essential to assure that the standards for information exchange that are developed through these implementations meet the full and broadest set of needs and are applicable across the Nation. Because each of these sites brings a different set of challenges to testing these implementations due to the differences in regional, state or organizational business processes, this continuation work will further align the required standards that allow interoperability. This would allow other entities to access a network to exchange health data. This is critical to ensure that proven implementations will spur the private sector to increase market activity,

advancing value in others connecting to the NHIN without support, and making available certified network products, thus expanding the potential coverage of the NHIN.

- Funds to support the identification of the best way to structure consumer permissions and prevent unauthorized access to electronic health information. This includes the identification of the best way to structure consumer permissions and a study to determine the appropriate role classifications for access to electronic health data.
- Continuation of the Memorandum of Understanding with the Centers for Disease Control and Prevention (CDC), to continue measuring the adoption rate of EHRs in physician offices and inpatient hospitals through established surveys.

ONC received a PART review in 2006, and received a Results Not Demonstrated rating. This was not unexpected with the office having been established just eight months earlier in August 2005. As a result of the PART review, ONC is taking actions to continue to develop milestones and targets for the annual measures, which will produce tangible outcomes and results. ONC has initiated development of a Health IT Strategic Plan and is identifying program/office priorities to achieve over the shorter-term (two years). These priorities will have outcome-oriented results and show clear links to the program's resources and overall mission.

Outcomes Table

#	Key Outcomes	FY 2004 Actual	FY 2005 Actual	FY 2006 Target	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2009 Target	Out-Year Target
Long-Term Objective 1: Increase adoption of Electronic Health Records (EHRs)										
1.3.2	Increase physician adoption of EHRs	N/A	10%	14%	N/A*	18%	14%	24%	30%	51% (2014)
1.3.3	Increase the percentage of small practices with EHRs	N/A	N/A	Baseline	4%	5%	Feb 08	8%	11%	16% (2014)
1.3.4	Percent of physician offices adopting ambulatory EHRs in the past 12 months that meet certification criteria	N/A	N/A	N/A		Baseline	Feb 08	25%	50%	55% (2010)
1.3.6	Develop a mature Nationwide Health Information Network (NHIN) architecture that will support broad health information exchange	N/A	N/A	Under Development						
1.3.7	Cost per physician for adopting certified EHRs	N/A	N/A	Under Development						

* The initial data reported in 2006 was based on 2005 surveys; no survey was conducted in 2006

OPERATIONS

	2007 Actual	2008 Enacted	2009 Estimate	FY 2009 + / - FY 2008
BA	\$ 10,306,000	\$ 9,450,000	\$ 8,050,000	\$ (1,400,000)
PHS Evaluation	-	-	-	-
TOTAL Program	\$ 10,306,000	\$ 9,450,000	\$ 8,050,000	\$ (1,400,000)
Authorizing Legislation:				None
Allocation Method:				Contract

Program Description and Accomplishments

The amount of work generated by the AHIC, as well as the self-directed work in ONC, could not have been anticipated when the office was established in late 2005. In order to immediately react and lead national initiatives without permanent staff in place, a number of large contracts were awarded to provide needed program support to the office. Through concentrated hiring efforts since its inception, the addition of staff has allowed the office to reduce the amount of funding needed for the contracted program support. ONC anticipates increasing the staffing level from 23 FTE at the beginning of FY 2008 to a total of 28 in order to fully meet ONC's responsibilities as the nationwide health IT leader, including the new tasks associated with coordinating the federal involvement and participation in AHIC 2.0 beginning in FY 2009.

Funds in this request will support the ongoing ONC operations as a functioning office within the Office of the Secretary and allow ONC to provide continuing leadership for the development and nationwide implementation of an interoperable health IT infrastructure to improve the quality and efficiency of health care. In addition, it will provide the funding necessary to cover the costs of our facilities, including rental increases, communications, acquisition of assets, and a small number of Memoranda of Understanding, Inter-Agency Agreements and contracts supporting ONC administrative, financial, logistical and planning activities.

