S. HRG. 113–264

HEALTH INFORMATION TECHNOLOGY: A BUILDING BLOCK TO QUALITY HEALTH CARE

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

JULY 17, 2013

Printed for the use of the Committee on Finance

U.S. GOVERNMENT PRINTING OFFICE
87–789—PDF WASHINGTON : 2013

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
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COMMITTEE ON FINANCE

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HEALTH INFORMATION TECHNOLOGY: A BUILDING BLOCK TO QUALITY HEALTH CARE

WEDNESDAY, JULY 17, 2013

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:20 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Wyden, Stabenow, Casey, Hatch, Grassley, Roberts, and Thune.

Also present: Democratic Staff: Mac Campbell, General Counsel; David Schwartz, Chief Health Counsel; Karen Fisher, Professional Staff Member; and Peter Sokolove, Robert Wood Johnson Fellow. Republican Staff: Kristin Welsh, Health Policy Advisor.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The hearing will come to order.

First, I apologize to the witnesses for the delay. We had a vote scheduled at 10. Senators are voting, and they will be coming back in the next, roughly, 10 minutes or so.

Senator Hatch, though, did tell me he had an interim conflict. He will be here a little bit later, but he had something else that came up that he has to take care of.

Ralph Waldo Emerson once wrote, “Progress is the activity of today and the assurance of tomorrow.” This committee has held several hearings on overhauling the health care system to emphasize value over volume. Today we will discuss a vital tool to assure that this mission is completed: health information technology.

Over the past decade, when you went to the doctor, he or she likely kept track of your important health information by handwriting notes onto a paper chart. Then that chart, several inches thick, was filed away, often in a storage room, where no other doctor saw it or had access to it.

If you needed to see a cardiologist or surgeon, that specialty doctor could not see your paper record. Maybe your primary care doctor faxed over your information, but more likely the specialist would just ask you the same questions and create their own paper record and duplicate the same tests as your primary doctor.

If you went to the hospital, the situation was about the same. Diagnostic and lab tests were all recorded on paper, and your primary care physician might have no idea what happened during your hospital stay. What resulted from this system? Duplicate, costly tests, fragmented care, and often dangerous medical errors. We needed a better system. Other industries were using information technology to reduce their costs and to improve their service. Health care needed to catch up.

In 2009, Congress passed the Health Information Technology for Economic and Clinical Health Act, known as HITECH. Under this law, Medicare and Medicaid gives providers financial incentives to adopt health information technology and meaningful use.

"Meaningful use" means prescribing medication electronically to eliminate errors from scribbled, handwritten notes. It means ordering a different medication when the IT system informs the doctor that the patient has a drug allergy. It means sharing information electronically among providers so they can coordinate the patient's care. The result is better care at reduced costs.

In 2009, we allocated $33 billion to help hospitals and physicians move to electronic systems. To date, Medicare and Medicaid have given out $15 billion. As of this past May, nearly 80 percent of hospitals and half of physicians have received incentive payments because they have invested in health information technology.

One of our witnesses, Dr. Farzad Mostashari, will tell us that 3 years ago nearly 93 percent of prescriptions were handwritten. Today, that number has dropped to less than half. There are clear signs of progress, but we need to learn more and do better. Is the 2009 law working as intended? Is the money being spent efficiently? How much longer until there is seamless, coordinated care for patients?

We also need to understand why there are disparities between rural and urban doctors. Only a third of rural hospitals have a health information technology system compared to half of all urban hospitals. What can be done to reduce this disparity? I might say that I hear it in spades from my hospitals and critical access facilities in Montana.

Ultimately, technology must become part of the culture of health care delivery. New payment models such as Accountable Care Organizations, medical homes, and bundled payments will drive providers to use information technology.

Providers are being held financially responsible for providing high-quality, low-cost care. To succeed, physicians must engage in coordinated care, disease prevention, and chronic care management. Health information technology is indispensable to accomplish this. Key to this transformation is interoperability. Computers must be able to talk to each other so that patients and the providers can access information wherever and whenever they need it.

We need to know where we are in achieving interoperability, how far have we come, what barriers are preventing us from moving faster, and how do we overcome these barriers?

Today we will hear from the administration about all of these issues. So let us assess the challenges and opportunities, and, more importantly, let us learn how we can best leverage technology to achieve better quality and better value for patients. The stakes are too high to let this opportunity elude us.

[The prepared statement of Chairman Baucus appears in the appendix.]

The CHAIRMAN. Senator Hatch is on his way, and, when he arrives, he will want to make a statement.

I am pleased to welcome our witnesses. First is Farzad Mostashari, National Coordinator for Health Information Technology at the Department of Health and Human Services; next, Patrick Conway, who is the Chief Medical Officer and Director of the Center for Clinical Standards and Quality, and Acting Director of the Center for Medicare and Medicaid Innovation at the Centers for Medicare and Medicaid Services.

I will just remind you that your statements will automatically be included in the record, and I urge you to summarize in about 5 minutes. You can take a little longer if you want, just whatever works.

Dr. Mostashari?

STATEMENT OF FARZAD MOSTASHARI, M.D., ScM, NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. MOSTASHARI. Thank you, Chairman Baucus, Ranking Member Hatch, distinguished committee members. Thank you for the opportunity to appear today on behalf of the Department of Health and Human Services. My name is Dr. Farzad Mostashari. I am the National Coordinator of Health Information Technology.

Building on decades' worth of bipartisan legislative work, in 2009 the Congress and President Obama enacted the Health Information Technology for Economic and Clinical Health Act as part of the American Recovery and Reinvestment Act of 2009.

I am pleased to be here today to discuss the policies and programs we have implemented to meet the goals of the HITECH legislation and the progress made by America's health care providers in expanding health information technology use. Working in close collaboration with our CMS colleagues and our Federal advisory committees, we have defined what it means to make meaningful use of electronic health records and the key certification criteria and standards for those software systems.

America's providers and software developers have stepped forward. Throughout the country, 62 regional extension centers have signed up more than 147,000 providers in over 30,000 different practices. This means that over 40 percent of the Nation's primary care providers have committed to meaningfully using EHRs by partnering with their local extension center.

The financial incentives and the hands-on assistance have contributed to a greater than two-fold increase in the EHR adoption among eligible professionals and a five-fold increase among hospitals.

As described in recent publications, there has also been strong progress in the routine use of specific functions that are strongly aligned with other policy drivers, including those championed by this committee, to help our health care system to become safer and more efficient and achieve higher quality.

For example, computerized provider order entry for medication orders, which is a meaningful use requirement, has been shown to cut out nearly half of all medication errors. Since HITECH was enacted, the percentage of physicians with CPOE has increased from 45 to 80 percent. For non-Federal acute care hospitals, the percent with CPOE more than doubled between 2008 and 2012, rising from 27 percent to 72 percent.

Our aging population and the rise in chronic diseases place a premium on population health management, which requires data systems that can routinely measure the quality of care delivered, provide recommendations for guideline-based care, and reach out to patients. As one provider remarked, "You can't provide accountable care if you can't count."

Improved care coordination among providers is another one of the goals of the HITECH legislation. Patient information must be available when and where it is needed.

However, much work remains to be done to achieve the full promise of meaningful use. While increasing rapidly, adoption still lags behind in small practices and critical access hospitals. The usability of many of the legacy software products is suboptimal and the cause of frustration for many clinicians on the front lines.

While the digitization of health care is well under way, the complementary and necessary optimization and redesign of practice work flows is still in its infancy. Perhaps most importantly, there is much work yet to be done to achieve higher levels of interoperability between health care providers who use EHR products from different developers.

As several Senators on this committee have pointed out, it is a daunting task to enable secure and private health information exchange among hundreds of thousands of providers using disparate systems already in place, while accommodating changes in technology.

Nevertheless, I believe that through the exercise of multiple policy levers and substantial public/private collaboration, we are on the path toward better care coordination through health IT.

Through leadership and support from the States, operational health information exchange organizations are increasing in number and in size, now covering over 120,000 health care providers. We have worked with industry and experts to achieve hard-fought consensus on technical standards for key health care transactions. The health care IT marketplace is currently in the process of undergoing more rigorous testing, validation, and certification to meet these interoperability standards.

Stage 2 meaningful use requirements significantly raise the bar for actual information exchange when care transitions, and patients, all too often caught in the middle between doctors who do not speak to each other, can finally get their own data in structured electronic format to share with whomever they please.

But perhaps most significant has been the work of this committee and CMS in shifting incentives towards rewarding value and discouraging uncoordinated and wasteful care. Readmission penalties, value-based purchasing, shared savings programs, and bundled payments are all contributing to a sea change in the incentives of health care providers and encouraging greater information sharing.

There is much work yet to be done before we realize the full value of health information technology, but, in partnership with the Congress and the community of health care providers, software developers, patient advocates, and researchers, we are well on our way to establishing the foundation for better health and better care at lower cost.

Thank you.

The CHAIRMAN. Thank you, Doctor, very much.

[The prepared statement of Dr. Mostashari appears in the appendix.]

The CHAIRMAN. We are honored to have Senator Hatch join us. Senator Hatch, would you like to make a statement? We would certainly like to hear it.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH

Senator HATCH. Well, thank you, Chairman Baucus. I am sorry I was a little late, but I had to go to a press conference. I hate press conferences, but I had to do this one.

But I appreciate you holding this hearing about health information technology, or health IT. This is really an important subject and topic, and the chairman has rightly stated that it can help improve the quality of health care in this country. I appreciate the witnesses who are here today.

I have witnessed firsthand the power of using IT to transform the delivery of health care. In Utah, Intermountain Healthcare System has long been one of the leaders in the field. This transformation did not happen overnight.

Dr. Homer Warner, a University of Utah cardiologist, helped establish the field of health IT in the 1950s. Now, his work and teaching, coupled with that of his colleague, Reed Gardner, inspired generations of clinicians to enter the field of informatics long before it became popular.

The promise of health IT is that it can facilitate evidence-based clinical care to decrease the number of errors, which are far too frequent in our complex, fragmented health care system, and allow each clinical visit to a health care provider to increase our knowledge base about effective care.

In preparing for this series of hearings on health information technology, we have heard from many providers, both large and small, as well as the vendor community. Most have said that they believe that the meaningful use program has spurred the investment in technology. Many were already in the process of establishing and purchasing health information technologies, and the meaningful use funds that they received simply helped offset the costs.

For others, it was the threat of financial penalty that spurred this type of investment. Regardless, I think health IT can be a very valuable tool, and its use should be encouraged. However, it is my hope that we are not judging the success of this program simply on the number of dollars going out the door, but rather by the positive impact on patient care and decreases overall in health care costs.

I also hope that as both CMS and ONC* establish requirements for the program, they consider all of the other burdens that providers face. As we have seen time and time again, not all providers are created equal. The size, sophistication, and availability of resources vary greatly.

I am very proud of the work that Intermountain Healthcare has done in this area, and their use of health information technology should be an example to all. But we have to acknowledge that they are really the exception, not the rule. As CMS and ONC develop future stages of meaningful use, we need to take into account all that we ask of our providers.

Let me be clear: I do not want to see progress stalled on implementing the use of technologies, but, if we ignore problems along the way and simply expect everyone to catch up, we will end up in worse shape.

The Federal Government cannot afford to spend money on programs that do not yield results. At the same time, providers cannot afford to invest in systems that do not work or have to be overhauled a year later as requirements change. It would seem to me that we have an opportunity to push the "pause" button and make sure that the program is working before we continue down a potentially unsustainable path.

I think many members would agree that we should hold providers and vendors to high standards, and perhaps the meaningful use program in its various stages has set the bar too low. In the end, I would rather ask more of our providers and vendors, and provide them with a reasonable time line to achieve those goals.

This hearing, along with the one scheduled for next week, is being held to allow us to hear from the administration's leaders in health information technology and from the community of vendors and providers using health IT and clinical care. It is an opportunity to take a mid-course pulse of the ongoing meaningful use incentive payments to providers, and to assess the kinds of improvements in health care that these funds intended.

Mr. Chairman, I am grateful that you are holding this hearing, and I look forward to hearing from our two witnesses.

The CHAIRMAN. Thank you, Senator.

[The prepared statement of Senator Hatch appears in the appendix.]

The CHAIRMAN. Let us hear from our other witness. Dr. Conway, you are next.

STATEMENT OF PATRICK CONWAY, M.D., MSc, CHIEF MEDICAL OFFICER AND DIRECTOR, CENTER FOR CLINICAL STANDARDS AND QUALITY, AND ACTING DIRECTOR, CENTER FOR MEDICARE AND MEDICAID INNOVATION, CENTERS FOR MEDICARE AND MEDICAID SERVICES, WASHINGTON, DC

Dr. CONWAY. Thank you, Chairman Baucus, Ranking Member Hatch, and members of the Finance Committee, for the opportunity to speak with you today about CMS's role in the adoption of health information technology.

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* The Office of the National Coordinator for Health Information Technology.

When I started practicing medicine, I distinctly remember trying to read hand-scrawled notes, struggling to find an X-ray in the basement of the hospital, faxing or mailing discharge summaries, and going to the lab to track down lab results for patients. It was not an efficient or effective system; worse, missed information can lead to patient harm.

Now I practice as an attending physician on weekends, including this past weekend, in a hospital with an electronic health record, or EHR, networked with other hospitals across the region. With the click of a button, I can pull up any lab result, X-ray, or CAT scan.

I can even show, as I did this past weekend, a radiologic image to a worried family on the computer screen and explain the treatment of care. Medication orders are checked for errors, and clinical guidelines are encompassed in the computerized order sets.

When I was at Cincinnati Children's Hospital, I led efforts using EHRs to measure quality across our system. We used EHRs as an essential tool to transform care. For example, I led quality improvement work that used the EHR as a key driver to rapidly adopt new evidence-based practices, as was just noted, across our large system in a matter of weeks, leading to better patient outcomes. Health IT alone does not make care better, but it is an essential ingredient to care improvement.

It is important to note that health IT has traditionally had bipartisan support, as was just noted, and I personally worked for former HHS Secretary Leavitt on health IT initiatives.

CMS is incentivizing and enabling the use of health IT to improve care for beneficiaries. The Medicare and the Medicaid EHR incentive programs provide incentive payments to eligible professionals, hospitals, and critical access hospitals as they adopt, implement, upgrade, and demonstrate meaningful use of certified EHR technology.

The process for becoming a meaningful user of EHRs is staged, with increasing requirements for participation. Stage 1 focuses on basic use and data capture. Stage 2 focuses on more advanced EHR functions, including interoperability, patient engagement, clinical decision support, and quality measurement. In Stage 3, we expect to focus on increasing interoperability in health information exchange and to focus on improved patient outcomes.

The incentive programs are achieving their intended result of encouraging and increasing EHR adoption. More than half of all eligible professionals in the U.S. and approximately 80 percent of all eligible hospitals and critical access hospitals have adopted EHRs.

But incentives alone cannot sustain the transition to EHRs. The long-term sustainability of investments in health IT will come as a result of the movement away from fragmented fee-for-service care and toward value-based, coordinated accountable care models.

CMS programs like Accountable Care Organizations and hospital value-based purchasing, and proposed rules like the recent one for complex care management, incentivize well-coordinated care and build a business case for providers to sustain their EHR systems over time.

The incentive programs are also helping to improve the quality of care for patients. By requiring reporting on quality measures, we establish quality benchmarks. We can provide feedback to providers, and we can focus quality improvement efforts on measures that matter most to patients. The incentive programs are also facilitating safer, more efficient care delivery.

One great example, as was noted, is e-prescribing, which gives providers the ability to better manage patient prescriptions and reduce adverse drug events. The EHR incentive programs require the use of this technology.

In the first 2 years of the program, health care providers who met meaningful use standards reported sending 190 million electronic prescriptions. The incentive programs are also improving the care experience for patients.

I helped take care of my father, who was a Medicare beneficiary with chronic illness, for many years before he passed away. We built his own personal health record from scratch, entering data from many paper records. No beneficiary or family will ever have to do this again, and can access their information electronically.

Meaningful use Stage 1 requires providers to give patients electronic copies of their diagnostic test results, problem list, and medication list, and the Blue Button initiative allows patients and families to download and use their health information.

By incentivizing the adoption of EHR, CMS is making a commitment to the health care delivery system of the future, a system that values high-quality, well-coordinated care for CMS beneficiaries. Health IT is a foundational building block for delivery system transformation and achieving better health outcomes for all Americans. I want to thank you for the opportunity to speak with you today, and I am happy to answer any questions that you have. Thank you.

The CHAIRMAN. Thank you, both of you, very much.

[The prepared statement of Dr. Conway appears in the appendix.]

The CHAIRMAN. First, I would like to remind everyone that we will have another hearing on this subject. Next week we will hear from providers and vendors to get a little bit different perspective here.

I would like to ask two questions. One is about the various stages. Would you modify them at all? How are they working out? For example, it is my understanding that in Stage 1 there are eligible professionals who must meet about 15 core objectives and 5 of 10 menu objectives. Eligible hospitals and CAHs must meet 14 core objectives and 5 to 10 menu objectives. In Stage 2, there are 17 core objectives, and 3 of 6 menu objectives must be met, and eligible hospitals, CAHs, must meet 16 core objectives and 3 of 6 menu objectives. Stage 3 requirements will be determined a little bit later.

Does that all make sense to you, those core objectives and those menus? How would you modify them, if at all, or do we need to worry about that?

Dr. CONWAY. I will start, and Dr. Mostashari may build on. I think the concept behind the core objectives was to require the core objective aspects of electronic health records and functionality that we thought were critical to coordinate care. With the menu objectives, the principle was to allow flexibility with selection of the menu objectives.

We also removed some core objectives and added some additional core objectives to raise the bar from Stage 1 to Stage 2. With Stage 3, we are evaluating that approach versus other approaches, based on stakeholder feedback. With that, I will turn it over to my colleague, Dr. Mostashari.

Dr. MOSTASHARI. As Dr. Conway said, the structure that was recommended to us by the Health IT Policy Committee has this feature for flexibility. As noted, all providers are not the same, and they do not all do the same things. Some of those menu objectives may not be applicable to all.

So, by providing the flexibility, we can say, if you report to a professional registry, that can count; but not everybody does. If you access imaging results a lot in part of your day, that can count; but not everybody does that. So it provides flexibility. It also provides the ability for us to introduce and signal functionality that is on its way, but it may be too soon to require everybody to be able to step up to it.

The CHAIRMAN. Well, there are $15 billion in payments. Are the dollars just paid, or is it paid under conditions, such as the providers meeting certain conditions?

Dr. CONWAY. I can start, if that is all right, and Dr. Mostashari can build on. So, they do have to meet requirements to receive payments, and you mentioned the core and menu objectives which are a significant portion of that requirement and the functional measures, if you will, for electronic health records. They also have to attest to electronic clinical quality measurement. In 2014, with Stage 2, they will be electronically submitting, either as individuals or batch reporting for groups, on those functional measures and the electronic clinical quality measure.

The CHAIRMAN. Are you on track? The administration delayed a floor mandate for various reasons, probably because they were not quite ready. How are we doing here? Are we on track? Have there been any delays?

Dr. MOSTASHARI. We are finishing Stage 1, and we have had, I think, good results in terms of participation and achievement of the standards for Stage 1. We are working, in 2013, on implementation of Stage 2, which is going to be a big step forward, particularly around patient engagement and interoperability. We are going to continually monitor where we are, how we are doing, how things are going, and react and adapt as needed.

The CHAIRMAN. This committee wants to help, so let us know. Just do not blind-side us with a telephone call one day that says, uh-oh, we are not doing this. Rather, let us know if there are some problems that we can help with, because clearly I do not know a Senator who does not believe in better health IT as a critical component.

About rural providers.

Dr. MOSTASHARI. Yes?

The CHAIRMAN. How are we going to help rural providers? It is harder for the smaller hospitals in a rural setting.

Dr. MOSTASHARI. It is. It is much more difficult. There are providers who live in areas where EHR vendors will not come out to demonstrate the system for them.

The CHAIRMAN. Right.

