

**Health Information Technology
American Recovery and Reinvestment Act (Recovery Act) Implementation Plan
Office of the National Coordinator for Health Information Technology**

A. Funding Table

	Total Appropriated <i>(Dollars in Millions)</i>
Privacy and Security*	\$ 24.285
National Institute of Standards and Technology (NIST)	20.000
Regional HIT Exchange	300.000
Unspecified	<u>1,655.715</u>
Total, Health Information Technology	\$ 2,000.000

*Note: This dollar figure, \$24,285,000, includes an estimated \$9.5 million for audits by the Office for Civil Rights and the Centers for Medicare & Medicaid Services. This estimate is subject to change. Updated Figures will be reported to Recovery.gov.

B. Objectives:

The Health Information Technology for Economic and Clinical Health (HITECH) Act provisions of the Recovery Act of 2009 create a historic opportunity to improve the health of Americans and the performance of the nation's health system through an unprecedented investment in health information technology (HIT). This initiative will be an important part of health reform as health professionals and health care institutions, both public and private, will be enabled to harness the full potential of digital technology to prevent and treat illnesses and to improve health. This is a remarkable and far-sighted commitment that the Office of the National Coordinator for Health Information Technology (ONC) is honored to lead and support.

The ONC is acutely aware that to fulfill its obligations under the Recovery Act it must act swiftly but thoughtfully. It must meet tight deadlines created by statutory requirements of the law while assuring that ONC's decisions and actions support the law's fundamental, long-term purposes: improving health and health care through the best possible applications of HIT. Meeting the long-term goals of the Recovery Act will require careful thought and planning while delivering to the American people quick action and effective investment of committed funds.

This operating plan outlines immediate actions to meet statutory requirements and to begin the huge task ahead. Over the next several weeks, ONC will hold hearings and meetings to develop and vet plans and procedures.

C - E. Activities, Characteristics and Delivery Schedules:

American patients and their caretakers will be the ultimate beneficiaries of the following activities aimed at achieving the President's health IT initiative to accelerate the adoption of health IT and utilization of electronic health records. All of the activities discussed in this section support the current two Federal Health IT Strategic Plan goals:

1. Inform Health Care Professionals: Provide critical information to health care professionals to improve the quality of care delivery, reduce errors, and decrease costs.
2. Improve Population Health: Simplify collection, aggregation, and analysis of anonymized health information for use to improve public health and safety.

- Privacy and Security Spend Plan*: Recovery Act Subtitle D - Utilizing fully competitive contract awards, HHS will implement time-sensitive, mandatory regulatory and enforcement requirements in Subtitle D, providing contract assistance to meet statutory deadlines requiring promulgation of a variety of regulations and guidance, conduct multiple studies, and submit a number of Congressional reports; enhance enforcement of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules by carrying out the extensive changes that Subtitle D makes to the existing HIPAA complaint investigation and enforcement scheme. This funding will enable the Centers for Medicare and Medicaid Services (CMS) and the Office for Civil Rights (OCR) to carry out mandated audits, make modifications in their case and document management systems, and train State Attorneys General in their new enforcement role. The Recovery Act also required that, no later than April 17, 2009, ONC was to issue guidance on technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals. This guidance was published in the Federal Register. A fully competitive contract award will be utilized to support the review and disposition of public comments. Final guidance will be published after a public comment period

Milestones:

Regulations, Guidance, Reports and Studies

DESCRIPTION	DATES(S)	PURPOSE	RESPONSIBLE AGENCY
For breach notification purposes, issue guidance specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals	April 18, 2009; annual updates	Required guidance under Section 13402	ONC in collaboration with OCR and CMS
Issue interim final regulations to implement breach notification for HIPAA covered entities and business associates	August 18, 2009	Issue regulation under Section 13402	OCR and FTC
Issue regulations to modify the HIPAA Enforcement Rule to implement revised penalty structure	February 18, 2010	Issue regulation under Section 13410	OCR in collaboration with CMS
Issue regulations to extend certain HIPAA Security Rule provisions to business associates	February 18, 2010	Issue regulation under Section 13401	CMS
Issue guidance on technical safeguards to carry out security	February 18, 2010; annual updates	Required guidance under Section 13401	CMS in collaboration with ONC
Report to Congress on breaches for which notice was provided to the Secretary	February 18, 2010 and annually thereafter	Issue report to Congress under Section 13402	OCR
Issue regulations to extend certain HIPAA Privacy Rule provisions to business associates	February 18, 2010	Issue regulation under Section 13404	OCR
Issue regulations to modify the HIPAA Privacy Rule's provisions regarding right to request restrictions, minimum necessary, access	February 18, 2010	Issue regulation under Section 13405	OCR
Issue regulations to modify the HIPAA Privacy Rule's provisions regarding marketing and fundraising	February 18, 2010	Issue regulation under Section 13406	OCR

