

IS “MEANINGFUL USE” DELIVERING MEANINGFUL
RESULTS?: AN EXAMINATION OF HEALTH
INFORMATION TECHNOLOGY STANDARDS AND
INTEROPERABILITY

HEARING
BEFORE THE
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION
COMMITTEE ON SCIENCE, SPACE, AND
TECHNOLOGY
HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

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**IS “MEANINGFUL USE” DELIVERING
MEANINGFUL RESULTS?:
AN EXAMINATION OF HEALTH INFORMATION
TECHNOLOGY STANDARDS AND
INTEROPERABILITY**

WEDNESDAY, NOVEMBER 14, 2012

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, D.C.

The Subcommittee met, pursuant to call, at 10 a.m., in Room 2318, Rayburn House Office Building, Hon. Benjamin Quayle [Chairman of the Subcommittee] presiding.

RALPH M. HALL, TEXAS
CHAIRMAN

EDDIE BERNICE JOHNSON, TEXAS
RANKING MEMBER

U.S. HOUSE OF REPRESENTATIVES
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Subcommittee on Technology and Innovation Hearing

***Is “Meaningful Use” Delivering Meaningful Results?: An
Examination of Health Information Technology Standards and
Interoperability***

Wednesday, November 14, 2012
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

Witnesses

Dr. Farzad Mostashari, National Coordinator for Health Information Technology, The Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services.

Dr. Charles H. Romine, Director, Information Technology Laboratory, National Institute of Standards and Technology.

Mr. Marc Probst, Chief Information Officer and Vice President, Information Systems, Intermountain Healthcare.

Ms. Rebecca Little, Senior Vice President, Medicity, Inc.

Dr. Willa Fields, DNSc, RN, FHIMSS, Professor, School of Nursing, San Diego State University.

**U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION**

HEARING CHARTER

***Is “Meaningful Use” Delivering Meaningful Results?: An Examination of Health
Information Technology Standards and Interoperability***

**Wednesday, November 14, 2012
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building**

Purpose

On Wednesday, November 14, 2012, the Subcommittee on Technology and Innovation will hold a hearing to examine progress on the development and implementation of interoperable technical standards and conformance testing procedures for health information technology (HIT). The Subcommittee will review the activities of the Office of the National Coordinator for Health Information Technology (ONC) and the National Institute of Standards and Technology (NIST) in promoting interoperability through the development of technical standards for HIT, and will examine the implementation of the Health Information Technology for Economic and Clinical Health (HITECH) Act, including the recently announced final rule for Stage 2 meaningful use of HIT under the Act.

Witnesses

Dr. Farzad Mostashari, National Coordinator for Health Information Technology, The Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services.

Dr. Charles H. Romine, Director, Information Technology Laboratory, National Institute of Standards and Technology.

Mr. Marc Probst, Chief Information Officer and Vice President, Information Systems, Intermountain Healthcare.

Ms. Rebecca Little, Senior Vice President, Medicity.

Dr. Willa Fields, DNSc, RN, FHIMSS, Professor, School of Nursing, San Diego State University.

Overview

Effective utilization of information technology in the health care arena has the potential to lower health care costs and to improve the coordination and provision of care by reducing duplicative or unnecessary tests and procedures, preventing medical errors, and by providing clinical decision support at the point of care. Major components of HIT include portable electronic health records (EHRs) (including systems to prescribe medicine, order tests, and provide clinical support) and the development of a secure health information network to exchange information among providers.¹

Despite the pervasiveness of information technology (IT) in the public and private sectors, the healthcare industry has historically been an IT laggard.² A variety of barriers account for this, including, the lack of interoperable standards for HIT technology, the significant capital investment required, the lack of economic incentives in the health care payment structure, and the complexity and diversity of the health care arena, just to name a few.

Interoperability is critical to realizing the benefits of HIT. Interoperability allows different EHR systems to communicate, enabling a seamless flow of patient information in continuity of care among different providers. The development and application of common technical standards is critical to achieving interoperability. Simply put, interoperability is critical to realizing the benefits of HIT and technical standards are the platform upon which to build a diversity of innovative systems.

Background

Office of the National Coordinator for Health Information Technology

In 2004, President Bush signed an Executive Order creating the Office of the National Coordinator for Health Information Technology (ONC) within the Department of Health and Human Services.³ The Executive Order charged the ONC with developing and implementing a strategic plan to coordinate nationwide efforts towards interoperability standards and the electronic exchange of health information in the public and private health care sectors. The ONC drafted a framework that outlined four goals for HIT: (1) informing clinical practice by accelerating the use of EHRs; (2) connecting clinicians allowing them to exchange information in a secure environment; (3) personalizing health care by enabling consumers to participate in

¹ Redhead, C. Stephen. *CRS Report for Congress: The Health Information Technology for Economic and Clinical Health Act*. April 27, 2009.

² DesRoches, et al. 2008 Electronic Health Records in Ambulatory Care – A National Survey of Physicians, *The New England Journal of Medicine*.

³ Executive Order 13335: Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator, available at <http://georgewbush-whitehouse.archives.gov/news/releases/2004/04/20040427-4.html>.

their care; and (4) improving population health through public health surveillance and through the acceleration and application of health research in clinical care.⁴

The ONC's mission includes promoting development of a nationwide HIT infrastructure that allows for electronic use and exchange of information; providing leadership in the development, recognition, and implementation of standards and the certification of HIT products; HIT policy coordination; strategic planning for HIT adoption and health information exchange; and establishing governance for the National Health Information Network.⁵

The National Institute of Standards and Technology and Health Information Technology

The National Institute of Standards and Technology (NIST) has collaborated with industry and other stakeholders on healthcare information infrastructure since the early 1990s. NIST has also worked extensively with the ONC on HIT voluntary standards development since 2004.

NIST's role in HIT has been further defined in the 2009-2012 Federal HIT strategic plans and the HITECH Act to:

- Advance healthcare information enterprise integration through standards and testing.
- Consult on updating the Federal HIT Strategic Plan.
- Consult on voluntary certification programs.
- Consult on HIT implementation.
- Provide pilot testing of standards and implementation specifications, as requested.⁶

NIST is widely recognized for its technical expertise and its leadership in bringing together various stakeholders to build consensus for standards development.

Health Information Technology for Economic and Clinical Health (HITECH) Act

The HITECH Act, which was incorporated into the American Recovery and Reinvestment Act (ARRA; H.R. 1), was signed into law in 2009. The Act codified the ONC and expanded privacy and security standards for electronically stored health information. In addition, the Act established mandatory and discretionary funding programs to promote adoption of HIT products, services, and infrastructure through incentive payments, grants, and low-interest loans.

The Act provides mandatory funding through Medicare and Medicaid incentive payments (transitioning to penalties over a period of time) to encourage providers (both physicians and hospitals) to adopt and "meaningfully use certified EHRs."⁷ To qualify under "meaningful use," providers must show that they are achieving specific milestones, such as using certified HIT products to record patient data, to order prescriptions, and to make referrals to other providers.

⁴ Redhead, C. Stephen. *CRS Report for Congress: The Health Information Technology for Economic and Clinical Health Act*. April 27, 2009.

⁵ http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__onc/1200

⁶ <http://www.nist.gov/healthcare/hit/index.cfm>

⁷ ARRA § 13301.

Meaningful use requirements and supporting technical standards are promulgated by the Secretary of HHS, based on recommendations by the HIT Policy Committee and the HIT Standards Committee, respectively.

According to the Centers for Medicare and Medicaid Services (CMS), EHR incentive payments to providers have totaled over 7.7 billion dollars through September 2012—paid out to 158,071 physicians and hospitals. At a Health Information Management and Systems Society (HIMSS) 2012 Policy Summit, ONC National Coordinator, Dr. Farzad Mostashari, estimated that CMS would pay out around 20 billion dollars in EHR incentive payments before incentives shift to penalties in 2015.⁸

Under the HITECH Act, ONC was directed to transfer \$20 million to NIST to conduct HIT activities including technical standards analysis and establishment of conformance testing infrastructure in coordination with ONC.⁹ Specifically, NIST develops, and the ONC approves, test procedures to certify EHR product conformance. NIST also accredits private labs that perform conformance testing for HIT products, and participates in both the ONC's HIT Policy and Standards Committees.

In addition to mandatory incentives payments, the ARRA appropriated two billion dollars in discretionary funds to ONC for HIT infrastructure investments, provider grants, and training programs. Among grant programs, HHS has dedicated grant funding for the HIT Extension Program, which established Regional Extension Centers (REC) around the country, and to the State Health Information Exchange (HIE) Program, which supports states' and state-designated entities' efforts in establishing information exchange ability among providers and hospitals.¹⁰

HITECH Act Meaningful Use Requirements

HITECH tasked ONC with developing meaningful use requirements for HIT. ONC has since established three meaningful use stages. Each stage consists of its own set of "core" and "menu" provider requirements determined by CMS to qualify for Medicare or Medicaid incentive payments.

Stage 1

Stage 1 aimed at introducing HIT into the healthcare industry through data capture and sharing, with the first building blocks focused on basic EHR functionality, data standardization, and privacy and security.

Stage 2

On August 23, 2012, CMS released the final rule for Stage 2. The requirements reflect a focus on improved access to information and advanced clinical processes. Previously CMS required

⁸ Diana Manos, *Mostashari: No cap on EHR incentive payouts*, HEALTHCARE IT NEWS, Sept. 13, 2012, <http://www.healthcareitnews.com/news/mostashari-theres-no-cap-ehr-incentive-payouts?topic=75,08,12>.

⁹ ARRA § 13201

¹⁰ <http://www.healthit.gov/policy-researchers-implementers/health-it-adoption-programs>

providers to progress to Stage 2 criteria after two years under Stage 1 meaningful use requirements; the original timeline would have required Medicare providers who first demonstrated meaningful use in 2011 to meet the Stage 2 criteria in 2013. However, the final rule for Stage 2 delays the onset of Stage 2 requirements with the earliest effective date in fiscal year 2014.

Stage 3 and Beyond

Even though the final rules of Stage 2 were just recently released, ONC and CMS have started the process for developing Stage 3 meaningful use requirements. Stage 3 aims at creating improved population outcomes and individual patient engagement. Using the current timeline, Stage 3 would begin two years after a provider successfully demonstrates Stage 2 requirements—no earlier than 2016. The HIT Policy Committee's Meaningful Use Workgroup¹¹ plans to submit their final Stage 3 recommendations to HHS by May 2013.¹²

Issues for Examination

As of May 2012, there were a total of 248,439 professional and hospital participants in the EHR incentive programs for both Medicare and Medicaid. However, while adoption of HIT products has increased since the passage of the HITECH Act, interoperability among the myriad of HIT systems has lagged. Absent interoperability, many of the potential benefits of HIT, such as improvements in coordination of care and increases in efficiency may go unrealized.

Additionally, key stakeholders, including the American Medical Association and the American Hospital Association, have expressed concern about Stage 2 meaningful use requirements.^{13,14} These concerns include whether the Stage 2 rules appropriately take into account the diversity and complexity of the healthcare industry. As a result, specialists may be required to invest in systems and electronically record data that do not apply directly to their provision of care.

Witnesses were asked to address in their testimony:

What is the goal for health information interoperability under the HITECH Act? How are Stage 1 and 2 meaningful use requirements and supporting standards advancing us towards this goal?

How have the lessons learned from the implementation of Stage 1 meaningful use requirements and supporting standards been applied in drafting Stage 2 requirements and Stage 3 proposals?

¹¹ HEALTHIT.GOV, <http://www.healthit.gov/policy-researchers-implementers/federal-advisory-committees-facas/meaningful-use>.

¹² HIT POLICY COMM., MEANINGFUL USE WORKGROUP STAGE 3 – PRELIMINARY RECOMMENDATIONS (2012) 3, http://www.healthit.gov/sites/default/files/mu_stage3_rec_hitpc_meeting_01_aug_12.pdf.

¹³ <http://www.ama-assn.org/resources/doc/washington/ehr-stage-2-certification-sign-on-letter-07may2012.pdf>

¹⁴ <http://www.ama-assn.org/resources/doc/washington/ehr-stage-2-certification-sign-on-letter-07may2012.pdf>

How does the ONC engage Federal agencies and other stakeholders (National Institute of Standards and Technology, vendors, and providers) in developing the meaningful use requirements and technical standards?

How does the HIT Standards Committee balance the need for common IT standards with the diversity of the healthcare industry? How does the Committee account for technology development and innovation in its standards recommendations?

How effective have HHS and the ONC been in establishing long-term goals and benchmarks for HIT adoption, interoperability, and provision of care?

What recommendations would you make for Federal policy makers as we consider future HIT policies?

Chairman QUAYLE. The Subcommittee on Technology and Innovation will come to order. Good morning. Welcome to today's hearing entitled "Is 'Meaningful Use' Delivering Meaningful Results?: An Examination of Health Information Technology Standards and Interoperability."

In front of you are packets containing the written testimony, biographies, and truth-in-testimony disclosures for today's witnesses.

I now recognize myself for five minutes for an opening statement.

Throughout this Congress our Subcommittee has been focused on advancing U.S. innovation in a constrained budget environment. We held hearings on cloud computing, start-up companies, standards development, spectrum R&D, manufacturing, and innovation policies. Today's discussion is a continuation of this conversation.

This is also the fourth hearing the Committee on Science, Space, and Technology has held on health information technology standards since the 109th Congress.

Effective utilization of information technology in the medical field has the potential to fundamentally change health care in our country. Application of health IT could lower healthcare costs by reducing duplicative and unnecessary tests and procedures. It could also lead to more effective care by helping to reduce medical errors and could help to improve public health outcomes by aiding in clinical decision making.

Given the strain of rising healthcare costs on our budget and the diverse array of healthcare providers, information technology will be a critical component of our future healthcare system. However, while information technology has become pervasive in our everyday lives, the healthcare industry has historically been slow to effectively deploy IT.

In 2004, President Bush signed an Executive Order establishing the Office of the National Coordinator for Health Information Technology, or the ONC, within the Department of Health and Human Services to develop, maintain, and direct a strategic plan to guide the nationwide implementation of health IT in the public and private healthcare sectors.

The National Institute of Standards and Technology has worked with industry and other stakeholders to advance healthcare information technology infrastructure since the early 1990s.

In 2009, the *HITECH Act* was passed as part of the American Recovery and Reinvestment Act to promote the adoption of health IT products, services, and infrastructure through a series of discretionary and mandatory funding programs. This legislation included \$2 billion in discretionary funds for the ONC to invest in health IT architecture and to provide grants and training programs to encourage health IT adoption.

Furthermore, the legislation provided financial incentives in the form of mandatory payments through the Medicare and Medicaid programs to encourage physicians and hospitals to adopt and use certified electronic health records, or EHRs. To date, incentive payments under these programs have totaled over \$7.7 billion. It is estimated that CMS will pay out approximately \$20 billion in incentive payments to providers under this program.

This is a significant Federal expenditure. Given our current budget situation, it is vital that these taxpayer dollars are spent

effectively in ways that lead to reduced costs and better health care down the road. Nearly four years after the *HITECH Act*, taxpayers should know what we have to show for it.

While adoption of health IT products and services has increased since the passage of the *HITECH Act*, I have serious concerns about our progress towards greater interoperability of health IT systems. Without interoperability many of the potential benefits of health IT could go unrealized.

Interoperability depends on the development and utilization of strong technical standards. I am interested in hearing from our witnesses about progress being made towards the development of these standards and what policy makers can do to advance interoperability.

Further, I am concerned that the meaningful use requirements do not effectively take into account the complexity and diversity of the healthcare marketplace. It is crucially important that health IT is used to improve care without burdening certain providers with requirements that divert valuable time and resources.

Clearly there are key questions that must be answered to ensure that taxpayer dollars are spent wisely and to ensure that IT in the healthcare industry is used to reduce costs and improve care.

We thank all of our witnesses for being here today, and we look forward to your testimony.

[The prepared statement of Chairman Quayle follows:]

PREPARED STATEMENT OF SUBCOMMITTEE CHAIRMAN DAN QUAYLE

Good morning, I'd like to welcome everyone to today's hearing, which is being held to examine the development of health information technology interoperable standards, and the implementation of the Health Information Technology for Economic and Clinical Health Act, more commonly known as the *HITECH Act*.

Throughout this Congress, our Subcommittee has been focused on advancing U.S. innovation in a constrained budget environment. We held hearings on cloud computing, startup companies, standards development, spectrum R&D, manufacturing, and innovation policies. Today's discussion is a continuation of this conversation.

This is also the fourth hearing the Committee on Science, Space, and Technology has held on health information technology standards since the 109th Congress.

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Further, I am concerned that the meaningful use requirements do not effectively take into account the complexity and diversity of the healthcare marketplace. It is crucially important that health IT is used to improve care without burdening certain providers with requirements that divert valuable time and resources.

Clearly, there are key questions that must be answered to ensure that taxpayer dollars are spent wisely, and to ensure that IT in the healthcare industry is used to reduce costs and improve care.

We thank our witnesses for being here today and we look forward to your testimony.

Chairman QUAYLE. I now recognize the gentleman from Michigan Mr. Clarke for his opening statement.

Mr. CLARKE. Thank you, Mr. Chair.

First of all, I would like to say, as someone who will not be returning to Congress, it has been an honor to serve with you. I also appreciate your diligence on examining this important need that we have, which is to make sure that we have electronic health records shared in a way that all physicians and healthcare providers will be able to exchange this information.

The Chair laid out the benefits of health IT in terms of the money that could be saved by eliminating duplicative testing, and also how health IT could help improve the quality of health care, especially with diabetics. There have been studies that have shown that when electronic health records are used, diabetic patients are able to manage their disease more effectively.

Now, the Chair mentioned his concern about the value of the incentives payments, and I acknowledge that, you know, our goal is to spend approximately \$20 billion, I believe, by 2015 on these incentive payments. I think they are absolutely critical, because if you look at the fact that most Americans get their primary care from offices that have five or fewer physicians, these small offices, they don't have the money or the resources to be able to set up a health IT system, especially when those physicians may not be sure if that system is going to really work in an interoperable way or if it could become obsolete in a short period of time. So I believe it is critical for us to move forward on the full implementation of this platform.

I look forward to speaking to the National Coordinator about his work with NIST since the *HITECH Act* directs a partnership—or I should say that this rule that we are now reviewing establishes a partnership which could help further develop a health IT platform that could result in the interoperability of electronic health records.

My one closing statement is this, is that even though this area is complex, because the healthcare industry is complex and health IT itself is complex, being able to have these records in an electronic form that could be shared can make a difference. Two months ago my first cousin, the closest blood relative I have here in this country, who is younger than me, passed away. She suffered organ failure, and I believe that a combination of prescription drugs may have been a contributing factor to that. It is likely that with these electronic health records we would be able to identify that type of prescription drug interaction before it happens.

So with that, I yield back the balance of my time.

Chairman QUAYLE. Thank you, Mr. Clarke.

[The prepared statement of Mr. Clarke follows:]

PREPARED STATEMENT OF SUBCOMMITTEE ACTING RANKING MEMBER HANSEN
CLARKE

Thank you, Mr. Chairman for calling this hearing on health information technology. Before I begin my opening statement, I'd like to take a moment to recognize Chairman Quayle for his leadership on the Subcommittee. It has been a pleasure working with you to address a wide range of issues. I thank you for your service to the Subcommittee and Congress and wish you the best in your future endeavors.

Today's hearing is fitting as just a few months ago the requirements for the second stage in the "meaningful use" of electronic health record technologies were announced by the Department of Health and Human Services. This morning's hearing provides us with the perfect opportunity to examine the progress we've made to date and to discuss what needs to happen in the future to increase the use of information technology in the healthcare industry.

Over the past 20 years, we have experienced a dramatic change in the way we share information. Nearly every sector across our economy, from financial services to entertainment to manufacturing, has embraced information technology and used it to increase productivity and quality. Yet the healthcare industry has lagged far behind with many physicians and healthcare providers keeping track of our medical information the same way they were 50 years ago.

The use of electronic health records—or EHRs—has real-world implications for the cost and quality of health care. Right now, a physician may order a duplicative test because previous test results from another hospital or doctor are not readily at hand, or they may miss a harmful drug interaction because a patient's full medication list is not available and the patient is not in a condition to provide that information.

Increasing the adoption and use of health IT could help prevent some of the medical errors that injure at least 1.5 million Americans each year and lead to an estimated 98,000 deaths annually. For example, a study of a medical center in Arizona found that the use of EHRs reduced prescription errors by 88 percent and in a Florida health system the use of electronic reminders decreased the number of patient charts that were missing allergy information from 36 percent to 11 percent.

Studies have also shown that the use of EHRs has helped diabetic patients manage their disease more effectively—lowering their blood pressure, cholesterol, and glucose levels. In addition to improving the quality of care and health outcomes, estimates have shown that a fully interoperable health IT system could save the United States billions of dollars in health care costs each year.

Given the complexity of our healthcare system, the task charged to the Office of the National Coordinator by the *HITECH Act* to promote the development of a national health IT infrastructure that allows for the electronic use and exchange of information is a difficult one. However, in the two years since the Subcommittee last examined this topic, the National Coordinator, by all accounts, has done an admirable job meeting tight deadlines and navigating the needs of various stakeholders. NIST has also played an important role by lending to HHS its extensive expertise in standards, testing, and certification.

Still, there are a number of factors that have contributed to the slow adoption of health IT such as the availability of a qualified workforce or privacy and security concerns. I believe a key barrier to adoption has been the lack of technical standards to support interoperability. In order for the full potential of health IT to be realized, adoption and implementation of EHRs must increase and true interoperability—meaning the seamless exchange of health information across vendors and providers must be achieved. Most Americans get their primary health care at offices with five or fewer doctors. These small offices are hesitant to take on the considerable expense of a health IT system that may not work with the system of a neighboring healthcare provider or may become prematurely obsolete.

However, I am encouraged by the criteria and standards included in the final rule for Meaningful Use Stage 2 released in August and hope to gain some insight from today's witnesses about the implementation of Stage 2. As I understand it, Stage 2 focuses on the challenge of interoperability in a number of ways. First, it defines a common dataset, including vital signs, medications, and discharge instructions that must be a part of a patient's summary of care record. Next, it details the standards and specifications necessary for the exchange of typical, but important medical information like laboratory results, immunizations, and electronic prescriptions. And maybe most importantly, Stage 2 creates a partnership between the Office of the National Coordinator and NIST in the development of a rigorous interoperability testing platform. Such a platform will ensure that once a physician or healthcare provider has adopted a certified EHR technology they will be able to send, receive, and use this critical health information.

However, as I am sure we will discuss today, we still have a ways to go in promoting interoperability, coordinating the numerous health IT projects that are underway, and implementing best practices to address privacy and security concerns.

The widespread use of health IT is imperative for lowering costs and improving patient care, and I look forward to hearing from our witnesses about how we can successfully meet the challenges ahead.

Thank you, again, Mr. Chairman, for calling this important hearing and I yield back the balance of my time.

Chairman QUAYLE. I now recognize the gentleman from Texas, Mr. Smith, for his opening statement.

Mr. SMITH. Thank you, Mr. Chairman. I do not have an opening statement, but I did not want it to go unnoticed that this might be your last hearing that you chair, and I just wanted to say that all of us who have been associated with you, whether it be on committees, and in this case you and I serve on two committees together, that all those who have known you and worked with you appreciate your service to the Subcommittee, the full Committee, the Congress, and our country, and I thank you for that.

Chairman QUAYLE. Thank you very much. Those are probably the most important words of this whole hearing today. I thank the gentleman for those kind remarks.

And I want to thank Mr. Clarke for his opening statement.

If there are Members who wish to submit additional opening statements, your statements will be added to the record at this point.

Chairman QUAYLE. At this time I would like to introduce our witnesses, and we will proceed to hear from each of them in order. Our first witness is Dr. Farzad Mostashari, National Coordinator for Health Information Technology at the United States Department of Health and Human Services.

Next we will hear from Dr. Charles H. Romine, Director of the Information Technology Laboratory at the National Institute of Standards and Technology.

Our third witness is Mr. Marc Probst, Chief Information Officer and Vice President of Information Systems at Intermountain Healthcare.

Our fourth witness is Ms. Rebecca Little, Senior Vice President of Medicity.

Our final witness is Dr. Willa Fields, Professor of Nursing at San Diego State University and Chair of the Board of Directors of the Healthcare Information and Management Systems Society. Thank you all for being here today.

As our witnesses should know, spoken testimony is limited to five minutes each. After all witnesses have spoken, members of the Committee will have five minutes each to ask questions.

I now recognize our first witness Dr. Mostashari for five minutes.

**STATEMENT OF DR. FARZAD MOSTASHARI,
NATIONAL COORDINATOR FOR HEALTH INFORMATION
TECHNOLOGY, THE OFFICE OF THE NATIONAL COORDINATOR
FOR HEALTH INFORMATION TECHNOLOGY**

Dr. MOSTASHARI. Chairman Quayle, Ranking Member Clarke, distinguished Subcommittee Members, thank you for the opportunity to appear today on behalf of the Department of Health and Human Services. I am Dr. Farzad Mostashari. I am the National Coordinator for Health IT.

I am delighted to be here today to tell you about the remarkable progress in health IT the country has made in the relatively short time since HITECH's passage. Under HITECH, eligible professionals and hospitals can qualify for incentive payments from the Centers for Medicare and Medicaid Services when they adopt and

meaningfully use certified EHR technology as defined by ONC certification criteria and interoperability standards.