Dr. MOSTASHARI. Workforce is a major limitation for them to be able to do it themselves. Critical access hospitals have, on average, 0.8 FTEs working on IT. The same person is often in charge of maintenance as well as IT.

The CHAIRMAN. Right.

Dr. MOSTASHARI. So they face unique challenges. One of the approaches that we have taken is to target rural providers, rural health clinics, critical access hospitals, for extra assistance through the Regional Extension Center program. The majority of rural primary care providers are working with an extension program modeled after the agricultural extension program that rural providers are familiar with. I think that has contributed to rural eligible professionals not falling behind in terms of the adoption rate.

The CHAIRMAN. Do you think it has contributed enough?

Dr. MOSTASHARI. We can always do more. The one area where we are working is on better collaboration between all the different Federal programs that touch rural providers. In Iowa, we recently did a pilot where we worked with the USDA to encourage them to look at the rural health care providers for the grant programs, the loan programs, that are available through the FCC Rural Utility Service. There are many programs that target rural providers, rural settings, and we need to bring all of our forces to bear in a coordinated way.

The CHAIRMAN. Thank you very much.

Senator Hatch?

Senator HATCH. Mr. Chairman, I am going to yield to Senator Grassley, who has a conflict and needs to leave.

The CHAIRMAN. I do not know if we can do that. [Laughter.]

Senator Grassley?

Senator GRASSLEY. Thank you, Senator Hatch, Mr. Chairman.

I have just one question for both of you, but I want to lead up to that question, so please listen. The purpose of our investment in health information technology is to make it possible to quickly capture, store, and share data.

It was our belief when we first started legislating in this area that quicker and more accurate data-sharing would lead to better care coordination and improve outcomes for patients, as well as savings to the Medicare program.

I recently introduced a bill with Senator Wyden that would advance the idea of data-sharing. The Medicare Data Act would require the Secretary of HHS to create a searchable database of all Medicare claims and payments made to providers. Last Congress, we saw increasing support for our bill and a broadening belief that more data transparency in the Medicare program is a good thing.

I applaud recent efforts taken by CMS to release Medicare hospital data for a limited set of procedures. Despite its limited fashion, I take the action to mean CMS recognizes the value of transparency in this area. The Grassley-Wyden bill goes even further by making public all Medicare claims and payments made by all participating Medicare providers.

Taxpayers deserve to know where their hard-earned dollars are going. More transparency also means more provider accountability to communities they serve and other professionals they work with.

So here is my question. You have described how health information technology will improve communication between providers and promote care coordination. Could a searchable claims database be used to complement these efforts by making providers more accountable to their peers and the public?

Dr. CONWAY. So, I will start, and then Dr. Mostashari can build on. First, we would welcome the chance to work with you and provide technical assistance on this legislation. As you noted, CMS is committed to transparency, committed to transparency both on performance and quality information, as well as cost data. We are committed to utilizing data to drive improved quality and decrease costs.

We have a number of mechanisms now where we are sharing data, both, as you noted, public use files for the public, and also our various compare sites which are run out of my center in CMS, both with data on the compare sites, downloadable data. We would welcome the opportunity to expand the ability to utilize CMS data to drive improvements and to work with the Congress on that.

Senator GRASSLEY. Dr. Mostashari, I would like to hear from you.

Dr. MOSTASHARI. We believe in the power of data for better decision-making and open data to the extent possible, given privacy concerns and operational realities. We have been, I think, strong supporters of making available data sets as part of meaningful use, making part of our certification products available, and working with the developer community to make good use of that open data.

Senator GRASSLEY. Thank you, Mr. Chairman. Thank you, folks.

The CHAIRMAN. Thank you, Senator.

Senator Wyden?

Senator WYDEN. Thank you very much. I want to thank Senator Grassley for the chance to work with him on that important bill, and I look forward to working with our colleagues on it.

Dr. Mostashari, let me start with you because, as you know, we are asking a lot of the Centers for Medicare and Medicaid Services in the days ahead, and we are obviously talking about medical records today. Just talking with Senator Stabenow, sometimes you feel, in discussing these issues, that it does not resemble English, that, if you parachuted in, you would be trying to figure out what in the world we are talking about.

So let me start with a question for you, Dr. Mostashari. How would you assess the quality of the computers today at the Centers for Medicare and Medicaid Services?

Dr. MOSTASHARI. I do not think that I have enough experience with computer systems at the Centers for Medicare and Medicaid Services to be able to answer that question. I do not know if Dr. Conway would——

Senator WYDEN. Well, I wanted to ask you, because it is kind of a lead-up, and maybe we will get into some other areas that would shed some light on it. Now, you mentioned that you are “encouraging institutions that have health data to make it easier for patients to gain easy electronic access to their data and to use that information in ways that improve their health and health care.”

Dr. MOSTASHARI. Yes.

Senator WYDEN. Do you believe that CMS is one of those institutions?

Dr. MOSTASHARI. In fact, I believe that CMS is a key institution for doing so. My mom, whom I have health care proxy for, downloaded 3 years of every claim submitted on her behalf and paid on her behalf from Medicare, and that information on her smartphone and on my smartphone has actually been really revolutionary in terms of us being able to manage her care better. So I think CMS——

Senator WYDEN. That would be a statement that the CMS computers are not exactly in the Dark Ages. Would that be fair to say?

Dr. MOSTASHARI. They have done a great job allowing the CMS Medicare Blue Button to be available to all 37 million Medicare beneficiaries.

Senator WYDEN. All right. So we have made some headway on the patient side, and I think that is clearly a plus. We also are hearing continually from providers that they are waiting for their data, that they are having problems getting it. We touched on this a little bit at our hearing last week. This is a hugely important point, as you know, because right at the heart of the bill is the concept of shared savings.

What we want to be able to say to providers all over the country is—and there is great bipartisan interest in this—that when you do well, when you are able to give good-quality care at more affordable prices, you will in fact get to share in the savings. It is locking in a set of incentives that has not traditionally been available in fee-for-service.

It is pretty hard to tap the potential of shared savings if the providers keep reporting to us and our various staffs that they cannot get their data. So what is your take on that, Doctor, and what do you think we can do to make sure that the providers can also get their data in a timely kind of fashion?

You have told me something that I think is plenty useful this morning. You said your mom essentially got a lot of useful data in a fashion that was helpful to her, but I am still getting complaints and concerns from providers. So what is your take about how we turn that around?

Dr. MOSTASHARI. Well, I will allow Dr. Conway to answer, but providers are now getting more data from Medicare than they ever have before, through the shared savings programs, the new CMMI programs, and also through, I think, the important measure in section 10322 for qualified entities to receive Medicare data for the purpose of benchmarking and providing assistance to providers.

So I think the Affordable Care Act provided important enablers of better data-sharing, and it is much improved compared to where it has been. I am sure that there are ways to improve, but it is better than it ever has been, I believe.

Dr. CONWAY. And just briefly, to build on that, through our various payment models, we do have monthly data feeds now. For example, in the Medicare shared savings program, Pioneer ACOs, and a number of payment models, that is much better in terms of frequency than previously, as you may have heard.

To build on the previous point on technical assistance, I think we would welcome the opportunity to provide technical assistance for what level of resources we would be able to achieve, what level of data feed, to what percentage of providers in America. So we would welcome the opportunity to work with you on this critical issue.

Senator WYDEN. My time is up. I am going to ask you to get back to me on the record, Dr. Conway, about a statement in your testimony. You make a point with respect to the vendors sharing information, because we obviously have to hold the vendors accountable. You state, "We recognize that some providers and electronic health record vendors may not have a business imperative to share health information across providers and settings of care."

Now, that is a pretty troubling statement, because taxpayers have spent billions of dollars to make this work, and the vendors have seen enormous growth since 2009. I think we need to know more, and specifically I would like to hear, in writing, how you are holding these vendors accountable, because that money is out the door. As Chairman Baucus talked about, it is huge sums. So can you get back to us, say, within a week on that, Dr. Conway?

Dr. CONWAY. We can commit to working with the Office of the National Coordinator to get back to you, and we will try to meet that time frame.

Senator WYDEN. Great.

Thank you, Mr. Chairman.

The CHAIRMAN. And send that to the committee.

Senator WYDEN. Yes. That is what I meant.

The CHAIRMAN. Senator Hatch?

Senator HATCH. Well, thank you, Mr. Chairman.

Dr. Mostashari, I do not think I can get mad at somebody who would wear a bow tie like that, I just have to tell you. [Laughter.] It is a beauty. I am kind of envious, to be honest with you.

Now, Dr. Mostashari, do you believe that a pause in meaningful use payments to hospitals and eligible providers would allow us to evaluate progress and readjust, if necessary, to get the return on investment that we have searched for with the electronic health record incentive program? Should a pause also coincide with a delay in penalties for the non-adopters?

Dr. MOSTASHARI. No, sir. I believe that a pause in the program would stall the progress that has been hard-fought. Given the movement that we have accomplished through Stage 1, we need to give Stage 2 a chance to move ahead and to meet the urgency of the moment in providing support for coordinated care, for the transformation in health care, and I believe that a pause would take momentum away from progress.

Senator HATCH. All right.

Dr. Conway, in your testimony you recognized the changes that providers experience in trying to comply with multiple, and each slightly different, quality measure reporting outcomes. Now, my constituents would agree. When can we expect all of these measures to be "harmonized" and, more importantly, reportable as an automated function from within the EHR itself?

Dr. CONWAY. Thank you for the question, Senator Hatch. So we have made significant progress in the last 2 years on this issue in my tenure as Chief Medical Officer. Specifically, we just proposed, in the physician fee schedule rule, the ability, for 2014, for groups of clinicians to report once and receive credit for all applicable programs, so the meaningful use program, PQRS—the Physician Quality Reporting System—physician value-based modifier, and, if they are an ACO, the ACO program. This is a very different place than we were a year or 2 years ago, so we are accepting comments on that rule, but we look to finalize it to meet your vision of reporting once on an aligned set of measures.

For hospitals, likewise, they now can, with this proposal—which we have comments coming back on, and look to finalize by August 1st—report once and receive credit for all hospital programs: inpatient quality reporting, hospital value-based purchasing, and the meaningful use program.

So it is a critical point. I used to manage reporting on quality measures for my health system in Cincinnati, and we have now met that goal of an aligned set of measures to allow people to report once and receive credit for all programs.

Senator HATCH. Well, thank you.

Dr. Mostashari, I have heard from providers that significant obstacles to interoperability still exist. Do you share this perspective? If so, what are these obstacles, and how can we resolve them?

Dr. MOSTASHARI. The obstacles include technical standards, nonproprietary open standards, for sharing information that there is consensus around.

Another obstacle is the business case for information sharing on the part of providers, which this committee has done really important work towards resolving.

Third, trust. Many health care providers feel that they are entrusted with the patient's information, and they are much more comfortable sharing as part of their normal delivery patterns of care than with remote individuals whom they are not on a first-name basis with. We are making progress on all three of those.

We heard testimony from Marc Probst, CIO of Intermountain Healthcare, at the House hearing last fall, that more could be done—and we are pushing on the standards—but that there has been clear progress toward the interoperability standards. Stage 2 of meaningful use and the 2014 certification criteria that the vendors are testing now, are taking a big step ahead. If you would like, I can describe a little bit what is on the pathway here.

Senator HATCH. All right.

Dr. MOSTASHARI. The standards that we are working on are in three domains. The first is around language, so terminologies, vocabularies, so that one person's medication list can be compared to and added to another person's medication list. We have never had a single standard for comparing medication lists. We do now as part of the 2014 certification criteria.

There are single vocabularies for immunizations, there is a single vocabulary for clinical diagnoses, there is a single vocabulary for procedures. So these are important to make sure that we reduce the cost and, frankly, safety problems when two different institutions try to compare local codes and local words and local maps. Laboratory results is another.

The second area we have made progress on is, for the first time in our Nation's history, we have consensus—hard-fought consensus—on a single standard for packaging patient information in an electronic format, so we move beyond PDFs and text files to actual structured data, where you know where the data elements are and you can reduce the cost of those interfaces between different systems. That is the consolidated Clinical Document Architecture which is part of the 2014 certification criteria.

Finally, we have, for the first time, agreement on what protocols to use when sending health information over the Internet in a way that can be secure and encrypted. So the combination of those building blocks are in the 2014 certification criteria, and, when they take effect, I believe we will see a measurable improvement in the ability of organizations to talk to each other.

Senator HATCH. Thank you, sir.

Mr. Chairman, thank you.

The CHAIRMAN. Thank you, Senator.

Senator Thune, you are next.

Senator THUNE. Thank you, Mr. Chairman. I want to thank you and Senator Hatch for holding this hearing. This is a hearing that I had written to you and requested a year ago, and I appreciate the fact that we are having a couple of hearings on what I think is a very important topic.

Earlier this spring, I worked with a number of my colleagues, including some on this committee, on a white paper that explored issues I hope we address today. I would like, if it is all right with you, Mr. Chairman, to submit it. It is called “Reboot: Re-examining the Strategies Needed to Successfully Adopt Health IT.” I would submit it for the record.

The CHAIRMAN. Without objection.

[The white paper appears in the appendix on page 78.]

Senator THUNE. I want to start by thanking Dr. Mostashari for the efforts that he has made in responding to questions posed to the administration as part of that “Reboot” report. We received a response last week, and I appreciate the substance of that response.

I want to ask a question. I am really concerned about the argument that we need to make sure that there is a sufficient business case for continued progress on interoperability and exchange of data between unaffiliated providers. At some point the ability for the Federal Government to provide sufficient carrot and stick incentives is limited by the resource constraints and an appropriate level of financial penalties.

So I am curious to know what you are doing to encourage the use of real market forces, not just government incentives and penalties, to create the business case for continued progress. I also wish to know what role the anti-kickback statute plays in constraining the types of market incentives that could be used to help make that business case.

Dr. MOSTASHARI. Absolutely. And to clarify, we believe that it is important for government to be part of, along with the States, along with commercial payers and purchasers, changing the context in terms of how the market operates.

We are not suggesting that we need more incentives akin to the health IT incentive program—paying people per transaction to create a business case for information exchange. It is more creating the context.

The readmission adjustments have had a market effect on hospitals' interests in coordinating care once they discharge their patients. They just have. We see that every day. The vendors now are much more interested in having interoperability because their customers are saying to them, the market is working.

Their customers are saying to them, when I discharge a patient to a nursing home, I want that nursing home to be able to get this information electronically. I want the primary care provider to get the discharge summary. If someone shows up in another emergency room, I want to hear about it, because I do not want them readmitted. That is what we mean by creating the business case for information exchange. It is really the business case for care coordination, which is what this committee is taking such important steps on.

In terms of the Stark law and the anti-kickback statute, we worked with CMS and the Department of Justice on a Notice of Proposed Rulemaking on that, and I will let Dr. Conway speak to that. But it was clearly one of the policy issues that we could use as a lever to make sure that if information systems and software are donated, that we also get the expectation out of them that they will not be used to lock in patient data to a given institution.

Dr. CONWAY. So, as Dr. Mostashari said, we have proposed a regulatory change that we think addresses some of those issues. Obviously, there are additional statutory changes you or other Senators are interested in. We would work with you on that. Just to amplify what Farzad said about the incentive structure, I have worked in delivery systems that migrated their contract models away from fee-for-service to accountable care models, and it does shift your incentives in a private market setting to incentivize sharing of information and coordination of care.

So, whether it is a readmissions program or new payment models, our goal is to incentivize those models that enable providers in the private market to achieve better health outcomes at lower cost.

Senator THUNE. I want to come back to something that Chairman Baucus talked about earlier. I am concerned about the digital divide that may only get larger as rural hospitals are expected to take a leap into the more rigorous requirements of Stage 2. They have already expressed grave concerns about Stage 2.

I am of the view that ONC and CMS ought to develop a way for rural hospitals to have more time to achieve Stage 2, while allowing the more advanced health care systems and providers to move on to Stage 3 if they are ready. So the question would be, will you commit to giving rural providers more time to achieve Stage 2?

Dr. MOSTASHARI. We meet with the rural providers, and we hear from them. Marty Fattig, whom you will hear from next week, is on our advisory group, and we have been, I think, quite open to dialogue with the rural community in terms of how we can help them achieve success and not necessarily accept that they are going to be further behind.

I think the Regional Extension Centers have helped now. We set a goal of getting a thousand critical access hospitals to meaningful use by the end of 2014. We are going to revise that goal to get a thousand critical access hospitals to meaningful use by the end of this year.

We think that we are making good progress with those hospitals through the technical assistance and through the coordination that is possible, so we are open to dialogue. But I would much rather see the rural hospitals be able to keep up rather than acknowledge that they are going to fall behind.

Senator THUNE. My time has expired, Mr. Chairman.

The CHAIRMAN. All right. Thank you, Senator, very much.

Senator Casey?

Senator CASEY. Mr. Chairman, thank you very much.

Dr. Mostashari and Dr. Conway, thank you for your testimony and your public service. When medical doctors and people with your education and experience are dedicating their time to helping all of us with regard to health care in the Federal Government, implementing the Affordable Care Act and all the work that you do, that is of great significance, so we are appreciative of your work.

I wanted to try to explore maybe two issues, but the principal focus that I will have in my questions will be with regard to children and pediatrics. Dr. Conway, you have spent a lot of years laboring in the vineyards of children's hospitals and working with kids, I know both in Cincinnati and in Philadelphia. How many years, one versus the other?

Dr. CONWAY. Approximately 2½ years in Philadelphia and 5 total in Cincinnati.

Senator CASEY. We want you to increase that Pennsylvania number. [Laughter.]

Dr. CONWAY. I am sorry; I will work on that.

Senator CASEY. I wanted to ask you in particular, when you focus on where we hope we are in Stage 3, when you are measuring quality more than you are in the earlier stages, tell us a little bit about how you measure quality, but in particular how you measure it as it relates to children.

Because, as you know, as you have, I am sure, said and the advocates tell us all the time, children are not small adults, so how you measure for adults will differ from children. But tell us about that, how you are beginning to implement it and how you hope it works in Stage 3.

Dr. CONWAY. Thank you for the question, Senator Casey. There are a couple of ways we are trying to address that issue, and it is a critical issue, as you mentioned. One, especially for Stage 2, we actually ensured that we had sufficient measures covering pediatric care so that, if you are a pediatric provider, you can report on measures relevant to your practice.

Two, we had had the concept of an adult-recommended core set of quality measures previously. We actually also did a recommended set of pediatric core measures to report on. Also, working with our colleagues at the Agency for Healthcare Research and Quality and Medicaid, we have worked on initiatives related to standardized electronic health records, working with vendors to make sure that there are electronic health records that meet the pediatric population needs.

In addition, through the CHIPRA funding, the Children's Health Insurance Program reauthorization, as you know, there was funding for pediatric measurement development. We are working with our colleagues on developing measures that I think will be the next generation of pediatric measures, everything from safety measures to care coordination to dental health, a wide spectrum of pediatric measures that will really put us in a much better place to make sure we are ensuring that we are measuring quality robustly for pediatric patients.

Senator CASEY. Dr. Mostashari, would you like to add anything on this in terms of your work?

Dr. MOSTASHARI. I would just agree with Patrick that there has been a lot of work to move measurement from many of the process measures, of which we have lots, to more outcome-based measures, measures that are more parsimonious, more broad-based, and more designed from the ground up to be used with electronic health records, instead of re-tooling measures that are meant for chart reviews, for which the data elements can often not be found or only found with difficulty with an electronic health record.

There was a recent article published last week out of Kaiser that found that they reduced the cost of chart review for quality measures by half. They cut it in half based on being able to extract information from the electronic health record. But it is still not good enough.

There are still too many quality measures that are re-tooled, that require elements that just do not make sense within the electronic health record context, and we are working in close collaboration with CMS to build new measures from the ground up that actually matter and that work.

Senator CASEY. And also, with regard to children, the development of databases, both regional and national—can you tell us about that?

Dr. CONWAY. I will start, and Dr. Mostashari may add on. I think we are working with our Medicaid office, for example, on the CHIPRA quality measures, working with States on quality reporting. In terms of database development, we are actually working across the Federal Government, from the National Institutes of Health to the Administrative Resource Center to others, on what would be the infrastructure to collect data to inform care for children.

