

**Testimony before the Subcommittee on Technology and Innovation
Committee on Science and Technology**



U.S. House of Representatives

**Standards for Health IT: Meaningful Use
and Beyond**

Statement of

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Chairman Quayle, Ranking Member Edwards, and distinguished Subcommittee members, thank you for the opportunity to appear today on behalf of the Department of Health and Human Services (HHS). My name is Dr. Farzad Mostashari and I am the National Coordinator for Health Information Technology.

As you may know, President George W. Bush created the position of National Health Information Technology Coordinator as part of HHS by Executive Order in 2004. In 2009, President Obama demonstrated his Administration's commitment to health information technology (health IT) by signing the Health Information Technology for Economic and Clinical Health Act (HITECH) as part of the American Recovery and Reinvestment Act of 2009 (ARRA). HITECH established the Office of the National Coordinator for Health Information Technology (ONC) by statute and provided the resources and infrastructure needed to stimulate the rapid, nationwide adoption and use of health IT, especially EHRs.

I am delighted to be here today to tell you about the remarkable progress we have made with our stakeholders in the relatively short time since HITECH's passage. Through incentives and other approaches supported by HITECH, including a network of Regional Extension Centers (RECs) providing technical assistance to providers and hospitals transitioning away from paper-based record keeping, support for health IT, and programs designed to rapidly train a health IT workforce, we have seen clear evidence that the health care community is embracing health IT to improve care. From 2008 to 2011 the adoption of any EHRs among office-based physicians rose from 38 percent to 57 percent. In addition, there have been substantial increases in adoption of EHRs with meaningful functionalities. Between 2008 and 2011, the percentage of office-based physicians with systems that meet the criteria for a basic EHR

doubled from 17 percent to 34 percent¹, and hospital adoption leaped almost threefold from 13 percent to 35 percent.²

The Medicare and Medicaid EHR Incentive Programs administered by the Centers for Medicare & Medicaid Services (CMS), as well as the hands-on technical assistance provided by RECs across the country, have been critical in facilitating this type of unprecedented progress. Under HITECH, eligible professionals and hospitals can qualify for incentive payments when they adopt and meaningfully use certified EHR technology. As of September 2012, more than 300,000, more than half of the nation's eligible professionals, as well as over 75 percent of eligible hospitals have registered to participate in the Medicare or Medicaid Incentive Programs. Since the program began in January 2011 more than 150,000 eligible professionals and 3,000 hospitals have received an incentive payment, exceeding an FY 2012 target of paying 140,000 providers. A network of local RECs in every state and territory lend a helping hand to our nation's primary care providers in achieving meaningful use of health IT. As of August 2012, the RECs have assisted over 135,000 primary care providers – including 2,553 in Arizona and 1,902 in Maryland – and have already helped over 90,000 of them with successfully adopting an EHR and working toward meaningful use of the EHR. More than forty percent of all primary care providers in the U.S. are working with RECs, over half of all primary care providers in rural areas, and over 75 percent of all Federally qualified health centers. Recognizing the need to strike a balance between the urgency of modernizing our health care system and the pace of change that can be absorbed by providers and IT vendors, CMS and ONC have already developed two stages of Medicare and Medicaid EHR Incentive Programs. Each stage is designed to add increased

¹ National Ambulatory Medical Care Survey (NAMCS) Electronic Health Record Supplement mail surveys, 2008-2011.

² ONC/AHA, AHA Annual Survey Information Technology Supplement, 2011.

functionality and advanced concepts improve patient care, enhance care coordination and population health management, and increase patient and family engagement. Published on July 28, 2010, the final rules for Stage 1 focus on functionalities that support the electronic capture of data and allow patients to receive electronic copies of their own health information. The final rules for Stage 2 were published on September 4, 2012 and they represent an important next step in helping doctors and hospitals use and exchange electronic health information. The Stage 2 rules focus on increasing standards-based health information exchange between providers and with patients, and we anticipate that the Stage 3 rules will continue to advance health IT capabilities by focusing on advanced clinical decision support, improving outcomes, population health management, and patient engagement tools.