HITECH also funded a number of other supporting activities, such as 17 beacon communities, community college and university-based workforce programs, and 62 regional extension centers that provide hands-on technical assistance to providers and hospitals transitioning away from paper.

HITECH is working. Between 2008 and 2011, the percentage of office-based physicians adopting the EHR system has doubled, and hospital adoption leaped almost threefold. As of September 2012, more than 300,000, or more than half of the Nation's eligible professionals, as well as over 75 percent of eligible hospitals have registered to participate in the incentive programs. More than 154,000 eligible professionals and 3,000 hospitals have earned their first incentive payment.

Achieving meaningful use is meant to be hard, but achievable. We need to strike a balance between the urgency of modernizing our healthcare system and the pace of change that can be absorbed by providers and IT vendors. Each stage of meaningful use is designed to build increased functionality and interoperability to improve patient care, enhance care coordination in population health, increase patient and family engagement, and protect patient privacy and security.

Recognizing that health IT is a complex and quickly evolving field, HITECH established two Federal Advisory Committees. The HIT Policy Committee Members are appointed by the Comptroller General, 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. The HIT Standards Committee includes providers, consumers, health plans, vendors, researchers, and other stakeholders.

As HHS develops the rules for the incentive program, we fully engage experts in the field, listening to both our private- and public-sector stakeholders and actively soliciting input through many mechanisms, including through the thousands of comments received and reviewed in response to our Notices of Proposed Rulemaking. One of the key messages we have heard time and time again is that successful health IT implementation relies on a predictable roadmap and adequate time.

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. There was simply no consensus on how the Internet could be used to securely send patient information. So we took initial steps that put us on the road to interoperability and focused Stage 1 on functionalities that support the consistent electronic capture of data and its effective use within practices.

Over the past two years, we worked with industry to accelerate the painstaking work of building consensus on these technical standards that were required. We provided an open, trusted place where the diverse health IT community can come together to work,

developing and harmonizing the standards and specifications they need to support interoperability.

Nearly 1,000 people, representing over 300 diverse organizations, have participated in 1 of more than 10 priority initiatives. As a result the Stage 2 rules, set to take effect for hospitals in October 2013 and for eligible professionals in January 2014, make substantial progress on standards-based care coordination and health information exchange. For the first time there is defined a common dataset to be sent securely during transitions of care, upon hospital discharge, and to be shared with the patients themselves. It is worth emphasizing that patients will have the ability to securely access this same information, download it or share it electronically with other providers and caregivers as the need arises.

Our good colleagues at NIST continue 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 and infrastructure used by them. ONC is working with NIST to develop an interoperability testing platform for Stage 2 that will rigorously test that the EHR technology can indeed send, receive, and incorporate standardized data across vendor boundaries. Any EHR technology that meets the demanding testing requirements should be able to send and receive standardized information with other certified EHRs.

In conclusion, our progress on the road to interoperability has been steadfast. Working in an open and transparent process, HHS has developed the meaningful use roadmap in stages to serve as milestones toward the future. Stage 1 focused on gathering structured data and basic EHR functionalities, including privacy and security protections. With Stage 2, HHS is working to improve care coordination and increase standards-based health information exchange between providers and with patients.

We anticipate that future rules will continue to advance health IT capability and interoperability as the foundation for better health and better care at lower cost. We look forward to continuing to work with you to accomplish these goals, and I would be happy to answer any questions you may have regarding my testimony.

Chairman QUAYLE. Thank you very much.

[The prepared statement of Dr. Mostashari follows:]

**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

Farzad Mostashari, M.D., ScM.

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

November 14, 2012

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.

Chairman QUAYLE. I now recognize Dr. Romine to present his testimony.

**STATEMENT OF DR. CHARLES H. ROMINE,
DIRECTOR, INFORMATION TECHNOLOGY LABORATORY,
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY**

Dr. ROMINE. Chairman Quayle and Members of the Subcommittee, I am Chuck Romine, Director of the Information Technology Laboratory at the Department of Commerce's National Institute of Standards and Technology. Thank you for the opportunity to appear before you today to discuss our roles in advancing the Administration's commitment to enabling electronic health records and developing a nationwide health information network that is reliable, usable, interoperable, and secure.

NIST has been hard at work fulfilling the mandate of making our Nation's healthcare system safer, more accessible, and more affordable through the use of information technology. This objective remains a priority for the Department of Commerce and the Acting Secretary. Reaching our common goal of interoperable EHRs will improve health care for all Americans.

Through direction in HITECH, NIST and ONC are collaborating with industry, healthcare informatics-related standards organizations, consortia, and government agencies to develop consensus-based, complete and unambiguous standards, and to build tools and prototypes to advance the adoption of IT in health care. For future stages of meaningful use, NIST is providing technical leadership in evolving standards for interoperable EHRs as well as medical devices, genomics, imaging, and text retrieval and analysis.

The Medicare and Medicaid EHR incentive programs are successfully increasing the rate of adoption of health IT, thus enabling the achievement of health and efficiency goals. The program is designed in a staged approach, with each stage providing more rigor in what is expected in a certified product and in meaningful use. Stage 1 standards and criteria, for example, set a baseline for electronic data capture and information sharing and were specifically selected to be achievable by the Nation's providers. Stage 2 takes the next step by reducing the optionality found in Stage 1 and includes new standards, including those for electronic health information exchange between providers.

To support these changes, the 2014 edition EHR certification criteria included new or updated requirements for security, usability or safety-enhanced design, and interoperability.

Each stage of meaningful use advances interoperability. NIST has developed a conformance test tool that will be used for the certification and testing program for the 2014 standards and certification criteria that will also be an initial tool in a test bed that simulates exchange between a test EHR technology and a standards-compliant EHR technology. This will eventually allow for all levels of interoperability to be assessed in the electronic exchange of transition-of-care and referral summaries. This capability will also provide a platform for testing more comprehensive forms of interoperability between EHR technologies.

The *HITECH Act* calls for ONC, in consultation with NIST, to recognize a program for the voluntary certification of health IT as being in compliance with certification criteria for EHR technology that can support meaningful use requirements. Under this program testing organizations authorized by ONC, use the NIST test methods and tools to evaluate EHR systems so healthcare providers have confidence in the systems they purchase. NIST's National Voluntary Laboratory Accreditation Program has been acknowledged by ONC in regulation, as the accreditation body for private-sector labs that perform the testing.

Some lessons learned about why these programs are succeeding and have received positive feedback from all sectors of the healthcare enterprise, including clinicians, consumers, developers, standards develop organizations and others: following a staged approach, allowing vendors and providers adequate time to transition to more advanced health IT; engaging the community throughout the process; relying on a consensus-based standards-development process that actively engages industry; soliciting and incorporating broad public comment; engaging the Federal Advisory Committees; and transparency in the process. We will continue to be guided by these lessons learned and are prepared to meet the challenges as each stage becomes more rigorous in its requirements.

In addition to its collaborations on standards, testing, security, usability, interoperability, and certification for meaningful use, NIST's cutting-edge research, advanced measurement science, and participation in standards development are building the infrastructure for a future that offers even more promise for emerging healthcare breakthroughs in the United States.

NIST initiatives are examining the best ways for humans to interact with next-generation health IT. They are significantly improving medical device interoperability and making health care safer in the process. NIST researchers are exploring innovative techniques by which critical patient diagnostic and treatment information can be collected and transmitted continuously in a safe and secure manner, which addresses patient privacy concerns.

NIST is pleased to contribute to making our exciting vision of health IT a reality. Thank you for the opportunity to testify today on NIST's activities in health IT, and I would be happy to answer any questions you may have.

Chairman QUAYLE. Thank you very much.

[The prepared statement of Dr. Romine follows:]

Testimony of

Charles H. Romine, Ph.D.
Director, Information Technology Laboratory
National Institute of Standards and Technology
United States Department of Commerce

Before the
United States House of Representatives
Committee on Science, Space and Technology
Subcommittee on Technology and Innovation

Health Information Technology

November 14, 2012

Chairman Quayle, Ranking Member Edwards, and Members of the Subcommittee, I am Chuck Romine, Director of the Information Technology Laboratory at the Department of Commerce's (DOC) National Institute of Standards and Technology (NIST). Thank you for the opportunity to appear before you today to discuss our roles in advancing the Administration's commitment to enabling Electronic Health Records (EHRs) and to developing a Nationwide Health Information Network (NwHIN) that is reliable, usable, interoperable, and secure. I am pleased to testify today on NIST's role in this endeavor, our collaboration with the Office of the National Coordinator for Health Information Technology (ONC) at the Department of Health and Human Services (HHS), the lessons we have learned to date, how we engage other stakeholders, such as standards development organizations (SDOs), and how our efforts to advance meaningful use requirements are moving us closer to the goal of an interoperable electronic health records system.

NIST ROLE AND COLLABORATION WITH ONC

NIST has been hard at work toward fulfilling the mandate of making our Nation's healthcare system safer, more accessible, and more affordable through the use of information technology. This objective remains a priority for the Department of Commerce, and the Acting Secretary. NIST continues to collaborate with the public and private sectors to enhance the adoption of interoperable EHRs. Reaching our common goal of interoperable EHRs will improve care for all Americans through:

- clinical decision support and improved performance by healthcare practitioners;
- empowered patients who are involved in their own care and wellness regimen and who have access to electronically enabled communications with providers;
- monitoring of, and research for, public health;
- availability of care anytime, anywhere via telemedicine and mobile health applications;
- and
- emerging technologies such as personalized medicine and body area networks.

NIST's laboratory activities in measurements and standards for health Information Technology (IT) are at the core of our mission to promote U.S. innovation and industrial competitiveness to enhance economic security and improve quality of life. In fact, NIST has a long and effective history of working with public and private partners to improve our Nation's healthcare infrastructure. Building on these interactions, shortly after the creation of ONC in 2004, NIST and HHS signed an interagency agreement to collaborate on the development, implementation, and maintenance of the HHS/ONC health IT strategic plan. NIST's roles have been articulated in both Federal Health IT strategic plans (2008 – 2012 and 2011 – 2015) and in the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act (ARRA) of 2009.

The creation of an integrated healthcare information infrastructure depends on all parties involved in the healthcare enterprise – consumers, healthcare professionals, researchers, and insurers – and on having systems, tools, and information that are complete, correct, secure and

interoperable. The basis for achieving this rests upon the availability of healthcare information standards that are complete, implementable, testable, and that contribute to interoperability.

Through direction in HITECH, ONC has responsibility for adopting standards and certification criteria, and for establishing certification programs to test and certify EHR technology that can be used to support providers' attempts to achieve meaningful use. Some of their activities in this area are oversight of the HIT Standards Committee, engaging the public in providing feedback, and the Standards and Interoperability (S&I) Framework (<http://www.siframework.org/>).

NIST's Information Technology Laboratory (ITL) and ONC are collaborating with industry, healthcare informatics-related standards organizations, consortia, and government agencies to develop consensus-based complete and unambiguous standards and to build tools and prototypes to advance the adoption of IT within healthcare systems. NIST focuses its efforts on developing the key standards that ONC needs for current and future meaningful use criteria. For the 2014 Edition Final Rule, "Standards, Implementation Specifications, and Certification Criteria for Electronic Health Records Technology; Revisions to the Permanent Certification Program for Health Information Technology," recently published in the Federal Register by ONC¹, NIST has been providing technical leadership on critical standards for areas such as secure messaging and document sharing. To support the ONC testing program, NIST is working with SDOs and others in areas such as electronic prescribing and public health. Each standard, test and test tool developed by NIST strengthens the infrastructure needed by ONC to certify systems to the Meaningful Use Stage 2 criteria and drives the healthcare enterprise towards interoperability.

For electronic prescribing, we are working with the National Council for Prescription Drug Programs (NCPDP), the American National Standards Institute (ANSI)- accredited standards organization responsible for the SCRIPT² standard to be used to send new prescription requests to a pharmacy. NIST staff are working with NCPDP to ensure the NIST-developed conformance test tool and test procedures cover the required elements necessary for compliance to the implementation guide (standard) NCPDP developed.

NIST is collaborating with the Centers for Disease Control and Prevention (CDC) on the testing program for reporting for Public Health (specifically, Immunizations, Syndromic Surveillance, Electronic Laboratory Reporting, and Cancer Registry), for which NIST staff are working with the Health Level 7 (HL7) implementation guide authors for those criteria specified in the final rule. The CDC is responsible for receiving the reports identified in the public health criteria. NIST has actively engaged subject matter experts in the development of the test tooling and test

¹ http://www.ofr.gov/OFRUpload/OFRData/2012-20982_PI.pdf

² SCRIPT is a standard created to facilitate the transfer of prescription data between pharmacies, prescribers, intermediaries, and payers. The current standard supports messages regarding new prescriptions, prescription changes, refill requests.

procedures, so that any interpretation and intent of meaning issues in the standards are addressed and tested correctly in the certification process.

NIST technical leadership and collaboration with industry and relevant SDOs was the basis for providing standards that were complete and unambiguous in time for ONC to rely upon those standards for the ONC rulemaking. For future ONC requirements, including future stages of Meaningful Use, NIST is also providing technical leadership in evolving standards for interoperable EHRs as well as medical devices, genomics, imaging, text retrieval and analysis, and semantics.

Meaningful Use Stage 1

In August, 2010, NIST published an ONC- approved test method (test procedures, test data, test tools) for testing EHR technology to meet the 2011 Edition EHR certification criteria, including standards and implementation specifications. During the development of the test method, NIST and ONC collaborated to ensure that the relevant standards and certification criteria were consistent and effectively represented within the test procedures. The approved NIST-developed test method evaluates EHR technology for functionality related to electronic prescribing, submission of laboratory results, plotting and display of growth charts, and control of access so that only authorized users can retrieve information.

According to ONC (see <http://onccchpl.force.com/ehrcert/CHPLHome>) more than 2500 EHR products developed by more than 800 vendors are currently certified to the 2011 Edition EHR certification criteria. All these products were tested using NIST-developed and ONC-approved test procedures.

ENGAGEMENT EFFORTS WITH STAKEHOLDERS IN THE ACCREDITATION PROCESS

The HITECH Act calls for ONC, in consultation with NIST, to recognize a program for the voluntary certification of health information technology as being in compliance with applicable certification criteria for EHR technology that can support meaningful use requirements. Meaningful use is being implemented in three stages. Financial incentives to physicians are tied to how well they conform to criteria described in rules associated with each stage.

Under the temporary health IT certification program, testing organizations authorized by ONC use the NIST test method and conformance tools to evaluate EHR software and systems so doctors' offices, hospitals and other healthcare providers have confidence in the systems they purchase. For the ONC HIT Certification Program, NIST's National Voluntary Laboratory Accreditation Program (NVLAP) has been acknowledged by ONC, in regulation, as the Accreditation Body for Test Labs, i.e., NVLAP accredits the private sector labs that perform the testing.

As set forth in Part 285 of Title 15 of the U.S. Code of Federal Regulations, NVLAP accredits testing and calibration laboratories that are found competent to perform specific tests or calibrations. Technical requirements for accreditation are specific for each Laboratory

Accreditation Program (LAP), and are developed based on relevant and impartial expert advice, ensuring that all interested parties have the opportunity for effective involvement. NVLAP's regulations specify that advice may be obtained directly through public workshops or other suitable means.

For the healthcare IT program, NVLAP organized a public workshop on April 26, 2011. Attendees represented a range of federal and private sector stakeholders. Establishment of the program was also announced in the *Federal Register*. In the time since the health IT program was launched, NVLAP has successfully accredited five laboratories. NIST intends to host additional workshops as new tools are developed and released.

LESSONS LEARNED

The Medicare and Medicaid EHR Incentive Programs, a financial incentive for achieving meaningful use of certified EHR technology, is successfully increasing the rate of adoption of health IT. This, in turn, is enabling the achievement of health and efficiency goals. The program is designed in a staged approach, with each stage "raising the bar," that is, providing more rigor in what is expected in a certified product and in meaningful use.

Stage 1 standards and criteria, for example, set a baseline for electronic data capture and information sharing and were specifically selected to be achievable by the Nation's providers. Stage 2 takes the next step by reducing the optionality found in Stage 1 and includes new standards, including those for online access for patients to their health information and electronic health information exchange between providers. To support these changes, the 2014 Edition EHR certification criteria also include new or updated requirements for security, usability (safety-enhanced design) and interoperability.

Some lessons learned about why these programs are succeeding and have received positive feedback from all sectors of the healthcare enterprise, including clinicians, consumers, developers, SDOs, and others include:

- The programs' staged approach, allowing vendors and providers adequate time for transitioning to more advanced health IT;
- The programs' commitment to engage the community in all parts of the process;
- The programs' reliance on an consensus-based standards development process that actively and successfully engages industry;
- The programs' commitment to solicit broad public comment and incorporate that as appropriate;
- The programs' engagement with the Federal Advisory Committees as established under the ARRA, as well as with working groups set up by those committees for advice and counsel; and
- The programs' commitment to transparency in its process, with outreach in multiple modalities.

NIST embraces all these principles and applies them to its health IT activities. We will continue to be guided by these lessons learned and are prepared to meet the challenges as each stage becomes more rigorous in its requirements for meaningful use and certification. At the same time, through these processes and stages, we will succeed in the ultimate goal of truly interoperable health records.

It is clear that the competencies of individual agencies alone cannot get this job done, and that the complementary expertise, experience, and subject matter experts of ONC and NIST are required to collaborate from the beginning and closely for alignment and success.

SECURITY

Central to reaching the goals of health IT is ensuring secure use and sharing of health information, with the assurance of the confidentiality, integrity, and availability of that information. NIST works actively with government, industry, academia, and others to provide security tools, technologies, and methodologies that provide for the security and privacy of health information.

In 2011, NIST developed and issued a Health Insurance Portability and Accountability Act (HIPAA) Security Toolkit Application to help organizations better understand and implement the requirements of the HIPAA Security Rule, which establishes national standards to protect individuals' electronic health information and provides the foundation for meaningful use security and privacy. With nearly ten thousand downloads to date, this toolkit is helping healthcare organizations of all sizes identify areas where security safeguards to protect electronic health information may need to be implemented or where existing implementations may need to be improved.

To assist organizations in addressing security and privacy concerns in the growing use of information technology in healthcare, NIST recently hosted its fifth annual HIPAA Security Rule conference, *"Safeguarding Health Information: Building Assurance through HIPAA Security,"* in June 2012. Co-sponsored with HHS' Office for Civil Rights (OCR), the organization with delegated authority for the administration and enforcement of the HIPAA Security Rule, this event successfully highlighted the present state of health information security, as well as practical strategies, tips and techniques for implementing the HIPAA Security Rule. The prominent role of the ONC in this event, further reinforced the importance of security and privacy to the adoption and use of electronic health records and health information technology.

The adoption and use of mobile technologies by both physicians and patients may lead to increased access to electronic health information as well as to improvements in the cost and quality of healthcare. Mobile device features are constantly evolving, as are the threats and the security safeguards necessary to combat those threats. Development and implementation of mobile computing solutions that provide trusted ways for physicians and patients to communicate with one another while ensuring protection of electronic health information are

critical. As NIST moves forward collaboratively with industry to bridge the security gaps presented by today's smart phones, tablets, and other mobile devices, it welcomes the opportunity to work closely with ONC and other interested healthcare stakeholders to assist in this work. And such efforts are already under way, for example, NIST is collaborating with ONC on mobile device security practices and participated in the roundtable co-sponsored by ONC and OCR on this topic.

Small Business Outreach

Providing for the security and privacy of electronic health information is often particularly challenging for small healthcare providers, who may lack the security infrastructure or expertise of larger healthcare providers. The security challenge for small healthcare providers, as for small businesses everywhere, is to identify security safeguards that are practical and can be implemented cost-effectively. Such organizations also need greater security awareness and education so that limited resources are well applied to meet the most relevant and serious threats to the information entrusted to them. To address this need, NIST, the Small Business Administration (SBA), and the Federal Bureau of Investigation (FBI) co-sponsor a series of training workshops on computer security for small businesses that provide an overview of information security threats, vulnerabilities, and corresponding protective tools and techniques, with a special emphasis on providing useful information that small business personnel can apply directly. NIST looks forward to working with ONC to tailor this workshop series to the security needs of the healthcare community.

National Cybersecurity Center of Excellence

NIST recently announced a partnership with the State of Maryland and Montgomery County, Maryland, to establish the National Cybersecurity Center of Excellence (NCCoE), a public-private collaboration for accelerating the widespread adoption of integrated cybersecurity tools and technologies. The NCCoE will bring together experts from industry, government, and academia to design, implement, test, and demonstrate solutions and promote the wide-spread adoption of practical, interoperable cybersecurity solutions that address the real-world needs of complex IT systems across a variety of industry use cases including the secure use and exchange of health information.

NIST established its first NCCoE project around health IT by leveraging the experiences of the HHS Office for Civil Rights and the Office of the National Coordinator. Healthcare providers increasingly need to securely exchange electronic health information with each other. The confidentiality, integrity and availability of this information must be protected. The secure exchange of electronic health information is often particularly challenging for small healthcare providers, who, as noted above, may lack security infrastructure or expertise. The goal of this NCCoE project is to build and demonstrate a security platform that will enable small healthcare providers to securely and cost-effectively exchange electronic health information. The security platform will be based on commercial off-the-shelf components that meet cybersecurity standards and best practices. Following successful demonstrations, NIST will publish a description of the security platform and its performance characteristics sufficient to permit

other organizations to develop and deploy solutions that meet the security objectives of the Nation's small healthcare providers.

USABILITY

Improving the usability of EHR systems represents a key way to support healthcare organizations in improving the efficiency, effectiveness, user satisfaction and safety of these systems. In the 2014 Edition Standards and Certification Criteria Final Rule, ONC has included a certification criterion around safety-enhanced design that references NIST technical guidance in this area.

NIST research and development on usability is focused on assessing and validating that doctors, nurses, other clinicians and all other end users of EHR systems can use them effectively, efficiently and without use errors.

Over the past two years, NIST has developed and published, technical guidance to aid the EHR community in measuring and improving the usability and safety of EHR systems, including a three-step protocol to validate usability. NIST has reached out extensively to industry, academia, other government agencies, healthcare organizations, and other stakeholders to gain feedback and inform the development of this guidance.

NIST technical guidance on usability of EHR systems is incorporated in the 2014 Edition Standards and Certification Criteria, which includes a certification criterion for Safety-Enhanced Design. NIST is authoring the test procedure for this criterion. NIST's work on EHR usability is also referenced in the Institute of Medicine's landmark report on health IT and safety (<http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx>). This report applauds the rapid progress in health IT and makes recommendations on this path forward to continue optimizing Federal efforts for this national priority. In addition, NIST guidance is being incorporated into system acquisition requirements by the Veterans Administration and other public and private healthcare organizations.

Recently, NIST worked with leading healthcare organizations, human factors experts and patient safety experts, to publish a technical report, titled "A Human Factors Guide to Enhance EHR Usability of Critical User Interactions when Supporting Pediatric Patient Care," (NIST IR 7865) which addresses how to improve the design, usability and safety of EHR systems used in the care of children, an example of a vulnerable population in need of special consideration.

Some important areas for future usability research include the usability of mobile health IT applications (The Healthcare Information and Management Systems Society, HIMSS, recently called on NIST to develop a validation protocol for mobile devices), consumer health IT systems (The National Academies of Sciences, NAS, recommended ONC and the Agency for Healthcare Research and Quality, AHRQ, partner with NIST to develop technical guidance in this area) and health IT workflow, especially as it relates to accountable care and other coordinated care models.

INTEROPERABILITY

The HITECH Act directs NIST to “test... standards and implementation specifications, as appropriate, in order to assure the efficient implementation and use of such standards and implementation specifications.” This primarily refers to implementation and use – i.e., conformance testing. There is an important distinction between conformance testing and interoperability testing. In conformance testing, a single implementation is compared to the standard to be sure that the implementation does what the standard specifies. Conformance testing is seen as a means to increase the probability that systems will operate as intended. Interoperability testing requires that several implementations be tested against each other, with the standard used as a reference to judge problems and incompatibilities, and as a guide to the functions that should be tested and the general behavior to be expected. Conformance testing, therefore, is used to verify that an implementation conforms to the established specifications of the standard. Interoperability testing may be viewed as a supplement to conformance testing, to verify that diverse implementations do indeed work together effectively to deliver the expected results. With NIST’s unique expertise in conformity assessment, and its mandate under the National Technology Transfer and Advancement Act (NTTAA - Public Law 104-113), NIST coordinates Federal, State, and local standards and conformity assessment activities with the private sector, with the goal of eliminating unnecessary duplication and complexity.

Each stage of meaningful use requirements and supporting standards is designed to advance interoperability. NIST has developed a conformance test tool that will be used for the certification testing program for the 2014 Standards and Certification Criteria that will also be an initial tool in a “test bed” that simulates exchange between a test EHR technology and a standards-compliant EHR technology. This will eventually allow for all levels of interoperability to be assessed in the electronic exchange of transition of care and referral summaries. This capability will also provide a platform for testing more comprehensive forms of interoperability between EHR technologies.