I currently care for mainly children in the hospital with multiple chronic conditions who are hospitalized, and that is a population where we often do not have the data and the evidence necessary to guide their care as best we can. Prior to coming to the Federal Government, I was part of an effort that actually linked children's hospitals on an electronic platform, both for improving care quality and also research to inform that next stage of care delivery.

Dr. MOSTASHARI. One thing I will add is that the pediatric community has actually been great at working together in collaboratives, whether it is around cancer or cystic fibrosis, and is a real model. If you look at the improvements in the death rates from childhood cancers and the number of children who end up in clinical trials, it is really a model for what we hope to be able to do for adults.

It is one of the goals, I think: not having a single centralized database of patient information, but rather having networks of organizations and institutions that can collaborate together. We are working on the standards for that to be able to share that information, and working with the Patient Centered Outcomes Research Institute to create that data infrastructure for distributed research as opposed to combining information in one database.

Senator CASEY. Thank you very much.

The CHAIRMAN. Thank you, Senator.

Senator Enzi, you are next.

Senator ENZI. Thank you, Mr. Chairman. Thank you for having this hearing. I am also pleased that next week we are going to have one with the private technology industry so that we can learn more about their involvement, as well as Federal impediments. I think that will be very helpful.

Dr. Mostashari, I have heard concerns from the Wyoming Health Information Exchange that the requirements for data exchange in Stage 2 of the meaningful use program represent a step backwards for the program. In particular, representatives from the health information exchange have informed me that the secure data exchange requirements are limited to e-mails and text messages, when their system has a much more advanced capability already.

Can you tell me how ONC is coordinating with States like Wyoming to ensure that the meaningful use program is not hindering State progress in deploying HIT? What is being done to ensure that these innovative approaches are not hamstrung by current Federal rules?

Dr. MOSTASHARI. Absolutely. We are working very closely with all of our grantees on the State health information exchange grants. We have health IT coordinators in every State funded through the program and designed by the Governors to coordinate with their local needs, their local resources.

The different models in different States are different. What happens in Texas and the approach taken there is different from the approach taken in Maryland. We do work with them to make sure that the plans that they have are in alignment with the national standards and have a path to sustainability.

Senator ENZI. Are you currently just doing the e-mails and the text messages? What about the other advanced capability? That is the main part of the question.

Dr. MOSTASHARI. Sure. No, sir. The requirements, both for meaningful use, the certification of electronic health records, and for the health information exchanges, are not limited. They are a floor, not a ceiling. We are supporting the States in development of more complex, more comprehensive query systems, even as we are also supporting the more directed messaging, which, to clarify, is not text or PDF, it is actually exchange of structured, codified electronic information through direct messaging.

Let me give you an example of a rural provider in Wyoming who has an independent practice in a small town.

Senator ENZI. That would be Dr. Gee. I talk to him all the time, so you do not need to answer any questions in regard to that. He is my authority.

Dr. Conway, a recent news article noted that more than 10,000 providers who participated in 2011 did not do so in 2012. Does this trouble you, as these providers are subject to penalties if they do not meet the Medicare meaningful use requirements year-on-year? What will you do to simplify the program, and were these providers more rural or urban providers, or located in a particular type of practice or area of the country? Who is it who dropped out?

Dr. CONWAY. So it is important to note that it was a relatively small percentage who dropped out of the program. However, it is an important question to look into the reason for it, so we have started.

Senator ENZI. Ten thousand is a small number?

Dr. CONWAY. What I mean by that is, if you think of the 300,000 participating providers, 10,000 is a significant number that we did look into. I just mean, as a percentage basis, it is a small percentage. We did, though, investigate this and look into the reasons. It was a mix of factors: people who were retiring, often people who were switching practices to a new or a different practice setting.

For some, there was education outreach. They did not realize you needed to come back in every year, so now we are doing some re-education and outreach, working with physicians and especially societies to make sure people understand it is an annual update program. So there were a host of other reasons—they wanted to switch vendors, for example. So there were a host of reasons. In terms of the program burden, we always look to find the right balance of moving the program forward but minimizing burden and eliminating unnecessary burden on providers.

Senator ENZI. Thank you. Because we have to work with these people one-on-one, even though it is 10,000.

Dr. CONWAY. Yes, sir.

Senator ENZI. And it is a small percentage, but each one of them has a major concern.

I have another question, I think along those lines. CMS stated it is increasingly incorporating the electronic quality measurements into payment systems. How are you going to assure providers that their performance is being fairly and accurately represented in the data submitted to CMS as part of that meaningful use program? What is your time line and plan for improving the integration of the quality measurement, especially the outcomes-based measurement, into the electronic health records?

Dr. CONWAY. Thank you for that question. We are aligning measurement programs. As I mentioned briefly, we have proposed, for this year's physician fee schedule rule, to enable providers to report once and receive credit for all applicable reporting programs: the EHR incentive program, PQRS, physician value-based modifier, and, if they are an ACO, the ACO program.

In terms of the validity and the reliability of the measures, we also work with the Office of the National Coordinator on certification criteria to attempt to ensure that electronic health records are capturing and reporting the data reliably.

Also, for Stage 2 we are enabling data intermediaries, enabling a private market for data intermediaries, to serve both for frequent feedback to clinicians and for standardized reporting to CMS, and, similar to what we have done in the hospital program, our goal is to provide feedback to providers and to ensure that we have valid and reliable electronic clinical quality measures.

Senator ENZI. I have to talk to my doctors to see if they can understand what you just said, because I had a little difficulty with it. I will have more specific questions on all those acronyms that you mentioned. My time has expired; I apologize.

The CHAIRMAN. No problem, Senator.

Senator Stabenow?

Senator STABENOW. Thank you very much, Mr. Chairman. This is a very important hearing. Let me just start by saying we have given you a massive task. When I think about where we started a few years ago with a number of us working on this for a long time and talking about going from a paper-based system to a digital, electronically based system, it is just amazing. So I know there is a lot of work to do.

I have a lot of concerns about specifics, but I just want to say in the beginning that we should at first recognize the fact that 50 percent of eligible providers, 80 percent of eligible hospitals, have gotten incentives to move to electronic health records, and, overall, adoption has more than doubled for physicians and quadrupled for hospitals.

So we have done a lot of important work, I think, together on the committee, as a Congress, working with all of you. The fact that participating provider practices have increased from 45 percent to 80 percent from 2008 to 2012, in terms of electronic health records, is very significant. We need to get it done, and we need to get it done right. As the chairman said, I do not know anyone who does not think this is absolutely necessary to do.

Given that, let me associate myself with Senator Hatch, who asked about health IT and quality measures, and just reiterate that. Dr. Mostashari, we are in a situation where I know that you are focused on streamlining measures, and we have all kinds of examples. I have hospitals in some cases reporting the same information twice in two different formats. We have to address that if this is going to be successful.

Let me talk about vendors and interoperability. I know that Senator Wyden and our chairman have expressed interest and asked you to respond for the record, but I would like to ask you to just talk about it for a moment, because I am hearing a lot of frustrations from hospitals and physicians.

They are purchasing systems that are unable to communicate with other systems. There is not enough information exchange infrastructure. The costs of products are overwhelming. In some cases, they are being sold products that are not interoperable and told, if they want them to be interoperable, it is going to cost them more money.

So what are we going to do about this? I mean, we see situations where some vendors form contracts that block the exchange of information. Certainly the vendors are very important, but this seems like it is a real problem, so I am wondering, Dr. Mostashari, if you would speak to that.

Dr. MOSTASHARI. Yes. Absolutely. There needs to be action on multiple fronts. We need to exert the regulatory levers judiciously, to not take too heavy of a hand, but not rely entirely on the invisible hand either. So, in our certification program, for example, we have required transparency from the vendors in terms of their pricing.

If a module is going to cost you extra, in addition, you need to be transparent about that with the customers. You have to be transparent about how you passed the certification test. We still hear providers saying, I do not understand how this product got certified. We indeed have pulled the certification for a vendor who did not respond to repeated questions about whether they in fact were doing what they were supposed to be doing. We also have requirements around user-centered design so that, particularly around safety issues, they meet those needs.

Senator STABENOW. I was just going to jump in and ask, do you think you have enough authority from a regulatory standpoint——

Dr. MOSTASHARI. Yes.

Senator STABENOW [continuing]. Or do we need to change the law?

Dr. MOSTASHARI. No. No. We have authority from a regulatory standpoint. The question is, the judicious exercise of that authority. We also need the market, the invisible hand, to work too. The customers need to be demanding and tough customers, and they need to ask for interoperability. We have regional extension centers helping the smallest practices with better vendor contracts, better negotiations, and so forth.

But in between the market competition and regulation there is something else, and that is kind of professional business norms and the social norms among the vendors. We have asked them to step up on that, and, in fact, the vendor association did just recently come out with a code of conduct, which I was very glad to see, where the vendor is saying there is actually a code of good conduct for electronic health record vendors that includes things like not blocking information. So I do think we are making progress on that. We need to continue to be vigilant.

Senator STABENOW. Let me just say, as my time is up, that also related to interoperability, of course, particularly in rural areas, is tele-health, which has such an important impact. We have a lot of leaders in Michigan, in what we call the Upper Peninsula of Michigan. Marquette General Hospital has received a lot of recognition for what they are doing. So I hope that we are using what we are doing in terms of leveraging tele-health with the interoperability standards that we are putting together. Particularly for rural areas, that is very, very important.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator. Thank you very much.

Senator Roberts?

Senator ROBERTS. Well, thank you, Mr. Chairman. I think I am riding drag on this posse. I want to associate myself with the remarks of Senator Enzi and the distinguished chairman and ranking member. Senator Stabenow pretty well summed it up with regards to the word getting out to all of our rural health care providers, and for that matter any health care provider. Who are you meeting with this Friday, or a week from Friday, in terms of the rural providers?

Dr. MOSTASHARI. We actually meet weekly. Our staff meets weekly with——

Senator ROBERTS. Who are these folks?

Dr. MOSTASHARI. It is the National Rural Healthcare Association.

Senator ROBERTS. All right.

Dr. MOSTASHARI. It is critical access hospitals, it is——

Senator ROBERTS. How many of them are there? Five, 10, 20? What? Three?

Dr. MOSTASHARI. I am sorry?

Senator ROBERTS. How many are there?

Dr. MOSTASHARI. Oh, I would have to get back to you on that.

Senator ROBERTS. Well, my concern is, I do not think we are getting the word west of Highway 81 in Kansas, or for that matter, what was it, Ten Sleep in Wyoming? That is 250 people. They have to go 40 miles to even see a doctor.

But I am worried about these folks, because it is a lot like Paul Harvey used to be with Page 1 and Page 2. You know, Page 1, and I will be back in just a minute. Well, you have Phase 1 and Phase 2. If we could just pause and make sure that most of the rural providers know what is going on, because I get two sides of the story. I talked with the folks in Topeka, our capital. They say everything is going as best as it possibly can. I get a lot of calls from providers saying this is the proverbial wet horse blanket.

Let me just ask a specific question. Well, my suggestion would be to take this show on the road, to go out to places. I would recommend probably Hays, KS, or Dodge City, KS. That is my hometown. I am not sure I would recommend wearing the bow tie in Dodge City, KS. But at any rate, we will let you do that. It would be easy. I could say, I cannot answer that question; ask the guy with the bow tie. I am not trying to pick on you here. [Laughter.]

But if you could go out and sort of take this, what, digital show on the road, I think that might be helpful, or maybe have these folks come in. That might be a better thing, because I know you are extremely busy. By the way, thank you for coming by and visiting with me.

You have stated that providers will also be required to communicate with patients through secure messaging, like encrypted e-mail, and make patients' health record information available to them electronically. Now, we have not seen any details on this, and this is probably premature, but how will this work for patients in physicians' offices who do not have sophisticated access to a computer or the Internet?

Dr. MOSTASHARI. So, Senator Roberts, I did find the numbers for you. We are working, through our Regional Extension Centers that are in the field, modeled after the agricultural extension program, with 23,650 rural primary care providers and 1,025 critical access hospitals, boots on the ground, helping them understand what the program is about and to be successful at the transition.

Senator ROBERTS. Now, I have 83 of those critical access hospitals in my State. I am not sure. You are saying you have been out there to visit with these folks?

Dr. MOSTASHARI. Not me personally, but we have——

Senator ROBERTS. Well, not you. I understand that.

Dr. MOSTASHARI. We have funded the Regional Extension Center in Kansas to work with them, and they are working with 207 providers who are working in critical access hospitals in Kansas.

Senator ROBERTS. I appreciate that. Thank you.

I want to go to a more specific question. I am running out of time here, so I will try to be brief. I have heard a lot from providers, more specifically, a radiologist, a pathologist, an anesthesiologist, that they fall subject to penalties for not participating in the requirements of an office-based program where they would simply be collecting data to report to the government to avoid a penalty.

Do we have any plans to improve the flexibility for these specialists? It seems a little ridiculous to me that, if we are just going to collect data that they would not otherwise gather in their practice, that would not be necessary.

Dr. MOSTASHARI. Yes, Senator. That is feedback that we heard from Stage 1 of meaningful use. Many of those specialists were originally classified as hospital-based providers, and there was a legislative change to include them as eligible professionals, which meant that they would be potentially eligible for the penalties as well. But we are now hearing about the difficulties they may face as users of the hospital-based system in meeting some of those requirements.

So we have, in Stage 2, in the final rule that CMS promulgated, provided for the opportunity for exceptions for hospitalists like anesthesiologists, pathologists, and radiologists, whose systems are the hospital systems that they use.

Senator ROBERTS. What is the length of the comment period on the final rule?

Dr. MOSTASHARI. I can get back to you. I think it is 60 days.

Senator ROBERTS. This is not an interim final rule where you have 30 days and then, bingo, you are——

Dr. MOSTASHARI. We had a Notice of Proposed Rulemaking, and we received, I think, a few thousand comments on that, and we did a final rule after 60 days of comment.

Senator ROBERTS. Is there any comment period after the final rule? I mean, is final final?

Dr. CONWAY. Once it is finalized, the rule is final. We always welcome comment to inform future stages of rulemaking, if there are any adjustments that we can make on a subregulatory basis. This is an important community that we are trying to work with to make sure the program works for them.

Senator ROBERTS. I appreciate that. Thank you for your answer, and thank you for coming.

The CHAIRMAN. Thank you, Senator.

Gentlemen, as you know, we are having another hearing with vendors and others. What will they tell us; what will their complaints be? What will their concerns be, and what is your response?

Dr. MOSTASHARI. I think you are going to hear different things, Senator, depending on whom you ask. There will be some who will say that we are not moving fast enough, not moving hard enough. There are others who will say it is too fast and the standards are too rigorous.

The CHAIRMAN. So what category is going to say “not fast enough,” and what is the category that is going to say “too fast”?

Dr. MOSTASHARI. Making broad generalizations in terms of the comments that we received from the Notice of Proposed Rulemaking, the consumer community believes and has written to us about needing to keep up the pressure, with purchasers and payers included in that group.

Some of the smaller, more nimble software companies feel that this is not that difficult to step up to the next stage of certification. On the other hand, the bulk of the larger vendors and some of those who have to deal with hundreds or thousands of separate——

The CHAIRMAN. So what is going to be the most legitimate complaint?

Dr. MOSTASHARI. Well, they are all legitimate, Senator.

The CHAIRMAN. I said "most legitimate."

Dr. MOSTASHARI. I think one of the lessons that we have learned, and one of the ways in which we need to continue to evolve the program, continue to make forward progress on the program, is going to be moving more towards outcomes, not just in our quality measures but also in the program, and aligning the program ever more tightly with the needs of delivery reform and payment reform.

So our goal is for this health IT to be truly a foundation for your work, to be able to create a higher quality, safer, more cost-effective health care system. The greater the alignment we can bring between the health IT and the payment and delivery reforms, the more successful both will be.

Dr. CONWAY. If I might build on that.

The CHAIRMAN. Sure. Go ahead.

Dr. CONWAY. You named one of the groups earlier that I think about a lot—and we need to make sure we address the issue sufficiently—and that is rural providers, small practice, small-town providers. By way of context, I grew up in a small town in Texas with a solo practitioner family medicine doctor. Many of my family are in small practices across the Midwest, including my sister, who is a solo practitioner specialist in the Midwest.

Farzad mentioned a lot of the Regional Extension Center work that we are doing that is terrific, but I think we need to continue that work, and we need to make sure that the program meets the needs of the rural and small practice providers. We also need to think about what support looks like in future years beyond the Regional Extension Centers.

The CHAIRMAN. I appreciate that. But boy, I urge you to get out. That is, out of your offices and get out to rural America and see it, smell it, and taste it, and know what it is. It is one thing to conceptualize it; it is something else to experience it. I mentioned to you, Dr. Mostashari, I do not know, but I sense you are a Philadelphia guy, or now you are an eastern guy, a big city guy, and there is a huge difference.

Eighty percent of life is showing up, just getting out there, just being there and seeing it. Get out from behind your desk. It is well worth it. You are going to make fewer mistakes with respect to rural providers if you get out and see what they experience.

Montana, for example. Let me put it this way. I forgot what the new data are, but the population density, I think, in New Jersey, is over 1,000 people per square mile. In Montana, it is about six. There are just huge distances. It is very small operations. You mentioned it, that somebody who is doing IT is also the person who is maybe the janitor, or might be doing something else. So, just get out there, talk to them, feel them, taste them.

Dr. MOSTASHARI. With the bow tie. [Laughter.]

The CHAIRMAN. With the bow tie. I do not care. With or without, it makes no difference. Just ask the right questions, because people will want to work with you.

Dr. CONWAY. I will come to Montana anytime.

The CHAIRMAN. I want you both to go to Montana. I brought Bill Roper out when he was CMS Administrator a few years ago. Unfortunately, it was during a blizzard. He flew into a small town, Lewistown, MT. As we were flying out, he was literally white-knuckled. He was scared to death. It worked. We got a little bump-up in reimbursement, I suppose. [Laughter.]

He saw what we are going through.

My time has expired. Senator Thune, go ahead.

Senator THUNE. Thank you, Mr. Chairman.

When you go to Montana, I think the bow tie is all right as long as you are wearing cowboy boots. That will be the ultimate equalizer.

Without beating this to death—and we have covered it a lot—I understand the aspiration you have to have all the rural providers being able to participate in this and to move along at the same rate as some of those in more urban areas, but as a practical matter, that is just probably an unrealistic thing to hope for. So I guess the only thing I would say is, I think we need to really carefully balance accommodating those rural needs, while not holding back those who are ready for a more advanced data exchange.

So I guess the only thing I would say in response to your earlier response, when I asked the question about whether or not you could give rural providers more time, is that you really should take a realistic approach to accommodating those needs, because I think, just practically speaking, the area that the chairman represents and the area that I represent are very remote, very rural, and these things are just, practically speaking, going to take a little bit more time.

Stage 1 of the meaningful use required no actual cross-platform exchange of information. Stage 2 requires one instance of information sharing, and that can be with a dummy server set up by the government. In 2013, how is it possible to meaningfully use information technology without actually sharing information outside of a proprietary network? So the question really is, has the bar really not been set too low for those who are ready for an advanced level of exchange?

Dr. MOSTASHARI. We do have, I think—again, listening to the community and everybody who is affected by this, including some rural providers who said that they do not have means of exchanging information, I think the challenge that you raised is exactly right. How do we not hold back those who want to be the trailblazers and yet make accommodations for the diversity that we have in our country?

The other observation that we have had with setting thresholds, Senator, is, we fight a lot and have a lot of discussions about what the threshold should be, and what we actually find is that, when the data comes in, when the providers actually do the workflow changes, they do not just do it for 10 percent or 20 percent or 30 percent of their patients. They do it consistently.

There was just a paper published this week that found that, whatever the threshold was, the actual median level of accomplishment on the part of hospitals was between 92 and 100 percent of the threshold. So for me, one of the lessons has been to focus a little bit less on fighting over the threshold and to just get folks to begin making that transition.