As requested by the Subcommittee, my testimony today will address the lessons learned from implementation of Stage 1 meaningful use requirements and how those lessons were applied to the development of the Stage 2 meaningful use requirements. I will also discuss how ONC engages other Federal agencies and stakeholders including the National Institute of Standards and Technology (NIST).

Federal Advisory Committees: The HIT Policy and Standards Committees

Recognizing that health IT is a complex and quickly changing field, HITECH established two Federal advisory committees under the Federal Advisory Committee Act (FACA) to advise the National Coordinator. The Health IT Policy Committee was created to make recommendations on a policy framework to support the development and adoption of a nationwide health information infrastructure. The Health IT Standards Committee is responsible for making recommendations on standards, implementation specifications, and certification criteria for the use and exchange of health information.

Both the Health IT Policy and Health IT Standards Committees (the Committees) 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. The Committees include a diverse membership, with representatives of various perspectives from both the public and private sectors. The Health IT Standards Committee, for example, combines standards experts from the private sector with Federal government leaders from the Office of Science and Technology Policy (OSTP), Department of Defense (DoD), Department of Veterans Affairs (VA), CMS, and NIST.

Working with Private Stakeholders

Both the Health IT Standards Committee and Health IT Policy Committee include experts from the private sector to help guide ONC and CMS in developing the rules for meaningful use and the certification of EHR technology. In large part, HITECH specified the different stakeholder perspectives that must be represented on the Committees. HITECH explicitly charged the Comptroller General of the United States with the responsibility of appointing 13 members representing various stakeholder groups to the Health IT Policy Committee. Additional diversity is provided by the members appointed by the Secretary of Health and Human Services, the Majority and Minority leaders of the Senate, and the Speaker and Minority leader of the House of Representatives. HITECH further specified that the Health IT Standards Committee include providers, ancillary healthcare workers, consumers, purchasers, health plans, technology vendors, researchers, relevant Federal agencies, and individuals with technical expertise on health care quality, privacy and security, and health information exchange.

To further enrich the advice they provide, each Committee maintains several workgroups that incorporate the perspectives of additional stakeholders from government and the private sector. Since their creation, the members of the Committees and their many working groups have

demonstrated incredible dedication and provided many thousands of hours of their time, meeting an average of once every other day for the past three years. Not only do we make each committee's meetings publicly available through live webcasts, but we also make available all of the workgroup meetings as well. I honestly believe that the Health IT Policy Committee and Health IT Standards Committee are two of the hardest working and most effective Federal advisory committees across the Federal government.

Working with Other Federal Stakeholders

Health care organizations regularly exchange health information with Federal agencies such as CMS, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the VA, DoD, the Centers for Disease Control and Prevention (CDC), and the Social Security Administration (SSA). The process for sharing information has historically been paper-intensive, and even as things move online, the data submission requirements differ among agencies and can result in a burden for health care organizations.

ONC is actively working with the Federal agencies that have a health mission through the Federal Health Architecture (FHA), an e-gov initiative managed by ONC. The FHA promotes Federal agency participation in multiple ONC activities to stimulate the effective development of national health IT standards, and as importantly, in promoting nationwide rollout of the standards. This collaboration has the potential to help States and private sector health care organizations ensure interoperability with Federal systems.

Reciprocally, health IT interoperability has the potential to make things much easier for Federal agencies. By creating standards-based methods for the electronic submission, receipt and processing of health IT, Federal agencies can improve the quality of the data they receive while

also reducing the number of expensive, one-off solutions for addressing the varied needs of the stakeholders they serve.

Partnership with NIST

HITECH's passage has strengthened the collaborative partnership between ONC and NIST. We have engaged NIST to be part of our initiatives and recognize our NIST colleagues as key resources and contributors to our success. In 2009 and 2010, NIST provided standards and conformity assessment technical expertise as ONC established the regulatory framework for EHR certification, a HITECH requirement designed to ensure the availability of EHR products that enable health care providers to meet meaningful use criteria. NIST continues to play a key role in supporting the design, implementation and maturation of the ONC HIT Certification Program, including the accreditation of testing laboratories, and the test procedures and testing tools/infrastructure used by them. We have also worked closely with NIST on issues of measuring and improving the usability of EHR products, including through several workshops. Experts from NIST also participate in various capacities on the Health IT Policy Committee and Health IT Standards Committee, as well as through the Standards and Interoperability Framework, a forum for stakeholders to use to identify and resolve standards-based issues impeding progress in the marketplace.