Funding History

FY 2004	NA
FY 2005	NA
FY 2006	\$ 8,799,000
FY 2007	\$ 10,306,000
FY 2008	\$ 9,450,000

Budget Request

The FY 2009 Budget Request is \$8,050,000, a decrease of -\$1,400,000 below FY 2008. Funding for Operations is reduced as ONC anticipates economies through greater use of onboard Federal staff in lieu of contractor support. This level of funding will allow ONC to support and manage its programs toward achievement of the President's health IT agenda and the Secretary's priority

related to advancing health IT while maintaining basic office operations, at a minimal level, and will allow ONC to prudently oversee and coordinate ongoing programs.

Public Health Service Act Evaluation Funds

ONC will use \$48,000,000 (+\$29,100,000 increase over FY 2008) of Public Health Service (PHS) Act Evaluation Funds to support the demonstration and evaluation activities described in the budget narrative discussions. These programs include Standards, Privacy and Security, and Architecture and Adoption.

SUPPLEMENTARY TABLES

**Office of the National Coordinator for Health Information Technology
Program Level by Object**

	2008 Enacted	2009 Estimate	Increase or Decrease
<u>Personnel compensation:</u>			
Full-time permanent (11.1).....	\$ 3,310,000	\$ 3,425,000	\$ 115,000
Other than full-time permanent (11.3).....	-	-	
Other personnel compensation (11.5).....	-	-	
Military personnel (11.7).....	108,000	112,000	4,000
Special personnel services payments (11.8).....			
Subtotal personnel compensation.....	3,418,000	3,537,000	119,000
Civilian benefits (12.1).....	1,029,000	1,065,000	36,000
Military benefits (12.2).....	30,000	31,000	1,000
Benefits to former personnel (13.0).....			
Total Pay Costs.....	4,477,000	4,633,000	156,000
Travel and transportation of persons (21.0).....	160,000	120,000	(40,000)
Transportation of things (22.0).....	-	-	-
Rental payments to GSA (23.1).....	1,665,000	1,765,000	100,000
Communication, utilities, and misc. charges (23.3)...			
Printing and reproduction (24.0).....	245,000	-	(245,000)
<u>Other Contractual Services:</u>			
Advisory and assistance services (25.1).....	2,000,000	1,750,000	(250,000)
Other services (25.2).....	38,848,000	49,691,000	10,843,000
Purchase of goods and services from government accounts (25.3).....	13,018,000	8,072,000	(4,946,000)
Operation and maintenance of facilities (25.4).....	50,000	50,000	-
Research and Development Contracts (25.5).....			
Medical care (25.6).....			
Operation and maintenance of equipment (25.7)...	8,000	-	(8,000)
Subsistence and support of persons (25.8).....			
Subtotal Other Contractual Services.....	53,924,000	59,563,000	5,639,000
Supplies and materials (26.0).....	50,000	50,000	-
Equipment (31.0).....	40,000	20,000	(20,000)
Total Non-Pay Costs.....	56,084,000	61,518,000	5,434,000
Total Budget Authority by Object Class.....	\$60,561,000	\$66,151,000	\$ 5,590,000