I think the menu items, the menu optional approach, was one way that we allowed for people in Stage 1 who were ahead to get credit for information exchange use, and for Stage 2 we said, now everybody has to be able to do it. So I would love to continue to work with you and with the committee on how we can continue to keep the pressure on interoperability and care coordination while accommodating the diversity we have in our country.

Senator THUNE. The Stage 3 rules have not been written. I am wondering how we achieve those goals that you have laid out between now and the end of Stage 3 in a reasonable way. I am also wondering what your plans are for after Stage 3. Are you planning future stages? If so, what do those stages look like?

Dr. CONWAY. Maybe I will start, and then Dr. Mostashari can build on. We plan to write the Stage 3 rule in 2014. To the previous question on interoperability, we put out a Request for Information on how we push interoperability forward, so we are taking that input in, both for Stage 3 rulemaking and for any other changes outside of meaningful use rulemaking. So we plan to propose Stage 3 in 2014.

Senator THUNE. Go ahead.

Dr. MOSTASHARI. In terms of the road map for meaningful use, I think I was just visiting Virginia Commonwealth University last week with Patrick and Jon Blum. Their journey is very similar, I think, to what many other providers are facing, where their first priority was making sure that within their practice, within their hospitals, all across their different sites and specialties, they can share the information and the information is available when they need it. That is kind of Stage 1, and that was their first priority the first few years of their journey.

The next priority for them was, now how do we reach out to our affiliated providers that we work closely with all the time? How do we make sure those referrals get to them, get back and forth, the laboratory results are getting where they need to go, the EKG results are going where they need to go? That is Stage 2, and much of what we have in place will support that sort of local coordination of care: planned care referral exchange, laboratory exchange, public health exchange, pharmacy exchange, the network of providers that are within your local community that you exchange information with.

For Stage 3, and where they are not quite there yet is, how do I allow someone else to query my system? There are lots of concerns that providers have before allowing that to happen. They are technical issues, but they are also issues of, how do I know that you are authorized to do this query? How do I know that you are going to get the right patient? What if I release information on the wrong patient? How do I know to trust you?

I think, if we look at the road map for where we are going in interoperability, the goal is always the same. The goal is that patient information is available when and where it is needed, but the staged approach accounts for the realities of where we are and where individual providers will be in their progression: first, let me get my own house in order; next, let me exchange information with those I talk to all the time in my local community; and then the next stage will be enabling what we all hope for, that, wherever we are, if we have a problem, our information can be accessed.

I will say that the other thing that Stage 2 permits is this: Stage 2 permits every patient, every family member, every caregiver who chooses to accept more responsibility and be empowered with their own information, to get their own information and share it with whomever they want to share it with. I believe this is going to be a major step forward, if health care providers also embrace that relationship, that new relationship, with the patient.

The CHAIRMAN. Good.

Senator THUNE. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator THUNE. Thank you, gentlemen.

The CHAIRMAN. What happens when someone tries to access John Smith's record but there are a million John Smiths? How do you handle that?

Dr. MOSTASHARI. That is one of the barriers toward enabling the sort of exchange that we hope to see. I was at Metro Health in Cleveland, and I saw a patient sitting next to a doctor who said, I got my care at Cleveland Clinic.

They went and they queried Cleveland Clinic, and they got the patient's records back, because it was not a query to the world asking, does anyone have information on the patient? The patient told them his records were at Cleveland Clinic. So they only asked Cleveland Clinic, and the universe of potential wrong matches is dramatically lower if you know who you are asking and they know whom you are responding to.

The CHAIRMAN. And if you do not?

Dr. MOSTASHARI. If you do not, it is much more challenging.

The CHAIRMAN. So what is the solution?

Dr. MOSTASHARI. We are going to continue to work on finding ways to improve the quality of patient matching, improve the data quality that is used to do that matching, and have guidance on what constitutes an adequate match and what are, frankly, the liability issues and protections in the case of incorrect matches.

The CHAIRMAN. So how do you build in trust? You mentioned some providers may not want to divulge information. They do not know if they can trust the person making the query.

Dr. MOSTASHARI. Correct.

The CHAIRMAN. How do you develop trust?

Dr. MOSTASHARI. So trust builds up, I think, over time in the people whom you work with, in sharing care for patients. That is first-name-basis trust. But we can also create institutional supports for that trust.

So one of the things that we are funding and working with are governance entities that can say, let us all agree to a common set of rules of the road in terms of how to treat patient information, how we authenticate the users, whether we get patient consent and how. Having different organizations that follow the same rules of the road can increase that trust, but it is no substitute for actual experience.

The CHAIRMAN. Yes. I am not nearly sufficiently technical to know how to ask the next question, but it is basically, what is the goal here? Is the goal here that all patients, all providers, will be able to access records?

Dr. MOSTASHARI. It is a staged approach, and our goal after Stage 2——

The CHAIRMAN. Is that the goal? Is that the end goal here?

Dr. MOSTASHARI. The end goal is that every patient care setting makes use of all the world's knowledge in taking care of that patient, and that that patient encounter then contributes to the world's knowledge. That is the end goal. How we get there is going to be an interactive process.

It is going to take time to get there. But we should start with just making sure that patient information is available within a practice, within a hospital, within an ACO, within a community, and work towards resolving the significant technical and policy barriers to the ultimate solution.

Dr. CONWAY. Sorry. May I——

The CHAIRMAN. Go ahead. Sure.

Dr. CONWAY. So, to try to build on that and sort of drill down to specifics, I think our health system's end goal is better health, better care, and lower cost. Underneath that I think you have measures of health care and cost. Underneath that, I think health IT is a foundational building block, but it is hard to get there without health IT. If you are my boss, Administrator Tavenner or Secretary Sebelius, I think our focus, as Farzad knows and is a key part of, is a focus on how we improve health outcomes for all Americans.

The CHAIRMAN. How can all this be gamed? There are a lot of nefarious people out there. Most are good people, but there are a few who are not. So, if you are a bad guy, put yourself in the shoes of somebody who wants to game this thing, make money he or she should not make off the system. How do you do it? How are you protecting against it?

Dr. CONWAY. I think we at CMS are always concerned about the potential for gaming or improper payments. Let me tell you what we are doing to date on that. One, based on feedback we got on the program, we have now instituted, not just pre-verification but also pre-payment audits, especially when there is abnormal data and random audits. So, pre-payment audits will try to ensure that we are not improperly paying.

We also have post-payment audits to focus on and try to eliminate any improper payments or gaming of the system. As you move to submitting data, we also will have actual data to analyze coming in in 2014, which will increase our ability to detect fraud and gaming of the system.

The CHAIRMAN. What about hackers? When you are building this up, I assume you design systems that tend to prevent or minimize hacking.

Dr. MOSTASHARI. The HITECH legislation gives eight responsibilities to the National Coordinator. The first one is to protect the privacy and security of the health information infrastructure, and it is one that I take very seriously.

The HITECH legislation also created the Chief Privacy Officer for ONC, Joy Pritts, who makes sure that we bake privacy and security into everything we do, and we coordinate with the Office of Civil Rights, which has undertaken a much more aggressive measurement of audits and enforcement, as well as education for providers. It is a shared responsibility.

One of the biggest security problems we have is health care providers, small and large, not paying enough attention to the security in the local setting: whether they encrypt the laptop, whether they put things on a thumb drive, whether they put passwords on a sticky note, whether they lock the server room. So it starts there, and patients need to be able to trust their providers to keep their information secure. You do not need to have a hacker get in if you can just steal a laptop from a car and have all those breaches.

The CHAIRMAN. Right. But a day does not go by these days where you do not see some new article about some hacking somewhere. There was an article in one of today's papers about hacking in the university systems. I know you are doing your best, but I would just urge you to think really carefully.

You are doing a good job, both of you. Clearly you are working as hard as you can; clearly you are very competent and have your hearts in the right place. We want to help. So, thank you very much for your service.

The hearing is adjourned.

[Whereupon, at 11:55 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Hearing Statement of Senator Max Baucus (D-Mont.) On Health Information Technology Improving Care and Reducing Costs

As prepared for delivery

Ralph Waldo Emerson once wrote, "Progress is the activity of today and the assurance of tomorrow."

This committee has held several hearings on overhauling the health care system to emphasize value over volume. Today, we will discuss a vital tool to assure this mission is completed: health information technology.

Over the past decade, when you went to the doctor, he likely kept track of your important health information by hand writing notes into a paper chart. Then that chart, several inches thick, was filed away in a storage room where no other doctor had access to it.

If you needed to see a cardiologist or surgeon, that specialty doctor couldn't see your paper record. Maybe your primary care doctor faxed over your information.

But more likely, the specialist would just ask you the same questions and create their own paper record and duplicate the same tests as your primary doctor.

If you went to the hospital, the situation was the same. Diagnostic and lab tests were all recorded on paper, and your primary care physician might have no idea what happened during your hospital stay.

What resulted from this system? Duplicative, costly tests, fragmented care and dangerous medical errors. We needed a better system.

Other industries were using information technology to reduce costs and to improve service. Health care needed to catch up.

In 2009, Congress passed the Health Information Technology for Economic and Clinical Health Act, known as HITECH. Under this law, Medicare and Medicaid gives providers financial incentives to adopt health information technology and "meaningfully use" it.

Meaningful use means prescribing medication electronically to eliminate errors from scribbled, hand-written prescriptions. It means ordering a different medication when the IT system warns the patient has a drug allergy. And it means sharing information electronically among providers so they can coordinate patients' care. The result is better health care at reduced costs.

The 2009 law allocated $33 billion to help hospitals and physicians move to electronic systems. To date, Medicare and Medicaid have given out fifteen billion dollars.

As of this past May, nearly 80 percent of hospitals and half of physicians have received incentive payments because they have invested in health information technology.

One of our witnesses, Dr. Farzad Mostashari will tell us that three years ago nearly 93% of prescriptions were hand-written. Today, that number has dropped to less than half.

There are clear signs of progress, but we need to learn more. Is the 2009 law, HITECH, working as intended? Is the money being spent efficiently? How much longer until there is seamless, coordinated care for patients?

We also need to understand why there are disparities between rural and urban areas. Only a third of rural hospitals have a health information technology system, compared to half of all urban hospitals. What can be done to reduce this disparity?

Ultimately, technology must become part of the culture of health care delivery. New payment models such as accountable care organizations, medical homes and bundled payments will drive providers to use information technology.

In these models, providers are held financially responsible for providing high quality, low cost care. To succeed, physicians must engage in coordinated care, disease prevention and chronic care management. Health information technology is indispensable to accomplish these tasks.

And key to this transformation is "interoperability." Computers must be able to talk to each other so that patients and their providers can access information wherever and whenever they need it.

We need to know where we are in achieving interoperability. How far have we come? What barriers are preventing us from moving faster? How do we overcome those barriers? Today we will hear from the administration about all of these issues.

Let us assess the challenges and opportunities. Most importantly, let us learn how we can best leverage technology to achieve better quality, better value care for patients. The stakes are too high to let this opportunity for progress to pass.

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STATEMENT OF
PATRICK CONWAY, MD, MSc

CMS CHIEF MEDICAL OFFICER AND DIRECTOR, CENTER FOR CLINICAL
STANDARDS AND QUALITY

ON
HEALTH INFORMATION TECHNOLOGY

BEFORE THE

U. S. SENATE COMMITTEE ON FINANCE

JULY 17, 2013

Senate Committee on Finance
Hearing on "Health Information Technology"
July 17, 2013

Chairman Baucus, Ranking Member Hatch, and Members of the Committee, thank you for the opportunity to discuss our work at the Centers for Medicare & Medicaid Services (CMS) related to health information technology (HIT). Through Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), CMS provides health care coverage for over 100 million people, and we are committed to ensuring that beneficiaries receive the highest possible quality of care and achieve better health outcomes at a lower cost.

Health information technology is an important building block that enables delivery system transformation. It allows for the seamless health information exchange needed to improve care delivery, ensure patient safety, enhance clinical decision making, track patient outcomes, support payment for care quality, and more. One of the most important elements of HIT is electronic health record (EHR) technology, the systems that will make individualized health information more readily available to patients, and that providers and hospitals are now using to track, record, and transmit information about their patients' health to improve health care.

CMS is incentivizing and enabling the use of technology as a key tool in improving care for CMS beneficiaries. CMS recently launched the eHealth initiative, which formally aligns CMS' HIT and electronic standards programs. The CMS eHealth programs include the Medicare and Medicaid EHR Incentive Programs, quality measurement programs such as the Physician Quality Reporting System (PQRS) and the Hospital Inpatient Quality Reporting Program, and the Electronic Prescribing (eRx) Incentive Program. Bringing these eHealth initiatives together sends an important signal that CMS firmly believes in the transformative potential of HIT to improve the effectiveness, quality, and efficiency of the U.S. health care system, and that CMS is committed to the notion of a streamlined workflow for providers where quality reporting is a natural outgrowth of EHR use.

Encouraging EHR Adoption

Since the passage of the American Recovery and Reinvestment Act of 2009 (Recovery Act), CMS has been hard at work implementing an important part of the Recovery Act—the Health Information Technology for Economic and Clinical Health Act (HITECH Act). The HITECH Act authorizes financial incentives, technical assistance, and encourages the widespread adoption and "meaningful use" of EHRs—that is, the use of certified EHR technology to improve quality, safety, efficiency, and reduce health disparities; engage patients and families; improve care coordination, population and public health; and maintain the privacy and security of patient health information.

The HITECH Act established the Medicare and Medicaid EHR Incentive Programs, which provide incentive payments to eligible professionals, eligible hospitals, and critical access hospitals (CAHs) as they adopt, implement, upgrade or demonstrate meaningful use of certified EHR technology. For example, eligible professionals can receive up to $44,000 through the Medicare EHR Incentive Program or up to $63,750 through the Medicaid EHR Incentive Program. To receive an EHR incentive payment under Medicare, providers have to show that they are "meaningfully using" their certified EHR technology by meeting thresholds for a number of objectives and by reporting clinical quality measures. CMS has established the objectives for meaningful use that eligible professionals, eligible hospitals, and CAHs must meet in order to receive an incentive payment.

For the Medicaid EHR Incentive Program, states verify provider eligibility for payments. Several additional types of health care providers are eligible for Medicaid EHR incentive payments, including nurse practitioners, certified nurse-midwives, dentists, and physician assistants who furnish services at a physician assistant-led Federally Qualified Health Center or Rural Health Clinic. There are also patient volume thresholds that providers must meet to be eligible for EHR incentive payments under Medicaid. Children's hospitals, however, are eligible for Medicaid incentive payments, regardless of Medicaid patient volume. In their first year in the Medicaid EHR Incentive Program, Medicaid providers do not need to meet the full requirements of Stage 1. Instead, providers must implement, adopt, or upgrade a certified EHR technology; meeting meaningful use requirements is not necessary until year two.

The Medicare and Medicaid EHR Incentive Programs are staged with increasing requirements for participation. Stage 1 of meaningful use of EHRs focuses on basic data capture; Stage 2 focuses on advanced functionality of EHRs, including interoperability, patient engagement, clinical decision support, and quality measurement; Stage 3 is expected to focus on increased health information exchange and interoperability and improved patient outcomes.

Participation in the EHR Incentive Programs has been robust. Approximately 80 percent of all eligible hospitals and critical access hospitals and over half of all eligible professionals in the U.S. have received payment in the Medicare and Medicaid EHR Incentive Programs for successfully adopting, implementing, upgrading, or meaningfully using an EHR.[1] As of May 2013, more than 220,000 of the nation's eligible professionals and over 3,000 of the nation's eligible hospitals have achieved the requirements for Stage 1 Meaningful Use.[2] Forty-nine states and three territories have launched their Medicaid EHR Incentive Programs. Those states have paid almost $2.1 billion to over 88,000 Medicaid-eligible professionals.[3] As of May 2013, the Medicare and Medicaid EHR Incentive Programs have paid out $15.1 billion in incentives to hospitals, doctors, and other health care professionals.[4]

With meaningful use Stage 1 underway, CMS's focus this year is to successfully implement meaningful use Stage 2 in 2014, including ensuring program integrity, advancing interoperability, achieving alignment across programs, and hitting clear adoption targets by year's end. Our goal is to ensure that providers have the greatest opportunity possible to take advantage of the program.

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[1] HHS News Release (May 22, 2013), http://www.hhs.gov/news/press/2013pres/05/20130522a.html

[2] CMS internal analysis presented at Health IT Policy Committee meeting, July 9, 2013, https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/HITPC_July2013_Full_Deck.pdf

[3] May 2013 EHR Incentive Programs Medicaid Incentive Payments Report: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/May_Medicaid_EHRIncentivePayments.pdf

[4] May 2013 EHR Incentive Programs Report: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/May_EHRIncentiveProgramsPaymentsReg_SummaryReport.pdf

CMS is also looking ahead toward advanced interoperability and widespread electronic health information exchange. In March 2013, CMS and ONC released a Request for Information that asked for input from industry and the general public to help us accelerate health information exchange across settings of care in order to support care coordination and delivery reform. We received hundreds of comment letters and are reviewing them to identify the most effective activities we can undertake to promote interoperability.

We believe efficient health care delivery is contingent on the adoption of EHRs and the electronic exchange of data. Such changes are required to facilitate the information infrastructure that is needed to transform the health care system into one that is truly patient-centered and value-based. We recognize that some providers and EHR vendors may not yet have a business imperative to share health information across providers and settings of care. The long-term sustainability of investments in HIT will come as a result of the movement away from fragmented, fee-for-service care and towards value-based, coordinated care. Managing information for individuals and populations, rather than for services rendered, is essential for transforming care delivery and managing total cost. HITECH has accelerated and shaped the development of the necessary infrastructure to enable providers to meet this transformed delivery system. The business case for providing better care at lower cost will rely on and support these investments over time.

CMS is supporting the business case for EHR adoption through initiatives that encourage health care providers to deliver high-quality, coordinated care at lower costs. These reforms are enabling us to pay for value, not simply the quantity of care provided, while promoting patient safety and seeing that care is better coordinated across the health care delivery system. Included among these initiatives are Accountable Care Organizations (ACOs)—groups of doctors and other health care providers that have agreed to work together to treat individual patients and better coordinate their care across care settings. They share—with Medicare—any savings generated from lowering the growth in health care costs while improving quality of care including providing patient-centered care. Another example is the Hospital Value-Based Purchasing Program. As required by the Affordable Care Act, beginning in October 2012, Medicare began adjusting payments to acute care hospitals according to how well they meet

Medicare's quality standards. These standards are consistent with evidence-based clinical practice for the provision of high-quality care. Hospitals are scored on improvement as well as achievement on a variety of quality measures. The higher a hospital's performance score during a performance period, the higher the hospital's value-based incentive payment will be for a subsequent fiscal year. Because these programs incentivize well-coordinated, high quality care, they help build the business case for providers to adopt EHR systems that help them manage and share information electronically across care settings.

Improving Quality

Increased EHR adoption will help improve the quality of care for CMS beneficiaries. The Medicare and Medicaid EHR Incentive Programs incorporate clinical quality measures (CQMs) as reporting requirements for meaningful use. CQMs are tools that help many stakeholders, including CMS and health care providers themselves, measure and track the quality of health care services provided by eligible professionals, eligible hospitals, and CAHs within our health care system. They measure many aspects of patient care including health outcomes, clinical processes, patient safety, efficient use of healthcare resources, care coordination, patient engagement, and population and public health. Measuring and reporting these CQMs helps to ensure that our health care system can deliver effective, safe, efficient, patient-centered, equitable, and timely care. To support providers in their quality reporting efforts, Quality Improvement Organizations (QIOs)—organizations in each state that work to resolve care quality issues and implement improvements in care quality—are actively assisting eligible professionals and hospitals in IT-enabled care management to focus on effective use of clinical decision support, clinical quality improvements, and using EHRs to track and improve population health and clinical targets.