CONCLUSION

In addition to its collaborations on standards, testing, security, usability, interoperability and certification for meaningful use, NIST’s cutting-edge research, advanced measurement science, and participation in standards development are building the infrastructure for a future that offers even more promise for emerging healthcare breakthroughs in the United States. NIST initiatives are examining the best ways for humans to interact with next-generation health IT. They are significantly improving medical device interoperability and making healthcare safer in the process. NIST researchers are exploring innovative techniques by which critical patient diagnostic and treatment information can be collected and transmitted continuously in a safe and secure manner, that addresses patient privacy concerns. NIST is enabling the integration of the results of its research into interoperable EHRs and a nationwide health information network. NIST is pleased to contribute to making our exciting vision of health IT a reality.

Chairman QUAYLE. I now recognize Mr. Probst for five minutes.

**STATEMENT OF MR. MARC PROBST,
CHIEF INFORMATION OFFICER AND VICE PRESIDENT,
INFORMATION SYSTEMS, INTERMOUNTAIN HEALTHCARE**

Mr. PROBST. Chairman Quayle, distinguished Committee Members, thank you for inviting me to testify today. My name is Marc Probst. I am the Chief Information Officer at Intermountain Healthcare, a nonprofit, integrated health system in Salt Lake City, Utah. I am also an appointed member of the Health Information Technology Policy Committee.

Nationally, Intermountain is known for providing high-quality care at sustainable costs. One way we achieve this is by identifying best clinical practices and applying them consistently. Research reviewed by Dr. John Wennberg of Dartmouth showed that Intermountain is the best model in the country of how you can actually change health care for the better. Dartmouth estimated that if health care were delivered nationally in the way it is provided at Intermountain, the Nation could reduce healthcare spending for acute and chronic illnesses by more than 40 percent.

Absolutely essential to Intermountain's ability to deliver high-value, coordinated patient care is the effective use of information technology.

As requested by the Subcommittee, I will address the question, has progress been made as a result of the *HITECH Act* towards greater health information technology interoperability? My answer is yes. Progress has been made, but it is only a beginning. We must commit ourselves as a Nation to set a clear roadmap and support an exchange infrastructure and the adoption of standards that will make it easier to share health information so clinicians and patients have the information in the form and at the time they need it to make appropriate healthcare decisions.

The Australian railroad provides a useful example of the importance of standards. In Australia, railroads developed independently, one by one. While trains and tracks did get built, the railroad system was constructed with many different gauges of rail, preventing railroad cars on one set of tracks from running on others. After many years of subpar train service, expensive workarounds, and increasing costs, Australia defined a standard gauge system. The process of standardizing the gauges was expensive and disruptive, but efficiencies continue to be realized today for those decisions.

There are parallels between the Australian railroad experience and America's HIT experience. On the HIT Policy Committee, work began almost immediately, and requirements were created with the goal to increase the meaningful use of EHRs across the country. The vast majority of these meaningful use requirements deal with functions that any EHR should be able to perform and requirements for what functions or data should be shared between EHRs.

The existing HIT systems, be they vendor-developed or self-developed, also were built one by one and applied differing standards. Although very effective for each institution, heroics are required to share even basic data between them. Applying standards is really

hard. This is why we now essentially have our own Australian railroad, and fixing it will require leadership and investment.

Numerous market-driven and private efforts have recognized the value of standards, and significant funds and efforts have been applied toward defining standards. Clearly there are examples of open markets which have achieved a set of standards that have yielded tremendous benefits to the citizens of our country, such as the financial industry and ATMs. However, health care is more complex than financial transactions. The vast quantity of data and the requirements for painstaking accuracy set health care apart. Further contributing to the complexity surrounding health data is both the overlay of regulations and the absolute need for privacy of health data. I simply do not believe that the current voluntary approaches to standard definition work.

In my opinion, what is needed is a mandate to: one, define the set of information system-related standards which will be applied to health care; two, ensure accountability to appropriately develop and document these standards; three, set a time frame in which to define and document the standards measured in months, not years; and, four, establish a realistic time frame in which the HIT community must adopt a federally supported set of standards, say 10 to 15 years.

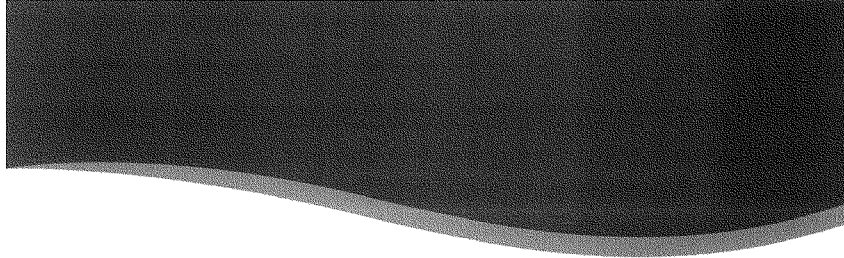
I realize this is a long time, but like the Australian railroad analogy, there is much infrastructure to be aligned, and we cannot stop providing health care or HIT services during the transition. In this way, we will achieve a nationwide health information technology infrastructure as called for in ARRA.

In conclusion, I believe that with true leadership and a commitment for long-range planning and support for transitions, appropriate standards and exchange infrastructure can be defined and implemented. If this is done, innovation in HIT will skyrocket, health-related data will be more secure, costs for technology and access to knowledge will be significantly reduced, and quality care across the country will be improved. If this is done, all ships can rise.

I look forward to working with you to achieving these goals and would be pleased to answer any questions you may have.

Chairman QUAYLE. Thank you very much.

[The prepared statement of Mr. Probst follows:]



**Is 'Meaningful Use' Delivering Meaningful Results?:
An Examination of Health Information Technology Standards and Interoperability**

Subcommittee on Technology and Innovation of the Committee on Science, Space and Technology
U.S. House of Representatives
November 14, 2012

**Marc Probst, Chief Information Officer and Vice President of Information Systems
Intermountain Healthcare**

www.intermountainhealthcare.org



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**Testimony of Marc Probst, Chief Information Officer and Vice President of Information Systems,
Intermountain Healthcare**

My name is Marc Probst, and I am the Chief Information Officer and Vice President for Information Systems at Intermountain Healthcare in Salt Lake City, Utah. Intermountain is a nonprofit integrated health system that operates 22 hospitals in Utah and Idaho; more than 185 clinics; and an insurance plan, SelectHealth, which covers approximately 500,000 lives in Utah. Intermountain's Medical Group employs approximately 900 physicians, and about 4,000 other physicians are affiliated with Intermountain. Intermountain has about 33,000 employees.

Nationally, Intermountain is known for providing high quality care at sustainable costs. One way we achieve this is by identifying best clinical practices and applying them consistently. Research reviewed by Dr. John Wennberg of Dartmouth showed that "Intermountain is the best model in the country of how you can actually change health care for the better." Dartmouth estimated that if healthcare were delivered nationally in the way it is provided at Intermountain, "the nation could reduce health care spending for acute and chronic illnesses by more than 40%." Essential to Intermountain's ability to deliver high value coordinated patient care is the effective use of health information technology.

In addition to my work as Intermountain's CIO, I am also an appointed member of the Health Information Technology Policy Committee (HITPC), created by the American Recovery and Reinvestment Act to advise the National Coordinator for Health Information Technology, currently Dr. Farzad Mostashari, with respect to the implementation of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information. I am proud to be a member of this hardworking and dedicated advisory committee. Last week, I attended the 42nd in-person meeting of the HITPC here in Washington.

I want to thank Chairman Quayle and other members of the Subcommittee for holding this hearing and inviting me to testify. With respect to the first question posed in your letter, which asks what progress has been made as a result of the HITECH Act towards greater health information technology (HIT) interoperability, my answer is yes, progress has been made, but this progress must be thoughtfully accelerated. We must leverage all of the expertise in the federal government to accelerate the adoption of standards that will make it easier to share health information so clinicians and patients have the information in the form and time they need it to make appropriate healthcare decisions. Presently, we lack a shared infrastructure that will make this interoperability possible.

A report issued recently by the Institute of Medicine (IOM) entitled *Best Care at Lower Cost* highlights this situation and calls for a dramatic transformation in healthcare delivery, saying "America's health

care system has become far too complex and costly to continue business as usual.” The IOM’s first recommendation (“The Digital Infrastructure”) focuses on the importance of health information systems and highlights a crucial aspect of their development that is too often overlooked – the issue of interoperability. Will the individual systems that are created be able to work together efficiently?

It’s an enormously important issue for healthcare broadly, and it will determine how effective those systems can be on a national level. At present, healthcare providers across the country are creating or enhancing their health information systems. In some cases, like ours at Intermountain Healthcare, those systems have a long history; we began instituting electronic medical records 40 years ago. Others are early in the journey. But all are being developed essentially for their own internal needs. Interoperability is too low on everyone’s priority list and requires nationwide planning and coordination.

Five healthcare providers who have been in the forefront of using electronic medical records have been collaborating on the creation of a Care Connectivity Consortium to pioneer the effective connectivity of electronic patient information across their systems. Those five are Intermountain Healthcare (based in Utah), Geisinger Health System (Pennsylvania), Group Health Cooperative (Washington), Kaiser Permanente (California), and Mayo Clinic (Minnesota). But even this ground-breaking effort will result in a multi-provider network, not a national one.

While we are already learning a great deal from the Care Connectivity Consortium and that learning can be broadly shared, it’s a **national network** that we ultimately need. Only a truly national network will allow the efficient transmission of secure patient information to best serve patients in multiple ways. It will serve them when they move (changing doctors or providers, traveling temporarily or relocating permanently); it will enable best practices to be shared across the country; and it will allow the broadest research and learning to advance healthcare delivery. It will truly allow, “all ships to rise.”

The IOM report recommends, in part, the following: “The National Coordinator for Health Information Technology, digital technology developers, and standards organizations should ensure that the digital infrastructure captures and delivers the core data elements and interoperability needed to support better care, system improvement, and the generation of new knowledge.” Here standard-setting is the key, and a good analogy for the problem can be seen in the evolution of the railroad in Australia.

In Australia, railroads developed independently, one by one: some for moving natural resources like coal; others for carrying freight, and still others for transporting people. While trains and tracks did get built, the railroad system was not constructed with common standards. Many different gauges of railroad evolved, preventing railroad cars on one set of tracks from running on others.

To overcome this obvious challenge, the railroads built new stations and invented new contraptions to move cargo from one set of train cars to another. They were clever indeed; excellent engineering, for sure; and I’ve included some pictures of the “work-arounds” in my testimony. But to be sure, each contraption and transfer station slowed the transportation system down, added risk of product loss, and increased the cost of shipping by rail. After many years of subpar train service and increasing costs,

Australia defined a standard gauge for its train system. It was likely a huge expense to make this change, but the efficiencies gained continue to be realized today.

The parallel is obvious for America's health information technology. We need national standards to ensure, as the IOM recommends, "that the digital infrastructure captures and delivers the core data elements and interoperability needed." The federal government has made a major investment in electronic medical records, having committed \$20 billion from the stimulus bill to it. We must now ensure that, as the capacities of many individual providers grow, they evolve into an efficient and effective national network.

While I am not representing it here, as noted earlier, I serve as a member of the Health Information Technology Policy Committee (HITPC). The HITPC is a hard-working, dedicated, experienced, and intelligent volunteer group. I have been honored to serve on this committee with such fine individuals. The first task of the HITPC was to define "Meaningful Use" and the requirements for certification of electronic health records (EHRs). Work began almost immediately, and the requirements were created with the goal to increase the Meaningful Use of EHR across the country. The majority of these requirements deal with functions that an EHR should be able to perform and requirements for what functions or data should be shared between EHRs. It is time now, however, for the HITPC to focus more on the longer-term plan and activities outside of Meaningful Use that are needed to fulfill our mandate provided in ARRA to "make recommendations to the National Coordinator relating to the implementation of a nationwide health information technology infrastructure."

It should be noted that the effort to achieve Meaningful Use is hard. It is difficult to develop and adopt electronic health records that do all that we want them to do, are easy enough to use that clinicians will use them, and that maintain and improve the patient privacy that is so important.

Indeed, despite Intermountain's long history of success using electronic health records and our sophisticated and largely self-developed information systems, Intermountain has not yet received Meaningful Use payments. Intermountain is on track, however, to receive our first Meaningful Use payments next year, and we have a plan in place to earn the maximum Meaningful Use payments achievable. More importantly, frankly, our plan will allow us to avert the penalties for failing to achieve Meaningful Use.

I share this Intermountain example to highlight two important facts: Achieving the requirements of the Meaningful Use program is not easy, and the Meaningful Use program has very real penalties attached to it. Providers and specifically CIOs across the country are increasingly feeling the pressures which Meaningful Use is creating. Coupled with programs such as Accountable Care Organizations, ICD-10 requirements and the need to ensure privacy and security of newly created petabytes of data, the lack of comprehensive standards is exacerbating the challenges of HIT across the country. What may seem like small steps required by Meaningful Use, are actually big efforts for provider organizations and if not done correctly will not only fail to achieve greater efficiencies for healthcare, but could ultimately create less secure and less safe healthcare delivery. The stages for Meaningful Use started fast and continue to be rolled out at a very quick pace. The work efforts which Meaningful Use defines in many aspects are

cumulative and we do need to be careful that future stages such as Meaningful Use Stage 3 are appropriately timed to allow the majority of our health system to do all that is being asked of it through these transformative times. Because of the difficulty and complexity of the program, I am concerned that the Request for Comment on Stage 3 is expected to be released this month while so many hospitals and physicians are still trying to achieve Stage 1, and the Stage 2 final rule was only officially published in September. I also worry about those providers who have fewer technical resources than Intermountain, and started from a lower level IT adoption – who will be left behind? With respect to the Subcommittee's second question about lessons learned from Stage 1 informing Stage 2 and suggestions for Stage 3, it is structurally impossible to fully benefit from lessons learned in earlier stages when the Meaningful Use timeline is so compressed. Further, everyone could learn from a systematic, independent evaluation of experience to date that looks at the impact on subgroups, such as rural and frontier providers

The goals of ARRA and Meaningful Use of Health Information Technology (HIT) encourage acceleration of the adoption of Electronic Health Record technology in our country. Meaningful Use and certification requirements have been successful in achieving these goals. The HITPC and ONC have focused on leveraging available technologies to significantly advance the gathering of digital data and incrementally introduce standards to support interoperability. While continuing to support the current momentum created by Meaningful Use, we must also focus on development of a long-range plan and architecture for a national healthcare information technology infrastructure and develop the path to comprehensive meaningful standards that can facilitate national interoperability, which will improve healthcare delivery quality, and significantly lower healthcare costs.

At one HITPC meeting not too long ago I stated there were probably 5-10 actions, which could be led by the HITPC and others with expertise in the federal government, that if done correctly could dramatically improve healthcare in the United States, achieving the goals of lower cost, increased access, and higher quality. These actions (see the seven enumerated items below) remain valid but require the federal government to define, set, and enforce a core set of standards (recall the rail gauge in Australia). Many of these standards already exist and could be selected quickly. Others may require a short time to finalize. Clearly, we have seen that volunteer processes can take decades to define and select standards – this is much of the problem and the basis for why I believe federal leadership is required for success.

I believe with true leadership and a commitment for long-range planning and support for transitions, appropriate standards and exchange infrastructure can be defined and implemented. If this is done, innovation in HIT will skyrocket, costs for interoperability and access to knowledge will be significantly reduced, and quality care across the country will improve. So in response to Question 3 about the effectiveness of HHS and ONC in establishing long-term goals and benchmarks for HIT adoption, interoperability, and provision of care, important work has been done, but there is much more to do.

As for Question 4, which asks for recommendations for federal policymakers, the areas I believe should be focused on, where standards should be defined and implemented include (and this list may not be exhaustive):

1. Standard terminologies.
2. Detailed clinical models.
3. Standard clinical data query language based on the models and terminology.
4. Standards for security (standard roles and standards for naming of types of protected data).
5. Standard Application Program Interfaces.
6. Standards for expressing clinical decision support algorithms.
7. Patient identifiers.

With true leadership and funding, based on the excellent work that has been performed already, I believe these standards could be defined, developed, and mechanisms for management put in place. Organizations such as HL7 (Health Level 7) have laid much of the groundwork. Once defined and developed, with mechanisms for support and management in place, realistic but aggressive dates should be set for adoption. Successfully achieving that transition will require significant advanced planning, phasing and educational support of health care providers as they change systems and workflows to adopt the new standards. My suggestion would be 10 years to give vendors, health systems, and other developers the time to change technologies to meet these standards. "Haste" is not wise in the health information technology arena.

Australia had a vision, one that would cost money and take time (and likely was more disruptive than helpful during the transition), but logic assured that by making the needed changes, railways in the country would be efficient, save money, and improve service. The United States can have a similar vision that will be disruptive and costly but will lay the foundation for healthcare quality improvements and cost savings for generations to come.

I believe that it would be appropriate for the Health Information Technology Policy Committee and the Health Information Technology Standards Committee to be charged with the mission to focus on the development and adoption of comprehensive standards across the industry – standards that would improve patient care and allow interoperability between systems and providers. This would then allow the efforts to achieve Meaningful Use to reach their full potential.

Information and information systems in healthcare have tremendous capabilities to improve patient care. Moving from paper-based to digital systems, as encouraged through the efforts toward Meaningful Use, is a crucial step in facilitating the sharing of knowledge, but long-term planning and ongoing support for widespread use of adequate standards are needed to allow for the ubiquitous sharing of data and, ultimately, enhanced knowledge. The potential is enormous, if we set the standards that will provide common tracks on which this railroad of information will run.

Thank you again for the opportunity to participate in today's hearing. I look forward to working with the Subcommittee and all who are committed to the successful adoption of national HIT standards and the realization of a shared infrastructure that will enable national interoperability.

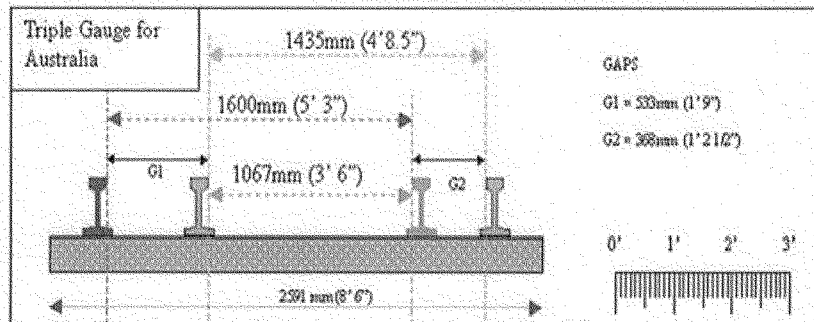
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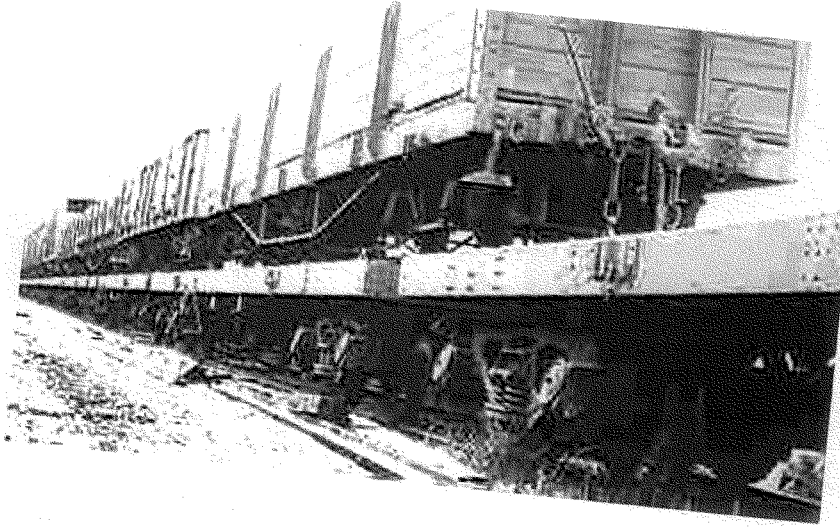
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Rail Gauge in Australia



Variations in gauge standards have been a problem for over a hundred years.





Chairman QUAYLE. I now recognize Ms. Little for her testimony.

**STATEMENT OF MS. REBECCA LITTLE, SENIOR VICE
PRESIDENT, MEDICITY**

Ms. LITTLE. Good morning, Chairman Quayle and Members of the Subcommittee. Thank you for inviting me to participate in today's discussion. My name is Rebecca Little, and I am here on behalf of Medicity, a health information exchange, commonly referred to as an HIE technology company, headquartered in Salt Lake City, Utah. Medicity is a wholly owned subsidiary of Aetna.

The software Medicity provides facilitates health information exchange. What that means is we supply the plumbing—the intelligent plumbing rather—that allows electronic medical records, electronic health records, lab services, pharmacies, hospitals, doctors' offices, and other providers to connect to one another.

To continue with the metaphor, it doesn't matter what electronic medical record or fixture a provider uses, whether a provider is using health information technology for the first time or has been using it for years. We can accommodate their needs at any state of readiness or sophistication. The Medicity HIE plumbing can connect any type of fixture to another so that health information and patient data can be safely and securely transmitted.

This matters to you as policy makers because Medicare and Medicaid costs are unnecessarily greater when the lack of information leads to bad outcomes or repetitive testing and procedures. The results can translate directly into lower healthcare costs. Improved use of diabetes medicine can cut risk of hospitalization by half. Diabetics who take their medicine less than 80 percent of the time were 2-1/2 times more likely to be hospitalized for a diabetes or cardiovascular-related condition in the next year. In total, poor adherence results in 33 to 69 percent of medication-related hospitalizations at a cost of roughly \$100 billion per year. These are costs that are absorbed by taxpayers in Medicare and Medicaid and cannot be addressed effectively without robust patient information. This is why interoperability across providers is so important.

Our plumbing is truly interoperable, allowing for the safe exchange of patient information across public and private HIEs, across multiple provider systems, between small and large physician practices, and across and within hospital systems.

True HIE interoperability, the seamless flow of patient data in a secure framework, is the necessary ingredient to transforming patient care and creating a more effective, efficient, and ultimately less costly healthcare system, because once the electronic connections are established across providers and networks, and the patient data begins to flow, other health information technologies can be put to work to turn that data into useful information for physicians and patients, saving lives, reducing medical errors, and substantially lowering costs.

These successes are happening today. A recent Health Affairs article demonstrated the success of a Medicare Advantage pilot in Maine where the provider collaboration relied on shared patient data in conjunction with patient coordination. The result of using patient data to improve patient outcomes and lower costs could not be clearer.

The result of the study of the population had a 50 percent fewer hospital days, 45 percent fewer admissions, and the corresponding costs were 16–1/2 to 33 percent lower than costs for patients not included in this pilot, but these types of successes could not be achieved without robust standards for interoperability and data sharing.

Even though health information exchange is a requirement for demonstrating meaningful use under the *HITECH Act*, health information exchange is really about preparing providers and healthcare organizations for the future of health care as delivery models and reimbursement constructs continuously evolve. This exchange of health information across providers, hospital networks, between different HIEs holds the power to improve care and improve efficiency by fostering care collaboration and lowering administrative costs. We are already seeing encouraging outcomes of how patient data can be turned into actionable information for physicians to use—to improve clinical outcomes for patients.

The rest of my written testimony provides examples around how Medicity and Aetna are meeting providers at their stage of readiness to employ cost-effective technology solutions that will drive towards efficient, low-cost, high-quality patient care.

Thank you again for the opportunity to testify in front of you.

Chairman QUAYLE. Thank you very much.

[The prepared statement of Ms. Little follows:]

Testimony by Rebecca Little, Senior Vice President, Medicity

Subcommittee on Technology and Innovation
United States House of Representatives

*Is 'Meaningful Use' Delivering Meaningful Results? An Examination of Health
Information Technology Standards and Interoperability.*

November 14, 2012

INTRODUCTION

Good morning, and thank you for inviting me to participate in today's discussion. My name is Rebecca Little and I am here on behalf of Medicity, a Health Information Exchange—commonly referred to as an HIE—technology company headquartered in Salt Lake City, Utah. Medicity is a wholly owned subsidiary of Aetna.

We are an HIE. And what that means is we supply the "plumbing," the intelligent plumbing, rather, that allows electronic medical records, electronic health records, lab services, pharmacies, hospitals, doctors' offices, and other providers to connect with one another.

To continue with the metaphor, it doesn't matter what Electronic Medical Record (EMR)—or fixture—a provider uses. Whether a provider is using Health Information Technology for the first time, or has been using it for years, we can accommodate their needs at any state of readiness or sophistication. The Medicity HIE plumbing can connect any type of fixture to another so that health information and patient data can be safely and securely transmitted.

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¹ D.T. Lau, "Oral Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes," *Diabetes Care*, 27 (2004): 9, 2149-2153.

² Osterberg L, Blaschke T. Adherence to medication. *N Engl J Med*. August 4, 2005;353(5):487–497.

health information technologies can be put to work to turn that data into useful information for physicians and patients--savings lives, reducing medical errors, and substantially lowering costs³.

These successes are happening today. A recent Health Affairs article demonstrated the success of a Medicare Advantage pilot in Maine, where the provider collaboration relied on shared patient data in conjunction with patient coordination. The result of using patient data to improve patient outcomes and lower costs could not be more clear: the patient population had 50 percent fewer hospital days, 45 percent fewer admissions. And the corresponding costs were 16.5 percent to 33 percent lower than costs for patients not included in the pilot⁴.

But these types of successes could not be achieved without robust standards for interoperability and data sharing. Even though health information exchange is a requirement for demonstrating "meaningful use" under the HITECH Act, health information exchange is really about preparing providers and health care organizations for the future of healthcare as delivery models and reimbursement constructs continuously evolve.

