



Medical Cyber Protection Security Guide

The Responsibilities of the
National Coordinator as it
relates to HIPAA and HITECH



MCP
MEDICAL CYBER PROTECTION

RESPONSIBILITIES OF THE NATIONAL COORDINATOR

The Department of Health and Human Services' (HHS) created the Office of the National Coordinator (ONC) for Health Information Technology through Executive Order 13335, Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator and established in law through the American Recovery and Reinvestment Act of 2009 (Public Law 111-5, —Recovery Act), and Health Information Technology for Economic and Clinical Health (HITECH) provisions. ONC's goal is to pursue the modernization of the American health care system through the implementation and meaningful use of health information technology.

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CHAPTER 1: PURPOSE OF THE NATIONAL COORDINATOR



1. To ensure patient's health information secured and protected.

It is a key component to building the trust required to realize the potential benefits of electronic health information exchange. If individuals and other participants in a network lack trust in electronic exchange of information due to perceived or actual risks

to individually identifiable health information or the accuracy and completeness of such information, it may affect their willingness to disclose necessary health information and could have life-threatening consequences.

2. To improve health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient centered medical care.

The healthcare industry is undertaking a structural change by aligning HIT with the delivery of care to improve quality, control costs, and enhance the efficiency of the system. The ONC is responsible for establishing the principles necessary to maintain the standards for HIT. Technology-based system has proven evidence of reducing human errors, thus reductions have been seen in non-health care models such as banking and aviation.

3. To improve the coordination of care and information among entities and authorized exchange of health care information.

The main goal is to meet patients' needs and preferences in the delivery of high-quality, high-value health care. This means that the patient's needs and preferences are known and communicated at the right time to the right people, and that this information is used to guide the delivery of safe, appropriate, and effective care.



4. To improve public health activities and facilitates the early identification and rapid response to public health threats and emergencies.

Public health surveillance is the ongoing, systematic collection, analysis, interpretation, and dissemination of data about a health-related event for use in public health action to reduce morbidity and mortality and to improve health. Surveillance serves at least eight public health functions. These include supporting case detection and public health interventions, estimating the impact of a disease or injury, portraying the natural history of a health condition, determining the distribution and spread of illness, generating hypotheses and stimulating research, evaluating prevention and control measures, and facilitating planning. Another important public health function of surveillance is outbreak detection (i.e., identifying an increase in frequency of disease above the background occurrence of the disease).

5. To promote early detection, prevention, and management of chronic diseases.

Chronic disease public health practitioners must make measurable contributions to the prevention and control of chronic disease – and by doing so, improve quality of life, increase life expectancy, improve the health of future generations, increase productivity and help control health care spending.

6. To promote a more effective marketplace and outcomes in health care services.

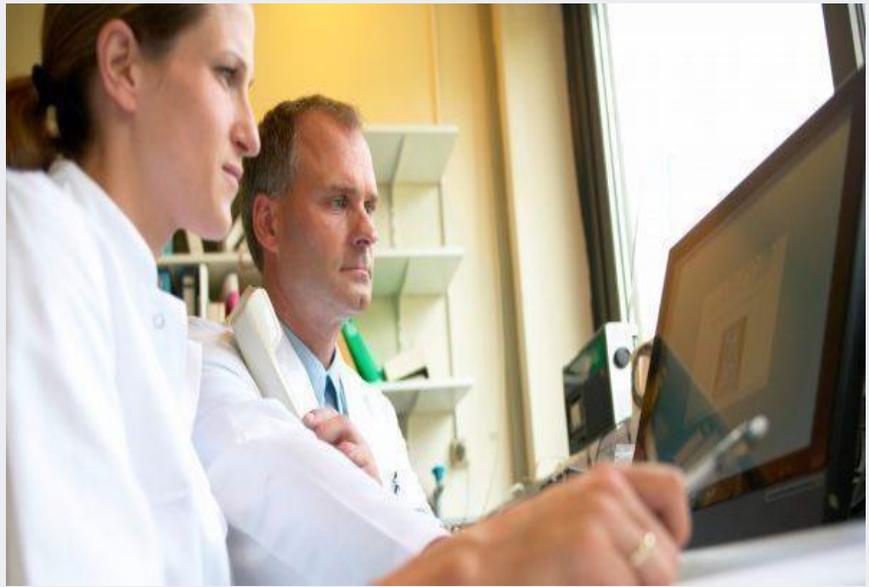
The Department continues its work to identify and promote high-value interventions yielding health care savings while building the evidence base that health care providers, insurers, consumers, states, and policymakers need to improve patient outcomes and reduce disparities in costs and quality between population groups and regions. The Affordable Care Act authorizes CMS, on behalf of HHS, to adopt and implement standards for certain transactions that achieve greater uniformity in the transmission of health information, enabling providers and payers to process financial and administrative transactions faster and at a lower cost than paper transactions.





