**Testimony Before the**
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**Committee on Science and Technology**
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# Standards for Health IT:

# Meaningful Use and Beyond

***Statement of***


## David Blumenthal, M.D., M.P.P.

***National Coordinator,***
***Office of the National Coordinator for Health IT***
***U.S. Department of Health and Human Services***


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Chairman Wu, Ranking Member Smith, distinguished Subcommittee members, thank you for the opportunity to submit testimony on behalf of the Department of Health and Human Services (HHS) on our progress and priorities related to interoperability and the security of electronic health records and health information technology (HIT) systems since the passage of the Health Information Technology for Economic and Clinical Health Act (HITECH Act).

The HITECH Act represents an historic and unparalleled investment in HIT, lays the groundwork necessary to pursue the President's goals related to improved health care quality and efficiency, and will help transform the way health care is both practiced and delivered. The provisions of the HITECH Act are best understood not as investments in technology *per se*, but as efforts to improve the health of Americans and the performance of their health care system.

Interoperability and privacy and security are themes that are present throughout the HITECH Act. Consequently, many of our policy and programmatic efforts also focus on those themes. We have made remarkable progress in the relatively short time since the HITECH Act's passage. Our recent accomplishments include: the establishment of two new federal advisory committees, the HIT Policy Committee and HIT Standards Committee; the completion of the three rulemakings necessary to establish meaningful use Stage 1 for the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs; strengthened coordination throughout the Executive Branch on HIT; and the responsible obligation of nearly all of the $2 billion we were authorized under the American Recovery and Reinvestment Act of 2009 through the creation of several programs that will have a lasting impact on the HIT landscape. As we take stock of our successes and complete the challenges in front of us, we recognize that much work still remains in order to reach our goals for the future.

The first half of my testimony focuses on the progress that the Office of the National Coordinator for Health Information Technology (ONC) has made thus far related to interoperability and privacy and security, generally, while the second half discusses the work we are currently pursuing with respect to standards in order to support the latter stages of meaningful use.

## Building on HITECH

### *The HIT Policy and Standards Committees*

Established by the HITECH Act, the HIT Policy and HIT Standards Committees both contribute a great deal to our activities and regularly issue recommendations on how to best fulfill our responsibilities and implement the ambitious agenda set forth by the HITECH Act. Both Committees include a diverse membership, with representatives of various perspectives from both the public and private sectors. The HIT Standards Committee, for example, combines standards experts from the private sector with Federal government leaders from OSTP, NIST, DoD, VA, and CMS.[1]

As we continue to implement the HITECH Act, we are acutely aware that it is paramount to implement appropriate policies to keep electronic health information private and secure. Privacy and security form the bedrock necessary to build trust. Patients and providers must feel confident in the processes, policies, and standards in place related to HIT and the electronic exchange of health information. Thus, to ensure that we have timely privacy and security recommendations related to the HITECH programs for which we are responsible, the HIT Policy Committee formed an interdisciplinary "Privacy and Security Tiger Team" of experts comprised

[1] OSTP: Office of Science and Technology Policy; NIST: National Institute of Standards and Technology; DoD: Department of Defense; VA: Department of Veterans Affairs; CMS: Centers for Medicare & Medicaid Services

of members from both the HIT Policy and Standards Committees. Members from the National Committee on Vital and Health Statistics (NCVHS) also serve on the Tiger Team to ensure the efforts of these committees are coordinated.

Building on the work of the Tiger Team, the HIT Policy Committee has, in accordance with its mandate in the HITECH Act, recently submitted recommendations regarding data segmentation technologies to ONC, as well as recommendations on obtaining patient consent in various contexts. In upcoming months, the Tiger Team in coordination with the HIT Policy Committee will continue to prioritize and address additional privacy and security issues including: the privacy and security requirements for participants in health information exchange activities who are not subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules; credentialing assurance levels; individual access; transparency; security safeguards; and de-identified data.

Like its sister committee, the HIT Standards Committee plays a critical role in guiding ONC. In August 2009, and again in March 2010, it issued recommendations to ONC on the standards and implementation specifications that should be considered to support meaningful use Stage 1. It has also formed workgroups which focus on clinical operations, clinical quality, and implementation. Most recently, the HIT Standards Committee established a vocabulary task force under the clinical operations workgroup to address vocabulary subsets and value sets as facilitators and enablers of meaningful use. In April, 2010, the HIT Standards Committee made recommendations to ONC based on the work of the clinical operations workgroup and taskforce. These recommendations broadly addressed several areas related to the identification,

development, review, testing, and maintenance of vocabularies, value sets, and code sets, as well as the establishment of an authoritative vocabulary infrastructure.