Listening and Learning as We Move To *Meaningful Use Stage 2*

As HHS developed the final rules for Stage 2, we listened to both our private and public sector stakeholders by soliciting input through many mechanisms including the Federal advisory committees, Requests for Comments (RFCs), town halls, listening sessions and, of course, through the more than 6,400 comments received and reviewed in response to the CMS and ONC Notices of

Proposed Rulemaking (NPRM). One of the key messages we heard from the provider and vendor communities is that successful health IT implementation relies on a predictable roadmap for meaningful use measures and certification criteria. Moreover, both the vendor and provider communities must be given enough time to implement it successfully.

We heard of the need for substantial progress on standards-based care coordination and health information exchange in Stage 2, as well as continued advances in the three key areas of patient engagement, patient safety in hospitals, and continuous quality improvement. Yet while we heard the call for ambitious, challenging Stage 2 requirements, we also heard that we needed to increase flexibility and reduce regulatory burden. The Stage 2 requirements provide new flexibility in definitions, exclusions, a shorter reporting period for the first year of Stage 2, and additional quality measures that account for the needs of many medical specialties to measure and improve the care they provide.

Our goal is to assist clinicians and hospitals in using technology to meaningfully deliver health care that is higher quality, safer, patient-centered, and coordinated. And, we want them to thrive in the new health care marketplace that puts a premium on value over volume, on coordination over fragmentation, and on patient-centeredness over all.

EHR Interoperability

As stated earlier, standards-based health information exchange is a key priority of Stage 2, and the final rules represent a major step forward in advancing the secure exchange of information between providers and with patients to support better care across the nation. We know that getting the right information to the right person at the right time is extremely important in delivering high quality care.

In 2009 when we were drafting the initial set of meaningful use criteria and required standards, our plans necessarily responded to the reality we faced. Different vendor products used different proprietary or local codes; there were strong disagreements about how laboratory results or patient summaries should be packaged; and there was simply no consensus on how the Internet could be used to securely send patient information. Over the past two years, thanks to the initial steps we took in Stage 1 and the relentless work of almost 1,000 industry participants in ONC's standards and implementation activities, those problems have been ameliorated, and we can now leap towards interoperability and exchange in Stage 2.

Overview of Standards Development Process

To help build nationwide EHR interoperability, ONC works to encourage and accelerate the development of health IT standards and move toward the seamless and secure exchange of health data across all stakeholders.

To achieve these goals, ONC's roles include:

- Enabling stakeholders to come up with simple, shared solutions to common information exchange challenges
- Overseeing a portfolio of standards, services, and policies that accelerate information exchange
- Collaborating with Federal agencies to coordinate Federal health IT priorities
- Validating conformance to the standards through the certification program
- Implementing pilots that support on-the-ground implementers in packaging standards and policy building blocks to solve providers' most pressing information exchange needs

- Disseminating and spreading these information exchange solutions
- Advancing standards adoption through meaningful use and other Federal policy levers

ONC believes that providing a mechanism for the health IT community to come together to solve problems is a highly effective way to accelerate the development of standards and specifications. In 2011, ONC launched the Standards & Interoperability (S&I) Framework to support national health outcomes and healthcare priorities. Through the S&I Framework, the health IT community is brought together to develop and harmonize the standards and specifications they need to support interoperability.

The S&I Framework is an example of “government as a platform” - enabled by integrated functions, processes, and tools – for the open community of implementers and experts to work together to develop and harmonize health information exchange standards. As of June 2012, over 1200 people had registered on the S&I Framework wiki (an Internet-based collaboration workspace), and over 500 people representing 300+ organizations had committed to participate in one or more of the ten initiatives of the S&I Framework. Among the S&I Framework’s successes, we are proud to note that, for the first time, the health IT community has reached general consensus on a standardized way to send healthcare information securely, to structure content for transitions of care documents, and to electronically report laboratory results.