Chapter 2: DUTIES OF THE NATIONAL COORDINATOR

1. Review and determine whether to endorse each standard, implementation specification, and certification criterion for the electronic exchange and use of health information that is recommended by the HIT Standards Committee under section 3003 for purposes of adoption under section 3004.

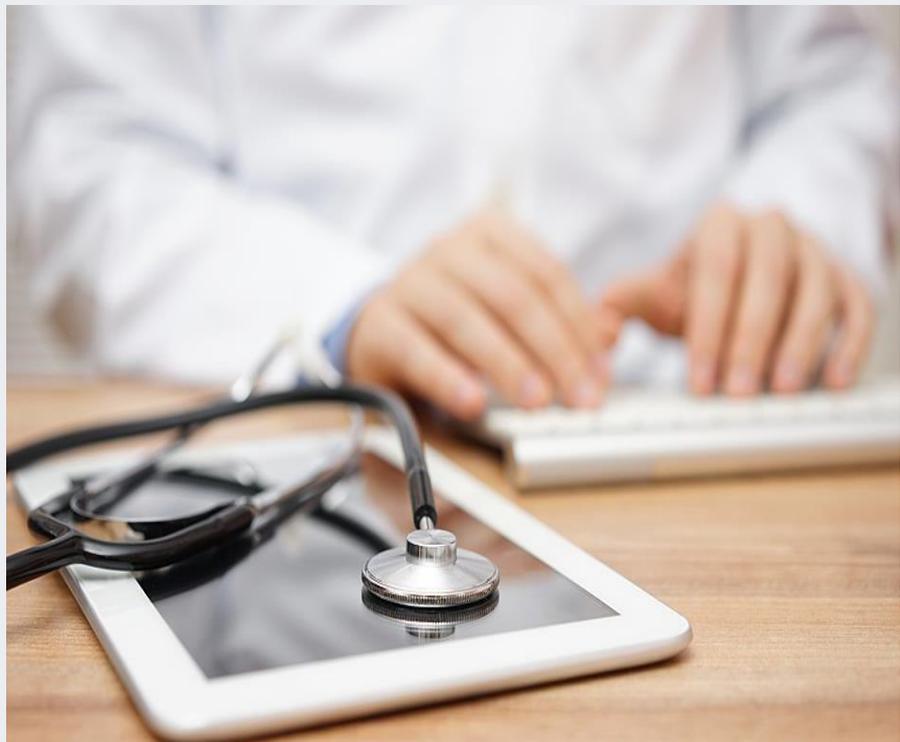


- The HIT Standards Committee issued recommendations for standards, implementation specifications, and certification criteria to the National Coordinator on September 28, 2011 and October 21, 2011.
- In fulfilling his duties under sections 3001(c)(1)(A) and (B) of the Public Health Service Act, the National Coordinator reviewed the recommendations made by the HIT Standards Committee, endorsed certain standards, implementation specifications, and certification criteria, and reported his determinations to the Secretary for consideration.
- On March 7, 2012, the Secretary published a proposed rule (77 FR 13832) with her determinations regarding the standards, implementation specifications, and certification criteria endorsed by the National Coordinator, as required by section 3004(a)(3) of the PHSA. The proposed rule solicited public comment

on the standards, implementation specifications, and certification criteria the Secretary proposed for adoption.