Issue regulations to clarify that certain entities are HIPAA business associates	February 18, 2010	Issue regulation under Section 13408	OCR
Report to Congress on HIPAA Privacy and Security Compliance	February 18, 2010 and annually thereafter	Issue report to Congress under Section 13424	OCR and CMS
Study and report to Congress on privacy and security requirements for entities that are not HIPAA covered entities or business associates	February 18, 2010	Issue report to Congress under Section 13424	ONC in collaboration with OCR, CMS and FTC
Issue guidance on the HIPAA Privacy Rule's requirements for de-identification	February 18, 2010	Issue guidance as required under Section 13424	OCR in collaboration with ONC
Study the HIPAA Privacy Rule's definition of "psychotherapy notes" with regard to including certain test data and mental health evaluations	February 18, 2010	Conduct study as required under Section 13424	OCR in collaboration with SAMHSA
Issue regulations to modify the HIPAA Privacy Rule's accounting of disclosures provisions	June 18, 2010	Issue regulation under Section 13405	OCR
Issue guidance on what constitutes "minimum necessary" for purposes of the HIPAA Privacy Rule	August 18, 2010	Issue guidance as required under Section 13405	OCR
Issue regulations to modify the HIPAA Enforcement Rule to implement willful neglect provisions	August 18, 2010	Issue regulation under Section 13410	OCR in collaboration with CMS
Issue regulations to modify the HIPAA Privacy Rule to generally prohibit exchanging health information for remuneration without individual authorization	August 18, 2010	Issue regulation under Section 13405	OCR
Issue regulations to modify the HIPAA Enforcement Rule to implement provisions for sharing civil money penalties or settlements with harmed individuals	February 18, 2012	Issue regulation under Section 13410	OCR in collaboration with CMS

Enforcement

DESCRIPTION	DATES(S)	PURPOSE
OCR Case Management Upgrade – Issue Task Order	Third Quarter 2009	Upgrade Case Management System to incorporate HITECH changes.
CMS Case Management Upgrade – Issue Task Order	Third Quarter 2009	Upgrade Case Management System to incorporate HITECH changes.
Training for State Attorneys General	Third Quarter 2009	Training on Section 13410(e) of the Act.
Issue Audit Task Order – OCR	Second Quarter 2010	Compliance with Section 13411 of the Act.
Issue Audit Task Order – CMS	Second Quarter 2010	Compliance with Section 13411 of the Act.
Completion of Projects	1 October 2011	

- National Institute of Standards and Technology (NIST): Recovery Act Authorizing Language
- HHS will transfer \$20 million to NIST for continued work on advancing health care information integration through activities such as technical standards analysis and establishment of conformance testing infrastructure.

Milestones:

	<u>Start</u>	<u>End</u>
Discussions between HHS and NIST to outline work requirements	03/31/2009	05/15/2009

Draft agreement to codify outcomes, deliverables, schedule and reporting requirements	05/16/2009	06/30/2009
Fully execute agreement	07/01/2009	07/15/2009

- Standards Rulemaking: Recovery Act §3004 (B) (1) - No later than December 31, 2009, HHS shall adopt and publish an initial set of standards, implementation specifications, and certification criteria. The rulemaking for this initial set of standards, implementation specifications, and certification criteria may be issued on an interim, final basis. Fully competitive contract awards will be utilized to support the impact analysis.

Milestones:

	<u>Start</u>	<u>End</u>
Complete Draft Rule/ Regulatory Impact Analysis	05/01/2009	08/26/2009
Submit for HHS Clearance	08/26/2009	09/25/2009
Clear OMB (up to 90 day process)	09/25/2009	12/24/2009
Publish in Federal Register	12/24/2009	12/31/2009

- Update Federal Health IT Strategic Plan: Recovery Act §3001 (c) 3, (A), (B), (D) - ONC will develop a draft update, receive input from stakeholders, review the impact on other projects, adjust the operating plan as needed, and publish the strategic plan on the HHS website. Strategic planning expertise will be engaged utilizing fully competitive contract awards.