Meaningful Use Stage 2 and Health Information Exchange Highlights

Common Standards and Implementation Specifications for Electronic Exchange of Information: To promote interoperability as part of the Stage 2 final rules, HHS has defined a common dataset for all summary of care records, including an impressive array of structured and

coded data to be formatted uniformly and sent securely during transitions of care, upon discharge, and to be shared with the patient themselves. These include:

- Patient name and demographic information including preferred language sex, race/ethnicity (OMB Ethnicity) and date of birth
- Vital signs including height, weight, blood pressure, and smoking status (SNOMED CT)
- Encounter diagnosis (SNOMED CT or ICD-10-CM)
- Procedures (SNOMED CT)
- Medications (RxNorm) and medication allergies (RxNorm)
- Laboratory test results (LOINC)
- Immunizations (CVX)
- Functional status including activities of daily living, cognitive and disability status
- Care plan field including goals and instructions
- Care team including primary care provider of record
- Reason for referral and referring provider's name and office contact information (for providers)
- Discharge instructions (for hospitals)

In addition, the Stage 2 rules identify a host of detailed standards and implementation specifications for a number of other transactions including quality reporting, laboratory results, electronic prescribing, immunizations, cancer registries, and syndromic surveillance.

What does this mean? It means that we are able to break down barriers to the electronic exchange of information and decrease the cost and complexity of building interfaces between different systems while ensuring that providers with certified electronic health record (EHR) technology have the tools in place to share, understand, and incorporate critical patient

information. It also means that providers can improve workflow and dig deeper into the data. Certified EHR technology must be able to support identity reconciliation—matching the right record to the right person—and will give doctors the tools to reconcile a new document with the information already on file, for instance by incorporating another provider's diagnoses and prescriptions into a patient's record, thus creating a comprehensive view of the patient. The Stage 2 regulations also require developers to build systems that allow each segment of the patient summary, whether it is procedures or lab results, to be securely retrievable by the end user, getting us closer to the goal of being able to efficiently search and assemble individual data elements through metadata tags.

Rigorous Testing of Exchange for Stage 2: To ensure that certified EHR technology supports providers in exchanging health information with greater frequency and across vendor boundaries, ONC will work with NIST to develop an interoperability testing platform for Stage 2 that will rigorously test whether EHR technology can send, receive, and incorporate standardized data using the specified standards and protocols. Any EHR technology that meets the demanding testing requirements should be able to send and receive standardized information with other certified EHRs.

Actual Electronic Exchange of Clinical Information: By 2014, providers who choose to participate in meaningful use Stage 2 will have to demonstrate, and vendors will have to support, the actual exchange of structured care summaries with other providers—including across vendor boundaries—and with patients. Whether through “push” or “query” methods, the requirements in the rule ensure that exchange *is* occurring while avoiding undue burden on providers and vendors to track and measure this exchange.

While any rulemaking includes some compromises between the aspirational goals we want to achieve and the reality of where the market is, we continue to make progress toward the ultimate

goal of nationwide health information exchanges. By setting ambitious but achievable targets for providers and vendors alike, I'm confident that we'll see the same steep upward progress we've seen for adoption of EHRs for information exchange. The push on standards-based information exchange and other Stage 2 requirements will enable the country to achieve the goals of the meaningful use roadmap for more coordinated, safer, and better care.

Conclusion

In conclusion, our progress to date has been steady and deliberate. Working within an open and transparent process with our public and private stakeholders, HHS has developed the meaningful use requirements in stages to serve as building blocks to the future. Stage 1 enabled us to utilize technology to gather structured data and focus on the functionalities of basic EHRs, including privacy and security protections. With Stage 2, HHS is working to improve access to information through care coordination and increasing standards-based health information exchange between providers and with patients. We anticipate that the Stage 3 rules will allow us to continue to support transformed care by continuing to advance health IT capabilities by focusing on advanced clinical decision support, team-based care, improving health outcomes, population health management, and patient engagement tools. We look forward to continuing to working with you all to accomplish these goals, and I would be happy to answer any questions you may have regarding my testimony.