Finally, in response to their charge under Section 1561 of the Patient Protection and Affordable Care Act, the HIT Policy and Standards Committees recently made recommendations to ONC for the Secretary's consideration regarding interoperable and secure standards and protocols that facilitate enrollment of individuals in Federal and State health and human services programs. On September 17, the Secretary adopted this first set of recommendations and they were published on ONC's website.[2]

*Meaningful Use Stage 1*

This past July marked the completion of the three interdependent rulemakings that were necessary to implement "Meaningful Use Stage 1," the first stage of the Medicare and Medicaid EHR Incentive Programs. The first rulemaking establishes the requirements that eligible health care providers[3] will need to satisfy in order to qualify for incentive payments. The second specifies the technical capabilities and standards that certified EHR technology will need to include to support these health care providers. And the third creates the processes for EHR technology to be tested and certified, thus providing confidence and assurance to eligible health care providers that the certified EHR technology they adopt will perform as expected. These rules, cumulatively, reflect over 2,000 public comments from stakeholders across the health care system, and illuminate the initial pathway to achieving an integrated and electronically connected health care system.

[2] http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3161
[3] "Eligible health care providers" is used to mean: "eligible professionals, eligible hospitals, and critical access hospitals"

In developing the policies for meaningful use Stage 1, the ONC and CMS worked collaboratively to strike a balance that reflected both the urgency of adopting EHR technology to improve our health care system and the challenges that adoption will pose to health care providers. Our approach attempts to move the health system upward toward improved quality and effectiveness in health care, but at a speed that reflects both the capacities of providers who face a multitude of real-world challenges and the maturity of the technology itself.

In order to ensure that eligible health care providers can obtain EHR technology capable of assisting their achievement of meaningful use Stage 1, the Secretary adopted an initial set of standards, implementation specifications, and certification criteria for EHR technology (the Initial Set). Much like meaningful use Stage 1, the Initial Set creates a foundation from which we expect to continue to build in order to enhance the interoperability and security of EHR technology. The Initial Set specifies several interoperability and security capabilities that certified EHR technology must include in order to support meaningful use Stage 1. With respect to interoperability, it specifies that certified EHR technology must be capable of submitting information to public health agencies in standard formats, that specific standards must be used for electronic prescribing, and it specifies certain standards (content exchange and vocabulary) that must be used when patient summary records are exchanged and when patients are provided electronic copies of their health information. With respect to privacy and security, the Initial Set requires that certified EHR technology must be capable of automatically logging-off a user, access control, authentication, generating audit logs, checking the integrity of information that is electronically exchanged, and encrypting health information (according to standards specified by NIST) .

To ensure proper incorporation and use of the adopted standards and implementation specifications EHR technology must be tested and certified according to the certification criteria adopted by the Secretary. In that regard, we issued, at the end of June, a final rule establishing the temporary certification program for health information technology that outlines how organizations can become ONC-Authorized Testing and Certification Bodies (ONC-ATCBs). Once authorized by the National Coordinator, the ONC-ATCBs will test and certify that EHR technology is compliant with the standards, implementation specifications, and certification criteria adopted by the Secretary. To date, three organizations have now been granted ONC-ATCB status by the National Coordinator. We are also working on a final rule for a permanent certification program that we expect to publish later this year and that will be fully operational in early 2012. We expect that this program will be more rigorous than the temporary certification program and will achieve greater incorporation of international standards and best practices through requirements such as accreditation and surveillance. In developing our proposals for both the temporary and permanent certification programs and, in accordance with the HITECH Act, we consulted extensively with our colleagues from NIST. During this time, we established an even closer working relationship with the experts at NIST and we anticipate continuing to work with them, as the certification programs mature. NIST has been an invaluable partner in all our efforts to implement the HITECH Act.

*Strengthened Coordination*

On a number of fronts, we have actively sought to strengthen coordination within the Executive branch on complementary activities where the use of adopted standards and implementation specifications may be appropriate. In this regard, the Federal HIT Task Force

was created to facilitate implementation of the President's HIT agenda through better coordination among Federal agencies. As noted, under the aegis of this HIT Task Force, we are working with the President's Cybersecurity Coordinator, Mr. Howard Schmidt, to take full advantage of security lessons learned from other Federal programs. We are also supporting our colleagues at the Department of Defense and the Department of Veterans Affairs on their implementation of the Virtual Lifetime Electronic Record (VLER) project, and continuing our work with the Federal Health Architecture (FHA).