CQMs are required as a core meaningful use objective, which means that eligible professionals, eligible hospitals, and CAHs who wish to participate in the EHR Incentive Program must use certified EHR technology to calculate their CQMs, and must report the results by attestation in order to receive an incentive payment. Beginning in 2014, providers in stage two of meaningful use will electronically report on at least nine CQMs across at least three of the National Quality Strategy domains. CMS is working with the states to develop electronic CQM submission systems, including enhanced Medicaid Health Information Exchange infrastructure funding, that will align with state Medicaid enterprises and health priorities.

CMS is also working to align existing CMS reporting requirements for eligible professionals and hospitals, and is encouraging the adoption of broad scale electronic reporting of quality data. The Physician Quality Reporting System (PQRS) is a reporting program that uses a combination of incentive payments and payment adjustments to promote reporting of quality measures by eligible professionals. The program provides incentive payments through 2014 to practices with eligible professionals who satisfactorily report data on quality measures for covered Physician Fee Schedule (PFS) services furnished to Medicare Part B fee-for-service beneficiaries. Eligible professionals will be able to report quality data once, and meet some of the requirements for the PQRS and the EHR Incentive Programs. Groups of physicians in ACOs may also meet the reporting requirements for the Medicare EHR Incentive Program, assuming they report via certified EHR technology. For the hospital setting, CMS is also beginning to align measures across the applicable programs as more measures become electronically specified. These programs include the Hospital Inpatient Quality Reporting, Hospital Value-Based Purchasing, and the EHR Incentive Programs. This new alignment across Federal programs will be critical not only for lowering the burden on providers, but also for focusing improvement on measures that matter most.

Through these and other programs, CMS is encouraging quality improvement and establishing benchmarks on which to assess future progress. The quality measures are generally endorsed by the National Quality Forum, meet validity and reliability requirements, and align with the National Quality Strategy, which outlines improvement goals for health care. We are increasing our focus on patient-centered outcome measures that matter most for improving health. Our vision for the future of quality reporting is to implement a unified set of electronic quality measures and e-reporting requirements to synchronize and align CMS quality programs, reduce provider burden, and maximize efficiency and improvement.

Transforming Health Care Delivery

In addition to facilitating higher-quality care, HIT can help to improve the safety and efficiency of care delivery. Through EHRs, providers can have reliable point-of-care access to patients' past medical history, lab results, and prescriptions. They also have a means of generating the information needed to support effective care transitions. In the first two years of the EHR Incentives Programs, eligible providers sent more than 4.3 million care summaries to other providers when patients were moving between care settings.[5] These summaries are used when a physician or practitioner refers or directs a patient's care to another setting or provider and are necessary for effective care coordination.

EHRs also support access to patients' health information, following them wherever they access care. But EHRs are more than simply a record of patients' medical history. EHR data can be used to display information in ways that are beneficial for providers and their patients. An EHR can check a patient's new prescription against current medications to avoid adverse events and errors, alert providers to a patient's life-threatening allergy, and tailor provider supports and prompts to the latest clinical guidelines. Through diagnostic and therapeutic decision support, clinical alerts and reminders, and built-in safeguards, EHRs can help providers make safe, effective decisions and provide high quality care for their patients.

One example of health care delivery improvement through HIT is electronic prescribing (e-prescribing), which gives providers the ability to better manage patient prescriptions while reducing adverse drug interactions or other preventable prescription errors. CMS' Electronic Prescribing Incentive Program uses incentive payments and payment adjustments to encourage e-prescribing by eligible professionals. Since 2012, the program has also applied a negative payment adjustment to those eligible professionals who are not successful e-prescribers on their Medicare Part B services. In addition, the certification of EHR technology, as administered by the Office of the National Coordinator for Health IT's Certification Program, requires that the technology be able to generate and transmit permissible prescriptions electronically. Moreover, the Medicare and Medicaid EHR Incentive Programs require the use of certified EHR

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[5] CMS internal analysis

technology for e-prescribing. In the first two years of the EHR Incentive Programs, health care providers who met meaningful use reported sending 190 million electronic prescriptions.[6] These two programs support the safe, efficient delivery of prescription drugs to patients.

Improving the Care Experience for Patients

In addition to its role as the platform for safe, effective, high-quality care, HIT is also allowing patients to become more engaged in their health and health care. For example, the Medicare and Medicaid EHR Incentive Programs Stage 1 criteria require eligible professionals and hospitals to provide patients with an electronic copy of certain health information including diagnostic test results, problem lists, and medication lists upon request, and to provide patients with clinical summaries after each office visit. The Stage 2 criteria require eligible professionals and hospitals to provide patients the ability to view online, download, and transmit certain health information. Already, health care providers have sent 4.6 million patients an electronic copy of their health information from their EHRs, and have sent over 13 million reminders about appointments, required tests, or check-ups to patients using EHRs.[7]

Recognizing the potential that giving patients access to their medical records has for improving patient engagement and outcomes, the Blue Button initiative gives Medicare beneficiaries a secure way to download their personal health information to an electronic file. The initiative is also spurring innovation in HIT, with mobile app makers developing intuitive interfaces to display Blue Button data. With access to their Blue Button data, patients now have the ability to more easily keep track of their medicines, chronic conditions, and laboratory results; share information with providers and caregivers; and plug the downloaded data into compatible apps and tools that help them better understand their health, prevent illness, and modify their behavior in healthy ways.

Conclusion

While HIT alone does not make care better, it is an essential ingredient to care improvement. HIT supports clinicians in their work, moving us away from the days of illegible notes and

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[6] CMS internal analysis
[7] CMS internal analysis

prescriptions, reams of paper charts, x-rays that cannot be found, and lost faxed lab results and toward a health system where the relevant information is at the fingertips of clinicians and patients and secure electronic systems support better care. It is enabling the higher quality care, better health, and lower costs that our health system is striving to achieve. By providing tools and incentives for EHR adoption, quality reporting, e-prescribing, and patient engagement in their health care, CMS is encouraging clinicians, hospitals, and beneficiaries to use HIT as a platform for improved health care quality and better health outcomes at lower cost. Our health system can improve and achieve better results. HIT is a foundational building block to enable a 21st century health system that achieves better health outcomes for all Americans.

STATEMENT OF HON. ORRIN G. HATCH, RANKING MEMBER
U.S. SENATE COMMITTEE ON FINANCE HEARING OF JULY 17, 2013
HEALTH INFORMATION TECHNOLOGY: A BUILDING BLOCK TO QUALITY HEALTH CARE

WASHINGTON – U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Senate Finance Committee, delivered the following opening statement at a committee hearing examining how health information technology (IT) can help improve the quality of health care in America:

Thank you, Chairman Baucus, for holding this hearing today on health information technology, or health IT.

This is an important topic that the Chairman has rightly stated can help improve the quality of health care in this country.

I have witnessed firsthand the power of using health IT to transform the delivery of health care.

In Utah, Intermountain Healthcare System has long been one of the leaders in this field.

This transformation didn't happen overnight. Dr. Homer Warner, a Utah cardiologist, helped establish the field of health IT in the 1950's. His work and teaching coupled with that of his colleague, Reed Gardner, inspired generations of clinicians to enter the field of informatics long before it became popular.

The promise of health IT is that it can facilitate evidence-based clinical care, decrease the number of errors that are far too frequent in our complex, fragmented health care system, and allow each clinical visit to a health care provider to increase our knowledge base about effective care.

In preparing for this series of hearings on health information technology, we have heard from many providers – both large and small – as well as the vendor community. Most have said that they believe the Meaningful Use Program has spurred the investment in technology.

Many were already in the process of establishing and purchasing health information technologies and the Meaningful Use funds they received simply helped offset the costs.

For others, it was the threat of financial penalty that spurred this type of investment.

Regardless, I think health IT can be a very valuable tool and its use should be encouraged.

However, it is my hope that we are not judging the success of this program simply on the number of dollars going out the door, but rather by the positive impact on patient care and decreases in healthcare costs.

I also hope that, as both CMS and ONC establish requirements for the program, they consider all of the other burdens that providers face.

As we have seen time and again, not all providers are created equal. The size, sophistication, and availability of resources vary greatly.

I am very proud of the work that Intermountain Health Care has done in this area, and their use of health information technology should be an example to all. But we have to acknowledge that they are really the exception, not the rule.

As CMS and ONC develop future stages of Meaningful Use, we need to take into account all that we ask of our providers.

Let me be clear, I do not want to see progress stalled on implementing the use of technologies. But, if we ignore problems along the way and simply expect everyone to catch up, we will end up in worse shape.

The federal government cannot afford to spend money on programs that don't yield results.

At the same time, providers can't afford to invest in systems that don't work or have to be overhauled a year later as requirements change.

It would seem to me that we have an opportunity to push the pause button and make sure that the program is working before we continue down a potentially unsustainable path.

I think many members would agree that we should hold providers and vendors to high standards.

And, perhaps the Meaningful Use Program, in its various stages, has set the bar too low.

In the end, I would rather ask more of our providers and vendors and provide them with a reasonable timeline to achieve those goals.

This hearing, along with the one scheduled for next week, is being held to allow us to hear from the administration's leaders in health information technology and from the community of vendors and providers using health IT in clinical care.

It is an opportunity to take a mid-course pulse of the ongoing Meaningful Use incentive payments to providers, and to assess the kinds of improvements in health care that these funds intended.

Mr. Chairman, thank you for holding this hearing and I look forward to hearing from our two witnesses.

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The Office of the National Coordinator for
Health Information Technology

Testimony before the Committee on Finance

U.S. Senate

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

July 17, 2013

Chairman Baucus, Ranking Member Hatch, and distinguished Committee 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.

Building on a decade's worth of bipartisan legislative work, in 2009, the Congress and President Obama enacted the Health Information Technology for Economic and Clinical Health Act (HITECH) as part of the American Reinvestment and Recovery Act of 2009 (ARRA). HITECH established the Office of the National Coordinator for Health Information Technology (ONC) in statute and provided the resources and infrastructure needed to stimulate the rapid, nationwide adoption and use of health IT, especially electronic health records (EHRs).

I am pleased to be here today to discuss how health IT benefits patients and provides the tools necessary to transform the delivery of care. Already, America's health care providers have made significant progress expanding health information technology use. Through incentives and other approaches supported by HITECH, we have seen clear evidence that the healthcare community is increasingly using health IT to improve care and change the way it is delivered.

Health IT is Transforming Care

Technology is just a tool - but it is a critical tool that can foster much-needed innovation in entrenched industries. The nation's healthcare system is poised for a transformation in how care is delivered and is paid for and how patients engage in their own health and health care. Health information technology supports these transformations.

In the past, our healthcare delivery system based its payments solely on the number of services provided and not on the quality of care delivered to patients. As a result, patients might receive duplicative tests or services that might not improve their health – and may cost them more in copayments or coinsurance. As required by the Affordable Care Act, HHS has launched several initiatives to link payments more closely with quality outcomes and promote value-based care.[1] These reforms promote value over volume and ensure that care is better coordinated across the healthcare delivery system.

As both public and private payers take concrete steps to change the incentives for paying providers, health IT provides the infrastructure for improved care coordination, better quality, and lower costs, as well as the data analytics that providers need to account for the quality and cost of care for populations they serve.

Moving Closer to Patient-Centered Care

Our goal is to assist clinicians and hospitals in using technology to deliver health care in a more meaningful way that is higher-quality, safer, patient-centered, and coordinated. We want providers to thrive in the new health care marketplace that puts a premium on value over volume, on coordination over fragmentation, and on patient-centeredness overall.

The Centers for Medicare & Medicaid Services (CMS) Medicare and Medicaid EHR Incentive Programs, the ONC-led certification program for health IT, as well as the hands-on technical assistance provided by the Regional Extension Centers (RECs) across the

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[1] See Statement of Richard J. Gilfillan, M.D., Director, Center for Medicare and Medicaid Innovation, Centers for Medicare & Medicaid Services on Reform of the Delivery System, Before the Committee on Finance, U.S. Senate, March 20, 2013.

country, are critical in facilitating unprecedented progress in EHR development, adoption and use. There are nearly 1,900 unique certified products produced by nearly 1,000 developers, and certified by one of five ONC-Authorized Certification Bodies. ONC's RECs have signed up more than 145,000 primary care providers (including over 20,000 Nurse Practitioners) in over 30,000 different practices. This means that over 40 percent of the nation's primary care providers have committed to meaningfully using EHRs by partnering with their local REC.

To participate in the CMS Medicare and Medicaid EHR Incentive Programs, eligible professionals and hospitals are required to certify that they have used the capabilities of certified EHR technology to meet defined Meaningful Use objectives. At HHS, we believe these meaningful use objectives are strongly aligned with other policy drivers to help our health care system to become safer and more efficient, and achieve higher quality.

Adoption of EHRs has accelerated rapidly in the years since passage of HITECH. As of May of this year, more than 293,000 eligible professionals and over 3,900 eligible hospitals have received incentive payments from the Medicare and Medicaid EHR Incentive Programs. That represents nearly 80 percent of eligible hospitals and over half of physicians and other eligible professionals. As of May 2013, more than 220,000 of the nation's eligible professionals and over 3,000 of the nation's eligible hospitals have achieved the requirements for Stage 1 Meaningful Use. Tens of thousands more have qualified for Medicaid incentive payments for adopting, implementing, or upgrading to certified EHRs.

While overall adoption of EHRs more than doubled in office practices and more than quadrupled in hospitals between 2008 and 2012, the capabilities of adopted systems have also improved dramatically. Analyses of nationally representative surveys of office-based physicians and non-federal acute care hospitals show that there has been strong and steady growth in both physician and hospital adoption of EHR technology to meet Meaningful Use objectives to improve quality, safety, and efficiency (Figures 1 and 2).[2] [3] For example, computerized provider order entry (CPOE) for medication orders, which is a Meaningful Use requirement, has been shown to cut out nearly half of medication errors.[4] Since HITECH was enacted, the percentage of physicians with CPOE has increased from 45 percent to 80 percent from 2009 to 2012 (Figure 1). For non-federal acute care hospitals, the percentage with CPOE more than doubled between 2008 and 2012, rising from 27 percent to 72 percent (Figure 2). Since HITECH, adoption of computerized capabilities related to Meaningful Use objectives generally has grown faster than adoption of those capabilities, which are not required for Stage 1 Meaningful Use (Figure 3).

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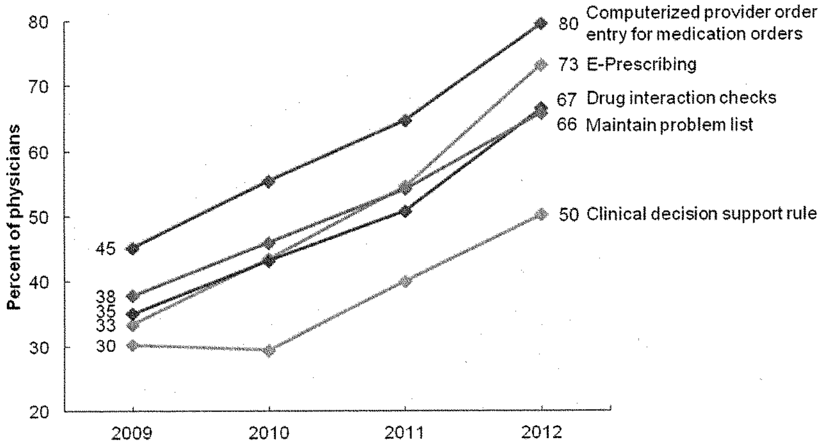
[2] King J, Patel V, Furukawa MF. Physician Adoption of Electronic Health Record Technology to Meet Meaningful Use Objectives: 2009-2012. *ONC Data Brief, no. 7.* Washington, DC: Office of the National Coordinator for Health Information Technology. December 2012.

[3] Charles D, King J, Furukawa MF, Patel V. "Hospital Adoption of Electronic Health Record Technology to Meet Meaningful Use Objectives: 2008-2012," ONC Data Brief, no. 10. Washington, DC: Office of the National Coordinator for Health Information Technology. March 2013

[4] Kaushal R, Shojania KG, Bates DW. Effects of computerized physician order entry and clinical decision support systems on medication safety: a systematic review. Arch Intern Med, 2003 Jun 23: 1409-16. Shamliyan TA, Duval S, Du J, Kane RL. Just what the doctor ordered. Review of the evidence of the impact of computerized physician order entry system on medication errors. Health Serv Res. 2008 Feb;43(1 Pt 1):32-53.

From 2011 to 2012, growth in physician use of EHR technology to empower patients and families in managing their own health care was especially strong; the share of physicians with computerized capability to provide patients with clinical summaries after each visit increased by 46 percent. Physician adoption of eight other computerized capabilities to improve quality, safety, and efficiency also grew substantially, with increases ranging from 21 percent to 42 percent. [5]

Figure 1. Percent of physicians with computerized capabilities to meet Meaningful Use core objectives: 2009-2012



2012 is significantly different from 2009 for all computerized capabilities ($p < 0.01$).
SOURCE: ONC analysis of National Center for Health Statistics' 2009-2012 National Electronic Health Records Surveys.

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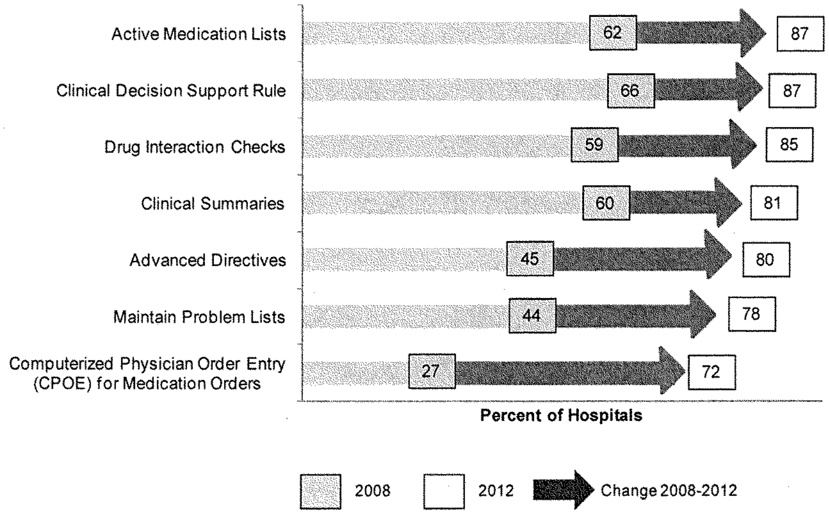
[5] King J, Patel V, Furukawa MF. Physician Adoption of Electronic Health Record Technology to Meet Meaningful Use Objectives: 2009-2012. *ONC Data Brief, no. 7.* Washington, DC: Office of the National Coordinator for Health Information Technology. December 2012.

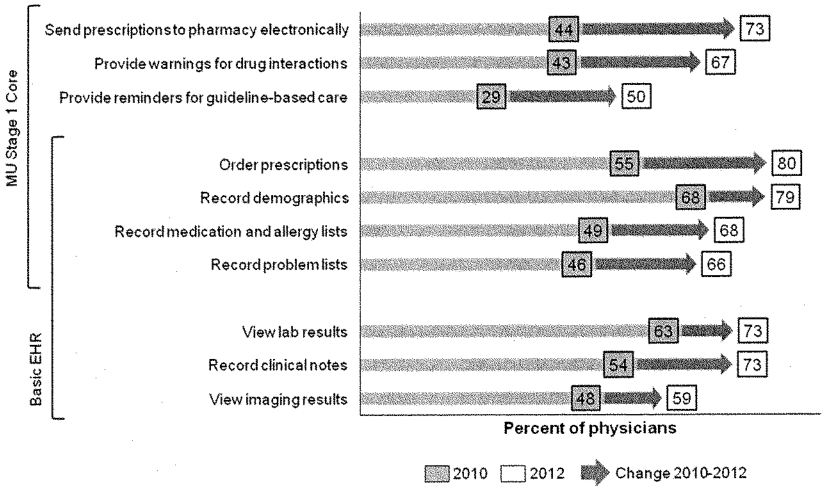
Figure 2. Percent of non-federal acute care hospitals with computerized capabilities to meet selected EHR Incentive Programs' Meaningful Use objectives: 2008-2012



All differences are statistically significant from the previous year ($p < 0.05$).