This exchange of healthcare information—across providers, hospital networks, and between different HIEs—holds the power to improve patient care and improve efficiencies by fostering care collaboration and lowering administrative costs. **We're already seeing encouraging outcomes of** how patient data can be turned into actionable information for physicians to use to improve clinical outcomes for patients.

The rest of my written testimony provides examples of how Medicity and Aetna are meeting providers at their state of readiness to employ low-cost technology solutions that will drive toward efficient, low cost, high-quality patient care.

HOW MEDICITY WORKS

Medicity's technology provides the foundational technology and capabilities to securely exchange patient health information in a vendor-neutral manner specifically we do this regardless of which electronic medical record a provider may be using and regardless of where the provider organization is along the technology adoption curve.

For example, Medicity currently connects healthcare providers using more than 150 unique clinical technology solutions. This gives doctors and other authorized and authenticated users involved in the patient care process timely access to current, accurate and actionable information. With current information, providers can make better decisions that often translate into better outcomes, higher quality and lower costs.

In 2007, the Delaware Health Information Network (DHIN) deployed the Medicity solution to successfully connect the major health systems and Labcorp to physicians (including the federally qualified health centers) across the state. Today, 100% of the hospitals in Delaware, all commercial labs are connected, and many of the free-standing diagnostic imaging centers; 10 Million results and reports are delivered to physicians annually where 26% of those clinical results **are delivered electronically and directly into the practice's EHR. There are 1.5 Million** unique patients in the DHIN system. The Delaware Health Network also collaborates with public health for electronic lab reporting, reporting of immunizations, etc.

³ Javitt, et al. "Using Claims Data-based, Sentinel System to Improve Compliance with Clinical Guidelines: Results of a Randomized Prospective Study," American Journal of Managed Care Feb.2005: 93-102

⁴ Claffey, et al. "Payer-Provided Collaboration in Accountable Care Reduced Use and Improve Quality in Maine Medicare Advantage Plan," Health Affairs Sept. 2012, Vol 31.

In an independent evaluation study conducted in 2011, a variety of comprehensive analyses were completed and among the providers interviewed, there was consensus that data provided in the DHIN will have an impact on care delivery including reduction in duplicate tests⁵. This was supported with an analysis of test results for tests that are often high cost and high volume. The rate of test results per unique patient sent through the DHIN (as determined by the Community Master Patient Index), in June 2011 as compared to June of 2009 was 30 percent lower for radiology exams and 33 percent lower for lab results.

Using the DHIN structure, savings of over two million dollars has been realized by data senders with providers who utilize the DHIN as the primary method for receiving results based on the average cost to send results using traditional methods of fax and mail. Additional savings of one million dollars could have been realized for the same period if all DHIN member providers were committed to use the DHIN as their primary source of results reporting

THE VALUE OF INTEROPERABILITY

Through successfully integrated/interoperable Health Information Exchanges (HIEs), providers can improve care and effectively track and manage the health care of their entire patient population across a spectrum of care providers.

Interoperability is critically important, especially given the highly fragmented nature of our health delivery system. For doctors and nurses, interoperability produces information at the point of care to track cost and quality across different healthcare providers. This is important in care models such as ACOs and medical homes, where information sharing across team members is critical to holding down costs.

The "seed money" provided through the ONC State Health Information (State HIE) Exchange Cooperative Agreement Program has helped many states take positive steps toward advancing the exchange of health information among providers and hospitals. We are encouraged by some of the early successes of the program, and yet we also recognize the challenges that remain.

Michigan Health Connect (MHC) is a Regional Health Information Organization (RHIO) that promotes and manages Health Information Exchange (HIE) services in the State of Michigan. One of the issues Michigan Health Connect (MHC) hoped to tackle through HIE was the referral process, which created a significant workflow problem for physicians, and involved filling out and faxing forms, as well as numerous phone calls between providers.

Within 120 days, MHC rolled out an electronic Referrals application (which is by the way, **compliant with the ONC's Direct Project**) to 100 practices — including 21 specialties — and is adding practices to the eReferral network at a rate of 9 practices per week. These practices are now able to replace the multiple phone calls and fax exchanges with secure, electronic care team networks that enable eReferrals, increase collaboration, and present a coherent picture of a **patient's health to all members** of the care team.

For patients, especially people with chronic conditions such as diabetes and / or high blood pressure, many often receive care from many different providers. There are currently about 24 million adults and children with diabetes, and that number is expected to increase dramatically over the next ten years. One of every five health dollars are spent on these patients.

⁵ Report was prepared for: Agency for Healthcare Research and Quality U.S. Department of Health and Human Services; Prepared by: Maestro Strategies, LLC Roswell, GA 30076

For these individuals and their families, it is especially important that care providers are able to know whether the patient is adherent to their care plan because diabetics are at greater risk of hospitalization, amputation and lower quality of life when they are not. This may mean ensuring prescriptions are filled and taken and wellness visits are scheduled and kept.

This matters to you, as policy makers, because Medicare and Medicaid costs are unnecessarily greater when the lack of information leads to bad outcomes or repetitive testing and procedures. The results translate directly into lower health costs. Improved use of diabetes medicines can cut risk of hospitalization by half; diabetics who take their medicines less than 80 percent of the time were 2.5 times more likely to be hospitalized for a diabetes or cardiovascular-related condition in the next year⁶. In total, poor adherence results in 33 to 69% of medication-related hospital admissions at a cost of roughly \$100 billion per year⁷. These are costs that are absorbed by taxpayers in Medicare and Medicaid, and they cannot be addressed effectively without robust patient information. This is why interoperability across providers is so important.

Fortunately, this is not a today problem with a tomorrow solution. Medicity supplies an army of doctors and other individuals involved in the care process with actionable information on diabetics today. But we could do much more if the Meaningful Use program were made more meaningful. This means solid, strong standards for interoperability sooner rather than later and a clearly defined role for HIEs in the program. We also believe that investing in new standards and protocols to replace existing, effective, and widely utilized protocols is not an effective use of tax dollars. Finally, we should include meaningful measurement in the technology, process and outcomes, so we are constantly improving, increasing standards, and providing patients with better health outcomes.

CONCLUSION

We appreciate the Subcommittee's efforts to reinforce the importance of health information exchange and interoperable exchange of health information, and I look forward to answering any questions you may have.

Thank you.

⁶ D.T. Lau, "Oral Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes," *Diabetes Care*, 27 (2004): 9, 2149-2153.

⁷ Osterberg L, Blaschke T. Adherence to medication. *N Engl J Med*. August 4, 2005;353(5):487-497.

Chairman QUAYLE. I now recognize Dr. Fields to present her testimony.

**STATEMENT OF DR. WILLA FIELDS,
DNSC, RN, FHIMSS, PROFESSOR,
SCHOOL OF NURSING, SAN DIEGO STATE UNIVERSITY**

Dr. FIELDS. Chairman Quayle, Members of the Subcommittee, thank you for the opportunity—whoops, excuse me. I knew that.

Chairman Quayle, Members of the Subcommittee, thank you for the opportunity to testify before you today. I am Willa Fields, a professor in the School of Nursing at San Diego State University in San Diego, California. Additionally, I was honored to be selected as the Chair of the Board of Directors of HIMSS, the Healthcare Information and Management Systems Society, as of July 1st this year.

I am honored to have the opportunity to provide you the perspective of HIMSS as well as my own on the status of health information technology adoption, some of the challenges we still face as a Nation, and recommendations on selected issues requiring Congressional attention in the coming years.

HIMSS is a cause-based, not-for-profit association exclusively focused on providing global leadership for the optimal use of health information technology for the betterment of health care. Founded 52 years ago, HIMSS is headquartered in Chicago, with additional offices in the United States, Europe, and Asia. We represent 50,000 individual members, of which more than 2/3 work in provider, government, and not-for-profit organizations. We also have 570 corporate members and more than 225 not-for-profit organizations that share our mission.

As you recognize, health IT is an essential foundational element of any meaningful transformation of the Nation's healthcare delivery system. Robust nationwide adoption of health IT, including electronic health records, health information exchange capabilities, and mobile health devices, all of these are essential to achieving safe, effective care delivery, payment reforms, and engaging patients in their care. Health IT also enables timely, accurate, and appropriate collection and dissemination of patient information in a private and secure manner.

While there is still much work to be done, adoption of interoperable health IT systems continues to expand thanks to the incentives provided by the *HITECH Act*. We are only two years into the program, and there has been a great shift toward electronic health records throughout the Nation.

HIMSS Analytics has performed a cross-reference of hospitals achieving Stage 1 meaningful use against their scores on the Electronic Medical Records Adoption Model, or EMRAM, which is a HIMSS analytic tool to track U.S. civilian hospitals on their progress toward a mature, paperless, electronic environment. The results demonstrate that hospitals are rapidly evolving to higher stages on the EMRAM scale. Such results are clear indicators that government incentives are achieving their mission at accelerating the widespread implementation and meaningful use of certified electronic health records in the United States. More importantly, the top-ranked EMRAM Stage six and seven hospitals reflect the

rapidly escalating move of United States hospitals toward interoperability, which will lead to information exchange. The EMRAM system and its findings are explained further in my written statement.

The evidence, including data from the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, and HIMSS Analytics suggests that as a result of the *HITECH Act* and the substantial investment the public and private sectors have made, a groundswell has been achieved in the adoption of health IT and specifically electronic health records.

We believe the time is very near when informed patients will use adoption and meaningful use of health IT as a key factor in selecting a caregiver and a care setting because of the opportunities these systems provide for access to information. Without the HITECH-authorized meaningful use of Electronic Health Record Incentive Program, the Nation would not be realizing adoption and implementation of these systems, which includes the rapidly expanding ability to exchange information privately and securely across systems and regions.

HIMSS strongly encourages the continued bipartisan support of Congress for the earliest nationwide adoption and implementation of electronic health records and the Meaningful Use Program.

In conclusion, in order to improve the quality of health care for all Americans, while also controlling costs, HIMSS recommends seven strategies for Congress: One, continue your strong bipartisan support for the adoption and meaningful use of electronic health records; two, continue to support and sustain the Meaningful Use Electronic Health Records Incentive Program; third, direct the Administration to initiate collaboration with the private sector on an appropriate study of patient data matching and the adoption of a nationwide patient data-matching strategy; fourth, support harmonization of Federal and State privacy laws and regulations to encourage the exchange of health information across systems, payers, and vendors; continue to support programs and services to educate providers and provider organizations on how health IT can and should be used to engage patients in their health care; continue to support and sponsor pilot programs addressing the collection, analysis, and management of clinical data and quality for reporting purposes; and, seven, preclude any additional delay in the nationwide implementation of ICD-10, the International Classification of Diseases that is set to be implemented October 1, 2014.

Let me reiterate, electronic health record adoption and implementation has passed the tipping point in America. The evidence, including HIMSS' own analysis, indicates continued process—I am sorry, continued progress on the implementation of health-information technologies. My written statement citing evidence of these upward trends in health IT adoption and discussing the rationale for these recommendations in more depth—in more depth has been provided for the record.

Clearly the Nation would not have made the significant progress toward electronic health record adoption and health information exchange that it has without the Meaningful Use Program authorized by the *HITECH Act*. Perhaps in many years health care might have caught up with other industries in the adoption in informa-

tion technology, but in the meantime quality of care and access to care have continued—would have continued to suffer, and the Nation would have continued to pay much more for health care than necessary.

There is more work to be done, especially in interoperability, health information exchange, privacy, and security. HIMSS recommends that in order to improve the quality of your constituents' health care while also reducing its costs, Congress should continue its strong bipartisan support for health information technology. I and my 50,000 professional colleagues stand ready to work with Congress and the Administration.

Thank you for the opportunity to speak with you today, and I would be happy to answer your questions.

Chairman QUAYLE. Thank you very much.

[The prepared statement of Dr. Fields follows:]



**Statement of
Willa Fields, DNSc, RN, FHIMSS
Chair of the Board of Directors
Healthcare Information and Management Systems Society (HIMSS)
Professor, School of Nursing, San Diego State University
before the
Technology and Innovation Subcommittee of the
Committee on Science, Space, and Technology
U.S. House of Representatives**

November 14, 2012

Introduction

Chairman Quayle, Ranking Member Edwards, members of the Subcommittee, thank you for the opportunity to testify before the Subcommittee today. I am Willa Fields and I am a Professor in the School of Nursing at San Diego State University in San Diego, California. Additionally, I was honored to be selected the Chair of the Board of Directors of the Healthcare Information and Management Systems Society (HIMSS) as of July 1st this year and this is my first opportunity to testify before Congress.

I am honored to have this opportunity to provide you the perspective of HIMSS, as well as my own, on the status of health information technology adoption in this country, including some of the challenges we still face as a Nation and recommendations on selected issues requiring Congressional support in the coming few years.

I have worked in the fields of clinical nursing, education, research, performance improvement, management, and information systems for more than 40 years. At San Diego State University, I teach Informatics, Personnel Management, and Quality Improvement in the graduate nursing program. My areas of research interest include exploration of practices that improve patient safety in the provision of patient care. Some of my specific investigations have included the effects of computerized

physician order entry on medication safety events and nurses' work, and attitudes, knowledge/skills, practice, and barriers to evidence-based practice (EBP).

From 2000 to 2006 I was the Vice President of Patient Care Systems in the Information Systems Department at Sharp HealthCare in San Diego, where I had responsibility for the patient care computer systems, including implementation of new core clinical systems that included physician order entry. I have published widely in the professional literature. I received my Doctorate in Nursing Science from the University of San Diego and a Master's of Science in Nursing from San Diego State University.

HIMSS and its Mission

HIMSS is a cause-based, not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare. Founded 52 years ago, HIMSS and its related organizations are headquartered in Chicago with additional offices in the United States, Europe and Asia. HIMSS represents nearly 50,000 individual members, of which more than two thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS also includes over 570 corporate members and more than 225 not-for-profit partner organizations that share our mission of transforming healthcare through the effective use of information technology and management systems. HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, research initiatives, and media vehicles designed to promote information and management systems' contributions to improving the quality, safety, access, and cost-effectiveness of patient care.

HIMSS is the primary organizer of National Health IT Week (NHIT), which this year was September 10-14, 2012. National Health IT Week is a collaborative forum where public and private healthcare constituents work in partnership to educate industry and policy stakeholders on the value of health IT for the U.S. healthcare system. National Health IT Week raises national awareness that comprehensive healthcare

transformation is not possible without system-wide adoption of health information technology to improve the quality of healthcare delivery, increase patient safety, decrease medical errors, and strengthen the interaction between patients and healthcare providers. This year we were joined by almost 260 partnering, government, corporate, and non-profit organizations in organizing and acknowledging NHIT Week. We were very gratified and appreciative that the President issued a Presidential Message in support of National Health IT Week, and that the U.S. Senate and the National Conference of State Legislatures passed resolutions supporting National Health IT Week 2012.

HIMSS adheres to four imperatives for the best use of information technology and management systems. These principles direct all of HIMSS' worldwide effort and leadership for the optimal use of information technology and management systems for the betterment of healthcare. Information technology and management systems must work toward:

- Improved Quality;
- Improved Safety;
- Increased Cost-Effectiveness; and,
- Increased Access to Care.

Status of Health Information Adoption in America

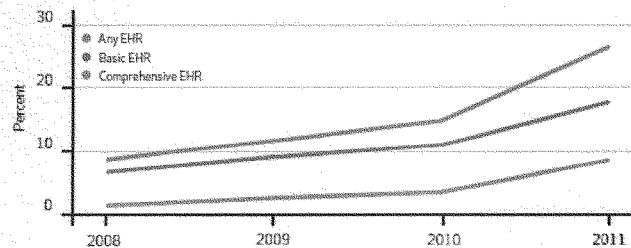
Although as a Nation we still have a ways to go, electronic health records adoption has passed the tipping point in America. The evidence suggests that as a result of the HITECH Act (Health Information Technology for Economic and Clinical Health Act - included in the American Recovery and Reinvestment Act of 2009) and the substantial investment the public and private sectors have made in health information technology, a groundswell has been achieved in the adoption of Health IT/EHRs. I believe the time is very near when providers coming out of their medical training will not want to work in an environment without a state-of-the-art electronic health records system, including provider order entry, clinical decision support tools, and

interoperable information exchange capabilities across the country. More importantly, the time is rapidly approaching when informed patients, fully engaged in their own care and with access to discriminating information on the quality of care achieved by available providers, will include the level of health information technology as a key discriminating factor when selecting a provider and hospital.

Status of EHR Adoption in America

The adoption rate of EHR systems has been increasing steadily. The percentage of physicians and hospitals that have adopted a basic EHR system, which includes some meaningful use requirements but not all, has increased from 11.5 percent in 2010 to 18 percent in 2011. Although comprehensive EHR adoption in hospitals has progressed more slowly, it is also trending upwards, increasing from 3.6 percent in 2010 to 8.7 percent in 2011:

Changes in the Adoption of Basic and Comprehensive EHR Systems Among US Hospitals, 2008-11

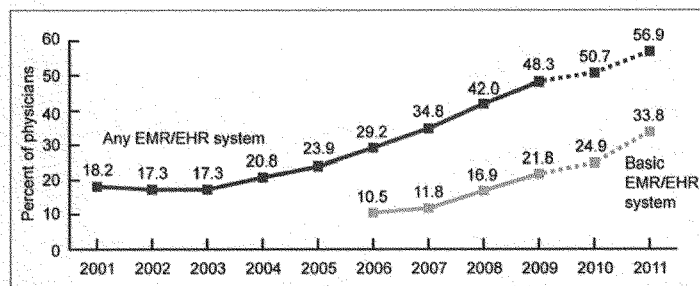


SOURCE: Authors' calculations of data from the American Hospital Association annual survey information technology supplement. **NOTE:** All analyses were statistically weighted for potential nonresponse bias.

Office-based physicians are also adopting electronic health records systems at increasing rates. In 2011, the Centers for Medicare and Medicaid Services (CMS)

released National Ambulatory Medical Care Survey data that reveals the percentage of physicians with basic EHR systems:

Percentage of Office-based Physicians with EMR/EHR Systems: United States 2001-2009 and Preliminary 2010-2011



NOTES: EMR/EHR is electronic medical record/electronic health record. "Any EMR/EHR system" is a medical or health record system that is all or partially electronic (excluding systems solely for billing). Data for 2001-2007 are from the in-person National Ambulatory Medical Care Survey (NAMCS). Data for 2008-2009 are from combined files (in-person NAMCS and mail survey). Data for 2010-2011 are preliminary estimates (dashed lines) based on the mail survey only. Estimates through 2009 include additional physicians sampled from community health centers. Estimates of basic systems prior to 2006 could not be computed because some items were not collected in the survey. Data include nonfederal, office-based physicians and exclude radiologists, anesthesiologists, and pathologists.

SOURCE: CDC/NCHS, National Ambulatory Medical Care Survey.

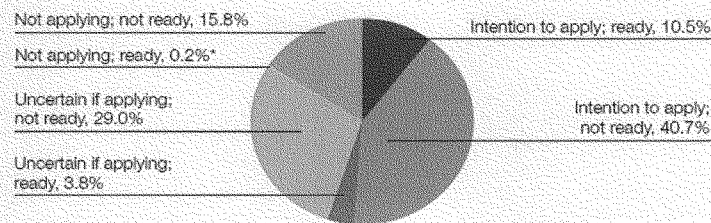
Medicare and Medicaid EHR Incentive Programs Registration and Payments to Date

The Centers of Medicare and Medicaid Services (CMS) opened registration for the EHR Incentive Programs in January 2011 and began distributing Medicare incentive payments in May 2011. Since then, the number of participants has been climbing at an increasing rate. Through September 2012, more than 307,000 Eligible Professionals and Eligible Hospitals had registered in the Medicaid and Medicare incentive programs. Over 158,000 of these providers and hospitals have met meaningful use requirements and have already received payments, totaling nearly \$4 billion from the Medicare EHR Incentive Program and \$3.5 billion from the Medicaid EHR Incentive Program. These numbers already exceed expectations for 2012.

Providers Planning to Attest to Meaningful Use

The majority of physicians and hospitals are preparing to apply to the incentive programs. To achieve meaningful use, they must have electronic health records systems that meet Meaningful Use core objectives (ten for physicians, twelve for hospitals). While only 10.5 percent of physicians are ready to implement the core objectives, 40.7 percent plan to apply:

Physicians' Readiness For Ten Stage 1 Core Objectives, By Intention to Apply, 2011



Source: Hsiao C, Decker S, Hing E, Sisk J. How ready are physicians for meaningful use? *Health Aff (Millwood)*. 2012;31(5). [Epub ahead of print]. archived and available at www.healthaffairs.org.

Notes: * Figure does not meet standards of reliability or precision. N=3,996. Excludes missing information on intention to apply, readiness, or ownership. Readiness for stage 1 core meaningful use objectives was defined by having the following 10 capabilities: recording patient demographic information; recording patient problem list; recording medications; recording patient allergies; ordering prescriptions; sending prescriptions electronically to the pharmacy; providing drug-drug and drug-allergy warnings; providing patients with clinical summaries for each visit; capability to exchange patient clinical summaries electronically with other providers; and providing reminders for guideline-based interventions or screening tests.

Hospitals are also approaching widespread implementation of Meaningful Use criteria. Between 2010 and 2011, the percentage of hospitals ready to apply increased from 4.4 percent to 18.4 percent. While 18.4 percent have achieved all twelve core objectives, an additional 33.6 percent have implemented between nine and eleven objectives and are nearing Meaningful Use classification.

HIMSS' Own Electronic Medical Record Adoption Model (EMRAM) Scores

HIMSS Analytics conducts an annual study on available information systems data and assigns Electronic Medical Record Adoption Model (EMRAM) scores to hospitals according to their stage of EHR implementation. The scores employ seven stages, delineating more specific categories of system implementation than the basic and comprehensive divisions used elsewhere. Stage 0 is an all paper environment while Stage 7 is a paperless environment with interoperable information exchange capability. Since HIMSS Analytics introduced the EMRAM model in 2006, 1.8 percent of U.S. hospitals have achieved Stage 7 on the model. Similar to other previously identified trend data the adoption of EHR systems, HIMSS EMRAM data also indicates clear upwards adoption trends, at increasing rates. The number of hospitals achieving a minimum of Stage 5 or higher on the EMRAM model has increased from 8.7 percent at the end of 2010 to 21.1 percent as of September 2012. This increase at Stage 5 and above represents a huge improvement in patient safety.

The stages, their descriptions, and quarterly percentages are listed in the table below:

US EMR Adoption Model™			
Stage	Cumulative Capabilities	2011 Q2	2012 Q3
Stage 7	Complete EMR: CCD transactions to share data; Data warehousing; Data continuity with ED; ambulatory OP	1.1%	1.8%
Stage 6	Physician documentation (structured templates); full CDSS (variance & compliance); full R-PACS	4.0%	7.3%
Stage 5	Closed loop medication administration	6.1%	12.0%
Stage 4	CPOE; Clinical Decision Support (clinical protocols)	12.3%	14.2%
Stage 3	Nursing/Clinical documentation (flow sheets); CDSS (error checking); PACS available outside Radiology	46.3%	41.3%
Stage 2	CDS; Controlled Medical Vocabulary; CDS may have Document Imaging; HIE capable	13.7%	11.2%
Stage 1	Ancillaries - Lab, Rad, Pharmacy - All Installed	6.6%	4.8%
Stage 0	All Three Ancillaries Not Installed	10.0%	7.4%

Data from HIMSS Analytics™ Database ©2012

N = 3,310 N = 3,110

Interoperability Status

The impactfulness of electronic health record systems adoption is highly dependent upon health information exchange (HIE), since EHR data can most effectively be useful if it can be exchanged across healthcare delivery systems, EHR vendors, and health information exchanges. HITECH includes elements of information exchange in the Meaningful Use criteria and provides for state investment in health information exchange infrastructure (referred to as HIEs) through the State Health Information Exchange Cooperative Agreement Program. While in Stage 1 of Meaningful Use, however, the growth of HIE has been somewhat limited. Now that the Meaningful Use Stage 2 final rule has been published and new standards have been set, we fully expect to see providers and hospitals creating a significantly expanded capacity to share information. Widespread HIE will emerge from multiple business models rather than a single plan.

Electronic Health Records Certification Program

Another measure of the progress we are making is the ONC Certification Program for Electronic Health Record (EHR) technologies. The program is designed to ensure EHRs meet the adopted standards and certification criteria to help providers and hospitals achieve Meaningful Use (MU) objectives and measures established by the Centers for Medicare and Medicaid Services (CMS). Eligible professionals and eligible hospitals who seek to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs are required to use certified EHR technology.

As of the end of June this year the Certified Health IT Product List (CHPL), the authoritative, comprehensive listing of Complete EHRs and EHR Modules that have been tested and certified under the Office of the National Coordinator included 2591 ambulatory and 859 certified inpatient EHRs and EHR Modules.

Return on Investment of Health IT

Perhaps in many years healthcare could have caught up with other industries in the adoption of information technology without the Meaningful Use Program including the EHR Incentive Program, but in the meantime quality of care and access to care would have continued to suffer and the Nation would have continued to pay much more for healthcare than necessary.

From both a cost of care and a quality of care perspective the nation cannot wait for a casual uncoordinated approach to this major national problem. A RAND Corporation study projected cost-savings of \$80 billion a year from EHRs.