- This final rule addresses comments received on the proposed rule and specifies the adoption by the Secretary, under sections 3004(a)(3) and 3004(b)(3) of the PHSA, of the standards, implementation specifications, and certification criteria that will establish the technical capabilities that electronic health record (EHR) technology must include to be certified.

- EHR technology certified to these standards, implementation specifications, and certification criteria makes it possible for eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) to adopt Certified EHR Technology (CEHRT) and subsequently attempt to demonstrate its meaningful use (MU) under the Medicare and Medicaid EHR Incentive Programs (the "EHR Incentive Programs").



2. Make such determinations and report to the Secretary such determinations not later than 45 days after the date the recommendation is received by the Coordinator.

- The Health IT Standards Committee (HITSC), a committee established in accordance with the federal advisory committee act (FACA), provides recommendations on health IT standards issues to the National Coordinator for his consideration.
- A formal transmittal letter must transmit the recommendations from the HITSC to the National Coordinator.
- Once the FACA has been satisfied (i.e., a transmittal letter sent from the committee to the National Coordinator), the National Coordinator can then determine the disposition of the recommendations.

3. Review Federal health information technology investments to ensure that Federal health information technology programs are meeting the objectives of the strategic plan published.

- The federal strategy for health IT has evolved through HITECH Act of 2009, as well as long-term development and use of electronic health systems by Department of Defense and Department of Veterans Affairs, the federal government invested heavily in health IT adoption and electronic information.
- Effort primarily concentrated on EHR adoption and foundational work to expand health information exchange. This led to a clearer federal understanding of marketplace strengths and



regulations, and aims to help health IT users to advance the learning health system to achieve better health.

- As federal agencies implement the Plan's strategies and assess their effectiveness, they will strive towards flexibility. The Plan's partners will collaborate with one another, monitor market impact, and assess how their actions are working to accommodate and guide the evolution of health IT.
- This flexibility centers on a constant aim that federal actions lead towards promoting trustworthy, accessible, and readily available information and technology that helps individuals across the nation achieve their full health potential.





CHAPTER 3: ROLES OF THE NATIONAL COORDINATOR IN HIT POLICY COORDINATION

1. The National Coordinator shall coordinate health information technology policy and programs of the Department with those of other relevant executive branch agencies with a goal of avoiding duplication of efforts.

- ONC develops and coordinates federal health IT policy to achieve national health priorities set forth by the White House and Secretary of HHS, and to implement statutory requirements such as those identified in Health Information Technology for Economic and Clinical Health (HITECH) Act and the Medicare Access and CHIP Reauthorization Act (MACRA).

- ONC guides achievement of goals and objectives outlined in the Federal Health IT Strategic Plan through collaboration with federal partners and engagement of stakeholders.



- ONC monitors progress toward the goals and objectives and works to

align federal activities with national priorities, goals, and objectives.

- ONC engages a diverse group of private, non-profit, and public-sector stakeholders to identify health IT policy issues and forge consensus-based solutions.

- By investigating alternative and creative solutions, ONC designs programs to remove barriers that limit market progress in achieving interoperability that supports health care delivery reform. These solutions must keep pace with the

evolving health IT market by continuing to create new opportunities for investment and improve purchasers' confidence in their health IT choices.



2. The National Coordinator shall be helping to ensure that each agency undertakes health information technology activities primarily within the areas of its greatest expertise and technical capability and in a manner towards a coordinated national goal.