Milestones:

	<u>Start</u>	<u>End</u>
Receive input from Federal and private-sector stakeholders to inform path forward	05/18/2009	08/30/2009
Review impact on other projects	09/01/2009	09/30/2009
Adjust operating plan, as needed	10/01/2009	10/15/2009
Submit for clearance	10/15/2009	12/15/2009
Publish revised plan on HHS Website	12/15/2009	12/31/2009

- Define “Meaningful Use of an EHR”: Recovery Act §4101- The Recovery Act authorizes that incentive payments may be made to eligible professionals and hospitals that are using EHRs in a meaningful way. Specific understanding of what constitutes meaningful use will be determined through a process that will include broad stakeholder input and discussion. HHS is developing milestones for major phases of the program’s activities with planned delivery dates.
- Recovery Act Public Communications: Recovery Act §3001 (c) (3) (A) (B) (D) - ONC will establish mechanisms for communications with the public, which would include creating a website like healthreform.gov. Through a fully competitive process, ONC will award a contract(s) to provide support in determining the best methods of broad communication and establish the resulting infrastructure. HHS is developing additional milestones for major phases of the program’s activities with planned delivery dates.

Considerations to Address Moving Forward - There are a number of complex issues that must be considered to fully implement the requirements of the HITECH Act and the intent of the Recovery Act. There is foundational work required to support the large investment that will be made through the Medicare and Medicaid Incentives programs at the Centers for Medicare & Medicaid Services (CMS). With the arrival of the new National Coordinator, decisions about how to best address standards development and harmonization, the certification and testing processes, privacy and security policy development, issues around governance, workforce training, and education for health care providers and consumers will be made.

Additionally, a notification for funding availability for the regional extension center grants will be published by the end of FY 2009. Awards are anticipated to be made in early FY 2010.

F. Environmental Review Compliance:

The activities described in this Implementation Plan do not trigger the requirements of the National Environmental Policy Act (NEPA), National Historic Preservation Act (NHPA) or related statutes.

G. Measures:

ONC has performance measures in place that relate to overall Recovery Act activities. These outcome, output, and efficiency measures support the President’s health IT initiative to accelerate the adoption of health IT and utilization of electronic health records.

Through the revision of the Strategic Plan, ONC will revise existing and develop additional performance measures that will more specifically support the individual programs funded with Recovery Act dollars. These measures will be tied to the goals and objectives of the revised Federal Health IT Strategic Plan and will, on a more granular level, gauge progress toward the intended outcomes of each program. Although current measures are reported annually, Recovery Act-specific measures are under development and will be reported quarterly.

HHS is working to develop cross-cutting outcome measures for health information technology activities across the Department. Initial outcome measures will be developed by December 1, 2009. Some of these new measures will be reported quarterly to help HHS track progress toward the program’s goals and objectives.

Current performance measures include the following:

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#	Measure	FY	Target	Result
1.3.2	Increase physician adoption of EHRs (<i>Outcome</i>)	2010	TBD	Feb 2011
		2009	25%	Feb 2010
		2008	24%	21% Target improved but not met

#	Measure	FY	Target	Result
		2007	18%	14% Target improved but not met
		2006	N/A	No survey conducted
		2005	Baseline	10%
1.3.3	Increase the percentage of small practices with EHRs (<i>Outcome</i>)	2010	TBD	Feb 2011
		2009	12%	Feb 2010
		2008	8%	13% Target met
		2007	5%	9%
		2006	Baseline	4%
1.3.4	Percent of physician offices adopting ambulatory EHRs in the past 12 months that meet certification criteria (<i>Outcome</i>)	2010	TBD	Feb 2011
		2009	35%	Feb 2010
		2008	25%	No survey conducted
		2007	Baseline	27%

Office for Civil Rights Privacy Measures

#	Measure	FY	Target	Result
1.1.5	Percentage of privacy cases resolved per privacy cases received (<i>Output</i>)	2010	103%	Nov 2010
		2009	100%	Nov 2009
		2008	93%	99.7% (Target Exceeded)
		2007	88%	87.4% (Target Not Met)
		2006	81.20%	91.8% (Target Exceeded)
		2005	74.20%	79.7% (Target Exceeded)
1.1.9:	Percentage of privacy complaints that require formal investigation, resolved within 365 days (<i>Output</i>)	2010	40%	Nov 2010
		2009	45%	Nov 2009
		2008	Set Baseline	42.3% (Baseline)
1.1.10	Percentage of privacy complaints that do not require formal investigation, resolved within 180 days (<i>Output</i>)	2010	63%	Nov 2010
		2009	66%	Nov 2009
		2008	Set Baseline	67% (Baseline)

H. Monitoring/Evaluation:

All Recovery Act programs will be assessed for risk and to ensure that appropriate internal controls are in place throughout the entire funding cycle. These assessments will be done consistent with the statutory requirements of the Federal Manager's Financial Integrity Act and the Improper Payments Information Act, as well as OMB's circular A-123, "Management's Responsibility for Internal Control."