<http://content.healthaffairs.org/content/24/5/1103.full>. A 2005 article by the same authors in Health Affairs estimated Net Potential Savings (Efficiency Benefits Over Adoption Costs) For Hospital And Physician Electronic Medical Record (EMR) Systems Adoption During A Fifteen-Year Adoption Period (2004-2018) at over \$580 billion. <http://content.healthaffairs.org/content/24/5/1103.full>.

Additionally the RAND Study estimated that system-wide implementation of EHRs would eliminate 200,000 adverse drug events with Computerized Physician Order Entry, and avoid thousands of deaths by improving preventative care and chronic-disease management. Additionally, some improvements in quality and efficiency have been documented. In 2008, HIMSS [presented](#) documented examples of both soft and hard ROI in recommendations directed toward the Obama administration.

The Success of the Meaningful Use Program

The Meaningful Use Program, authorized by the HITECH provision of the American Recovery and Reinvestment Act of 2009 has been an undeniable success for the Nation. The data to support this conclusion comes from government sources and HIMSS' own analytics. HIMSS continues to be a very strong supporter of the Meaningful Use Program and the EHR incentives it provides to adopters of EHRs. The

staged approach to adoption of health information technology by providers and facilities tied to the demonstrated use of these capabilities in a “meaningful way” is producing real results.

Without the Meaningful Use Program we would not be nearly as far along this path to transforming healthcare as we are. Not only the substantial public and private investment in adopting electronic health records, including the Incentive Program, but a carefully choreographed three-stage Meaningful Use Program of health information technology criteria, electronic health records certification, standards, and interoperability have resulted in a more rapid and orderly transition and faster adoption nationwide. The Meaningful Use Program is the mechanism by which we are ensuring we are getting value for our national investment. The faster we keep this progress moving, the sooner we will realize real savings in healthcare costs, the sooner we impact the quality of healthcare, the sooner individual clinical care is improved, and the sooner we can realize the promises of real population health management.

Without the Meaningful Use Program we would not be surely and steadily moving toward system-wide interoperability and nationwide health information exchange capability.

On September 4, 2012, the Department of Health and Human Services released the Meaningful Use Stage 2 and the Standards & Certification Criteria Final Rules. HIMSS believes the Stage 2 regulations allow the healthcare community to continue the necessary steps to ensure that health information technology will support the transformation of healthcare delivery in the United States by placing greater emphasis on the next level of health information exchange and online patient access to their health records.

This Stage 2 final rule expands upon the Stage 1 criteria with a focus on encouraging the use of health IT for continuous quality improvement at the point of care and the

exchange of information in the most structured format possible. Included in this regulation are more demanding requirements for e-prescribing, incorporating structured laboratory results, and the expectation that providers will electronically transmit patient care summaries with each other and with the patient to support transitions-in-care. Patient engagement is an important focus of Stage 2, which includes measures that require patient activity.

Portions of this final rule, which are applicable beginning in payment year 2013, specify the Stage 2 criteria that eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) must meet in order to qualify for Medicare and/or Medicaid EHR incentive payments. Additionally, this regulation specifies the timeline for payment adjustments for EPs, EHs, and CAHs for failing to demonstrate meaningful use of certified technology. This final rule also revises the previous Stage 1 criteria, details new clinical quality measures and reporting mechanisms, and discusses volume calculation within the Medicaid program.

In our initial review of the Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Stage 2 Final Rule from the Centers for Medicare and Medicaid, HIMSS identified several significant policy decisions, including:

- Setting the Meaningful Use Stage 2 start date as 2014, which will maximize the number of eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) prepared to meet Stage 2 requirements
- Allowing a 90-day reporting period in Year 1 of Stage 2, which is consistent with HIMSS' recommendations on the proposed rule
- Accepting 2013 as the attestation deadline for EPs, EHs, and CAHs to avoid a Medicare payment adjustment, and allowing for exceptions, including limited availability of information technology
- Finalizing Clinical Quality Measure submission specifications for EPs, EHs, and CAHs

The Office of the National Coordinator for Health Information Technology's (ONC) efforts in the Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition streamline the administrative process of certifying EHR products. We note that the Final Rule both adopts and concurs with a number of HIMSS recommendations illustrative of the collaborative approach the Department of Health and Human Services continues to employ with provider and other stakeholders across the country. The HIMSS response to the proposed rule had requested several points of clarity and additional specification around certain criterion, and we commend the government's thorough review and inclusion of additional information to clarify many topics.

Stage 3 is planned for a final rulemaking in early 2014 with Stage 3 starting in 2016.

Health Information Technology Provisions of the Patient Protection and Affordable Care Act

In addition to its more controversial healthcare reform components, the Patient Protection and Affordable Care Act (ACA) also contained important health information technology related provisions. Each of the following provisions of the ACA is important to helping America realize the full benefits of the investment the public and private sectors have made in health information technology.

Accountable Care Organizations (ACOs) - The Medicare ACO Program or the Medicare Shared Savings Program (MSSP) authorized by the ACA encourages healthcare providers to manage and coordinate all care for patients through an ACO (Section 3022). ACOs will be required to promote evidence-based medicine, encourage patient involvement, report on quality and cost measures, and coordinate care across all settings, and can be eligible to receive payments for shared savings. The ACO program requirements will depend on the use of health IT, the integration of EHRs and electronic prescribing, deployment of health information capabilities, the use of

tele-health and other enabling technologies to engage patients and providers in a variety of healthcare settings. CMS published the Accountable Care Organization Final Rule on October 20, 2011.

Quality Reporting - Several ACA provisions require different agencies, including HHS, CMS and ONC, to develop mechanisms to collect data on quality, establish national standards for data collection and interoperability, and create strategies to utilize healthcare data to improve quality of care overall. EHRs and other reporting tools are essential for aggregating and analyzing data for quality improvements. The ACA also includes reporting requirements for group or individual health insurance issuers, and extends the Physician Quality Reporting Initiative (PQRI) program, which integrates PQRI's quality reporting measures with reporting requirements for meaningful use of EHRs, through 2014.

Quality Measures Development - The ACA directs the establishment of new quality measures where no quality measures exist, and to improve, update, and expand existing quality measures with the help of health IT. Preference in providing grants to aid in developing quality measures is authorized for providers that demonstrate meaningful use of Health IT. Programs such as the CMS "Innovation Center" and "National Pilot Program on Payment Bundling" require reporting of quality measures and will use health IT (such as home telehealth, patient registries, EHRs, health information exchange capabilities and other technology) to report these measures and improve quality of care.

Availability of De-Identified Medicare Data - The ACA authorizes HHS to release extracts of de-identified Medicare claims data for items and services under Medicare parts A, B and D to be made available to measure quality of provider and supplier performance.

Health IT Interoperability Standards and Protocols - The ACA requires the HHS Secretary and the Health IT Policy and Standards Committees to develop

interoperable and secure standards for the enrollment of individuals in federal and state health service programs. Their recommendations, published September 17, 2010, include initial standards and protocols that encourage adoption of modern electronic systems and processes that allow a consumer to seamlessly obtain and maintain the full range of available health coverage and other human services benefits.

Administration Simplification - The ACA establishes a single set of operating rules regarding eligibility and claims status, electronic funds transfers, healthcare payment and remittance rules, health claims, enrollment in health plans, health plan premium payments, referral authorizations, and unique health plan identifiers, for the purpose of simplifying the administration of healthcare. It also amends the HIPAA provisions of the Social Security Act relating to Transaction Standards to provide for “operating rules” for the electronic exchange of information.

State Health Insurance Exchanges (HIX) and Consumer Access to Data - The ACA recognizes that health IT is crucial towards developing HIXs and supporting consumer access to information regarding health insurance. HIXs will provide individuals and small businesses with a “one-stop shop” to find and compare affordable, quality health insurance options. The law also creates a consumer-friendly website where consumers can compare health insurance coverage options and pick the plan that is best for them (Section 1311). The interoperable and secure standards include processes that allow a consumer to seamlessly obtain and maintain the full range of available health coverage and other human services benefits.

Fraud and Abuse - The ACA requires entities that offer health insurance options through the State Insurance Exchanges to include the use of technology and data to enable real-time investigation of potential fraud and abuse. The ACA also requires manufacturers of drugs, medical devices, biologics and medical supplies under federal programs to report payment data to be made publicly available online; expands the Office of the Inspector General’s access and ability to use this data; and grants ACO

participants responsibility for detecting fraud related to the electronic exchange of information and data sharing. The ACA also requires CMS to expand its integrated data repository to include Medicaid and other federal agencies' data in order to help detect fraud, waste and abuse.

Health IT Workforce - To address the significant increase in demand for a trained Health IT workforce created by the HITECH Act and the Meaningful Use program, the ACA authorizes community-based interdisciplinary "health teams" to provide support services and implement Health IT; the "National Healthcare Workforce Committee" to address the demand for labor in the Health IT field; and the "Interagency Working Group on Health Quality" to address the supply of qualified health IT specialists. Other provisions set up primary care training and health IT enhancement programs, federal grants for training in Health IT, and require the HHS Secretary to conduct a project that updates nursing practices and facilities for the use of Health IT.

Challenges and Issues to be Addressed:

Interoperability

Since the passage of the HITECH Act, a new process for oversight of health IT interoperability and standards was implemented through the Office of the National Coordinator for Health IT (ONC). While forward progress is being made, especially in the Standards and Interoperability (S&I) Framework, we encourage coordination of efforts to ensure health IT standards and specifications that are recommended in subsequent stages of Meaningful Use include standards for transport, financial transactions, and basic security, which are essential for achieving interoperability.

HIMSS also urges CMS, ONC and NIST to ensure that all contractual engagements for standards and interoperability are coordinated, thereby complementing rather than duplicating each agency's efforts towards creating testing procedures, tools, services

and reference implementations. These efforts should also embrace a transparent and open consensus process with the private sector.

We also recommend that HHS:

1. Promote the adoption of implementation guidance for all selected international standards;
2. Further adopt data transport, financial transactions, security and health information exchange standards as soon as possible;
3. Publish the process and schedule for harmonizing standards; and
4. Set up one repository (such as the National Library of Medicine) for licensure and access to all standards and implementation guides.

Necessity for a Consistent National Patient Data Matching Strategy

One of the largest unresolved issues in the safe and secure electronic exchange of health information is the need for a nationwide patient data matching strategy to ensure the accurate, timely, and efficient matching of patients with their healthcare data across different systems and settings of care.

In 1996, the Health Insurance Portability and Accountability Act (HIPAA) mandated “a *Unique Individual Identifier for healthcare purposes.*” However, the 1999 Omnibus Appropriations Act (PL 105-277) stated:

“SEC. 516. None of the funds made available in this Act may be used to promulgate or adopt any final standard under section 1173(b) of the Social Security Act (42 U.S.C. 1320d-2(b)) providing for, or providing for the assignment of, a unique health identifier for an individual (except in an individual's capacity as an employer or a health care provider), until legislation is enacted specifically approving the standard.”

This language has been carried forward in Labor HHS Appropriations bills ever since, including FY13.

Since 1999, three successive administrations have interpreted the Appropriations language to mean no study, no standards, and no criteria, i.e., not addressing the issue at all. Others believe that the language simply means no attempt to finalize a rule or solution until HHS reports to Congress on how any proposed solution will protect patient privacy and security.

With passage of the HITECH Act in 2009, Congress has placed a clear mandate on the nation's healthcare community for adoption of interoperable electronic health records (EHRs) including financial incentives for adopting EHRs and disincentives of reduced Medicare reimbursement rates for not doing so. Additionally, the Administration has made health information technology (IT) and the ability to exchange data an essential component of the nation's healthcare transformation strategy; Meaningful Use Stage 2 of the Medicare and Medicaid EHR Incentive Program emphasizes this focus on health information exchange (HIE). Furthermore, data is increasingly generated outside the traditional care environment, expanding the need for sound approaches to the matching of patient data.

However, the lack of clear Congressional intent as a result of the Labor HHS Appropriations bill provision poses a huge impediment to the optimal adoption of health information exchange, endangering patient safety while raising costs. As providers increasingly communicate using HIEs, the risk of mistakenly matching data with the wrong patient exponentially increases. Compromise in data integrity may occur as information is exchanged between different entities using different hardware and software.

Patient-data mismatches remain a significant and growing problem. According to industry estimates, between 8 and 14 percent of medical records include erroneous information tied to an incorrect patient identity. The result is increased costs,

estimated at hundreds of millions of dollars per year to correct information. These errors can result in serious risks to patient safety. Mismatches, which already occur at a significant rate within an individual institutions and systems will significantly increase when entities communicate among each other via HIE —a Meaningful Use Stage 2 requirement - that may be using different systems, different matching algorithms, and different data dictionaries.

Since Congress enacted the restriction in 1999, health information technology has made significant strides toward improving clinical care, enhancing patient outcomes, and controlling costs. Similar advances have been realized in the area of protecting the privacy and security of health information. Nationwide healthcare transformation is virtually impossible without meaningful, system-wide adoption of EHRs and HIE, including a technologically advanced nationwide patient data matching strategy.

HIMSS does not recommend a particular technology or solution but, rather, is encouraging Congress to direct a study of the issue and the approaches to a nationwide strategy to health information exchange and optimized patient-data matching across systems, while enhancing patient safety, privacy and security. A technologically advanced nationwide patient data matching strategy does not mean that every system has to use the same patient identity method but, rather, means creating national standards and solutions that can be used for exchanging information across systems.

An informed nationwide patient data matching strategy would enhance, not compromise, the privacy and security of patient health information. Such a nationwide patient data matching strategy does not mean a national identity number or card. Technological advances now allow for much more sophisticated solutions to patient identity and privacy controls, including patient consent, voluntary patient identifiers, metadata identification tagging, access credentialing, and sophisticated algorithms.

In the absence of a nationwide patient data matching strategy, the states, HIEs, large health plans, various consortiums, and individual electronic health record vendors have had to develop individual patient identity solutions that do not necessarily work well across systems. As our nation moves forward with greater urgency toward system-wide health information exchange, this essential core functionality to ensure the accurate match of a patient with his or her information remains conspicuously absent. The multitude of different solutions and the lack of a national coordinated approach pose major challenges for our health information infrastructure and result in millions of dollars of unnecessary costs. Patient safety, privacy, and security depend on getting this core element right, and soon.

Congress should include language in the Labor HHS Appropriations bill to clarify that it does not prohibit federal agency study and leadership developing an appropriate consistent nationwide patient data matching strategy. Rather, HHS has clear Congressional authority to exercise its appropriate leadership role. Consistent with the Labor HHS Appropriations bill language, Congress expects the HHS to commission an appropriate study of a nationwide patient data matching strategy and provide appropriate recommendations to Congress. Such study should include the prevalence and costs of patient-data mismatches nationwide, the costs of correcting these errors, the patient safety risks of NOT having a nationwide strategy, the benefits and implications of applying a nationwide strategy, the impact on privacy, security, and safety of a nationwide strategy, current and near-term available technologies, the costs/benefits and practicality of adopting a nationwide strategy, and best industry practices currently employed to ensure acceptably reliable patient data matching across systems while enhancing patient privacy, security, and safety, with report back to the committee not later than six months.

Harmonization of Federal and State Privacy Laws

The ability to exchange health information confidently and securely across healthcare systems is a fundamental requirement to transforming America's healthcare delivery

system, achieving improved quality clinical outcomes, and controlling costs. With passage of the Health Information Technology for Economic and Clinical Health Act (HITECH Act; included in the American Recovery and Reinvestment Act of 2009), Congress placed a clear priority on the adoption of interoperable electronic health records (EHRs), including financial incentives for adopting EHRs and disincentives of reduced Medicare reimbursement rates for not doing so. Additionally, acting upon Congress' clear guidance to make the financial incentive requirements increasingly stringent over time, the administration has made health information exchange (HIE) an essential component of the nation's healthcare transformation strategy. Meaningful Use Stage 2 of the Medicare and Medicaid EHR Incentive Program focuses on HIE.

Conflicting privacy and security laws are among the most serious potential barriers to HIE adoption. Legal barriers to HIE implementation are pronounced and pervasive, from the lack of laws in some states, too many conflicting laws, legal standards and regulations in other cases. There is a lack of national guidelines for the interpretation of these laws and some existing state and federal laws are not well-adapted to HIEs. Each state has its own privacy and security laws that often conflict with other state or federal laws, causing more confusion on which law(s) applies in a given situation.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA; Pub.L. 104-191, 110 Stat. 1936), as well as its amendments in the HITECH Act, sets a floor for national privacy laws regarding Personal Health Information (PHI). HIPAA generally permits the use and disclosure of information for treatment, payment and healthcare operations, without the patient's written consent. However, HIPAA is superseded by state privacy laws that are more stringent. States' privacy laws have varying levels of stringency, which makes the exchange of information between and among states challenging as the entities must know and comply with federal law, the laws of the receiving and sending states, and interpret how those laws interact.

Examples of conflicting federal and state privacy laws that serve as barriers to HIE:

Clinical Laboratory Improvement Amendments (CLIA) (a federal law for clinical research) restricts the providers with whom a laboratory may share health information, but states that a state law may also specify who is authorized to receive a clinical laboratory test result. Only seven states have licensing laws that allow direct access to laboratory test results by the patient. State laws have varying levels of stringency in regard to lab results:

- a) New York State requires the provider's written consent to issue lab reports to patients except for a few standard tests results such as blood type and states that the results belong to the provider and not the patient.
- b) In New Hampshire, PHI belongs to the patient, and the laboratory may release test results only to the ordering provider without the patient's consent.
- c) Oregon permits the release of test results directly to the patient seven days after receiving the request from the patient; prior access to test results requires a written authorization from the ordering physician. After the waiting period, a patient may access the results without the provider's concurrence.

The lack of laws, legal standards, regulations, and guidance specific to the privacy and security concerns related to HIE is also a barrier to HIE adoption and implementation. Data stewardship, the responsibility, guided by principles and practices, to ensure the knowledgeable and appropriate use of data derived from individuals' personal health information¹, is inconsistent. For nationwide HIE to work, it is crucial to determine which jurisdiction is responsible for providing protections in the data exchange process or alternatively, develop rules for exchange based on a set of defined and accepted principles.

¹ <http://www.ncvhs.hhs.gov/090930lt.pdf>

Differences in authentication requirements also greatly hinder PHI exchange. There is currently no specific legal requirement for any particular type of authentication information or processes for electronically “signing” EHRs. Additionally, all personal health information (PHI) created, received, maintained or transmitted by an organization is subject to the federal HIPAA Security Rule, which requires covered entities to ensure the confidentiality, integrity and availability of PHI, and identify and protect against threats to security or impermissible uses or disclosures. The HIPAA Security Rule is aimed at regulating individual healthcare organizations and is not specific to HIEs.

Finally, the lack of understanding about how all of these laws interact with each other, and to whom they apply and when, creates an enormous question regarding liability. Private and federal right of actions regarding patient privacy is extensive and can be harsh with respect to damages. A reconciliation of the differing laws and standards across a national scale being very difficult, developing rules for exchange based on a set of defined and accepted principles could lead to more innovation and implementation of HIEs and a decrease in potential liability.

HIMSS recommends that Congress support harmonization of federal and state privacy laws and regulations by: (1) when considering future legislation, be aware of the roadblocks to information exchange created by the current differing laws and regulations; (2) convene hearings on the challenges and possible solutions to mitigating the divergence of federal and state privacy and security laws and regulations; and (3) direct HHS to promulgate the ONC Privacy and Security Framework to protect personal health information while eliminating barriers to interstate exchange of health information.

Long term Sustainability of Public and Private Health Information Exchanges

Health Information Exchange (HIE) is a key building block towards realizing many industry initiatives including Meaningful Use, Care Coordination, Accountable Care Organizations and shifting from traditional fee for service to new emerging payment models. HIE can, and is often referred to as both a noun and a verb. The noun HIE (the organization providing governance oversight and/or operational management) and the verb HIE (the process of data exchange within an organization and across multiple organizations) are both critical for achieving the goals of the industry as well as supporting improved patient care quality.

HIE organizations include state-level health information exchanges, regional health information exchanges and the private sector exchanges such as those supported by hospitals and health systems. HIEs can support many state and federal initiatives including Medicaid, public health initiatives, bio-surveillance and state insurance exchanges.

Privacy and Security Laws and Regulations - lack of consistency across the federal and states.

The ability to exchange health information confidently and securely across healthcare systems is a fundamental requirement to transforming America's healthcare delivery system, achieving improved quality clinical outcomes, and controlling costs. Conflicting privacy and security laws are among the most serious potential barriers to achieving health information exchange.

Legal barriers to information exchange implementation are pronounced and pervasive. Each state has its own privacy and security laws, regulations and program requirements that often conflict with those in other state or federal laws, causing confusion on which law(s) applies in a given situation. There is a lack of guidance on the interpretation of these laws and some existing state and federal laws are not

well-adapted to health information exchange. The lack of understanding about how all of these laws interact with each other, and to whom they apply and when, creates an enormous question regarding liability. Private and federal right of actions regarding patient privacy is extensive and can be harsh with respect to damages.

The lack of guidelines on data stewardship, unclear liability standards, and differing privacy and security laws make the interstate exchange of health information increasingly complicated and greatly impedes health information exchange implementation.

Patient Access to PHI and Patient Engagement

HIMSS supports the Department of Health & Human Services' Office of the National Coordinator for Health Information Technology (ONC) efforts to empower individuals to be partners in their healthcare through health IT. HIMSS supports the national campaign to educate and engage the public on the value and benefits of health information technology (health IT) in improving health and health care.

HIMSS has pledged to lead the effort to equip clinicians and other front-line personnel with the education, tools and resources needed to make smart decisions on when and how to e-engage consumers to improve the quality, cost-effectiveness, safety and access to healthcare. Through outreach to all facets of HIMSS stakeholders - from leaders to point of care professionals - HIMSS will provide opportunities to members and non-members for involvement in and education on the importance of, and processes for, e-engagement with consumers.

ICD-10 Adoption

HIMSS is a strong supporter of the most rapid nationwide adoption of the International Classification of Diseases or ICD-10 Implementation. We appreciate the recent release by the Secretary of Health and Human Services of the final rule adopting a unique

health plan identifier (HPID) in response to requirements in the Affordable Care Act to cut red tape in the healthcare system and to save up to \$6 billion over ten years. The rule also makes final a one-year proposed delay - from Oct. 1, 2013, to Oct. 1, 2014- in the compliance date for use of the ICD-10 diagnosis and procedure codes.

ICD-10 represents one of the most comprehensive projects in healthcare today with far-reaching impacts throughout the healthcare delivery system.

- ICD-10 is the very basic foundation for other healthcare transformation efforts, including Meaningful Use.
- ICD-10-CM/PCS will have positive implications for patients. Better clinical intelligence data can describe multiple levels of severity, which should result in improved care algorithms to support accurate, more individualized patient care and lead to or promulgate improved outcomes.
- ICD-10-CM/PCS will provide more accurate payment structures for providers over time.
- ICD-10 has the potential to reduce costly requests for health information.
- Increased research capabilities, quality metrics and public health tracking and reporting made possible due to ICD-10 cannot be overemphasized.
- The ICD-9 numbering system cannot accommodate today's current medical technology used for patient procedures.
- Continued use of ICD-9, with its limited codes, will hinder progress towards clinical best practice and evidence-based medicine.

HIMSS' survey of providers suggests that most of the larger providers are taking the necessary steps to be ready for ICD-10. Based on research released at the 2012 HIMSS Annual Conference & Exhibition, nearly 90 percent of the 302 healthcare IT

executives responding to HIMSS' 23rd Annual Leadership Survey said they expect to complete the conversion to ICD-10 by the original deadline. In fact, two-thirds of respondents (67 percent) indicated that implementing ICD-10 continues to be their top focus for financial IT systems.

To assist providers in achieving ICD-10 readiness by the newly established October 1, 2014 deadline, HIMSS offers a comprehensive and credible portfolio of ICD-10 related tools, resources, education, and community for health providers. HIMSS and AHIMA have released the "ICD-10 Critical Pathway to Getting Started - 2012 and Beyond." This readiness tool is designed to help providers just starting on their ICD-10 conversion efforts.

Additionally, HIMSS and the Workgroup for Electronic Data Interchange (WEDI) are taking leadership in collaborating with healthcare stakeholders across the industry to implement an ICD-10 National Pilot Program with end-to-end testing and Regional Solutions Centers. This program will publish incremental outcomes data to assist providers in their implementation through the ICD-10 PlayBook as soon as information becomes available. HIMSS seeks the support and involvement of CMS in this program.

Mobile Technology

The emerging mobile technologies hold enormous promise for healthcare especially in the areas of patient engagement, remote patient monitoring, patient information and education, and home care to name a few. The use of mobile devices is bolstered by the fact that over 95.6 percent of all Americans live within the coverage of one of 69 mobile broadband networks. mHealth, short for mobile health technologies, includes devices such as tablets, smartphones, wearable sensors, and applications (apps). Mobile technologies also present a major opportunity to shift the cost curve of healthcare. However, a number of barriers prevent the adoption of mobile devices as a solution to emerging healthcare problems which include a complex regulatory

environment, limited incentives to adopt, provider reimbursement issues, and privacy and security concerns.

HIMSS recommends Congress should continue to foster an environment of interagency support; work quickly to remove barriers to advancing mHealth technologies; address broadband availability issues, and provide a regulatory framework that is responsive to the needs of patients, providers, and the emerging mHealth industry.