SOURCE: ONC/AHA, AHA Annual Survey Information Technology Supplement

Figure 3. Percent of physicians with selected computerized capabilities : 2010-2012



2012 is significantly different from 2010 for all computerized capabilities ($p < 0.01$).

Source: *Health Affairs*, July 9 web exclusive, insert exact cite when released.

However, much work remains to achieve the promise of Meaningful Use in paving the way for a higher quality, more efficient and safer health care delivery system. While increasing rapidly, adoption still lags behind in small practices and critical access hospitals. The usability of many of the legacy software products are sub-optimal and the cause of frustration for many clinicians on the front lines. While the digitization of healthcare is well underway, the complementary and necessary optimization and redesign of practice workflows is still in its infancy, and perhaps most importantly, there is much work yet to be done to achieve higher levels of interoperability between healthcare providers who use EHR products from different developers.

Stage 2 and a Focus on Interoperability and Exchange

When HITECH was enacted, we understood our mission to be two-fold as the nation moved toward improved health and healthcare through the use of information technology. First, we need to achieve the adoption of certified health IT. Since the law's enactment, we have made good progress towards achieving this goal. We know from the hospitals and clinicians that have achieved meaningful use that it is hard work and the payment represents an important milestone of achievement.

Second, we want to ensure that the systems that have been put in place are interoperable. As several Senators on this Committee have pointed out, improving care coordination through secure and private health information exchange among hundreds of thousands of providers using disparate systems already in place, while accommodating changes in technology, is a daunting task. Nevertheless, I believe that through the exercise of multiple policy levers, and substantial public-private collaboration, we are making steady progress on this path as well.

The escalating stages of the Medicare and Medicaid EHR Incentive Programs and EHR certification criteria and standards are a critical component of our interoperability strategy. Stage 1 supported the systematic conversion of key medical information into structured digital format, while we forged consensus on initial national standards for secure communication between systems. We are working with industry to ensure that EHR technology will be significantly more interoperable when Stage 2 begins in 2014. Guided by two Federal Advisory Committees, we have viewed the EHR Incentive Programs as an escalator that moves progressively upward toward greater interoperability and improved outcomes. Before we discuss that progress, however, I think it is important that we have a common definition of "interoperability" because the term often means different things to different people. At ONC, we refer to a definition used by the Institute for Electrical and Electronics Engineering (IEEE) which defines interoperability as "the ability of two or more systems or components to exchange information and to use the information that has been exchanged. [6] That means that there are two parts to the definition of interoperability: 1) the ability of two or more systems to *exchange* information; and 2) the ability of those two systems to *use* the information that has been exchanged.

Health information *exchange* (HIE) is a general term used to convey a variety of ways in which information is electronically shared across all providers of health care to support care delivery. HIE encompasses a broad array of strategies, technologies, types of exchange and applications to facilitate better communication, enabling more coordinated and connected care across the full continuum of provider types and settings. Effective communication and information sharing is essential to improving health, health care delivery, and lowering costs.

It will take time to build to a fully *interoperable* system of coordinated care and communication across health providers. HHS is working hard to seek out opportunities to accelerate and promote the development of this capacity across the health care system by providing incentives and by reducing barriers to interoperability. HHS is fully committed to ensuring ubiquitous, standards-based, secure exchange of health information across care settings, through consistent, incremental, iterative steps.

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[6] See IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries (New York, NY: 1990).

When the new requirements related to Stage 2 of the Medicare and Medicaid EHR Incentive Programs begins in 2014, EHR technology will be significantly more interoperable. To achieve meaningful use in Stage 2, providers will have to exchange, and EHR developers will have to enable the exchange of, a patient care summary with other providers in structured way, (in other words, in a way that can be used) including those with different EHR products. ONC issued its 2014 Edition Standards and Certification Criteria final rule on September 4, 2012,[7] which defines the common content, format, and structured data that must be used in order for these systems to be certified. These standards will enable providers to share information as patients make a transition from one care setting to another, which is critically important to support patient care, ensure safety, improve quality, and lower costs.

Meaningful Use Stage 2 places a strong emphasis on electronic health information exchange with other providers. In Stage 2, both hospitals and eligible professionals will be required to send a summary of the patient's record electronically to the next provider of care following transitions of care to a new provider or care setting. They will also be required to communicate with patients through secure messaging (like encrypted email) and make patients' health record information available to them electronically. We believe that these exchange requirements are important steps forward in advancing interoperability.

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[7] This final rule is entitled "Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology" and is available at: http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf.

As envisioned by HITECH, we believe there is an important federal role in recognizing national healthcare standards, and that the certification program authorized by HITECH is a critical tool in achieving interoperability across disparate, competing products. The Medicare and Medicaid EHR Incentive and Certification Programs already require the use of unified standards for recording important clinical information (*e.g.*, problem list, medication list, medication allergy list, race and ethnicity, laboratory test results, etc.) as well as unified standards for the format and transmission of data. As noted by the Bipartisan Policy Center for Health Information Technology Initiative in its report on interoperability,[8] the initial standards needed for clinicians to support care transitions are, in general, "well supported by Stage 2 requirements."

There is significant work yet to be done on accelerating consensus on interoperability standards that enable additional healthcare information to be securely exchanged and used across healthcare organizations and software systems. The ONC Standards and Interoperability Framework[9] provides an effective forum for convening industry and experts in identifying unified solutions to high-priority interoperability challenges.

Furthermore, in March, ONC and CMS released a request for information that asked the industry for input to help us accelerate health information exchange across settings of

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[8] Accelerating Electronic Information Sharing to Improve Quality and Reduce Costs in Health Care. Bipartisan Policy Center Health Information Technology Initiative, October 2012. http://bipartisanpolicy.org/sites/default/files/BPC%20Accelerating%20Health%20Information%20Exchange format.pdf.

[9] http://www.siframework.org.

care in order to support care coordination and delivery reform[10]. We recognize that both providers and EHR vendors do not always have a business imperative to share individual-level health information across providers and settings of care. To further accelerate and advance interoperability and health information exchange beyond what is currently being done through ONC programs and the Medicare and Medicaid EHR Incentive Programs, HHS is considering a number of policy levers using existing authorities and programs. The overarching goal is to develop and implement a set of policies that would encourage providers to exchange health information routinely through interoperable systems in support of care coordination across health care settings.

HHS has been leveraging HHS programs and resources to promote interoperability. For example, ONC's State HIE Program has worked with each state to plan and implement an approach to promoting information exchange that is tailored to each state's circumstances and resources.

Indiana, for example, is providing vouchers to hospitals, health centers, labs and radiology centers to help them connect to existing HIE services that blanket the state. Maryland has developed a more centralized statewide HIE infrastructure focused on activities such as alerting primary care providers when patients are discharged from hospitals and geo-mapping health care utilization across the state to identify areas where quality, safety, and efficiency improvement efforts should be targeted. These grant-funded activities have enabled nearly 20,000 health care-related organizations and over 112,000 clinical and administrative staff to exchange patient's health information in support of better, safer

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[10] https://www.federalregister.gov/articles/2013/03/07/2013-05266/advancing-interoperability-and-health-information-exchange.

care. During the first quarter of 2013, the program's grantees reported more than 172 million secure messages were sent to support activities such as safe transitions of care and receipt of lab results. An additional 5 million queries for patient information helped improve care coordination where information had not followed the patient. ONC has also worked closely with CMS to ensure HIE is accelerated through new programs such as the State Innovations Model Initiative, the Health Care Innovation Awards, and Medicaid waivers.

Although ONC and CMS have been diligently working on health information exchange, we know we still have work to do. Through our work and research, we have identified a number of barriers to health information exchange. Currently, there is limited sharing of health information during transitions of care among providers.[11] A 2012 Commonwealth survey of primary care physicians in the United States found that less than one in four physicians is notified when their patient visits the emergency room and less than half receive information needed to help manage their patient's care within 48 hours after discharged from the hospital. Furthermore, only 16 percent receive information from specialists regarding changes made to their patient's medication or care plan.

Increasing providers' capability to exchange information electronically with other providers has the potential to help address existing gaps in health information sharing between health care providers. Providers overwhelmingly believe that electronic health

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[11] Commonwealth Fund. Article Chartpack. Schoen C & Osborn R. The Commonwealth Fund 2012 International Health Policy Survey of Primary Care Physicians. International Symposium on Health Care Policy. November 2012. http://www.commonwealthfund.org/Surveys/2012/Nov/2012-International-Survey.aspxC.

information has the potential to improve the quality of patient care and coordinate care.[12] Expanding interoperability can make it easier and less costly to share health information among providers.

ONC recognizes that increasing electronic exchange of health information among providers will involve a multi-pronged approach. Some key challenges perceived by physicians relate to technical barriers, such as the ability of EHR systems to communicate with other systems, the lack of an exchange infrastructure, and the costs of exchanging health information, such as interface costs and transaction fees.[13] Additionally, there have not been significant business drivers to promote information sharing to date – historic reimbursement structures that pay for more tests and services as opposed to the quality of care delivered to patients have generally encouraged providers to hold onto patient information rather than share it. A large number of health care organizations have implemented systems that were not built according to national standards. Furthermore, system-wide change within provider practices can often be time-consuming and disruptive. The steps we have outlined address these problems head-on and should promote health information exchange and interoperability over the coming years.

Promoting Innovation and Care Coordination

HITECH established several programs to promote EHR adoption across the United States for eligible hospitals and professionals and to assist providers with implementation.

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[12] Clinician Perspectives on Electronic Health Information Sharing for Transitions of Care Bipartisan Policy Center Health Information Technology Initiative. October, 2012

[13] Clinician Perspectives on Electronic Health Information Sharing for Transitions of Care Bipartisan Policy Center Health Information Technology Initiative. October, 2012

As it becomes evident that health IT is a fundamental component to new payment and delivery system models, several of these programs are helping to support providers as they prepare for system changes.

Small practices have historically had challenges optimizing health IT to improve the quality of care they provide to their patients, due to a lack of resources and/or expertise. Per the 2010 National Ambulatory Medical Care Survey (NAMCS), small independently-owned practices with 10 or fewer physicians provide over 85.5 percent of all ambulatory care visits.[14] These providers play an essential role in the national health care delivery network by serving as the home-base for preventive care, information and services patients and families need to stay healthy, and as a linkage to the broader health care system, including hospitals and specialists. Several of the HITECH programs specifically address disparities in EHR adoption among providers working in underserved areas (including rural areas and those with high numbers of uninsured patients).

RECs Enabling Care Delivery Transformation– The REC Program consists of 62 heterogeneous non-profit organizations and the national Health Information Technology Research Center (HITRC) that provides state-of-the-art technical assistance on best practices for EHR adoption. RECs directly assisted providers in their understanding of the Medicare and Medicaid EHR Incentive Programs, support providers during the EHR The RECs are successfully reaching out to support primary care providers operating in medically underserved regions nationwide to implement certified EHR technology and demonstrate Meaningful Use. Based upon a recent study, REC enrollment rates were

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[14] The National Ambulatory Medical Care Survey 2010, Centers for Disease Control and Prevention

highest in rural areas.[15] Specifically, REC enrollment rates were found to be higher for small rural (non-Core Based Statistical Area, 56 percent) and micropolitan areas (47 percent) compared to urban or metropolitan areas. Critical access hospitals (CAHs) and selection process for their practices; and, train practice staff in workflow redesign, project management, and technology and security assessments.

The REC program has been successfully assisting primary care providers nationwide to adopt EHRs and demonstrate Meaningful Use. A Government Accountability Office (GAO) report found that Medicare providers working with RECs were over 2.3 times more likely to receive an EHR incentive payment then those who were not working with a REC.[16] Almost half (46 percent) of providers who received incentives from the Medicaid EHR Incentive Programs for attesting to Meaningful Use, and one-fifth (21 percent) of providers who received incentives from the Medicare EHR Incentive Programs have participated in the REC program.[17]

The RECs are successfully reaching out to support primary care providers operating in medically underserved regions nationwide to implement certified EHR technology and demonstrate Meaningful Use. Based upon a recent study, REC enrollment rates were highest in rural areas.[18] Specifically, REC enrollment rates were found to be higher for

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[15] Samuel CA, King J, Adetosoye F, Samy L, Furukawa MF. Engaging providers in underserved areas to adopt electronic health records. *American Journal of Managed Care.* 2013;19(3):229-34

[16] GAO, *Electronic Health Records: Number and Characteristics of Providers Awarded Medicare Incentive Payments for 2011,* GAO-12-778R (Washington, D.C.: July 26, 2012).

[17] Customer Relationship Management (CRM) Tool, maintained by the Office of Provider Adoption and Support (OPAS) at ONC, March 19, 2013 merged by NPI to data on EPs in the Medicare or Medicaid EHR Incentive Programs as of January 31, 2013.

[18] Samuel CA, King J, Adetosoye F, Samy L, Furukawa MF. Engaging providers in underserved areas to adopt electronic health records. *American Journal of Managed Care.* 2013;19(3):229-34

small rural (non Core Based Statistical Area, , 56 percent) and micropolitan areas (47 percent) compared to urban or metropolitan areas. Critical access hospitals (CAHs) and small rural hospitals have also recently shown progress toward achieving Meaningful Use, with strong enrollment in RECs as well.[19]

REC enrollment rates were also found to be highest in counties with the greatest health professional shortages. In particular, for whole-county Healthcare Provider Shortage Areas (HPSAs), which are areas that have provider shortages spanning an entire county, RECs assisted 52 percent of providers. In geographic HPSAs, which have shortages in specific geographic areas within the county but not the entire county, RECs assisted42 percent of providers.

More than 80 percent of all Federally Qualified Health Center (FQHC) grantees are enrolled with a REC. Many FQHCs have specific quality improvement goals such as efforts to promote the use of proven self-management education programs by individuals with chronic conditions such as heart disease and diabetes.

Because health IT is an integral component to the transformation of the delivery and payment of health care, ONC believes that the RECs are uniquely equipped to support better quality care and lowering costs by helping providers to identify, understand, and implement best practices and quality improvement initiatives using health IT.

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[19] Heisey-Grove D, Hufstader M, Hollin I, Samy L, Shanks, K. Progress towards the meaningful use of electronic health records among critical access and small rural hospitals working with Regional Extension Centers. ONC Data Brief, no. 5. Washington, DC: Office of the National Coordinator for Health Information Technology, November 2012.

Additionally, with the strong uptake of Meaningful Use of EHRs by providers in 2012, RECs are well positioned to continue to assist providers with the full implementation of the EHR Incentive Programs and further develop and implement other core competencies such as privacy and security assessments, health information exchange, and education. Supporting providers' efforts to use health IT to transform the delivery of care is a natural extension of the RECs' work to get providers to meaningfully use EHRs.

RECs continue to leverage their ability to provide technical assistance and support by working in partnership with other agencies, for example, CMS, on priorities such as the Comprehensive Primary Care (CPC) Initiative and the Medicare Shared Savings Program, which includes participation from Accountable Care Organizations (ACOs). A good example of this support is the New Jersey Health Information Technology Extension Center (NJ-HITEC), New Jersey's REC. The Barnabas Health Accountable Care Organization in New Jersey partnered with NJ-HITEC to receive support for its ACO. Specifically, NJ-HITEC assisted Barnabas with initial data analytics, which required matching of over 1,000 providers to beneficiaries and then extracting quality data from the EHRs and paper-based charts. The REC then conducted in-office analytical review of both the EHR and paper-based records. Once reviewed and analyzed, the abstracted quality data was entered into Medicare's group quality reporting system, which generated real-time analysis that was necessary for ACO Improvement, reports card delivery and, education to the physician ACO members.

Comprehensive Primary Care Initiative

ONC collaborated with CMS's Center for Medicare and Medicaid Innovation (Innovation Center) to recruit providers for the Innovation Center's Comprehensive Primary Care Initiative, reaching out to providers that were both enrolled or not yet enrolled with the REC program. The Innovation Center selected 500 practices and over 2,000 providers into the initiative. The RECs in New Jersey, Arkansas, New York, and Ohio are currently working with the Innovation Center to support providers participating in the initiative in their respective markets. The ONC and the CMS Innovation Center continue to collaborate on opportunities to enhance technical assistance to providers in the initiative.

Beacon Community Program Lighting The Way -- The Beacon Community Cooperative Agreement Program demonstrates how health IT investments and Meaningful Use of EHRs advance the vision of patient-centered care, while improving quality and helping to improve the efficiency of the health care system. These 17 communities throughout the United States have demonstrated progress in the development of secure, private, and accurate EHR systems and health information exchange infrastructure and are providing important lessons for transforming delivery systems throughout the country. As of the end of 2012, over 8,700 providers were participating in the Beacon Communities, and Beacon investments touched over eight million lives. Each of the 17 communities—with its unique population and regional context—is actively pursuing the following areas of focus:

- Building and strengthening the health IT infrastructure and exchange capabilities within communities, positioning each community to pursue a new level of sustainable health care quality and efficiency over the coming years;

- Translating investments in health IT to measureable improvements in cost, quality and population health, and;
- Developing innovative approaches to performance measurement, technology and care delivery to accelerate evidence generation for new approaches. For example, in the Greater Cincinnati Beacon Collaboration has been testing innovative solutions to improve asthma care using hospital admission, discharge and admission-discharge-transfer alerts (ADT alerts) which are improving transitions of care, and preventing avoidable emergency department and inpatient hospital visits. [20]

Aligning Quality Measures – As we move into a transformed delivery system, we hear from providers about the need for the federal government to work more closely to align our efforts with both public and private partners. I want to assure you how seriously we take this concern and how important we believe this effort is to successful delivery system reform. To this end, ONC has worked closely with CMS in the development of clinical quality measures that enable providers to better understand their performance relative to quality standards. In addition, ONC has developed a rigorous testing platform as a component of our 2014 EHR technology certification program that requires that every EHR capture the data necessary to compute clinical quality measures, calculate the measures accurately, and report the results of that calculation in a standard way to CMS.

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[20] To date, 27,000 alerts have been shared across 21 hospitals, 87 primary care practices, and 2 post-acute providers. According to Cincinnati Beacon's 2012 annual report, children admitted to the hospital for asthma are now 50 percent less likely to be readmitted or to be seen in the emergency department within 30 days, and are 23 percent less likely to return within 90 days.

State HIE Program Ensuring Exchange Tools Are Available for All – The State HIE Program has awarded funds to all 56 states and territories to ensure exchange tools are available across the broad health care eco-system. To date, 49 states have exchange services available that help providers make transitions of care safer and more than 30 states have services available to help providers look-up patients' health information even if they are not sure where the patient has previously received care. In addition to supporting providers working to achieve meaningful use, the State HIE Program has worked to ensure ineligible providers are not left behind. ONC has funded four states (CO, MD, MA, OK) to develop replicable approaches to improve long-term and post acute care (LTPAC) transitions. The initiatives are piloting approaches that meet LTPAC providers where they are today across the health IT adoption spectrum.

Since 2011, representatives from Florida, Michigan, Kentucky, Alabama, Nebraska, Iowa and New Mexico have participated in the Behavioral Health Data Exchange (BHDE) Consortium to address legal and technical barriers to the exchange of behavioral health data between health care providers, among organizations, and across state lines.

Ensuring that Patient Information Is Safe and Secure

Underlying all our efforts is the core understanding that we will not succeed if patients do not trust that their health information will be kept safe and secure in an increasingly electronic and interoperable world. We firmly believe that everyone who is involved in the health care sector (including the government, the developers, the health plans, the providers, and the patients) shares the responsibility for protecting patient information.

We address this complex issue from a number of different perspectives.

First, pursuant to HITECH, HHS has used its regulatory authority to expand the protections afforded to individually identifiable health information. The Privacy Rule issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) limits the use and disclosure of identifiable health information held by most health care providers. Its companion rule, the HIPAA Security Rule, requires health care providers to have administrative, technical, and physical safeguards for electronic identifiable health information. These protections are intended to ensure that health information remains private, that it is not inappropriately changed or deleted, and that it remains available.