Specific activities include:

Health IT Policy: Engages stakeholders to collaboratively identify emerging issues and forge consensus-based solutions. Investigates alternative solutions in real world settings, incorporating best practices into the Meaningful Use and Certification Programs. Ensures a coordinated and consistent approach to the federal regulation and the governance of health IT.

Privacy and Security: Provides subject matter expertise and technical assistance to organizations as they navigate the legal, regulatory, and technical issues surrounding the privacy and security of health information. Through direct engagement with stakeholders and coordination of federal regulations, the Chief Privacy Officer ensures that privacy and security standards are addressed in a consistent manner that reinforces the protection of private health information.

Health IT Safety and Usability: Coordinates Departmental health IT safety activities to identify and mitigate the safety risks associated with the use of health IT. The program coordinates activities around health IT design, integrates clinical workflows, educates

and trains health IT consumers, and develops processes designed to identify and correct unsafe conditions or uses of health IT.

Clinical Quality Improvement (CQI): Ensures a comprehensive approach to integrating clinical knowledge into health IT. Provides subject matter expertise on policies, standards, and tools that give providers and consumers the information and tools needed to identify high risk conditions, assist in decision making, and measure care quality.

3. The National Coordinator shall be a leading member in the establishment and operations of the HIT Policy Committee and the HIT Standards Committee and shall serve as a liaison among those two Committees and the Federal Government.



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

- The HIT Policy Committee is charged to provide recommendations to the National Coordinator on a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the Federal Health IT Strategic Plan and that includes recommendations on the areas in which standards, implementation specifications, and certification criteria are needed.



- The HIT Standards Committee is charged to provide recommendations to the National Coordinator on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption, consistent with the implementation of the Federal Health IT Strategic Plan, and in accordance with policies developed by the Health IT Policy Committee.



Chapter 4:
ROLES OF THE
NATIONAL COORDINATOR
IN STRATEGIC PLAN

I. The National Coordinator shall update the Federal Health IT Strategic Plan to include specific objectives:

- The electronic exchange and use of health information and the enterprise integration of such information.
- The utilization of an electronic health record for each person in the United States by 2014.



- The incorporation of privacy and security protections for the electronic exchange of an individual's individually identifiable health information.
- Ensuring security methods to ensure appropriate authorization and electronic authentication of health information and specifying

technologies or methodologies for rendering health information unusable, unreadable, or indecipherable.

- Specifying a framework for coordination and flow of recommendations and policies under this subtitle among the Secretary, the National Coordinator, the HIT Policy Committee, the HIT Standards Committee, and other health information exchanges and other relevant entities.
- Methods to foster the public understanding of health information technology.



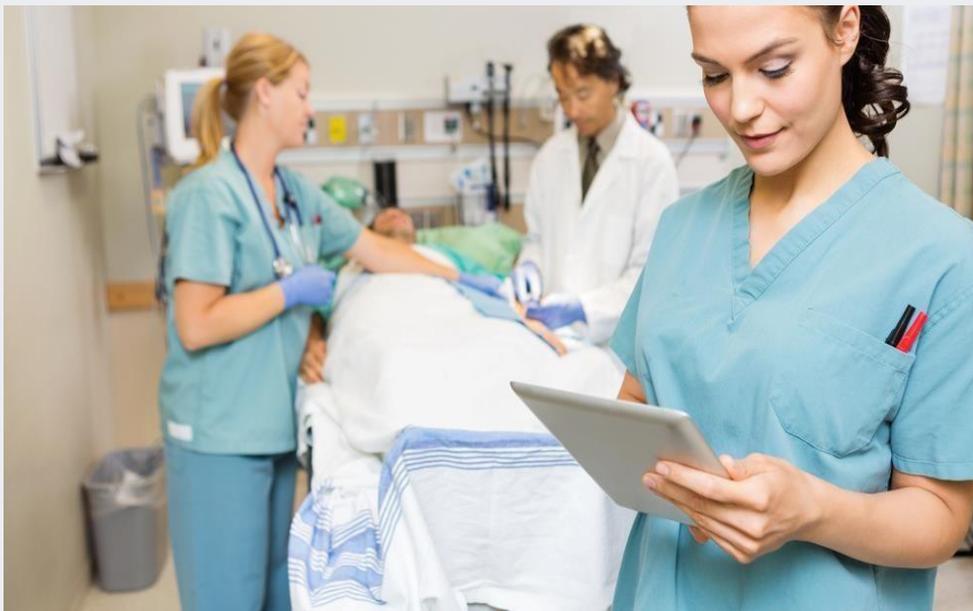
- Strategies to enhance the use of health information technology in improving the quality of health care, reducing medical errors, reducing health disparities, improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.
- Specific plans for ensuring that populations with unique needs, such as children, are appropriately addressed in the technology design, as appropriate, which may include technology that automates enrollment and retention for eligible individuals.