HIMSS Recommendations for Congress

In conclusion, in order to improve the quality of healthcare for all Americans while also controlling costs, HIMSS recommends that Congress should:

1. Continue its strong bipartisan support for the adoption and use of electronic health records and interoperability.
2. Continue to support and sustain the Meaningful Use and Electronic Health Records Programs.
3. Direct the administration to initiate an appropriate study of a nationwide patient data matching strategy with a report back to Congress.
4. Support harmonization of federal and state privacy laws and regulations to encourage the exchange of health information across health systems, payers, and vendor systems.
5. Continue to support programs and services to educate providers and provider organizations on how Health IT can and should be used to engage patients in their healthcare with personal health data in a secure manner.

6. Continue to support and sponsor pilot programs addressing the collection, analysis and management of clinical data for quality reporting purposes to assist providers and provider organizations make informed decisions for public health, patient care and business purposes.
7. Preclude any additional delay in the nationwide implementation of ICD-10, International Classification of Diseases beyond the current October 1, 2014 deadline.

Conclusions

EHR adoption and implementation has passed the tipping point in America. The evidence, including data from the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, and HIMSS Analytics' analysis suggests that, as a result of the HITECH Act and the substantial investment the public and private sectors have made, a groundswell has been achieved in the adoption of health IT/EHRs. We believe the time is very near when informed patients with access to information on the quality of care delivered by available providers will consider the providers' impactful use of health IT as a key factor when selecting a caregiver and care setting.

Clearly, the Nation would not have made the significant progress toward EHR adoption and health information exchange (HIE) that is has without the Meaningful Use Program authorized by the HITECH Act of 2009.

The public dialogue, open consensus-building process, standards based approach, and phased implementation provided by the Meaningful Use process have been critical to bringing the country to the current level of accomplishment and rapidly increasing adoption rates that have been achieved.

There is more work to be done especially on the issues I have discussed including interoperability and health information exchange across systems, and privacy and security. HIMSS recommends that in order to improve the quality of your constituents' healthcare while also reducing costs, Congress should continue its strong bipartisan support for Health Information Technology.

I and my 50,000 HIMSS professional colleagues stand ready to work with Congress and the administration to make the transformation of healthcare in America a reality, through the implementation of health information technology. Thank you for the opportunity to speak with you today. I would be happy to answer your questions.

Chairman QUAYLE. And I want to thank all the witnesses for their testimonies.

Reminding Members that Committee rules limit questioning to five minutes, the Chair will at this point open the round of questioning, and I recognize myself for five minutes.

Dr. Mostashari, I want to start with you. One of the things—I had a lot of inquiries and comments from constituents leading up to this hearing about the meaningful use requirements and how they might not be applicable to their practice. They were more specialists in different fields, and Stage 2 provided a temporary hardship exemption. But we need to ensure that the criteria is going to be applicable for these types of physicians, and so my question is, is it appropriate to have the same core and menu requirements for different types of physicians? Are there steps that the Administration is taking to ensure that the requirements take into consideration the unique nature of different medical fields and practices? Because what I have been hearing is that the various meaningful use requirements in different specialties do not match up, make it more difficult for them to actually fulfill these requirements, and then if they are going to be punished for not actually doing this, it is going to have a detrimental effect on their own practices.

Dr. MOSTASHARI. That is an issue that we have been working on with stakeholders in the Policy Committee for the past two years. The Stage 1 rules did set in place a kind of common infrastructure and common core set. So the assumption was that if we are going to be able to exchange information, there should be a common set of information around medical diagnoses, or smoking status, or blood pressure. And we heard a lot, and since the implementation of Stage 1, that that may not be relevant; this is a national program, and it may not be relevant for all practices.

So the challenge is how do we get to a place where there is, for the things that really—at the planning level, the things that really we want interoperability on, we get that sort of interoperability across all practices, and yet allow for the differences in practice and what is relevant to different specialists.

In Stage 2 we made a number of accommodations to that reality. So we, for example, provided guidance and in the rule said if it is really not—if collecting blood pressure is not relevant to your practice, you are a pathologist, then you can have an exclusion from that requirement.

And we also heard from Stage 1 that many of the quality measures were—the ones that were available at the time were not relevant to all specialists. So for Stage 2 we said, okay, you don't have to report on the quality measure for smoking if that is really not relevant to your practice, although it is hard to imagine; you know, there is not that many practices for whom smoking status is not relevant, but—

Chairman QUAYLE. So will all these kind of kinks be ironed out prior to the temporary reprieve where people will start getting penalized for not actually complying with this when in certain specialties smoking would not be extraordinarily useful? So will that all get ironed out? That is one of the big things that I am trying—those will get ironed out before the penalties will be put into place?

Dr. MOSTASHARI. So all of the flexibilities that I mentioned, there are many more, are part of Stage 2, which is going to be in effect before the penalties.

Chairman QUAYLE. Okay. Okay, great. Thank you very much.

And Mr. Probst, I want to get to your testimony, because in your testimony you stated that, you know, voluntary consistent—consensus-built standards don't work within the healthcare industry. And in previous hearings, you know, we have had NIST here a lot, and that was one of the main things with NIST—is it is very consensus driven with the stakeholders, and it has worked very well.

Why do you not think in the healthcare industry that that is the best way to go and instead come up with a set of standards from basically kind of more of a top-down approach rather than the voluntary consensus? I just want to get your take on that.

Mr. PROBST. Well, I think the very fact that we are having this conversation suggests that it hasn't worked. They have been doing it for a long time. And that is not to slam HL7 or DICOM or any of the groups that have been working towards standards. There are varying incentives in those groups. The people that formed those groups have different rationales for why they want standards or what standards they might like.

But, again, I think the fact that we haven't come to some basic standards, like the gauge of rail that they did in Australia, we are dealing with all the discussions around health information exchange, what kind of contraptions can we put together to move data from one system to another that loses fidelity and costs time. So I just think history is a good educator for the future, and I don't see how we are going to get to standards without some direction on some basic core standards.

Chairman QUAYLE. If we are going to have that direction, how, in your estimation, do we set those standards so that we can still have the flexibility for technological innovation going forward, since that seems to be—from past testimony on the consensus building, that seems to be where we have had some really good innovation? But in the way that you are kind of seeing this in the outlook, how do we leave that flexibility in place so that the innovation can continue to progress?

Mr. PROBST. I think what we don't want is standards that suggest everything that we have to do. But we do need standards, and I listed several of them in my written testimony, basic core foundational IT standards to put in place. If those are put in place, then innovation happens. Then you have Internet kind of innovation that can occur ubiquitously across large groups of people. So that is the gist of my testimony.

Chairman QUAYLE. So you basically—you put the trunk, and then the tree—you know, the limbs of that trunk can go up, and that is where the innovation would be able to take place, something—I mean, to use a—

Mr. PROBST. Exactly, if you get the foundation in place.

Chairman QUAYLE. The foundation. Okay, great. Thank you very much.

I now recognize the gentleman from New Mexico Mr. Luján for five minutes.

Mr. LUJAN. Thank you. I yield to Mr. Clarke.

Mr. CLARKE. Thank you, Mr. Luján, for yielding me time.

In order to implement these health information technologies and to operate them on a day-to-day basis, you need an adequate workforce. I represent the City of Detroit, the metro Detroit area. We have very high unemployment, but also we have got some great hospital systems. The potential for job growth in that region and also nationally, because of the complexity of our healthcare delivery system and the growing number of people who need health care—we are going to need a lot of people in this workforce area. An interoperable health IT system will create jobs.

The *HITECH Act* directed your Office, the Office of National Coordinator, to establish education programs, which I think is great. Now, one thing that causes me concern, though, is this eHealth Initiative survey that indicates that nearly a quarter of the health information exchanges are not hiring students from ONC-funded workforce development programs.

You know, Dr. Mostashari, or anyone who would like to comment on that, I mean, is this survey accurate? Is there some fundamental basis for concern about the adequacy of the training programs that your office is funding? And if that is the case, what can we do to correct that? My assumption is that this is a whole new industry that can be created that could transform our entire workforce nationally and even internationally. How can we get people prepared to operate these health IT systems?

Dr. MOSTASHARI. Your concern is very well put. There is going to be a lot of jobs in—and there are a lot of job openings, huge increases in job openings, for skilled health IT workforce, even as we have many students and others who would wish to fill those jobs. So to meet that we have established a curriculum that is openly available, we have created a competency exam working with AHIMA, we have funded university-based training slots as well as 81 community colleges that have graduated over 15,000 students to meet the expected need of 50,000—a shortage of 50,000 jobs in health care IT.

As you say, one of the things we have learned is if you don't have experience in health care, it is hard to get into health care IT and get a job. So one of the things we are working with, for example, in Ohio at the community college there is working with a hospital association to have internships and placements and apprenticeships. Those are, I think, some of the answer to meeting—making these two sides connect up with each other.

Mr. CLARKE. Thank you, Doctor.

Anybody like to comment on this?

Dr. FIELDS. I actually would—

Mr. CLARKE. Dr. Fields?

Dr. FIELDS. Thank you.

I would like to expand on the program through ONC. I personally use some of the slides that have been posted to teach my students, graduate students in informatics in nursing. So what that says—you don't capture that in your numbers of the benefits. So I am using the materials that ONC has funded through work done by others. I then have up-to-date information that I can incorporate into my classes, which makes the graduate students in nursing more capable of taking these complex HIE jobs. And then when

they move into the health care IT positions, it opens up less experienced types of positions, which the survey that you quoted in the information, Dr. Mostashari, that you talked about, this information, these data don't get captured.

Mr. CLARKE. Thank you, Dr. Fields.

And I yield the balance of my time to the gentleman from New Mexico, Mr. Luján.

Mr. LUJAN. Thank you very much, Mr. Clarke.

A lot of conversation as to what we need to get done here with the implementation of this, and I think in the end what we can all certainly agree on is that we all want to make sure that we have more consistent treatment, better outcomes, cost-saving measures as well.

And with the limited time that I have left, one thing I just want to point out is as we implement medical records, and we hopefully will find a way to do this as effectively and efficiently as possible, the importance of partnerships between the Federal Government, local governments, and private entities to be able to implement this, the importance of standards.

And I just want to highlight one project that has come out of New Mexico. It is Project ECHO™, which is the Extension for Community Health Care Outcomes, led by Dr. Sanjeev Arora out of the University of New Mexico Hospital, who are now partnering with the VA as well, a program dependent on the implementation of distance medicine, and we are seeing huge, huge benefits and positive outcomes there. So I look forward to talking about that a little bit more throughout this hearing and getting your perspective on that.

Thank you, Mr. Chairman, and with that I yield back.

Chairman QUAYLE. Thank you very much.

I now recognize the gentleman from Illinois, Mr. Hultgren, for five minutes.

Mr. HULTGREN. Thank you, Mr. Chairman. Thank you all very much.

A question for all of you. Interoperability—I can't speak this morning—is critical to realizing the many potential benefits for health information technology. So far the Federal Government, I know, has spent approximately \$2 billion in appropriated funds for HIT infrastructure and \$7 billion in mandatory incentive payments for HIT adoption. Wondered if each of you could give thoughts, given this investment, have we made appropriate progress on interoperability, and why have we or why have we not made the progress that you all think we should?

Dr. MOSTASHARI. I believe that we have made substantial progress on both the adoption and the meaningful use of electronic health records, which includes the interoperability. And this is a long road. As Marc pointed out, these are complex. It is much more complex than saying 4 feet, 8-1/2 inches should be the width of the railway gauge, which the U.S. Congress did in 1853.

These are quite complex, but I think we have a roadmap, and we have, through meaningful use, a phased approach to being able to bring the whole country, bring the floor up and create that infrastructure in stage after stage after stage to help increase that journey towards interoperability.

Dr. ROMINE. I would certainly like to agree with my good friend and colleague Dr. Mostashari about this. I think we have made substantial progress. NIST has a long history of working on both conformity assessment and also interoperability, and I think the steps that we are taking, and particularly the emphasis on this phased approach that allows us to sort of bring the community along in an aggressive but achievable manner, is absolutely essential to doing this.

Mr. PROBST. Yes, I believe meaningful use has made good progress forward toward the exchange of information and the ability to use it, you know, between organizations. Although it was 4 feet, 8 inches for the rail gauges, and that is pretty simple, this is incredibly complex, and therefore interoperability is way more complex than the rail system, and it needs to be taken care of.

So I agree with what we are doing around meaningful use because we have an infrastructure we need to leverage and we are providing better care, I believe, because of the efforts that are happening. But I still would stand on the fact we need to define a—define—maybe define, but define a core set of standards that would allow for true interoperability, because the way we are saying interoperability right now, what is really happening is information exchange. Interoperability, to me, is far deeper, with a far greater capability to save lives and money.

Ms. LITTLE. We would also agree that substantial progress has been made, and we certainly agree that meaningful use Stage 1 began the proliferation of adoption of electronic health records, and without robust standards for interoperability, the spread of electronic health records will be stifled or limited.

We encourage HHS to adopt standards that would support the clinical needs of coordinated care, such as requirements for accountable care organizations, medical homes, and hospital readmission programs.

Lastly, I would observe that occasionally Federal programs and program rules are not aligned. Providers must comply with different standards for different programs, which make them less attractive. We are pleased to see HHS proposing alignment of rules across meaningful use, accountable care organizations, physician quality reporting, and medical homes.

Dr. FIELDS. And, yes, I am going to agree also, but with that I am going to tell you some data that I personally collected on a research study at a hospital in San Diego.

So I look at interoperability not only across organizations, but within organizations, and this particular hospital had been digital for decades. The emergency department had one system, critical care had one system, women services had another, pharmacy was on another, and on and on and on. And so this is—yes, it was the railroad gauge absolutely. So each group of practitioners had the best system for them, but they couldn't share easily information across systems.

We implemented an integrated—I wouldn't call it interoperable because it doesn't go across organizations except within our healthcare system. And in this research study when I surveyed the nurses on the use of the system before we went live with the integrated one and then one year after implementation with the one

system or with the sharing of the information, that they clearly were using the new system much more. They were accessing it for information, for patient data, for patient engagement.

I then interviewed the nurses one year after to find out what did the transition go like, how was the system, what were the changes they found, and without a doubt the nurses resoundingly said that they were able to provide better care because they had all of the information in front of them. They had the emergency department information in front of them. With the click of a button, they would be able to look up past hospitalizations.

So we have improved care in this one organization where they can look at the physician office patient episode, they can look at previous hospitalizations, they can look at the information from throughout that hospitalization, yet if that same patient goes to another hospital within our community, that information is not available.

But I will also compliment ONC because San Diego is fortunate enough to be one of the beacon communities, and so money has been invested so that in San Diego we can have that same type of sharing of information not only within Sharp Healthcare, but we can have it throughout San Diego.

Mr. HULTGREN. Thanks. I see my time has expired. I yield back. Thank you.

Chairman QUAYLE. Thank you very much.

I now recognize the Ranking Member, the gentlelady from Maryland, Ms. Edwards, for five minutes.

Ms. EDWARDS. Thank you, Mr. Chairman, and I want to thank my colleague Mr. Clarke for sitting in for me today, I really appreciate that. And Mr. Chairman, thank you as well for your service. We have had some great hearings in this Subcommittee, and I really do appreciate your leadership.

To our witnesses today just a couple of questions. Dr. Mostashari, in your testimony you indicate that any rulemaking includes some compromises between the aspirational goals we want to achieve and the reality of where the market is, really important questions for us today. And I wonder if you could elaborate on that and additionally what the impact on small or rural practices is if the expectations of meaningful use are set too high.

Even in my own State of Maryland, we are a small state, 5.5 million people, a lot of people live in our metropolitan areas, but a lot of folks don't. And so even in a small State you could have a two-tier system if we are not really careful about this.

Dr. MOSTASHARI. Thank you, Ranking Member Edwards, for the question. It is absolutely true that one of the fundamental challenges we face in setting the meaningful use policy is this is an escalator that we want people to get on and continue to advance through the different stages. How fast up that escalator can we push? What is the rise and the run so that people don't fall off the escalator? Because we could set the standards very, very high, and, you know, only a few institutions, signal institutions, across the country would be able to qualify for those standards, and we would not have succeeded in improving health and health care for all Americans. So it becomes really important for us to not set them so low that we are not changing the intrinsic capabilities and inter-

operability of the systems, but not set them so high that only a few can participate as well.

The issue around the rural providers and small practices are particularly important because historically those have been the kinds of providers who haven't had the resources to implement health IT effectively, and they have consequently the lowest rates of adoption of EHRs. So when we took our Regional Extension Center Program funded through HITECH, we said focus on the small practices, focus on the primary care providers, focus on the critical access hospitals, the rural health clinics, the community health centers. And I think it is in part due to these efforts that we have seen, for example, rural adoption of electronic health records now among office space providers is 38 percent higher than the national average of 34 percent. So it can be done, but we have to make sure that we set the rules appropriately and we provide them with the services they need to be able to get there.

Ms. EDWARDS. I want to ask you a question that is somewhat related, and it is regarding the issue of upcoding. The New York Times recently profiled and wrote about some instances in which hospitals, particularly those Medicare providers, in using these IT systems actually were billing at much higher rates. And I have a question just about the design, whether it is—and maybe NIST can comment on this, too—we can have some way of testing these, the designs of IT systems, so that we get a more intelligent design that might factor in the potential for abuse or the potential for upcoding when it doesn't result in a better patient outcome or a better quality of care so that we can actually guard against increases in costs in a system rather than seeing more efficiency in the system because of the implementation of the technology.

Dr. MOSTASHARI. I would note that the article you mentioned examined trends in billing leading up to 2010, which actually predates the implementation of the EHR incentive program, which is moving electronic health records industry away from just being documentation and billing machines and towards things that, as Ms. Little commented, help us do the new payment models of the future with accountable care, and bundled payments, and shared savings and so forth.

That said, I want to assure you that HHS is taking the appropriate steps to investigate and correct any possible improper billing associated with EHRs. The Centers for Medicare and Medicaid Services is conducting a comprehensive review of potential improper billing through the use of electronic health records. We also plan to convene a summit of stakeholders to develop those potential policy and EHR design responses, as well as conduct a pilot of hospital audits using EHR technology functionality that supports fraud enforcement and investigation so that EHRs are used as tools to combat fraud, not encourage it.

Ms. EDWARDS. And is it possible, though, that in testing for standards that NIST actually might come up with a design that looked more intelligently at these systems so that, you know, if there were system prompts or the software was coded in such a way that it would automatically kick out things that, you know, looking at an entire record, might actually indicate that there was

that upcoding going on, as opposed to coding correctly for a given medical condition or circumstance.

Dr. ROMINE. So from this perspective—thank you for the question.

Our role has really been in trying to ensure that we provide the best technical advice to get the best technical standards from the community with regard to interoperability, security, privacy, and so on. But that also includes usability. And one of the things that may be related to this issue is ensuring that the usability of these systems are testable in a way that might prevent I would call inadvertent, mistaken coding, or things of that nature where the usability of the system can help avoid those kinds of issues.

With regard to the policy issue of trying to prevent intentional fraud, I think that would really kind of be beyond our scope. I'm not sure how we would contribute to that.

Ms. EDWARDS. Thank you, Mr. Chairman.

Chairman QUAYLE. Thank you very much.

I now recognize the gentlelady from Oregon, Ms. Bonamici, for five minutes.

Ms. BONAMICI. Thank you very much, Mr. Chairman. And thank you for calling this hearing today.

Thank you for all of our panelists for sharing your thoughts and ideas about this important issue. Many people in my home State of Oregon are talking about the importance of increasing access while reducing costs. So this is certainly an important topic.

I represent a district that includes an area that's known as the Silicon Forest; it's like the Silicon Valley, only with trees.

And we have a lot of technology companies, Intel, doing a lot of great work in developing our health IT infrastructure. The Oregon hospital systems have been early adopters of using common IT systems, and they have been working through informal collaboration.

I recently hosted a roundtable discussion that brought together many of the stakeholders. We had the Oregon Office of Health Information Technology, the Medical School, Oregon Health Sciences University, the Oregon Healthcare Work Force Institute, community colleges, software developers, the Oregon Center for Aging and Technology, and many others, to talk about where we were going, the development so far, and some of the challenges.

One of the interesting issues that came up, and I believe you touched on, Dr. Mostashari, was the importance of having some medical knowledge in the actual software and systems development phase. The medical workflow is really important in the initial design of the software and the developments. So that's an issue that we feel really needs to get addressed.

And also there was a discussion about involving providers at every level from, you know, hospitals to home care and in many cases to completely fulfill the use of the medical records. You have patients and caregivers who are involved, and they need to be comfortable with the technology as well.

So could Dr. Romine, and perhaps Dr. Mostashari, I know there has been some discussion about how you go about engaging healthcare professionals in the actual development of the technology. But would you also comment, please, about the work that

you've done in engaging healthcare professionals in the implementation as well?

Dr. ROMINE. The way that NIST works most effectively in working with the community to develop standards, particularly in a space where historically we don't have a lot of expertise in medicine. We do a lot of life science research, but that's quite different from clinical practice, for example.

And so we have to engage the communities. Most effectively, we do that with the standards development organizations that do have the various technical background that we need. So standards development organizations such as—we've worked with ASTM and HL7 and other organizations that are involved in this arena specifically to look at the ways that we can help develop the standards necessary in this space to be the most effective. And that does include looking at the workflow associated with this.

We also could not actually contribute to this without the very strong partnership with ONC, where a lot of that expertise resides. And so I'm very pleased that the partnership that we have with ONC is as strong as it is.

Dr. MOSTASHARI. The issue you raise is of critical importance. The software, and there are—and it is wonderful. There are hundreds of new vendors, hundreds of new products. And 60 percent of those vendors have 50 or fewer employees. They are small companies. And it's critical that as we have technological innovation, those technologies are more usable and work for the frontline clinical staff, the nurses and doctors. And the usability issue here is something absolutely critical.

We've been doing a lot of work with our stakeholders, including our Chief Medical Officer, with many of the providers groups within the usability space.

I do, though, having been in the space for some time now, I might be interested in hearing Willa's perspective on this as well. The products are a lot more usable today. If you look at products that came out four or five years ago, it's really night and day in terms of how usable they are, you know, iPad applications, and a whole host of new innovations around usability are now coming to the forum. As it should be, competition between vendors for the most useful product I think is going to be yielding us tremendous results in the future.

Ms. BONAMICI. Thank you. Dr. Fields, did you want—

Dr. FIELDS. Yes. The usability is an issue. They are more usable than they used to be, and hopefully they aren't as usable as they will be, that we aren't where we need to be. That said, we need to continue with the implementation. And one of the barriers in the United States, if you look at the literature, clearly a major barrier to implementing these systems is cost. And thanks to our Federal government, the cost barrier is being lessened because of the incentive program.

So with that we'll have the—what Dr. Mostashari talked about, all the new vendors. We're having the increased competition in the innovation. And the users, the nurses I talk to, the physicians I talk to, they want systems that are easy to be used.

And we as a public are very computer savvy. I looked up some data—80 percent of the households have computers. And of that 80

percent, 70 percent of adults—so that's not kids—it's 70 percent of the adults, are using the Internet, and 80 percent of that 70 percent are getting health information. So that means that the majority of your constituents in getting their health care, the number one thing is looking for healthcare information. They know how to use the systems. They are going to be demanding that our clinicians know how. And the usability is getting better, but it's not written in slate.

Ms. BONAMICI. Thank you. My time has expired. Thank you.

Chairman QUAYLE. Thank you very much. Now recognize the gentleman from Maryland, Mr. Harris.

Mr. HARRIS. Thank you very much, Mr. Chairman.

And I have a couple of specific questions, and then a more general, I guess.

Dr. Mostashari, it's good to see you again.

As you know, last time we met, we'd talked about the difficulties that some different specialties have, which I think you appreciated, with regard to meaningful use.

Now, as an anesthesiologist, you know I know that hospital-based physicians a lot of times lack face-to-face interactions and other things. And I—so that I think Stage 2 granted the hardship exemptions to at least three categories—radiologists, pathologists, anesthesiologists. But in the absence of meaningful—of developing meaningful use criteria for those specialties, is it the intention of the Administration to continue a hardship exemption until those are worked out, you know, some kind of meaningful use parameters are worked out? I mean, to my understanding, this is kind of a one-time, one-year hardship exemption. That doesn't provide consistency long term.

Dr. MOSTASHARI. Yes. As you know, the—particular issue for those three categories, anesthesiologists, pathologists, and radiologists, was not only that they practiced, in some cases, where they have less patient interaction, it's also that the systems that they use are oftentimes provided by the hospital where they practice rather than purchased by the providers themselves within their private practice.

So the exemptions, we asked about whether there should be more blanket exemptions for those categories, and in Stage 2, we find that it can be up to five years.

Mr. HARRIS. Okay.

Dr. MOSTASHARI. So I think that given the current legislation, I think that is the means that are available to us.

Mr. HARRIS. Thank you very much.

Dr. Romine, is that how I pronounce it? Okay.

I have a very specific question. It has to do with one of these things that I think NIST is involved with, which is the prescription, the drug-to-drug interactions and drug allergy checks. And this is very specific to anesthesiology.

And when I was in the operating room last week, on one patient, I had a list of 10 drugs, if you count two inhalation agents. Only one of those was one where another provider was involved, which is the prophylactic antibiotic, which a nurse had requested from the pharmacy, which an electronic system in use could have picked up a drug-to-drug interaction or an allergy. But of the other nine

drugs I administered, all of them are documented really after the administration. That's just the way the workflow occurs. So software in a health information technology system really wouldn't pick up drug-to-drug interactions or drug allergy interactions in that setting.