**Office of the National Coordinator for Health Information Technology
Salaries and Expenses**

	2008 Estimate	2009 Estimate	Increase or (Decrease)
<u>Personnel compensation:</u>			
Full-time permanent (11.1).....	\$ 3,310,000	\$ 3,425,000	\$ 115,000
Other than full-time permanent (11.3).....			
Other personnel compensation (11.5).....			
Military personnel (11.7).....	108,000	112,000	4,000
Special personnel services payments (11.8).....			
Subtotal personnel compensation.....	3,418,000	3,537,000	119,000
Civilian benefits (12.1).....	1,029,000	1,065,000	36,000
Military benefits (12.2).....	30,000	31,000	1,000
Benefits to former personnel (13.0).....			
Total Pay Costs.....	4,477,000	4,633,000	156,000
Travel and transportation of persons (21.0).....	160,000	120,000	(40,000)
Transportation of things (22.0).....			
Rental payments to Others GSA (23.2).....			
Communication, utilities, and misc. charges (23.3)....			
Printing and reproduction (24.0).....	245,000	0	(245,000)
<u>Other Contractual Services:</u>			
Advisory and assistance services (25.1).....	2,000,000	1,750,000	(250,000)
Other services (25.2).....	38,848,000	49,691,000	10,843,000
Purchase of goods and services from government accounts (25.3).....	13,018,000	8,072,000	(4,946,000)
Operation and maintenance of facilities (25.4).....	50,000	50,000	0
Research and Development Contracts (25.5).....			
Medical care (25.6).....			
Operation and maintenance of equipment (25.7).....	8,000		(8,000)
Subsistence and support of persons (25.8).....			
Subtotal Other Contractual Services.....	53,924,000	59,563,000	5,639,000
Supplies and materials (26.0).....	50,000	50,000	0
Total Non-Pay Costs.....	54,379,000	59,733,000	5,354,000
Total Salary and Expense.....	\$ 58,856,000	\$ 64,366,000	\$ 5,510,000
Direct FTE.....	28	28	0

**Office of the National Coordinator for Health Information
Technology
Detail of Full Time Equivalents (FTE)**

	<u>2007 Actual</u>	<u>2008 Enacted</u>	<u>2009 Estimate</u>
Health Information Technology....			
ONC FTE Total.....	23	28	28

Average GS Grade

2006.....	12.9
2007.....	12.8
2008.....	13.2
2009.....	13.4

Office of the National Coordinator for Health Information Technology

Detail of Positions

(Dollars in thousands)

	<u>2007 Actual</u>	<u>2008 Enacted</u>	<u>2009 Estimate</u>
SES.....	\$ 795,556	\$ 876,340	\$ 919,240
Total - SES Salary.....	\$ 795,556	\$ 876,340	\$ 919,240
GS-15.....	\$1,279,053	\$1,319,771	\$1,277,589
GS-14.....	704,669	420,312	644,645
GS-13.....	503,439	528,764	452,755
GS-12.....		68,315	70,542
GS-11.....	66,849		
GS-10.....			
GS-9.....	265,500	204,516	172,229
Total - GS Salary	\$2,819,510	\$2,541,678	\$2,617,760
Average SES salary.....	\$ 159,111	\$ 175,268	\$ 183,848
Average GS grade.....	13.1	13.2	13.4
Average GS salary.....	\$ 104,426	\$ 84,723	\$ 113,816
Average CO salary.....	\$ 95,888	\$ 108,132	\$ 111,268

SIGNIFICANT ITEMS IN APPROPRIATION COMMITTEE REPORTS

FY 2009 CONGRESSIONAL JUSTIFICATION CONFERENCE REPORT NO. 110-424

Item

Medical Device Information Sharing – The conference agreement includes \$66,151,000 for this activity, of which \$27,651,000 is provided in budget authority and \$38,500,000 is made available through the Public Health Service program evaluation tap. The House provided a combined total of \$61,302,000 for this activity; the Senate provided a combined total of \$71,000,000. The conferees encourage the Department to develop an interoperability standard, tool set, and validation protocol that facilitates seamless medical device information sharing and device connectivity. (p. 163)

Action taken or to be taken

ONC staff have participated in public and private-sector activities related to medical device information sharing. For example, staff presented information at a conference, *Improving Patient Safety through Medical Device Interoperability and High Confidence Software*, a Joint Workshop On High Confidence Medical Devices, Software, and Systems (HCMDSS) and Medical Device Plug-and-Play (MD PnP) Interoperability, June 25-27, 2007 in Boston, MA. <http://rtg.cis.upenn.edu/hcmdss07/index.php3>. The Federal Health Architecture Program will work with Federal partners to inform the standards process related to interoperability for medical device information sharing and device connectivity.