HHS recently has issued regulations under HITECH that expand the categories of organizations and people who are required to protect electronic protected health information under HIPAA to the contractors of HIPAA-covered health care providers and health plans, including health information organizations, e-prescribing gateways, and others that facilitate data transmission, as well as their subcontractors. The EHR Incentive Programs requires providers to conduct or review a security risk analysis in accordance with the HIPAA Security Rule as part of the meaningful use core objectives.

In addition to HIPAA, a number of federal and state privacy laws restrict the disclosure of sensitive health data including those pertaining to behavioral health, HIV status, genetic tests, reproductive rights, and adolescent treatment, among others. These laws often protect individuals from the most vulnerable segments of our society and who represent a disproportionate share of healthcare costs in this country. Many of these laws, including 42 CFR Part 2 (for substance abuse), establish detailed requirements for obtaining patient consent for sharing health information. Currently, most EHR and HIE systems do not have the capacity to manage these consents or to control the re-disclosure of select types of information as required which poses a significant barrier to the integration of primary and specialty health care, especially behavioral health care.

In order to address the diversity in privacy regulations, ONC initiated the Data Segmentation for Privacy (DS4P) Initiative to develop and pilot test standards for managing patient consents and data segmentation. An implementation guide for consent management and data segmentation was released in the summer of 2012 and is currently being piloted. HHS is focused on developing solutions to protect patient privacy and enable integrated care without creating data silos that could negatively impact the quality of care for patients with sensitive health conditions.

Furthermore, HHS has taken steps to encourage and require developers of EHRs to build security into their products. This will make it easier for health care providers to secure their health information in a cost-effective manner. In particular, ONC has included the following security-related capabilities that EHR technology must have in order to be certified under the 2014 edition standards and certification criteria. To be certified, EHR technology must be able to:

- By default, encrypt the electronic health information stored on end user devices such as desktops, laptops, and smart phones;
- Authenticate users of the EHR technology system;
- Limit access to the EHR technology system;
- Record, by default, auditable events such as accessing data; and
- Produce an audit report.

In addition, HHS has endorsed the Office of the Inspector General's recommendation that it use its leadership role to provide guidance to the health care industry on security best practices by developing and publishing a number of privacy and security technical assistance materials in a variety of easy-to-use formats including short videos and training games. Just one example of this work is our on-line resource center for securing mobile devices. Early on, we recognized the trend toward using mobile devices in health care and within less than one year, developed and posted numerous plain language materials to educate providers on how to secure these devices. We intend to continue to assess the ever evolving health IT market and to address privacy and security vulnerabilities as they develop.

Moreover, HHS will continue to monitor for any unintended consequences across the health system. The Health IT Patient Safety Action and Surveillance Plan ("Safety Plan" or "Plan") addresses the role of health IT within HHS's commitment to patient safety and builds upon the recommendations made in the 2011 Institute of Medicine (IOM) Report *Health IT and Patient Safety: Building Safer Systems for Better Care.*[21] The Plan has two related objectives:

1. ***Use health IT to make care safer***, and
2. ***Continuously improve the safety of health IT.***

Consistent with the premise that all stakeholders share the responsibility to ensure that health IT is used to make care safer, the Plan leverages existing authorities to

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[21] http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx.

strengthen patient safety efforts across government programs and the private sector—including patients, health care providers, technology companies, and health care safety oversight bodies. It also lays out concrete steps to increase knowledge about the impact of health IT on patient safety and maximize the safety of health IT-assisted care.

ONC released the Health IT Safety Plan for public comment on December 21, 2012 and published the final version on July 2, 2013. ONC is coordinating the Plan's implementation through our Health IT Safety Program.[22]

FDASIA Workgroup on Risk-Based Regulatory Framework for Health IT

Because of its demonstrated success in providing sound advice on health IT initiatives, ONC looked again to the HIT Policy Committee when the Congress, through the Food and Drug Administration Safety and Innovation Act (FDASIA), required the Food and Drug Administration (FDA) and the Federal Communications Commission (FCC), in collaboration with ONC, to develop a report on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.[23] On April 18, 2013,[24] ONC, FDA, and FCC announced the members of the FDASIA Workgroup –

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[22] http://www.healthit.gov/policy-researchers-implementers/health-it-and-patient-safety.

[23] Section 618(a) of FDASIA charges the HHS Secretary (acting through the FDA Commissioner, in consultation with ONC and with the FCC Chairman) to publish a report by January 2014 that contains "a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."

[24] See http://www.hhs.gov/news/press/2013pres/04/20130418a.html for a complete list of workgroup members.

under ONC's HIT Policy Committee -- that will help that Committee provide expert advice to FDA, ONC, and FCC for the development of the report required by FDASIA. Consistent with the statute, the workgroup is geographically diverse and includes representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise. As with ONC Federal Advisory Committee Workgroups, FDASIA Workgroup meetings are public, and documents discussed at the meetings are publicly available, as appropriate. We greatly appreciate the leadership and interest of Senators Harkin, Hatch, Bennet, and Enzi on these issues and we look forward to continuing to work with the Congress to promote innovation and protect patient safety.

Consumers – The Most Underutilized Resource in Healthcare

Over the past few decades, we have seen information technology improve the consumer experience in almost every aspect of our lives, including the way we manage our finances, shop, and book travel. But, health care has been slower to leverage this technology. Most notably, relevant information is not available to patients when and where it is needed.

Technology helps enable the use of consumer knowledge by helping consumers to:

- Better understand their health and healthcare, *e.g.*, via tailored educational resources;
- Coordinate their care by sharing data among providers and other members of their care team;

- Communicate with providers between visits in real time (*e.g.*, via secure messaging)
- Use software applications apps and tools to manage their health and healthcare and to meet the health goals they set for themselves; and
- Improve the quality of data about them (*e.g.*, identify and address errors or omissions in their records).

Increasingly, people are taking their health into their own hands—whether that means tracking their health through a smartphone app or a remote monitor, participating in online patient or caregiver communities, or accessing their medical records online. Changes in consumer technology, such as the growth of mobile phones, are helping to drive this change -- nearly nine out of ten people own a mobile device and nearly half of all Americans own a smartphone.[25] Mobile devices offers several advantages over traditional PCs—they can help remove traditional barriers such as geography and time, can break down the digital divide in underserved communities, can enable remote treatment, and can facilitate more continuous health monitoring, which makes health care more convenient and personalized.

The mobile devices in our pocket can help us access a world of information at the right time to help make the right health decisions, which is important since 80 percent of Internet users have gone online seeking health information.[26] The Department of Defense has developed apps to help veterans and their caregivers cope with post-traumatic stress disorder. Mobile phones can be an incredible tool for empowering consumers to take

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[25] Pew: http://pewinternet.org/Reports/2012/Cell-Internet-Use-2012/Main-Findings/Cell-Internet-Use.aspx

[26] Pew: http://www.pewinternet.org/Reports/2011/HealthTopics.aspx.

control of their health, their care, and their healthcare finances and as we know from the literature, more engaged consumers get better outcomes[27].

ONC's strategy in consumer eHealth is to work with partners to increase patients' ability to access their own health data, to increase the use of these data for actionable apps and services, and to shift attitudes around patient empowerment. An increasingly popular symbol for access to personal health data and the greater consumer engagement it supports is the "Blue Button" – a blue circle with a download arrow in the center first used by the Department of Veterans Affairs (VA) on their patient portal to enable veterans to download their health records "at the click of a button." In 2010, the Department of Defense (DOD) also incorporated Blue Button into their TRICARE Online PHR site. Military retirees and or veterans discharged after 1979 now have secure online access to lab results, patient histories, diagnoses, and provider visits.

Building on Blue Button's initial popularity, in 2011 responsibility for the Blue Button brand and functionality nationwide was transferred officially to HHS. To support that effort, ONC has been coordinating closely with the VA and the Presidential Innovation Fellowship Program through which a total of six private sector fellows have been assigned to develop technical guidelines (called Blue Button Plus) for data holders and developers. In addition, we are also encouraging institutions that have health data to make it easier for patients to gain easy, electronic access to their data and to use that information in ways that improve their health and health care. The Blue Button Pledge Program is a voluntary

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[27] Bipartisan Policy Center: Improving Quality and Reducing Costs in Health Care: Engaging Consumers Using Electronic Tools. http://bipartisanpolicy.org/sites/default/files/BPC_Engaging_Consumers_Using_Electronic_Tools.pdf

mechanism for supporting consumers' access to their health data. The Blue Button Pledge Program now includes more than 450 organizations that are committed to learning and collaborating in efforts to increase patient access to, and use of, health data. The Pledge Program, launched in 2011, includes "data holders"—such as health care providers and insurers—who pledge to improve the accessibility of health data to patients and other authorized users, and "non-data holders"—such as software developers and consumer advocacy organizations— who pledge to educate consumers about the value of getting and using their health data. The "data holder" organizations that participate in the Blue Button Pledge Program collectively reach more than 88 million Americans.

The government is leading by example in implementation of Blue Button. Veterans today can access their medical records online, and download their records with a simple click of a "Blue Button"- and more than one million veterans have done so. Medicare beneficiaries can access and download three years of their Medicare claims online today – and by using an app like iBlueButton, carry that information on their mobile devices. HHS is also encouraging Medicare Advantage plans to expand the use of Blue Button to provide beneficiaries with one-click secure access to their health information. And the Federal Employee Health Benefits program has asked carriers to do the same.

Meaningful Use Stage 2, as part of the Medicare and Medicaid EHR Incentive Programs, requires eligible providers to use secure e-mail with patients and to provide patients with a way to view, download, and transmit their own health information beginning in 2014 for hospitals and eligible professional such as doctors. Under Stage 2, patients will be able not only to view their health information online, but also to export their data from EHRs in structured and human-readable formats; share those data with others; and use tools and applications to store, analyze, or otherwise make use of their information. Stage 2 also establishes thresholds for the proportion of patients using these functions, which will encourage providers to promote their use. Through both Meaningful Use and the Blue Button initiative, HHS is increasing the flow of personal health data to patients and consumers directly, and thus inviting them to engage more fully in their health and health care. Among the most powerful benefits of such engagement is that consumers themselves will be able to serve as the connection point among numerous members of the care team, functioning as their own "health information exchanges." It is not uncommon for an individual to have multiple providers – the average cancer patient has 32 – so the capacity to coordinate care among them is essential. Many patients also have a significant network of informal caregivers. Consumers or patients are arguably best positioned to decide whom to bring into their circle of care, and when and with whom to share their vital health information.

Conclusion

We are rapidly moving toward a 21st century healthcare system with smarter, higher quality care that is both patient-centric and less costly. We are changing how we pay for healthcare by focusing on improved care coordination and on new delivery and payment models. Health IT is critical to the success of these new programs; programs such as ACOs, bundled payments, health and medical homes, and the implementation of CMS's hospital readmissions policies.

In addition to better coordination of care, through the use of health IT, there will be greater access to patient health information that is integral to improving the quality, efficiency, and safety of health care delivery. Already, across the country, more and more clinicians are using health IT as a tool to provide safer and more secure care.

We have already seen the successes of electronic health records and health IT: clinicians are securely exchanging patients' records and improving outcomes by ensuring that patients do not have to undergo duplicate or unnecessary procedures; more than two-thirds of office-based doctors check medication orders for harmful drug interactions, over half share clinical summaries with their patients; and, with access to their own information, patients become more engaged in their care and experience better outcomes.[28]

New technologies – including health IT and mobile applications – offer great promise to transform the way health care is delivered. Our progress in moving towards these goals has been steady and deliberate. Working within an open and transparent process with our public and private stakeholders, we are on a path toward achieving a truly interoperable health system in which clinicians and patients can talk to each other online – no matter which EHR system they have in place.

To transform delivery, health care providers must also redesign and reengineer the workflow of care. Though this work is well underway, it does not happen overnight. Health IT holds tremendous promise for delivering "smart health" to patients right at their fingertips to help all of us achieve the best possible outcome for each individual. We must carefully balance the need for the widest innovation possible, with protection of patient privacy, security, and safety.

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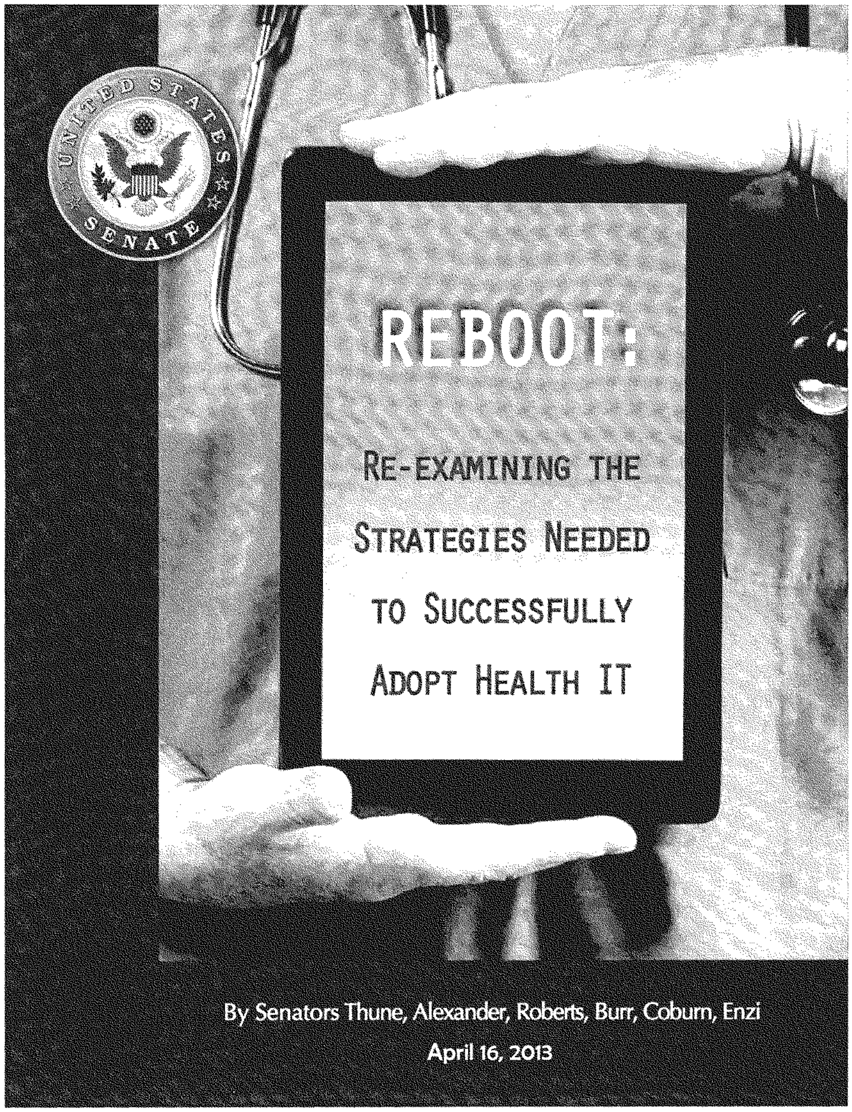
[28] Aspen Institute: Adopters of Health Information Technology Starts to See Its Benefits. August 2012 http://www.aspeninstitute.org/sites/default/files/content/docs/pubs/HIT_Policy_Brief_Final_Aug_2012.pdf

We look forward to continuing to working with the Congress to accomplish these goals. I would be happy to answer any questions that you may have regarding my testimony.



UNITED STATES SENATE

REBOOT:

RE-EXAMINING THE STRATEGIES NEEDED TO SUCCESSFULLY ADOPT HEALTH IT

By Senators Thune, Alexander, Roberts, Burr, Coburn, Enzi

April 16, 2013

United States Senate
WASHINGTON, DC 20510

April 16, 2013

Dear health information technology stakeholders and members of the public,

We write to seek your feedback on federal progress promoting health information technology adoption and standards. Health information technology (health IT) is rapidly changing, altering the status quo for health care delivery in the United States. The American Recovery and Reinvestment Act of 2009 included the Health Information Technology and Economic and Clinical Health (HITECH) Act which aimed to promote the adoption and meaningful use of health IT. Since the passage of the HITECH Act in 2009, the Department of Health and Human Services (HHS) has released hundreds of pages of regulations to implement the program. In addition, $35 billion over ten years will be spent to implement this program.

The HITECH Act was enacted to promote the adoption and meaningful use of health IT. The goal is to create a secure network in which hospitals and providers can share patient data nationwide. Unfortunately, it is unclear whether the HITECH Act has expanded the use of health IT in a meaningful, effective way. We have significant concerns with the implementation of the HITECH Act to date, including the lack of data to support the Administration's assertions that this taxpayer investment is being appropriately spent and actually achieving the goal of interoperable health IT.

To begin a discussion of these health IT programs, today we released "REBOOT: Re-examining the Strategies Needed to Successfully Adopt Health IT." This white paper outlines our concerns with current health IT policy, including interoperability, increased costs, potential waste and abuse, patient privacy, and sustainability.

In order to evaluate the current return on taxpayer investment in health IT and ensure that health IT programs are effectively implemented, we are soliciting feedback from all health IT stakeholders and members of the public. We respectively ask for feedback on "REBOOT: Re-examining the Strategies Needed to Successfully Adopt Health IT" from anyone who wishes to submit comments, including health care providers, patients, electronic health record vendors, scholars, or interested members of the public. We hope stakeholders can provide information about the areas of concern we have identified, any additional areas of concern, and potential solutions to improve HITECH implementation.

We ask that feedback be sent to HealthIT_CommentPeriod@thune.senate.gov by May 16, 2013. We hope this process will begin a robust dialogue on how best to achieve the promise of health IT in the future.

Sincerely,

Lamar Alexander
Senator Lamar Alexander

Senator Richard Burr

Tom Coburn
Senator Tom Coburn

Michael B. Enzi
Senator Mike Enzi

Senator Pat Roberts

John Thune
Senator John Thune

EXECUTIVE SUMMARY

The advancement of health information technology holds the promise of increasing efficiency in the health care system; reducing costs for payers, providers, and patients; and improving quality of care for patients and their families. To achieve these goals, in 2009 Congress passed legislation devoting some $35 billion to promote providers' adoption and use of federally certified health information technology (health IT).[1] This law, the Health Information Technology and Economic and Clinical Health (HITECH) Act, was included as part of President Obama's economic stimulus, the American Recovery and Reinvestment Act of 2009 (ARRA).

However, while promoting the use of health IT is a laudable goal, a growing body of objective analysis and empirical data suggests the program needs to be recalibrated to be effective. Congress and the administration need to work together to "reboot" the program to accomplish the aims of meaningful use and interoperability and ensure appropriate stewardship of taxpayer dollars in the process.

The key implementation deficiencies can be summed up in five points:

- **Lack of Clear Path Toward Interoperability.** The HITECH Act, a $35 billion program of grants and incentive payments in ARRA, was created to promote the use of electronic health records (EHRs) among hospitals and physicians, with the ultimate goal of incentivizing the adoption and use of health information technologies meeting a certain data standard so that providers can share patient health data nationwide.[2] The ability to share data, it was said, would reduce the overall need for as many tests, arm providers with better patient information, and enhance the quality of patient care. However, to achieve this aim, having interoperable systems is necessary. Unfortunately, early reports suggest that federal incentive payments are being made without clear evidence that providers can achieve "meaningful use," or the ability to use the health IT program internally, and without an adequate plan to ensure providers can share information with each other.

- **Increased Costs.** Members of Congress and policy analysts across the political spectrum have promoted health IT as one tool to help bring down health care costs. Through efficiencies in storing and sharing records and ordering and coordinating patient care, as well as structural savings through better data and research, cost savings are estimated in the billions of dollars in the next decade alone. For example, the Congressional Budget Office estimated that the HITECH Act will save the Medicare and Medicaid programs a total of about $12.5 billion through 2019.[3] However, early reports raise concerns that health IT may have actually accelerated the ordering of unnecessary care as well as increased billing for the same procedures.