- II. The National Coordinator shall be updated strategic plan through collaboration of public and private entities.

- III. The National Coordinator shall be updated the strategic plan include measurable outcome goals.

- IV. The National Coordinator shall republish the strategic plan, including all updates.

- V. The National Coordinator shall maintain and frequently update an Internet website to ensure transparency in promotion of a nationwide health information technology infrastructure.



- VI. The National Coordinator shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle.



Chapter 5: Roles of National Coordinator in Certification and Publications

1. The National Coordinator shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report on any additional funding or authority the Coordinator or the HIT Policy Committee or HIT Standards Committee requires to evaluate and develop standards, implementation specifications, and certification criteria, or to achieve full participation of stakeholders in the adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information not later than 12 months after the date of the enactment of this title.



2. The National Coordinator shall prepare a report that identifies lessons learned from major public and private health care systems in their implementation of health information technology, including information on whether the technologies and practices developed by such systems may be applicable to and usable in whole or in part by other health care providers.

3. The National Coordinator shall assess and publish the impact of health information technology in communities with health disparities and in areas with a high proportion of individuals who are uninsured, under insured, and medically underserved individuals (including urban and rural areas) and identify practices to increase the adoption of such

technology by health care providers in such communities, and the use of health information technology to reduce and better manage chronic diseases.

4.The National Coordinator shall evaluate and publish evidence on the benefits and costs of the electronic use and exchange of health information and assess to whom these benefits and costs accrue.

5.The National Coordinator shall estimate and publish resources required annually to reach the goal of utilization of an electronic health record for each person in the United States by 2014, including:

- the required level of Federal funding;
- expectations for regional, State, and private investment;
- the expected contributions by volunteers to activities for the utilization of such records;
- the resources needed to establish a health information technology workforce sufficient to support this effort.

6.The National Coordinator may provide financial assistance to consumer advocacy groups and not-for-profit entities that work in the public interest for purposes of defraying the cost to such groups and entities to participate under, whether in whole or in part, the National Technology Transfer Act of 1995 (15 U.S.C. 272 note).

7.The National Coordinator shall establish a governance mechanism for the nationwide health information network.





Chapter 6:
Office of the National
Coordinator:
Detail of Federal Employees and
Chief Privacy Officer

I. Detail of Federal Employees

Upon the request of the National Coordinator, the head of any Federal agency is authorized to detail, with or without reimbursement from the Office, any of the personnel of such agency to the Office to assist it in carrying out its duties under this section.



Any detail of personnel under paragraph:

- shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee;
- shall be in addition to any other staff of the Department employed by the National Coordinator.

Notwithstanding any other provision of law, the Office may accept detailed personnel from other Federal agencies without regard to whether the agency described under paragraph (1) is reimbursed.



II. CHIEF PRIVACY OFFICER

The Secretary shall appoint a Chief Privacy Officer of the Office of the National Coordinator, whose duty it shall be to advise the National Coordinator on privacy, security, and data stewardship of electronic health information and to coordinate with other Federal agencies with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information not later than 12 months after the date of the enactment of this title.