SPECIAL REPORTS REQUIRED BY THE APPROPRIATIONS COMMITTEE HOUSE REPORT NO. 110-231

Item

Health information technology strategic plan – The Committee has not provided the full budget request for health information technology due to concerns that this office has yet to develop a detailed and integrated implementation plan for achieving the health information technology program's strategic goals, as recommended by the General Accounting Office. The Committee requests that, no later than **March 1, 2008**, the Secretary submit a report to the House and Senate Committees on Appropriations that provides an implementation plan for health information technology (including related activities funded through the Agency for Healthcare Research and Quality and the Centers for Disease Control), which includes performance benchmarks, milestones, and timelines for achieving program objectives. This report should also identify the resource requirements for achieving specific performance benchmarks. (p. 213)

Action taken or to be taken

ONC has prepared a draft Health IT Strategic Plan and plans to release it in the second quarter of 2008.

Item

Framework for Health Information Exchange – In addition, the Committee requests that the Secretary develop and make available for public comment, not later than March 1, 2008, a privacy and security framework that will establish trust among consumers and users of electronic personal health information and will govern all efforts to advance electronic health information exchange. The framework shall address generally accepted fair information practices, including transparency; specifying the purposes of any data collection; collecting only what is necessary for that purpose; adhering to the uses agreed to by the individual; allowing individuals to know and have a say in who and how their information is used; maintaining the integrity of the data; security; audit; strong oversight; and appropriate remedies in the event of breach or misuse. The development of this framework should include participation by affected stakeholders and be conducted with adequate opportunity for public comment and review. The Committee requests that the Secretary report to the House and Senate Committees on Appropriations on the development and implementation of this framework by no later than **June 30, 2008**. This report shall describe the appropriate enforcement mechanisms to assure general conformity with the privacy and security framework, including how various enforcement tools, such as federal and state statutes, government procurement policy, third-party certification, self-attestation, business contracts, and FTC enforcement of public claims, may assist in achieving general adoption of the privacy framework. The Secretary's report should also include any appropriate recommendations for Congressional or executive action. The Committee requests that the Secretary issue, after an appropriate public comment and review period, such rules, regulations, and technical requirements as may be needed to assure implementation of the privacy and security framework, consistent with the report to Congress. The Committee further requests that the Secretary ensure that any Federally endorsed or funded standards development and harmonization or product certification products be developed consistent with all elements of the privacy and security framework. (pp. 213 – 214)

Action taken or to be taken

As a foundational document and a supplement to existing laws that protect health information, a Nationwide Health Information Technology Confidentiality, Privacy and Security Framework, begun in 2007, will be the result of a federal-led effort involving stakeholders community-wide and will serve to increase trust among consumers and users of electronic individual health information and to govern all efforts to advance electronic health information exchange. ONC is developing a draft document and will obtain input from affected stakeholders. This document will address generally accepted fair information practices, such as transparency; specifying the purposes of any data collection; collecting only what is necessary for that purpose; adhering to the uses agreed to by the individual; allowing individuals to know and have a say in who and how their information is used; maintaining the integrity of the data; security; audit; oversight; and appropriate remedies in the event of breach or misuse. Both internal departmental and external HHS and private-sector involvement in the development of the framework are seen as critical to its acceptance and adoption. It is anticipated that the document will be completed in 2008.

SPECIAL REQUIREMENTS

Unified Financial Management System Operations and Maintenance (UFMS O & M)

Unified Financial Management System Operations and Maintenance (UFMS) has now been fully deployed. The Program Support Center, through the Service and Supply Fund, manages the ongoing Operations and Maintenance activities for UFMS. The scope of Operations and Maintenance services includes post-deployment support and ongoing business and technical operations services, as well as an upgrade of Oracle software from version 11.5.9 to version 12.0. ONC will use \$41,565 for these Operations and Maintenance costs in FY 2009.