Additionally, ONC has maintained a close working relationship with HHS' Office for Civil Rights (OCR) and consulted with OCR as it developed the proposed modifications to the HIPAA Privacy, Security, and Enforcement Rules required by the HITECH Act to strengthen the privacy and security protections for health information and to improve the workability and effectiveness of the HIPAA Rules. The proposed regulatory provisions would, among other things, expand individuals' rights to access their information and restrict certain disclosures of protected health information to health plans; extend the applicability of certain Privacy and Security Rules' requirements to the business associates of covered entities; establish new limitations on the use and disclosure of protected health information for marketing and fundraising purposes; and prohibit the sale of protected health information without patient authorization. This proposed rulemaking will strengthen the privacy and security of health information, and is an integral piece of the Administration's efforts to broaden the use of HIT in health care today.

*HITECH Programs*

Through implementing the new authorities provided by the HITECH Act, we have committed to fostering the support, collaboration, and ongoing learning that will mark our progress toward electronically connected, information-driven medical care. Several new programs will contribute to this progress, including:

- *The State Health Information Exchange Cooperative Agreement Program* – A grant program to support States or State Designated Entities in rapidly building capacity for exchanging health information across the health care system both within and across states.
- *The Beacon Community Program* – A grant program for communities to build and strengthen their HIT infrastructure and exchange capabilities. These communities will demonstrate the vision of a future where hospitals, clinicians, and patients are meaningful users of health IT, and together the community achieves measurable improvements in health care quality, safety, efficiency, and population health.
- *The Health IT Workforce Program* – A multi-pronged approach designed to support the education of HIT professionals, including new and expanded training programs, curriculum development, and competency testing.
- *The Strategic Health IT Advanced Research Projects (SHARP) Program* – A grant program to fund research focused on achieving breakthrough advances to address well-documented problems that have impeded adoption: 1) Security of Health Information Technology; 2) Patient-Centered Cognitive Support; 3) Healthcare Application and Network Platform Architectures; and, 4) Secondary Use of EHR Data.

- *The Health Information Technology Extension Program* – A grant program to establish Health Information Technology Regional Extension Centers to offer technical assistance, guidance, and information on best practices to support and accelerate health care providers' efforts to become meaningful users of EHRs.

## Supporting Standards Needs beyond Meaningful Use Stage 1

We anticipate that future stages of meaningful use will build on the foundation we have now established and will require progressively more rigorous electronic health information exchange requirements. In order to develop those requirements, we have again asked the HIT Policy Committee to make recommendations on what meaningful use Stages 2 and 3 should encompass. The HIT Policy Committee and its Meaningful Use workgroup have received testimony and held numerous hearings on topics such as care coordination, patient/family engagement, and eliminating disparities in health care. This fall the Meaningful Use workgroup will be holding additional public meetings, and will be closely monitoring implementation of meaningful use Stage 1 to inform its recommendations to the HIT Policy Committee. As before, and in response to the meaningful use policy priorities identified by the HIT Policy Committee, we anticipate that the HIT Standards Committee will also begin to focus on the standards, implementation specifications, and certification criteria that will be necessary for future stages of meaningful use. We also expect the HIT Standards Committee to issue recommendations that focus on strengthening the security capabilities of EHR technology and on standards for electronic health information exchange in support of meaningful use.

In order to support future stages of meaningful use as well as our other initiatives, we determined that a comprehensive standards and interoperability framework was needed, and we are currently in the process of establishing that framework. The "Standards and Interoperability

Framework" is intended to help us coordinate our standards development efforts, and to facilitate the development, adoption, and use of high-quality standards and implementation specifications. We believe by using the Standards and Interoperability Framework, we can develop and maintain a well organized set of standards that can be reused across different use cases, and allow for greater coordination among public and industry stakeholders.

Interoperability will be critical to our success in Stages 2 and 3 of meaningful use. In the Initial Set, we adopted several standards for the electronic exchange of health information, but we recognize that greater specificity is necessary to reach our goals. In that respect we will be working on adopting additional implementation specifications; achieving agreement on vocabularies and code sets for particular exchange purposes; and comprehensive privacy and security capabilities for EHR technology.

## Conclusion

The HITECH Act provides for an unprecedented amount of funding to improve the quality and efficiency of health care through HIT, and its historic investment will undoubtedly help transition our current antiquated, paper-dominated health care system into a high-performing 21st century health care system. With a nationwide infrastructure of HIT in place, that provides the capability of secure interoperable health information exchange through consensus built standards, patients, providers, and the public will experience the true value added for improving health care delivery. It is my privilege to testify before you today and I look forward to answering any questions you might have.