As programs are developed, ONC will also develop performance metrics and reporting requirements within the contract or grant language to ensure that adequate progress is being made toward the defined goals of the program.

Spending of Recovery Act dollars requires coordination with the Office of the Inspector General (OIG), which has been tasked with analyzing the spending plans to assess the risk potentials associated with the proposed contract and grant expenditures. The risk assessments are both internal and external. Internally, the OIG will assess and, when appropriate, test the necessary management controls that need to be in place to adequately manage the proposed contracts and grants inclusive of the program development and execution stages and the administration of the programs. Externally, the OIG will perform any audits necessary to insure that intended grant recipients are financially stable and have auditable financial systems; they will also ensure that contractors' financial systems are auditable.

I. Transparency:

ONC and other agencies administering HITECH funded activities will be open and transparent in all of its contracting and grant competitions and regulations that involve spending of Recovery Act funding, consistent with statutory and OMB guidance.

ONC and other agencies administering HITECH funded activities will work closely with Federal partners to codify agreements that will support the reporting of all Recovery Act activities in compliance with Section 2.9 of the OMB February 18, 2009 Guidance. MOU language will be developed with the relevant agency outlining the expectations for information to be gathered, frequency of reporting, ability to assure that the data are reliable, timely and complete. ONC will post this information in the required Websites beginning July 10, 2009. For projects that are directly funded by ONC, language will be incorporated into contracts and other awards specifically spelling out the requirement for reporting data, as described above.

ONC and other agencies administering HITECH funded activities will ensure that recipient reporting required by Section 1512 of the Recovery Act and OMB guidance is made available to the public on Recovery.gov by October 10, 2009. ONC and other agencies administering HITECH funded activities will inform recipients of their reporting obligation through standard terms and conditions, grant announcements, contract solicitations, and other program guidance. ONC and other agencies administering HITECH funded activities will provide technical assistance to grantees and contractors and fully utilize Project Officers to ensure compliance with reporting requirements.

J. Accountability:

To ensure that managers are held to high standards of accountability in achieving program goals under the Recovery Act, ONC and other agencies helping to administer HITECH funded activities will build on and strengthen existing processes. Senior ONC officials in the Office of the Executive Director will meet regularly with senior Department officials to ensure that projects are meeting their program goals, assessing and mitigating risks, and ensuring transparency. The personnel performance appraisal system will also incorporate Recovery Act program stewardship responsibilities for program and business function managers.

Accountability in terms of business functions will be monitored and documented through performance plans. Recovery Act awardees will be required to provide quarterly reports on progress. Following a thorough review of the progress reports, selected site visits will be taken if progress in meeting stated goals is delayed.

K. Barriers to Effective Implementation:

Staffing levels in ONC must be increased. With the current staff of 30 FTE, plans are to use all available human resources vehicles to increase the level of staffing. This will include term appointments for projects with short-term needs; details as permitted by Recovery Act legislation; a limited number of permanent positions for long-term projects; and other temporary and contractual agreements.

In order to ensure success of the HIT initiative, ONC will need to engage and ensure buy in from stakeholders in both the private and public sectors. ONC will engage stakeholders throughout the development process. ONC and other agencies helping to administer HITECH-funded activities will continue to increase communications and will develop consistent, measurable goals by which project execution will be measured, linking the planning process and the execution of the project plans in detail. Currently, there are many ways for stakeholders to get involved in ONC's deliberations, including:

- Listening to and participating during the public comment periods at the Health IT Policy Committee and the Health IT Standards Committee meetings.
- Commenting on draft program descriptions.
- Providing expert input and information to inform a report.

ONC and other agencies helping to administer HITECH funded activities will include in all funding announcements the requirement to accelerate work wherever possible. In addition, all grantees and contract awardees will be required to report quarterly to both ONC and through Recovery Act channels. ONC will also reflect the use of multi-year funding in the risk management plan and will include risk mitigation strategies. Furthermore, to ensure effective coordination of Federal health information technology activities, HHS will continue discussions with HHS partners such as OCR and CMS and others throughout the federal government such as VA, DoD, OPM, and SSA.

L. Federal Infrastructure Investments:

The activities described in this Implementation Plan are not related to building requirements or construction environmental impact issues.