HHS Consolidated Acquisition System (HCAS)

The HHS Consolidated Acquisition System (HCAS) initiative is a Department-wide contract management system that will integrate with the Unified Financial Management System (UFMS). The applications within the HCAS are Compusearch PRISM and a portion of the Oracle Compusearch Interface (OCI). PRISM is a federal contract management system that streamlines the procurement process. PRISM automates contract writing, simplified acquisitions, electronic approvals and routing, pre-award tracking, contract monitoring, post award tracking, contract closeout and reporting. ONC will use \$2,248 to support the completion of HCAS implementation in FY 2009.

Federal Health Architecture (FHA)

The Federal Health Architecture (FHA) is a partnership among federal agencies, the Office of the National Coordinator for Health IT (ONC), and the Office of Management Budget (OMB). The Department of Health and Human Services (HHS) is the Managing Partner; together with the Department of Defense (DoD) and the Department of Veterans Affairs (VA); all Lead Partners provide program funding. In addition, approximately 20 agencies, all with health-related responsibilities, contribute time and expertise to participate in specific FHA activities. These agencies collaborate to advance health information interoperability between Federal agencies and tribal, state, and local governments and the private sector.

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 priorities, Federal mandates and the national Health IT agenda to enable better care, increase efficiency and improve population health. FHA's priorities are driven by value, where FHA will demonstrate the value of each task or activity and ensure that every undertaking is Stakeholder-driven. This ensures alignment of FHA objectives, deliverables and timeframes to agency priorities and mandates.

In FY 2007, FHA developed its strategy and goals to include development of four main initiatives:

- 1) Federal Adoption of Standards for Health IT (FAST) to provide support and guidance for implementation of Health IT Standards
- 2) Federal Health IT Planning and Reporting (FHIPR) to provide health IT specific guidance to agencies for the purposes of planning health IT investments and reporting
- 3) Federal Health Interoperability Architecture (FHIA) to provide support and guide program managers and enterprise architects in implementing products created by the national health IT agenda
- 4) Nationwide Health Information Network - Connect (NHIN-C) to enhance federal sector participation in the nationwide health information exchange initiative

The first three initiatives provide for information dissemination and guidance across federal agencies. NHIN-C will facilitate the standardization of federal nationwide health information connection solution architecture design and identified services with the help of other federal partners. Ultimately, this will enable stakeholders to connect and exchange health information between federal agencies and with private organizations. Each of the initiatives has been designed to support the President's health information technology plan.

Schedule risk will be managed throughout the entire lifecycle of the program. FHA has a risk mitigation plan that is available upon request. In addition, FHA has developed a strategic plan, which outlines the following years' deliverables as well as adjusting the direction of the program as a whole when needed. The identified tasks have been prioritized by the Leadership Council and project charters, project plans and project cost estimates are developed for tracking purposes.

Changes in scope are assessed for cost and appropriateness by the Leadership Council prior to moving forward.

The cost of establishing the FHA is based on a number of assumptions. To address this risk, the FHA program will update its cost estimates for the program incorporating the new mission/vision/goals. For the out-years through FY 2014, FHA is in the process of defining the specific workload for the program by conducting strategic planning sessions involving various federal agencies having health IT interoperability issues. Agency partners will contribute to and review FTE estimates each year. By using an iterative approach, estimates will improve over time. A dedicated project manager will closely monitor schedule and expenditures. EVM will also be used to monitor progress.

Changes to FHA activities will be prioritized and managed by the partners throughout the life cycle. FHA 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. Since FHA is not building a system but rather architecture, the operations and maintenance costs should be minimal. FHA partners reevaluate the lifecycle costs yearly during strategy planning to identify the next year's work plan.

FUNDING

FEDERAL HEALTH ARCHITECTURE PROGRAM

	Funding to Date	2008 Enacted	2009 Estimate
Health & Human Services	\$ 11,769,568	\$ 3,522,000	\$ 3,662,000
Veterans Affairs	\$ 5,164,907	\$ 1,861,000	\$ 1,936,000
Defense	<u>\$ 4,164,927</u>	<u>\$ 1,861,000</u>	<u>\$ 1,936,000</u>
Total Funding Contributed	\$ 21,099,402	\$ 7,244,000	\$ 7,534,000