Do you think that—and anesthesiologists are kind of unique in the number of times we—the number of drugs we use and the fact that we are doing it on a momentary basis. So there's no—it's hard to prospectively identify and write an order, check it in the computer, things like that.

Should they be exempt from the requirement until such time that we can figure out how to work that into an electronic system?

Dr. ROMINE. Congressman, I'm a mathematician, but I'll try to address that.

I would say—I don't know the system that you used in to obtain the nine drugs that you did apply.

Mr. HARRIS. No, they sit in a cart in the room.

Dr. ROMINE. I see. Okay.

Mr. HARRIS. We have access. They sit in a cart. That's the problem. And that's the way anesthesiologists practice in most settings. You have access to a variety of drugs. You make a decision sometimes on a momentary basis which drug you have to administer without time to prospectively enter it into a system.

Dr. ROMINE. From this perspective, we're happy to work on developing the standards. But the expertise with regard to where certain interactions might take place, or working with ONC, for example, on drug-to-drug interaction, allergies, and so on, all of the guidance with respect to the kinds of issues that you're just talking about would not come from NIST. We don't have that expertise.

Mr. HARRIS. All right. We have to work with Dr. Mostashari's office, I guess, with that.

One final thing is, I guess the question of interoperability, and Ms. Little kind of suggested, I guess Medicity is kind of a translator system. No matter what language a given group speaks, you're the translator between these.

And I guess interoperability can occur two ways, it can be by declaring that everybody speaks the same language, or that everybody has access to a translator that works.

Which is the system that we're going to go to? Because a lot of institutions, as Mr. Probst indicated, a lot of institutions invested heavily in a proprietary scheme. And it would seem that the easiest way to get a broad—if it's technologically feasible—broad acceptance at this point is just to allow translators to exist. Is that the scheme?

Dr. MOSTASHARI. I think the answer is yes. We need both.

Mr. HARRIS. But both is not specific. I mean—and, again, if you're going to tell a provider, why don't you go—you know, you got to go ahead and invest in a system now. But we might down the road change the rules and say that you actually have to have a system has these qualifications and too bad if yours didn't, as opposed to saying, okay, you have now invested in this now we're going to actually spend our energies on making sure translators exist that accurately translate.

Dr. MOSTASHARI. Let me be more specific. I think it is important to, as much as possible, make sure that two different certified EHR systems can talk to each other without the need for requiring that a translator be present, particularly since the availability of such, you know, health information exchange organizations throughout the country are still limited. It's growing, but it's still limited. So I think it's important for us to have, as much as possible, the precoordination and have those national standards at the electronic health record in place so that the systems can talk to each other.

It also greatly, I think, reduces the work of the translators if the people speaking the languages at least speak them consistently instead of having to translate. And much of the cost on the information exchange side is doing all those variations on all the different languages that people are speaking.

So I think the reality is that there are translators in place today. And we've made—I think we've encouraged the development of information exchange at the state level and others. And it's a reflection in reality. But we can't give up on the idea that we're going to get to the point where the EHRs can speak to each other without the need for translators.

Ms. LITTLE. I would agree with Dr. Mostashari. I think the need for the middle-ware, the translator or the plumbing, as you called it, is particularly important now as standards are relatively nascent.

We see—and Dr. Romine and Dr. Mostashari may have a different statistic than I—but dozens if not hundreds of permutations of the continuity of care document today.

And so, for us, it's an important part of making sure that the right information gets to the right person at the right time within their workflow. I do also agree that over time systems will be better able to communicate with each other.

Dr. Fields mentioned that the systems we have today are better but hopefully not as good as the ones we'll have in the future.

The other, I think, important component part that the translator provides for, as to the point you made, sir, whereby changes evolve and standards evolve, the middle-ware, the translator oftentimes can buffer and provide a little bit of runway as systems become more operable and then adopt those new standards. So I agreed with Dr. Mostashari, I think we need both.

Mr. HARRIS. Thank you very much, Mr. Chairman.

Chairman QUAYLE. Thank you very much. Now recognize the gentleman from Michigan, Mr. Clarke, for five minutes.

Mr. CLARKE. Thank you, Mr. Chair.

And I wanted to thank the Ranking Member from Maryland, Ms. Edwards, for giving me this opportunity. Back two years ago when I served as Ranking Member of the Michigan Senate Committee on Health Policy, I actually convened an informal hearing on the health information exchanges to see how we could get those set up. So this is an issue that's important to me. And thank you again.

With that, I yield my time to the gentleman from New Mexico, Mr. Luján.

Mr. LUJAN. Thank you very much, Mr. Clarke.

And, Mr. Chairman, I also, as our Ranking Member, Ms. Edwards, want to commend you for your work on this Subcommittee,

Committee as a whole, and your time in the House. It's been great to get to know you. Appreciate your leadership, and I know that it won't be too long before we see you again, sir. So it's always an honor, Mr. Quayle. Really appreciate that, sir.

Dr. Mostashari, all of us as Representatives represent about the same population, plus or minus a few hundred or maybe a few thousand people. The difference between our districts is some of us represent a few square blocks, others represent 47,000 square miles, like my district in New Mexico. The longest drive I have is about 8-1/2 hours drive time. Out here, we can go through about six, seven States in that amount of time.

The reason I bring this up is when we talk about the stages of the implementation versus urban, metro, and rural areas, what sensitivity is paid attention when we start talking about the smallest of clinics, smallest of communities, that need more assistance or time as we talk about the implementation of the stages and the requirements associated inherently therein and the capital necessary to be able to do that?

Dr. MOSTASHARI. You're absolutely right that we need different approaches in different parts of the country.

This is why the regional extension center program is based out of local institutions that understand the local needs and the local resources.

So a program like the one I ran in Brooklyn and the Bronx in New York City is going to be structured differently than the program in New Mexico. Both are successful, but they take different approaches to the issue. And I think it's been that sensitivity to what the local needs are that has made the success that we've enjoyed in making sure that a digital divide does not develop. Because as one rural provider said to me, "My patients now come to me knowing that the best technology that they could get anywhere in the world is in their doctor's office here in my rural practice."

He also said it's very important on the telehealth side, that you mentioned earlier, "that if my patient drives 300 miles to go to a specialist that I referred them to that when they get there they have the information that they need instead of having the patient turn around or be told, 'sorry, we're going to have to repeat all those tests,' or, 'sorry, we didn't get the paperwork on you.'" So we have to pay particular attention to the rural areas and we are doing that.

Mr. LUJAN. I appreciate that.

If anyone else would like to weigh in and in addition to the impact as we talked about the standards on telemedicine as well.

Mr. PROBST. Yes. And I think I come from a geography in Utah very similar to yours.

And I can assure you that our smallest hospital, which probably consists of about eight beds, very small, serving a rural population, has the exact same level of sophistication as our Salt Lake City based hospitals. That comes down to using standard technologies and the ability to train across the organization and move those things out.

If we had to do something independent in each of those rural areas, the costs would be prohibitive and the value to the organization would be very slim. So I guess I'm stuck on the standards

route. But, again, by applying good, solid standards with good technology, if I get in an accident in Panguitch, Utah, which hopefully none of you know where it is, they have exactly the same information and can provide me just the exact level of care.

Mr. LUJAN. Appreciate that, Mr. Probst.

Dr. ROMINE. I appreciate that. I also agree that standards actually can help to drive the adoption more readily in all sectors, including rural sectors, because of products that are affiliated with those standards or that conform to those standards are well understood.

I will also say some of the testing infrastructure that NIST is developing in partnership with ONC is publicly available. In fact, all of our testing infrastructure is publicly available, our test tool kits are publicly available. We try to make them as friendly as possible for providers to be able to use.

And so we pay close attention to that.

Mr. LUJAN. I appreciate that.

And as my time expires, Mr. Chairman, just again, as we look to programs across the United States, again to highlight what's happening in New Mexico with Project ECHO™, the extension for community healthcare outcomes, now providing opportunities with our veterans as well, where via telehealth they are able to reach out across rural parts of the country now. And through the communication they actually have a series of physicians that can enter into any of these diagnoses and they can work together collectively. They can also come out and talk about the best-case scenarios or mistakes that were made. So they are learning together, they are keeping their certifications up together. But they are also making sure that they are delivering the best possible care, especially when it comes to the shortage that we have of family care specialists in some areas, that even in the most remote parts of the country they are able to get that.

So thank you very much, Mr. Chairman.

Chairman QUAYLE. Thank you, Mr. Luján.

Now recognize the gentleman from Texas, Mr. Neugebauer. Five minutes.

Mr. NEUGEBAUER. Thank you, Mr. Chairman. Mr. Mostashari, Mr. Romine—Dr. Romine.

Authenticating the patients is an important part of the critical health IT part and setting up security parameters to protect that. And how—what are we doing in the IT world to be able to make sure we got the right patients being matched up with the records?

Also, what are we doing to allow patients to look at and to use those records and to, you know, verify them that those records are correct? And can you kind of share a little bit about what's going on in the next phase?

Dr. MOSTASHARI. Absolutely. When we talk about being patient centered, we have to take that very seriously. And one of our most important principles is not just having the patient be at the center of the care, but the patient literally being able to access their own information and to participate in their care as partners. Someone said if we want to get better care at lower cost, we've got to use every resource we have. And the patient is the most underutilized resource in healthcare.

So we've actually been big advocates for and pushing on the standards side as well as on the policy side for patients to be able to exercise their legal right to get access to their own health records online and to be able to view it, to be able to download it, to be able to store it securely.

That all requires, as you point out, that there be means of authenticating the patient. And many of the organizations who have implemented this at a large scale are able to—whether it's the Veterans Administration, which has had a million downloads among veterans of the blue button of their health record, whether it's other organizations, healthcare institutions that have found that by engaging with their patients online, they help have patients keep their appointments, take their medications, and be more active in their healthcare. It's a high priority for us.

Dr. ROMINE. I'd like to make mention of three quick things. One is we're working in the area of patient identification matching and our researchers have developed a tool that supports the testing of patient identifier cross-reference and patient demographic query, test cases for both HL7 versions 2 and 3.

The second thing is NIST is the home to the program office for the National Strategy for Trusted Identities in Cyberspace, which is a major program for identity management, broadly speaking, but I think will have serious implications with regard to helping in this context.

And, third, we have a National Cyber Security Center of Excellence that we have just stood up. And our first use case is going to be on health IT and patient records, particularly focused on small providers' ability to transfer secure and private records.

So all of those things I think will contribute.

Mr. NEUGEBAUER. I think someone—did you?

Dr. FIELDS. Yes. I wanted to comment on your question patient matching. The lack of patient matching is a major health safety issue. You can imagine if we merge records that shouldn't be merged.

Congress actually prohibited the use of appropriated funds—I'm going to quote here—"to promulgate or adopt any final standard for unique health identifier for an individual."

You may remember that part of HIPAA, back in 1996 or '98, there was the request for a unique patient identifier. And it's been prohibited by Congress to actually evaluate that.

And one of the tasks that HIMSS had when we were on the Hill in the fall was not that we dictate what type of identifier we have, but that Congress have a consistent, nationwide patient data matching strategy that we start to look into, that Congress actually authorized the ability for us to look into a patient data matching strategy. Because without that, we are at risk for patient safety.

Mr. NEUGEBAUER. Yes.

Mr. PROBST. Might I second Dr. Fields.

We spend about \$5 million a year trying to do patient identification accurately for our patients. You talk about waste in the system, that's a significant amount of waste and it seems to be something—it's one of the seven standards I wrote in my written testimony—that we need to tackle because it's incredibly frustrating and unsafe.

Dr. FIELDS. And it takes time and delays care. What happens from a practical point in a hospital, when the computer doesn't—when the computer is programmed to say these two patients, these two records may not be the same patient, but maybe they are, then that data goes into a holding zone where a human being then looks at it to determine what happens to it. So while it's in that holding zone, that data is nowhere near available for clinicians to be able to give care.

So each organization has come up with their own strategy, because we as providers recognize the importance that the data that goes into the computer has to be for the patient that we think it is. So we have these complex algorithms and complex human processes that eat up time and actually interferes with the ability to give care.

So I really plead with you to promote this investigation for a national strategy for patient identification. We have it for the clinicians, we have it for the insurers. We do not have it for the patients. And that's where the risk is.

Mr. NEUGEBAUER. I would make a suggestion that—you say Congress hasn't given that permission. I'm pretty sure that the patients would be better off if Congress didn't make that decision.

But if the industry would come forward with, you know, a recommendation where you've actually had some experience, what's working, what's not working, but, you know, for Congress to set those standards—

Dr. FIELDS. Oh.

Mr. NEUGEBAUER. —I think we would rather hear from you than—I'm pretty sure I've got some really smart colleagues, but I feel a lot of them don't really know a lot about this particular issue.

Dr. FIELDS. Thank you. Let me correct myself. I don't mean for Congress to in any way set the standard. What I am asking for Congress is to take away what had previously been stated and that we come up with a strategy that Congress allow the investigation, that Health and Human Services, ONC, the appropriate government agency, bring together the private sector, the government sector in to study the situation and come up with a strategy. Because from my understanding that Congress prohibits the use of appropriated funds to be able to look into this.

Ms. LITTLE. I think I would just like to add and agree with Dr. Fields. What I think we would really like to see is an opportunity to collaborate on a strategy and see a strategy come forward.

As a technology supplier who provides software that connects things together, we also provide software that provides patient matching. And once you get outside of an individual healthcare organization, even a large delivery network like Intermountain Healthcare, and you complicate that with a regional implementation or a statewide health exchange implementation, those complexities and algorithms become even more important and the accuracy of them become more important. So we would also value and look forward to participating in the opportunity to see a strategy.

Chairman QUAYLE. Thank you very much.

Now recognize the gentleman from California, Mr. Rohrabacher, for five minutes.

Mr. ROHRABACHER. Thank you very much, Chairman Quayle, and to our witnesses as well.

I'm the first one to admit that I have limited knowledge into the area that we are talking about. So I guess I have to ask some fundamental questions.

We seem to be talking about interoperability and privacy is some of the issues, but as the discussion has gone on, it seems that we are talking about more than electronic health records. It seems to me that we're morphing into a discussion at some point into setting up a system of medical cooperation that will ensure that any hospital has the best technology available to it. That's different than medical records.

So far, I take it the original goal was to have a national system where we could easily exchange information. That seemed to be a goal that people could actually accomplish within a certain budget.

I mean, I know people have apps right now. My wife actually invented an app over the Internet. And it's relatively—a lot of people are utilizing the Internet in a relatively inexpensive way. But we've already spent \$2 billion on this information sharing, which does mirror some of the things that I think I've seen on the Internet.

But are we now morphing this into something that's far beyond just medical records that's going to cost more money that we may not ever have?

Dr. MOSTASHARI. The payments authorized under the CMS Medicare and Medicaid Health IT Incentive Program are specifically for the meaningful use of certified electronic health records.

Mr. ROHRABACHER. Just for the records—

Dr. MOSTASHARI. Certified—

Mr. ROHRABACHER. I'm not saying that we can't do a lot of other things in the healthcare arena that are—that will be to the benefit of our people. But I do know that when people try to do everything, they generally don't get anything done.

And so we're just focused on the records. This program is still focused on just setting up a system so that if someone goes into a hospital his medical records can immediately be available?

Dr. MOSTASHARI. The Medicare and Medicaid incentive payments are specifically for the meaningful use of electronic health records that are certified to meet interoperability and functional standards.

Mr. ROHRABACHER. How much has been spent for that already? You said it was \$2 billion?

Dr. MOSTASHARI. There's \$2 billion in appropriated funds for the grant programs and to establish the infrastructure like the regional extension centers is the examples I gave. And then there are mandatory payments, as Chairman Quayle described in the beginning, for eligible professionals and hospitals, and approximately 7—a little bit over \$7 billion has been spent to date out of an estimated \$20 billion.

Mr. ROHRABACHER. That's to come up—that money was spent to come up with a basic set of standards or to set up a system?

Dr. MOSTASHARI. Those payments are for individual eligible professionals and eligible hospitals who earn those mandatory payments if they adopt a certified a health record and they use them in these certain ways, check for drug, drug allergies, collect information needed, and exchange it.

Mr. ROHRABACHER. So what we have spent the \$2 billion on is to encourage people to participate in a system that is a standard system for the country. Is that right?

Dr. MOSTASHARI. The incentive payments, which is the—the 44,000—up to \$44,000 over five years for eligible professionals and the 2 million-plus for hospitals is payments to them for whatever system they choose, but the systems have to meet the national standards.

Mr. ROHRABACHER. And so but the point is to establish the national standard?

Dr. MOSTASHARI. The goal is to get widespread adoption and meaningful use of the electronic health records, which include the standards.

Mr. ROHRABACHER. Let me just suggest that \$20 billion to set up a standard is a big price category.

Dr. FIELDS. May I jump here?

Mr. ROHRABACHER. Chairman Quayle will—

Dr. FIELDS. May I speak?

Chairman QUAYLE. Go right ahead.

Dr. FIELDS. Further, the point I want to make is that the goal is to have tools to help clinicians provide care. The ultimate outcome is improved patient care and health outcomes, a healthy American population.

Mr. ROHRABACHER. Okay, that's different than what he just said.

Dr. FIELDS. No, it's the same.

Mr. ROHRABACHER. No, I'm afraid it's not. That's your opinion on that. He just said it was medical electronic records, not what you just said.

Dr. FIELDS. And what I am saying is the medical electronic record is imperative for us in the United States to be able to give high quality care, which ultimately will be healthy people. Without these tools so we can go through research study after research study that those organizations that have standards based electronic health records, and they are using it in a meaningful way, like Intermountain Healthcare, and many other organizations, because of the data that is available to them to give care to individual patients and then to their population, it's because of that information that we're able to have healthier populations, which I believe is something that everyone in this room wants.

Mr. ROHRABACHER. No one has any argument with the fact that we need to have the ultimate amount of information available to anyone who's a health provider for the person that comes in for treatment. There's no doubt about that.

It seems to me, however, Mr. Chairman, that billions of dollars were to set a standard that would permit that type of availability. As I say, I see people setting up businesses every day on the Internet that provide information on a global scale to various businesses and various enterprises. And it just doesn't seem to take that much money. And at a time when we're trying to bring down the level of deficit spending so we can actually provide the medicine, provide the x-ray, that it seems like to me the \$20 billion expenditure is an awfully high price tag for something that the private sector seems to be doing and offering at a much lower rate.

Thank you very much.

Chairman QUAYLE. Thank you.

Now recognize the gentleman from Michigan, Mr. Benishek, for five minutes.

Mr. BENISHEK. Thank you, Mr. Chairman.

I have a question. I'm a physician as well. And I've been familiar with several different electronic medical records. And some of them work better than others. I mean, I worked at the VA system, and that's a pretty good system as far as they go, as far as I'm concerned.

My biggest concern really is this mandating the implementation of electronic medical record that doesn't work as well as the VA system. Because many of the systems I've seen in the private sector are expensive, they are costly to maintain, and they don't do what we want them to do, which is provide, you know, sort of a universal access to information.

You know, I know in my practice we have electronic medical records but we're still sending or trying to get a fax of an x-ray report because it's not available on this electronic medical record that I have.

And there's a lot of people in private practice that simply can't afford to spend, you know, 65,000 or \$150,000 dollars on a electronic medical record system for their practice, plus a \$5,000 a month maintenance fee for a system that doesn't produce.

So I have a real problem with, you know, mandating implementation of a system that doesn't do, you know, what result that we want.

And I think that, frankly, this implementation or interoperability, you know, when you can't get a lab test because it was done in another hospital that your system does not talk with, it wasn't worth that \$150,000 for me to tell my girl to have to get, you know, get this test. You know.

So explain to me why are we implementing it before it's universally interoperable.

Dr. MOSTASHARI. So I think you're raising the issue of upfront costs and not just the costs for purchasing the system, but also implementing it and changing the work flows and the challenges that are there.

And you mentioned, you know, for a practice with a few physicians, it can cost tens of thousands of dollars. That has been what has held back the adoption of the electronic health records in the U.S.

And Congressman Rohrabacher's question about what are we paying for, what we're paying for is providers like yourself to be able to be receiving the payment over a period of several years if they choose to adopt and meaningfully use the technology.

Mr. BENISHEK. Payment doesn't cover those costs. Okay. I've talked to, since I've been here in Congress, I've been talking to many small hospital administrators. And they say, we got this one-time payment to implement this electronic medical record, but, you know, it's not going to cover what it's going to cost us. So I don't know what we're going to have to cut in order to comply with this rule. But, you know, our budget is not getting bigger, you know, with reimbursement. It's getting smaller. And this is a one-time

payment we got but now we have an ongoing cost associated with it that we're not being paid for.

It's really frustrating to me to hear, you know, a small, critical-access hospital telling me this.

Dr. MOSTASHARI. Sure.

Mr. BENISHEK. Because, you know, they don't have any extra places to find money.

Dr. MOSTASHARI. There are—one of the approaches that Congress took in HITECH was not to have the Federal government procure the software, but to really leave it to the market-based approach to let the hospitals and providers be the ones to choose what system works best for them. And there are a greatly expanded range now of software products each with their own usability and the cost structures, lease models, web-based models and so forth that providers can now choose from.

And what we're seeing in practice is that the amount of the incentive payments has been sufficient to produce this great acceleration in the adoption of electronic health records.

Mr. BENISHEK. Well, the people have implemented them because they are sort of terrified of the Federal government, you know, cutting their reimbursement. The people I've talked to said they had to do it because the rule came in. But they are finding that their costs exceed, you know, what they're getting reimbursed. So to me, that's a problematic issue.

And I didn't hear any answers in any of your testimony to this part of the problem. Because I have seen it in real life myself and, you know, I visit lots of hospitals. What I just mentioned to you, you guys didn't talk about at all in any of your testimony.

So it's a great concern to me.

I mean, it all sounds great. I mean, I want great medical records. And, you know, it's great to have the medical record in your hand. But if the hospital goes broke, that access to care is not there either.

I think my time is up. Thanks.

Chairman QUAYLE. Doctor, you want to answer that?

Dr. MOSTASHARI. The program is designed and legislation passed by Congress in HITECH does not have a mandate, that it's a voluntary program. And if providers sign up for the program, as 75 percent of the hospitals have already done and more than half of providers have done, then they can earn the incentive payments. And if they don't, it basically says that the Government feels that Medicare is not getting 99 cents on the dollar value for the care that we are buying from the providers.

So it is the way that the legislation was set up. And I believe that it is an important step towards getting a national infrastructure that can help public health, that can help research, and that can help patient care.

Chairman QUAYLE. I want to be real quick.

But it is true that if you don't participate, you get cut in your Medicare and Medicaid reimbursements. Is that correct?

Dr. MOSTASHARI. Yes.

Chairman QUAYLE. I do want to thank all of the witnesses for their valuable testimony, and the Members for their questions.

Members of the Subcommittee may have additional questions for the witnesses, and we will ask you respond to those in writing. Record will remain open for two weeks for additional comments and statements from members.

Before we gavel this closed, this is more than likely going to be the last Subcommittee hearing of this Congress. And I just want to thank all of the Members of this Subcommittee for their valuable input. I really want to thank the Ranking Member. She has been a great partner to work with. And this Subcommittee has been very bipartisan. We want to focus on the technological and innovation in this country.

And I also do want to thank all of the staff both on the majority and the minority side for making sure that this whole Subcommittee runs so smoothly.

And, Ms. Edwards, would you like to say anything?

Ms. EDWARDS. Mr. Chairman, I want to echo that. And I just want to say to you that I know a lot gets said about how Congress works or it doesn't. And I just want to say to you that it has actually been a real joy to be on this Committee with you as Chairman because we've had some incredibly thoughtful discussions with great witnesses and exploring areas that you don't often get to do in the Congress and looking for the future. And this panel today was more evidence of that.

So I really do appreciate your leadership, appreciate your service in the United States House of Representatives representing your Congressional district in Arizona. And I wish you incredibly good luck, good fortune into the future. Thank you.

Chairman QUAYLE. Thank you very much. And I echo those sentiments to you as well. This has been a great two years on this Subcommittee.

And I want to thank you, the witnesses, again. This was a great hearing today. And you are excused. Thank you all for coming. Hearing is now adjourned.

[Whereupon, at 11:45 a.m., the Subcommittee was adjourned.]

Appendix I

ANSWERS TO POST-HEARING QUESTIONS

ANSWERS TO POST-HEARING QUESTIONS

Responses by Dr. Farzad Mostashari

QUESTIONS FOR THE RECORD
THE HONORABLE BEN QUAYLE (R-AZ)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation

*Is "Meaningful Use" Delivering Meaningful Results?: An Examination of Health Information
 Technology Standards and Interoperability*

Wednesday, November 14, 2012

**1. Can you describe how the move to the cloud is affecting HIPAA compliance? Is this
 an area where we need greater guidance and oversight by HHS?**

The Department of Health and Human Services (HHS) Office for Civil Rights (OCR) administers and enforces the HIPAA Privacy and Security Rules. The HIPAA Privacy and Security Rules allow a covered entity to use cloud-based applications and services to process or store electronic protected health information, provided appropriate safeguards are in place to protect the information from unauthorized access. This includes entering into a business associate agreement with the cloud provider, where appropriate, to ensure that the cloud provider agrees to protect the information in the same manner the covered entity is required to. At this time, HHS is not aware that the increased use of cloud services by covered entities has increased the number of breaches that covered entities are experiencing. Indeed, most breaches reported to HHS continue to involve patient information that was stored on lost or stolen unencrypted electronic devices, such as laptops, thumb drives, and others. In terms of greater guidance in this area, OCR is in the process of developing guidance materials to ensure that covered entities and business associates are aware of the risks of using cloud-based applications and services for electronic protected health information and are clear on their obligations to protect such patient data.

**2. You have indicated that the Medicare and Medicaid incentive programs will have
 provided approximately \$20 billion in payments before incentives turn to penalties.
 What constitutes success? How important is interoperability to realizing the benefits
 of HIT?**

Through incentives and other approaches supported by the Health Information Technology for Economic and Clinical Health (HITECH) Act, including a network of Regional Extension Centers (RECs) providing technical assistance to eligible professionals and hospitals transitioning away from paper-based record keeping, we have seen clear evidence that the health care community is embracing health IT.

As of October 31, 2012, 164,593 individual hospitals and eligible professionals have received incentives through the Medicare and Medicaid EHR Incentive Programs for meaningfully using

EHRs, which exceeds our goal of providing payments to 140,000 health care providers by September 30, 2013. In addition to the strong response to the Medicare and Medicaid EHR Incentive Programs, at its annual meeting on December 12, 2012, ONC announced new figures from the Centers for Disease Control and Prevention's National Center for Health Statistics (NCHS) showing that the percentage of doctors adopting electronic health records has increased from 48 percent in 2009 to 72 percent in 2012. The ONC report of NCHS data shows that since 2009, the percent of physicians with computerized capabilities to e-prescribe has more than doubled, from 33 percent to 73 percent. Within the past year, more physicians (56 percent) have the computerized capabilities to engage with patients and their families by providing patients with summaries after visits, an increase of 46 percent from last year.

While the milestones established by the Medicare and Medicaid EHR Incentive Programs can help us measure success, the funds provided by HITECH have enabled us to invest in a health IT infrastructure which can be used for research, monitoring, and care coordination. Our ultimate goal will be to improve patient outcomes for the long-term.

ONC believes that interoperability is a key component to success, and it has worked with the industry, government agencies, standards developing organizations (SDOs), professional societies, and others to develop standards and related testing for health care data and information exchange. To push for change in this area, the final rules for Stage 2 strongly emphasize the secure exchange of information between providers and with patients—including across vendor boundaries -- as a core requirement to achieve meaningful use. We know that getting the right information to the right person at the right time is extremely important in delivering high quality care.

QUESTIONS FOR THE RECORD
THE HONORABLE LAMAR SMITH (R-TX)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation

*Is "Meaningful Use" Delivering Meaningful Results?: An Examination Health Information
 Technology Standards and Interoperability*

Wednesday, November 14, 2012

- 1. Has HHS and NIST taken enough time to fully evaluate the implementation of Stage 1 and the lessons learned before proceeding on with final Stage 2 rules? How should HHS and NIST evaluate the implementation of each of the three stages before proceeding on to the next one? What are your top concerns if this rollout is moving too quickly? Conversely, how do we ensure that we plan ahead for technological improvements to Health IT systems?**

HHS, along with our partner, the National Institute of Standards and Technology (NIST), worked deliberately to take the time required to evaluate lessons learned prior to the issuance of the regulations that establish the criteria for meaningful use Stage 2. Examples include elevation of thresholds for computerized provider order entry and requiring provider accountability for patient access.

Shortly after the HITECH Act's enactment, HHS initiated a very deliberate, inclusive, and predictable policy-making approach for meaningful use. First, we relied upon recommendations from two highly respected multi-stakeholder federal advisory committees established by Congress (whose members are appointed by both parties). With their help and public input, we laid out an incremental vision for 3 stages of meaningful use. The HIT Policy Committee and HIT Standards Committee then provided specific recommendations on meaningful use Stage 1. After those rules were finalized, the HIT Policy Committee began considering recommendations for Stage 2 by holding hearings and soliciting public comment. After considering HIT Policy Committee's recommendations and the Medicare and Medicaid EHR Incentive Programs' results to date, HHS issued the Stage 2 regulations. The HIT Policy Committee is now working on Stage 3 recommendations, and a request for comment is currently open for public input.

The incremental, stage-based approach has enabled HHS to learn from each stage to inform the next stage. However, the pace at which we implement each stage has been a delicate balance. As much as we would like to see rapid technological advancements with respect to EHR technology and its interoperability, we also remain cognizant that each regulatory change we make has implications for provider workflow and the ability to safely and effectively care for patients. As we roll out each stage, we try to balance the demand from those who would like us to push harder and faster on issues such as interoperability and exchange and the demands

from those who would like us to slow down so they can effectively implement the EHR system within their own organizations.

In the two years between the publications of the Stage 1 and Stage 2 final rules, HHS has worked with our partners at the National Institute of Standards and Technology (NIST) to create the technical infrastructure necessary to more rigorously certify that EHR technology can enable providers to electronically exchange health information. NIST will continue to provide leadership in evolving standards and testing. Under the Stage 2 final rule and 2014 Edition EHR Certification Criteria final rule, beginning in 2014, providers 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 more complex “query” methods). Thus, over the next 9-12 months, every electronic health record technology developer will be hard at work incorporating into their products the standards we recently adopted and rolling out upgrades to their customers.

2. Health care providers and electronic health record (EHR) vendors have told us that some Health IT systems are being built to block the exchange of information between EHRs if their system is not made by the same vendor. Do you consider information blocking among health care providers a problem? Wouldn't information blocking defeat the intended purpose of the meaningful use program? If you agree this is a problem, how are you discouraging the practice of information blocking between health care providers?

HHS is committed to the principle that information should securely follow patients across organizational and vendor boundaries to ensure that the highest quality, safest, and most cost-effective care is delivered.

Indeed, as is noted in the response to Question 1, as a condition of certification, EHR technology must be capable of exchanging data using interoperability standards, and, beginning in 2014, providers are required to use this technology to demonstrate exchange across vendor boundaries in order to receive their incentives. For the first time, in Stage 2, we have a single standard for exchange of standardized summary care records (content and transport). We believe this is a huge step forward in promoting the exchange of information between different EHR systems.

HHS will continue to work with our advisory committees, standards developing organizations (SDOs) and our colleagues at NIST to further hone our approach to EHR technology testing and certification. We also continue to bring industry stakeholders together through the Standards and Interoperability Framework -- a venue we have created to enable the community to work on common problems and rapidly develop solutions.

At HHS, we view meaningful use of health IT as foundational for payment and delivery reforms. Certified EHR Technology enables the technical infrastructure on top of which more advanced

delivery reform programs can occur. Meaningful Use of health IT asks providers to focus on care coordination and patient engagement practices that support new delivery models such as accountable care organizations and patient-centered medical homes. As new payment and delivery models align to create value based on quality not volume, the ability of health systems to exchange health information with each other will help them to succeed.

3. *You indicated that the Medicare and Medicaid meaningful use programs will provide approximately \$20 billion in incentive payments before turning to penalties. How do you think the Health information technology environment will look at the conclusion of the incentive payments phase? How do you anticipate the transition to penalties will affect the HIT environment?*

It's important to remember that Medicare and Medicaid providers are on different incentive payment tracks. Incentive payments for Medicaid providers are available all the way through 2021 and there are no downward payment adjustments under Medicaid. By 2015, when the downward payment adjustments for Medicare providers will apply, we believe that the vast majority of clinicians and hospitals in the U.S. will have adopted Certified EHR Technology and received an incentive payment. We hope that there will be minimal actual imposition of payment adjustments.

Responses by Dr. Charles H. Romine

Romine

**QUESTIONS FOR THE RECORD
THE HONORABLE BEN QUAYLE (R-AZ)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation**

*Is "Meaningful Use" Delivering Meaningful Results?: An Examination of Health
Information Technology Standards and Interoperability*

Wednesday, November 14, 2012

- 1. Can you describe how the move to the cloud is affecting HIPAA compliance? Is this an area where we need greater guidance and oversight by HHS?**

Answer:

The HHS Office for Civil Rights (OCR) enforces the HIPAA Security Rule. With this responsibility, OCR is the most appropriate organization to describe the effect of cloud computing on HIPAA Security compliance. In our role, NIST has produced a series of guidelines that provide information on standards, technologies, reference architectures, and security and privacy considerations to support the adoption and implementation of cloud computing technologies. Our goal is to enable the electronic protected health information (EPHI) that is transmitted, processed, stored, or created in a cloud computing environment to be protected as it would be in any other environment.

QUESTIONS FOR THE RECORD
THE HONORABLE LAMAR SMITH (R-TX)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation

Is "Meaningful Use" Delivering Meaningful Results?: An Examination Health Information Technology Standards and Interoperability

Wednesday, November 14, 2012

- 1. Has HHS and NIST taken enough time to fully evaluate the implementation of Stage 1 and the lessons learned before proceeding on with final Stage 2 rules? How should HHS and NIST evaluate the implementation of each of the three stages before proceeding on to the next one? What are your top concerns if this rollout is moving too quickly? Conversely, how do we ensure that we plan ahead for technological improvements to Health IT systems?**

Answer:

The evaluation of successful implementation of each of the three stages, with each stage "raising the bar" in what is expected in a certified product and in meaningful use, can be evaluated by the rate of adoption of health IT. Currently, this rate is increasing, which, in turn, is enabling the achievement of health and efficiency goals.

NIST will continue to be guided by the lessons learned from Stage 1 and the current implementation of Stage 2 as we prepare, with HHS, to meet the challenges for Stage 3 and for future advances in technological improvements to health IT and to delivery of improved, more accessible, and more affordable healthcare for all consumers.

- 2. Health care providers and electronic health record (EHR) vendors have told us that some Health IT systems are being built to block the exchange of information between EHRs if their system is not made by the same vendor. Do you consider information blocking among health care providers a problem? Wouldn't information blocking defeat the intended purpose of the meaningful use program? If you agree this is a problem, how are you discouraging the practice of information blocking between health care providers?**

Answer:

The complete, unambiguous, testable standards that NIST is helping develop and implement will enable interoperability of health IT systems. This will allow information exchange between systems made by different vendors, which, in turn, will permit health

care providers to be able to meet meaningful use and interoperability requirements regardless of which systems are used.

For further information on this question, we refer to the Department of Health and Human Services, the Office of the National Coordinator's response.

Responses by Mr. Marc Probst

**Responses to Questions for the Record, the Honorable Ben Quayle (R-AZ)
U.S. House Committee on Science, Space and Technology
Subcommittee on Technology and Innovation**

Is "Meaningful Use" Delivering Meaningful Results?: An Examination of Health Information Technology Standards and Interoperability

From Marc Probst Chief Information Officer, Intermountain Healthcare

Wednesday, November 14, 2012

- 1. Can you describe how the move to the cloud is affecting HIPAA compliance? Is this an area where we need greater guidance and oversight by HHS?**

Answer: In general, the cloud is just another technology provided by a vendor. It could be better or worse, more secure or less secure, than other technologies currently in use by medical providers depending on the cloud technology vendor's commitment to privacy and security and the medical provider's ability to monitor and ensure compliance with the Business Associate Agreement.

One of Intermountain's privacy leaders, Jutta Williams, stated that it would be immensely useful for HHS to provide additional clarification of expectations and interpretations of HIPAA requirements. Because there is significant room for interpretation with respect to HIPAA compliance, sometimes publication of enforcement actions represents the first time that expectations from HHS have specifically been articulated, particularly with respect to emerging technologies. A recent example was the sanction by HHS of a physician group in Arizona for use of text messaging. Until that enforcement action, many believed that the point-to-point transmission of protected health information over a telephone carrier network was little different than a phone call. This leaves it up to the industry to make assumptions about what compliance should entail and in some cases, the assumptions are either higher or lower than what the standard should likely be. The 2012 results of HHS HIPAA audits show that there is a gap between health industry practices and HHS expectations, underscoring the need for greater clarity from HHS.

- 2. In your prepared testimony you state, "The lack of comprehensive standards is exacerbating the challenges of health information technology (HIT) across the country." Is the problem that the standards are not being created, or not being adopted? There are a number of standards that currently exist, many that even pre-date the Health Information Technology for Economic and Clinical Health (HITECH) Act. What is the cause of the bottleneck – is it necessary to develop new ones?**

Answer: There are certainly some standards that still need to be developed, however, many already have been developed. Actually, in some instances there are too many standards available, which means there is no standard at all. We pick and choose among multiple competing standards, and thus uniformity is lacking; so in effect, it is as if there are no standards. Going back to the Australian railroad analogy each individual railroad had their own standard, and laid track according to that standard. But, because Australia lacked a *national* standard, trains could not go across the country without complicated "fixes." National standards

need to be defined and adopted – that will be the easier step. Once defined, sufficient time must be allowed for their adoption and implementation. That will be the hard part.

- 3. In your testimony, you call for a stronger focus on interoperability. The Center for Medicare and Medicaid Services (CMS) has already paid out about \$7 billion in electronic health record (EHR) incentive payments and providers have invested significantly more in EHR technology. Is it possible that some of these systems will not be able to communicate with each other at the conclusion of Stage 3 of meaningful use? If not, what would be the incentives for providers to achieve interoperability in the future?**

Answer: The focus of the incentive payments has been on meaningful use, not primarily on interoperability. At the conclusion of Stage 3, many of these systems will be able to communicate at some level with each other. They clearly won't be interoperable and it is highly likely that some will not be able to communicate with each other at all. Without the adoption of, and compliance with, appropriate national standards, systems will not be truly interoperable. Achieving true interoperability will facilitate the provision of the best possible care at the lowest appropriate cost. This should provide incentive enough to develop a clear vision that will enable a nationwide health information technology infrastructure as called for in HITECH that will enable true interoperability.

- 4. Has the office of the National Coordinator for Health Information Technology (ONC) and National Institute of Standards and Technology (NIST) been clear in defining program goals and benchmarks for interoperable health information technology (HIT)? What recommendations would you make with respect to laying out goals and benchmarks?**

Answer: They have been clear in specific targeted areas. I would recommend establishing a ten year target (plan, if you will), then working backwards from there to establish interim goals and a timeline to achieve them. As noted in my written statement, we must leverage all of the expertise in the federal government to develop a long-range plan and architecture for a national HIT infrastructure and outline the pathway to comprehensive use of meaningful standards that facilitate national interoperability. This will improve healthcare delivery quality and significantly lower healthcare costs. Successfully achieving that transition will also require significant advanced planning, phasing and educational support of healthcare providers as they change systems and workflows to adopt the new standards.

Responses to Questions for the Record, the Honorable Lamar Smith (R-TX)
U.S. House Committee on Science, Space and Technology
Subcommittee on Technology and Innovation
Is "Meaningful Use" Delivering Meaningful Results?: An Examination of Health Information Technology Standards and Interoperability

From Marc Probst, Chief Information Officer, Intermountain Healthcare

Wednesday, November 14, 2012

- 1. Has HHS and NIST taken enough time to fully evaluate the implementation of Stage 1 and the lessons learned before proceeding on with final Stage 2 rules? How should HHS and NIST evaluate implementation of each of the three stages before proceeding on to the next one? What are your top concerns if this rollout is moving too quickly? Conversely, how do we ensure that we plan ahead for technological improvements to Health IT systems?**

Answer: No. I am concerned about the pace with which Stages 2 and 3 are being rolled out. Key concerns are safety and the industry's ability to sustain systems both financially and technically. However, CMS has gathered a lot of data, and I think there is good information about where the problems are. This knowledge must inform the program because actual experience in one stage of the program should shape the next stage of the program. With respect to planning ahead, we must set a clear road map and support an exchange infrastructure and the adoption of standards that will facilitate national interoperability. I would recommend establishing a ten year target of where we need to be as an industry then working backwards from there to establish interim goals and a timeline to achieve them.

Responses by Ms. Rebecca Little

Little

QUESTIONS FOR THE RECORD
THE HONORABLE BEN QUAYLE (R-AZ)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation

Is "Meaningful Use" Delivering Meaningful Results?: An Examination of Health Information Technology Standards and Interoperability

Wednesday, November 14, 2012

1. Can you describe how the move to the cloud is affecting HIPAA compliance? Is this an area where we need greater guidance and oversight by HHS?

The security of personal health information is paramount to Medcity and is fundamental to all of our HIE software design. We work every day to maintain patient health information in a confidential and secure manner compliant with applicable law, while meeting clinical needs of hospitals, consumers, physicians, and other authorized and authenticated care providers.

Data security is a double-edged sword—on the one hand, it is imperative for all of us to protect personal health information, but on the other hand, it's critical that we develop the tools and capabilities that enable care givers to have the right information at the right time to optimize the health outcome.

All new technologies bring with them new challenges. The emergence and increased use of "cloud based computing" is no different. The "cloud" raises new challenges of ensuring HIPAA compliance, but they are not insurmountable. Several companies—Dell, IBM, Cisco, and Verizon for example—provide cloud based models that not only meet HIPAA requirements but provide security beyond those requirements.

QUESTIONS FOR THE RECORD
THE HONORABLE LAMAR SMITH (R-TX)
U.S. House Committee on Science, Space, and Technology
Subcommittee on Technology and Innovation

Is "Meaningful Use" Delivering Meaningful Results?: An Examination of Health Information Technology Standards and Interoperability

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1. Has HHS and NIST taken enough time to fully evaluate the implementation of Stage 1 and the lessons learned before proceeding on with final Stage 2 rules? How should HHS and NIST evaluate the implementation of each of the three stages before proceeding on to the next one? What are your top concerns if this rollout is moving too quickly? Conversely, how do we ensure that we plan ahead for technological improvements to Health IT systems?

Health information technology continues to advance and its uses and capabilities continue to grow. Knowing that to be true, we need a meaningful use program that will evolve with these technology advances, not stifle them.

This doesn't mean the meaningful use program is being rolled out too quickly; to the contrary. What it does suggest is that the MU rules are not able to accommodate or sufficiently evolve so that new, better, fast, quicker health information technologies can be employed by physicians and hospitals.

Here are a few examples of how the Meaningful Use program is not keeping pace with how physicians and hospitals provide care, or with the technological demands associated with the level of care:

- **Measures of Quality:** Meaningful Use does not sufficiently require the appropriate quality framework that maximizes patient safety and quality outcomes. We support the inclusion of outcomes measures--that are computable by an EHR--as they improve patient care and outcomes. Process measures, such as documenting whether a patient's blood pressure has been taken, simply are not enough.
- **Patient Centered Care:** HHS should continue to work on standards and data access that better engage patients and improve patient outcomes, such as by providing on-line and electronic access to their health information. This is very important especially for those with chronic illnesses and multiple conditions. These patients expect their providers to use technology to manage their care.
- **Data Blocking:** A key goal of Meaningful Use is to share information to lower costs and improve care. Yet the Meaningful Use rules allow for vendors to block

access to data or restrict its transmission. Data blocking limits the exchange of information, making it near impossible to support the objectives of the meaningful use program. Data blocking puts patients at risk and limits the ability for physicians to make informed decisions in real-time.

- **Direct Standard:** The Direct protocol is an appropriate standard for some providers and for patient engagement with providers, but falls well-short of meeting the needs of most providers and, in fact, for some use-cases, could be seen as a step backwards. For those providers and systems that have technology and have made advances beyond “secure email,” they should not be forced/asked to replace their existing capabilities with the Direct standard.

Responses by Dr. Willa Fields, DNSc, RN, FHIMSS

Fields

**QUESTIONS FOR THE RECORD
THE HONORABLE BEN QUAYLE (R-AZ)
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1. Can you describe how the move to the cloud is affecting HIPAA compliance? Is this an area where we need greater guidance and oversight by HHS?

As with traditional EHR services, in order to be compliant with HIPAA/HITECH, the healthcare organization must conduct a security risk assessment that includes consideration of the cloud outsourcing. Guidance and resources on cloud computing/outsourcing and HIPAA/HITECH compliance are available from NIST, HIMSS and other government and industry entities (see below). As an additional step, the OCR audit protocol and/or related information could be updated to contain a discussion of the security and compliance implications of cloud outsourcing. The opportunity for oversight could be addressed as part of the Department of HHS Office of Civil Rights (OCR) HIPAA audit program.

HIMSS feels that these current guidance and oversight measures are adequate. Overall emphasis on improving privacy and security must continue at all levels. HIMSS sees no need for additional regulation for health information managed by cloud outsourcing.

Healthcare organizations are making use of several different types of "cloud computing" or "outsourcing" technologies depending on their assessment of what is best for their organization within the scope of the types of managed services offered by the cloud vendor. With each type, the cloud vendor assumes varying levels of responsibility for the security of the customer data and infrastructure. However, it is never the case that the customer can "outsource security" completely.

Cloud computing is not necessarily more secure or insecure than traditional internet communication. Nor is it the case that an organization using cloud computing services will or will not be compliant with HIPAA/HITECH. The reality is that there can be many security advantages to "cloud computing," especially for smaller organizations that may not have the in-house expertise or resources to fully implement security and opt to make use of cloud provider's services. That said, a healthcare entity can never fully outsource security or assert compliance by saying "my cloud vendor takes care of that."

Healthcare organizations are learning that security and related HIPAA/HITECH compliance is a joint effort between the cloud provider and the healthcare organization and that the healthcare organization is ultimately responsible for compliance. The most

desirable outcome is that the healthcare organization has visibility into the services that are provided by the cloud provider as well as the security controls provided as part of those services and infrastructure components. Similar to traditional EHR services, this can be achieved by careful scoping and documentation through the Service Level Agreement (SLA) (or contract for services) and, if applicable, the Business Associate Agreement (BAA). In order to address these challenges, there are a variety of contractual protections that health care organizations can use to manage data privacy and security risks, and to mandate the required response if a breach occurs. Such measures are important not only as good business practice, but also to facilitate compliance with HIPAA/ HITECH and other laws that apply to health care organizations.

Resources

NIST

The NIST Definition of Cloud Computing: Recommendations of the National Institute of Standards and Technology, <http://csrc.nist.gov/publications/nistpubs/800-145/SP800-145.pdf>, September 2011

Guidelines on Security and Privacy in Public Cloud Computing, <http://csrc.nist.gov/publications/nistpubs/800-144/SP800-144.pdf>, December 2011.

HIMSS

HIMSS Cloud Security Toolkit,
http://www.himss.org/ASP/topics_PStoolkit_CloudSecurity.asp
HIMSS White Paper, Navigating HIPAA While Moving to the Cloud

Cloud Security Alliance

Security Guidance for Critical Areas of Focus in Cloud Computing V2.1,
<https://cloudsecurityalliance.org/csaguide.pdf>
December 2009.

QUESTIONS FOR THE RECORD
THE HONORABLE LAMAR SMITH (R-TX)
U.S. House Committee on Science, Space, and Technology
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Is "Meaningful Use" Delivering Meaningful Results?: An Examination of Health Information Technology Standards and Interoperability

Wednesday, November 14, 2012

1. Has HHS and NIST taken enough time to fully evaluate the implementation of Stage 1 and the lessons learned before proceeding on with final Stage 2 rules? How should HHS and NIST evaluate the implementation of each of the three stages before proceeding on to the next one? What are your top concerns if this rollout is moving too quickly? Conversely, how do we ensure that we plan ahead for technological improvements to Health IT systems?

In accordance with the requirements of the HITECH Act, the EHR Incentive Program is only to be available for four years. Thus, the ambitious goals of the programs must be achieved within that timeframe and the program was intended to move quickly. The designers of the Meaningful Use Program created an iterative, collaborative process to achieve the system wide adoption of electronic health records and interoperability. Therefore, the Meaningful Use Program was designed to be implemented in at least three incremental steps. Meaningful Use is new and uncharted territory and is definitely a learn as we go effort.

HIMSS Public Policy Principles approved by the Board of Directors December 7, 2012, HIMSS recommends:

3.9 Ensure that eligibility requirements for meaningful use are clear and realistic. Ensure that all [Meaningful Use Program] Final Rules and associated changes and new standards are published at least 18 months before the beginning of the required implementation period to allow adequate time for developers to make the needed technology changes, for the industry to develop its response, for certification, to occur, and for providers to plan and implement required software and process changes.

A new analysis of HIMSS Analytics' Medical Record Adoption Model (EMRAM) scale reveals that in the five most recent quarters, beginning with the first incentive payments from the Medicare and Medicaid Incentive Program in 2011, U.S. acute care hospitals achieving EMRAM Stage 5, Stage 6, or Stage 7 have increased by 80 percent. Hospitals at Stages 0, 1, 2, and 3 have seen a decrease of 10 percent. These data suggests that the HITECH Act EHR Incentive Program is achieving its intended result of encouraging increased implementation and meaningful use of electronic health records among hospitals. Facilities moving to the EMRAM Stages 5, 6 and 7 are laying the groundwork for interoperability. The HIMSS' EMRAM is recognized as the standard to measure acute care hospitals' adoption of health information technology. For more information on HIMSS Analytics' EMRAM please see <http://www.himssanalytics.org/emram>.

In summary, HIMSS supports the efforts of HHS and NIST within the statutory requirement of the Meaningful Use Program to establish standards and evaluate the results and still meet the goals for the program established by the Congress. HIMSS supports the current, ambitious Meaningful Use schedule. HIMSS will continue to respond to all MU proposed rules and pledges our support and that of our 50,000 professional members to making the Meaningful Use program a success.