- **Lack of Oversight.** Based on Department of Health and Human Service's Inspector General and Government Accountability Office (GAO) reports as well as stakeholder comments and a review of program data, it is increasingly clear that the Administration does not have adequate mechanisms in place to prevent waste and fraud in its health IT programs. Too often we have heard stories of

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[1] $35 billion includes $32.7 billion in incentive payments and nearly $2 billion in grants. Redhead, Stephen C. "*The Health Information Technology and Economic and Clinical Health (HITECH Act).*" Congressional Research Service, Report No. R40101. 2009.

[2] "HITECH Act." *HealthIT.gov.* http://www.healthit.gov/policy-researchers-implementers/hitech-act-0

[3] Redhead, Stephen C. "*The Health Information Technology and Economic and Clinical Health (HITECH Act).*" Congressional Research Service, Report No. R40101. 2009.

"money spent" being used as a metric of success, rather than specific, concrete program goals and tangible deliverables that are focused on achieving interoperability. There have been reports of taxpayer dollars being paid to providers who cannot or do not have to demonstrate that the technology is actually used as prescribed, because the administration relies on provider "self-attestation" in many cases to determine eligibility for payments. In some cases, contractors receiving government funds may be creating obstacles to interoperability. In other cases, providers who have previously received federal incentive grants are reportedly now forced to adopt less advanced technologies to meet current standards, effectively forcing them to scrap prior federally subsidized investments.

- **Patient Privacy at Risk.** We are concerned the administration has not done enough to protect sensitive patient information in a cost-effective manner. Among other problems, regulations related to payments made to providers do not require providers to demonstrate that the technology is secure; consequently, patients' sensitive, personal medical information may be at risk. In fact, the Inspector General of the U.S. Department of Health and Human Services found that the security policies and procedures at the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology – two federal entities which oversee the administration of the health IT program – are lax and may jeopardize sensitive patient data.[4] Being proactive in addressing privacy and security concerns while minimizing the additional burden on providers is a critical part of ensuring the long-term success of EHRs. Further, problems with data entry, computer programing errors, and other unforeseen complications can affect the security of patient data and have the potential to jeopardize patient care.

- **Program Sustainability.** For providers who have accepted grants or incentive payments, it is unclear how much it will cost to maintain their health IT systems after the initial grant money and incentive payments run out. For example, in 2015, incentive payments in most scenarios cease, and providers face penalties in the way of reduced Medicare reimbursements if they do not comply with federal requirements. Even worse, these penalties are most likely to affect small providers who may not have the economies of scale needed to make complex electronic systems cost-effective. Moreover, the complicated patchwork of overlapping reporting and compliance requirements is already placing ongoing compliance burdens on all participating providers. We are concerned that compliance and maintenance costs for providers may be unreasonably burdensome.

This white paper addresses each area of concern in depth. We present this paper as part of our broader effort to solicit feedback from the administration and foster an ongoing conversation with the stakeholder community – health care providers, technology vendors, and others. It is our goal to work cooperatively with the administration, our colleagues in both parties in Congress, and the American people to learn more about the issues raised here and to address the problems identified.

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[4] Lewis, Nichole. "Federal Agencies Fail Health IT Security Audits." *Information Week.* May 18, 2011. http://www.informationweek.com/healthcare/security-privacy/federal-agencies-fail-health-it-security/229502471

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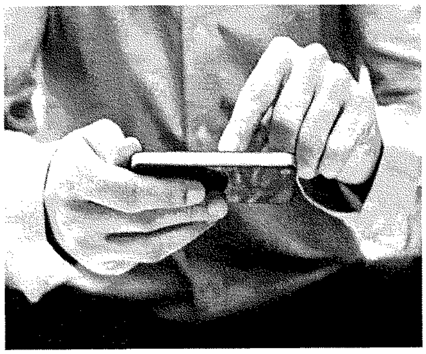
Introduction

Since the dawn of the modern communications revolution, transformations in health information technology (health IT) have been evolving at an increasingly rapid pace. Today's creative and powerful health IT solutions have the potential to dramatically upend the status quo and reshape the delivery of health care in our country. Today more than ever, Americans are searching for medical information online, checking drug interactions or symptoms with their smart phones, or e-mailing their family doctors. Physicians can access digital records of a patient even if they are in another city, state, or country. Clinical notes are recorded with increasing speed and ease, and other transformations offer the promise of increased efficiency, reduced costs, and improved quality of care. However, the details of federal law and regulation may be inadvertently incentivizing unworkable, incoherent policy goals that ultimately make it difficult to achieve interoperability.



In 2009, the Health Information Technology and Economic and Clinical Health (HITECH) Act was passed as part of the American Recovery and Reinvestment Act (ARRA).[5] The HITECH Act was enacted on the heels of several existing federal incentive programs designed to promote the adoption and effective use of electronic health records (EHRs). The ultimate goal of this act was to create standards for the secure exchange of patient data nationwide, whether the site of care was a hospital or a local primary care physician's office. In other words, the goal of the HITECH Act was for providers across the country to be able to adopt technology that would allow them to store and access EHRs, to share them seamlessly in a timely manner, and to create a network for providers' systems to be interoperable. ARRA appropriated approximately $35 billion for the Office of National Coordinator for Health IT and the Centers for Medicare and Medicaid Services (CMS) to achieve this goal. Now, nearly four years after the enactment of the HITECH Act, and after hundreds of pages of regulations implementing the program, we see evidence that the program is at risk of not achieving its goals and that $35 billion in taxpayer money is being spent ineffectively in the process.

This paper addresses the following five concerns:

- **Lack of Clear Path Toward Interoperability**
- **Increased Costs**
- **Lack of Oversight**
- **Patient Privacy at Risk**
- **Program Sustainability**

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[5] American Recovery and Reinvestment Act of 2009. Public Law 111-5. http://www.gpo.gov/fdsys/pkg/BILLS-111hr1enr/pdf/BILLS-111hr1enr.pdf

Of the $35 billion in incentive payments and grants authorized by ARRA, as of February 28, 2013, CMS estimated it has paid out nearly $12.7 billion in incentive payments.[6] Of that sum, nearly $1.2 billion was paid in December of 2012 alone.[7] With so many dollars flowing out of CMS, Congress has the fiduciary responsibility to ensure that these taxpayer dollars are being used to efficiently accomplish the end goal of reduced health care costs through the appropriate sharing and use of health information.

We present this white paper in an effort to initiate a dialogue with the administration and the stakeholder community. The purpose of this paper is to foster cooperation between all stakeholders – including providers, patients, EHR vendor companies, and the Department of Health and Human Services – to address the issues raised in this paper, evaluate the return on investment to date, and ensure this program is implemented wisely.

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[6] Centers for Medicare and Medicaid Services. *EHR Incentive Program Report, February 2013.* http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Feb_EHRIncentiveProgramsPaymentsReg_SummaryReport.pdf

[7] Conn, Joseph. "Whopping $1.2 billion in EHR Payments in December." *Modern Healthcare*. January 8, 2013. http://www.modernhealthcare.com/article/20130108/NEWS/301089956

Background

The Health Information Technology for Economic and Clinical Health (HITECH) Act is the most recent major health IT law, but it followed on the heels of the establishment of a patchwork of programs and laws first created in 1996. These laws all attempt to promote the widespread adoption of health IT while ensuring patient privacy is protected. "Health information technology," as referred to in federal law and in this white paper, broadly refers to electronic storage of records, electronic billing, electronic ordering of tests and procedures, and even a shared, interoperable network to allow providers to communicate with each other. Health IT initiatives undertaken by the private sector, such as mobile applications used by insurance plans, are not addressed in this white paper.

Underlying much of the federal government's health IT policy efforts has been an assumption that health IT will help to improve outcomes for patients and reduce costs in the health care system.[8] The expectation has been that providers will be able to coordinate and provide care more efficiently with comprehensive records stored at their fingertips. The fast and easy sharing of patient data across providers should improve patient outcomes, the conventional wisdom goes, by, for example, identifying harmful drug interactions, reducing unnecessary duplicate testing, and helping physicians manage patients with multiple conditions.

Landscape of Health IT Policy

Multiple overlapping programs form the framework of federal health IT policy. The main laws and programs are outlined as follows:

> **HITECH Act.** The HITECH Act of 2009, adopted as part of the American Recovery and Reinvestment Act of 2009 (ARRA), promotes widespread health IT adoption.[9] The act codified the Office of the National Coordinator for Health Information Technology, which is tasked with establishing standards necessary to share health care data nationally through a secure digital environment. It also established a number of financial incentives, including grant programs and Medicare and Medicaid incentive payments, to promote adoption of health IT among health care practitioners. (See summary below of HITECH Act's major provisions.)
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> **HIPAA.** The Health Insurance Portability and Accountability Act (HIPAA) of 1996 created federal requirements for the protection of personal health information.[10] These include provisions regarding security standards to safeguard electronic health information against unauthorized access, use, and disclosure, such as off-site backups, restricting access to computers, passwords, and encryption, and rules about when and how protected health information can be disclosed. The HITECH Act of 2009 made modifications to HIPAA to expand enforcement provisions, and the final rule implementing these additional federal mandates was published in the Federal Register on

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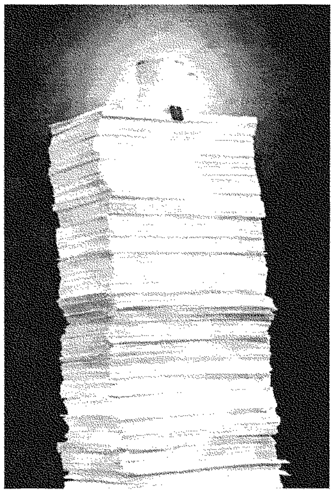
[8] Girosi, Federico, et al. *Extrapolating Evidence of Health Information Technology Savings and Costs*. RAND Health. 2005. http://www.rand.org/content/dam/rand/pubs/monographs/2005/RAND_MG410.pdf

[9] American Recovery and Reinvestment Act of 2009. Public Law 111-5. http://www.gpo.gov/fdsys/pkg/BILLS-111hr1enr/pdf/BILLS-111hr1enr.pdf

[10] The Health Insurance Portability and Accountability Act of 1996. Public Law 104-191. http://www.gpo.gov/fdsys/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf

January 25, 2013.[11] Failure to comply with HIPAA results in civil penalties of up to $50,000 per violation and $1,500,000 per year.[12]

PQRS. The Physician Quality Reporting System (PQRS) was initially created by the Tax Relief and Health Care Act of 2006.[13] What was originally a voluntary program that created an electronic reporting system under Medicare for providers to report clinical quality measures now has its own set of penalties of reduced Medicare reimbursements for non-participating providers.[14]



eRx Incentive Program. The Electronic Prescribing (eRx) Incentive Program was created by the Medicare Improvements for Patients and Providers Act of 2008, and provides incentive payments to eligible physicians who e-prescribe Medicare Part D medications using a qualified system.[15] Starting last year, providers who did not use eRx were subject to reduced Medicare reimbursements as a penalty.

Grant Programs. ARRA appropriated $2 billion in the HITECH Act for grants to fund health IT infrastructure and grants to states for low-interest health IT loans. The Agency for Healthcare Research and Quality (AHRQ) has awarded $300 million in federal grant money to over 200 projects in 48 states to promote access to and encourage adoption of health IT.[16] Over $150 million in Medicaid Transformation Grants have been awarded to 35 states and territories for health IT initiatives in the Medicaid program, pursuant to the Deficit Reduction Act of 2005.[17]

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[11] Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the HITECH Act and the Genetic Information Nondiscrimination Act; Final Rule, 78 Fed. Reg. 5566, January 25, 2013. http://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf

[12] Penalties for HIPAA violations are found at 42 USC § 1320d-5. http://www.gpo.gov/fdsys/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap7-subchapXI-partC-sec1320d-5.pdf

[13] Tax Relief and Health Care Act of 2006, Public Law 109-432. http://www.gpo.gov/fdsys/pkg/PLAW-109publ432/pdf/PLAW-109publ432.pdf

[14] "Electronic Prescribing (eRx) Incentive Program." Centers for Medicare and Medicaid Services. Last modified September 19, 2012. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ERxIncentive/index.html?redirect=/erxincentive

[15] Medicare Improvements for Patients and Providers Act of 2008. Public Law 110-275. http://www.gpo.gov/fdsys/pkg/PLAW-110publ275/pdf/PLAW-110publ275.pdf

[16] "Health IT at AHRQ." Agency for Healthcare Research and Quality. Last modified November 2011. http://healthit.ahrq.gov/portal/server.pt/community/about/562

[17] Hayes, Heather. "CMS Awards More Medicaid Transformation Grants." Government Health IT. October 5, 2007. http://www.govhealthit.com/news/cms-awards-more-medicaid-transformation-grants

Federal Offices, Initiatives. A number of entities were created by Congress and the administration to address health IT implementation issues. The Office of National Coordinator for Health IT (ONC) established the Health Information Security and Privacy Collaboration (HISPC) to develop a national privacy and security framework. The Healthcare Information Technology Standards Panel (HITSP), another ONC creation, is a public-private effort to develop standards for the certification of health IT products. The Department of Health and Human Services secretary created the National eHealth Collaborative (NeHC), a public-private advisory body to make recommendations on health IT adoption and usability. The AHRQ created the online National Resource Center for Health IT to serve as a public resource for information on health IT. Finally, the Health Resources and Services Administration (HRSA) works to improve access and use of health IT for safety net providers.

HITECH ACT

While the HITECH Act built on previous federal efforts to encourage health IT adoption, it is now the primary piece of legislation directing the bulk of federal health IT policies and programs.[18] In addition to $2 billion in grants funded through the HITECH Act, the Congressional Budget Office (CBO) estimates that $32.7 billion will be spent from 2009-2019 in Medicare and Medicaid through HITECH. Notably, according to CBO estimates at the time the law was enacted, HITECH was *not* required for the adoption and use of health IT to spread. In fact, without HITECH, the CBO predicted 45 percent of hospitals and 65 percent of physicians would have adopted Health IT by 2019. With HITECH, CBO estimated 70 percent of hospitals and 90 percent of physicians will adopt health IT in that time frame.[19] This white paper will examine the accuracy of that estimate at a later point. HITECH includes four major provisions.

First, HITECH codified the Office of National Coordinator for Health IT, which has as its goal the establishment of standards that support the nationwide electronic exchange of health information (called "interoperability") in a secure computer network. Hence, the Office of National Coordinator for Health IT is building the National Health Information Network (NHIN), a nationwide, secure platform that connects health networks using shared standards and policies (a "network of networks"). The Office of the National Coordinator for Health IT also established HISPC to develop a national privacy and security framework and HITSP to develop standards for the certification of health IT products.

Second, HITECH established $2 billion in grant programs to fund investment in health IT infrastructure, resource centers, workforce programs, standards development, research projects, and privacy and security programs, as well as grants to

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[18] This does not include DOD and VA efforts.

[19] Redhead, Stephen C. "*The Health Information Technology and Economic and Clinical Health (HITECH Act).*" Congressional Research Service, Report No. R40101. 2009.

states to provide low-interest loans to help providers finance health IT. As of March 1, 2013, $1.985 billion of that $2 billion has been allocated.

Third, HITECH funds Medicare incentive payments to encourage doctors and hospitals to adopt and use certified electronic health records (EHRs). The incentive payments will be phased out over time and replaced with penalties for not "meaningfully using" health IT. Additionally, HITECH authorized the federal government to pay 100 percent of the cost to adopt certified EHR systems for certain Medicaid providers. To date, a total of $12.7 billion has been distributed to 388,593 providers or hospitals.[20]

Fourth, HITECH amended HIPAA to expand and strengthen certain privacy and security requirements. HITECH created a right to be notified in the event of a breach of identifiable health information. It also increases civil penalties for certain HIPAA privacy violations.

While CBO estimated that HITECH would save the Medicare and Medicaid programs a total of $12.5 billion during the budget window, the net cost of HITECH over the ten-year scoring period was $20.8 billion.[21]

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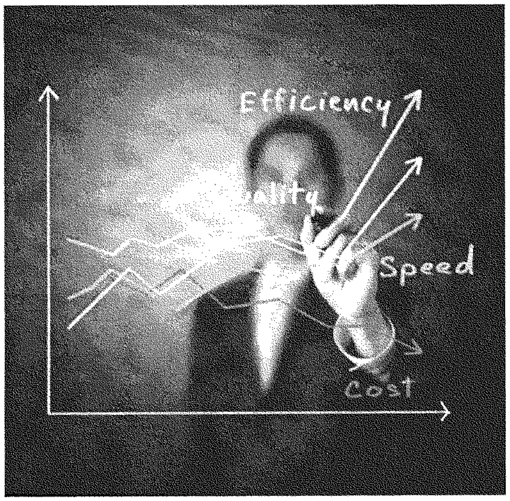
[20] Centers for Medicare and Medicaid Services. *EHR Incentive Program Report, February 2013.* http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Feb_EHRIncentiveProgramsPaymentsReg_SummaryReport.pdf

[21] Congressional Budget Office Letter to Honorable Nancy Pelosi, Speaker of the House, on the Conference Agreement for the American Recovery and Reinvestment Act, February 13, 2009. http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/99xx/doc9989/hr1conference.pdf

I. Lack of Clear Path Toward Interoperability

Supporters of the HITECH Act have argued that it was enacted to facilitate the electronic sharing of data among health care providers. This function, called "interoperability," was envisioned to encourage physicians, hospitals, and other health care providers across the country to share patient information, such as medical histories or results of diagnostic tests, through a secure network. Supporters view this network as necessary to achieve the potential cost savings and quality improvements promised by health IT. Sharing patient information was supposed to improve care and allow physicians to coordinate by preventing duplicate testing and preventing harmful drug interactions.



Interoperability is the key to achieving efficiencies in care with health IT; however, interoperability has to date proven very difficult to establish. Ideally, hundreds of thousands of providers, from small family practitioners to very large hospital systems, all need to be using a network and infrastructure that allows for the sharing of information. The network will have to be robust and secure enough to prevent any misuse of sensitive patient information. And such a system has to somehow be developed to work with the hundreds of thousands of IT systems already in place. Moreover, this system must also be flexible enough to accommodate future changes in technology. Additionally, this system must be affordable and simple enough for the wide range of providers to implement.

We are seriously concerned that, despite the billions of taxpayer dollars spent and providers who may be penalized, CMS does not yet seem to have an adequate plan to achieve secure, meaningful interoperability. A lack of meaningful interoperability means $35 billion and years of effort are at risk of being wasted.

Three Stages of HITECH Implementation

As stated in the HITECH Act, one of the purposes of the Office of National Coordinator for Health IT is to "improve the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information."[22] Coordination is primarily achieved through interoperability, and in an effort to achieve

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[22] Section 3001 of the American Recovery and Reinvestment Act of 2009. Public Law 111-5. http://www.gpo.gov/fdsys/pkg/BILLS-111hr1enr/pdf/BILLS-111hr1enr.pdf

interoperability, the Office of National Coordinator for Health IT and CMS adopted regulations that create a staged approach where eligible providers will proceed through three stages of requirements. Before focusing on interoperability, these stages largely focus on achieving "meaningful use," or the ability to use software to achieve government-established milestones largely within a single provider or practice.

Stage 1 requires eligible providers and hospitals to select from both a core set and a menu set of objectives. To achieve Stage 1 meaningful use, the provider or hospital must satisfy all of the core set and a percentage of the menu set objectives.[23] For Stage 2, eligible providers and hospitals must meet Stage 1 requirements for a 90-day period in the first year of participation in the meaningful use program and for a full year in the second year of participation.[24] Stage 2 also involves a growing and more complex set of core and menu objectives over those required in Stage 1. None of the required core or menu objectives in Stage 2 requires communication with other health care providers. This means steps towards interoperability are neither being required nor measured. Examples of some of the 17 required core objectives for Stage 2 include:

- recording demographic information,
- incorporating clinical lab-test results into Certified EHR technology, and
- recording smoking status for patients 13 years old or older.

While the Stage 2 requirement to "submit electronic data to immunizations registries" is a small step towards the sharing of health information, it does not require providers to effectively and securely share this data with other providers. Although a request for comments was published in the Federal Register for Stage 3, Stage 3 regulations have not been promulgated, and CMS recently announced a delay in rulemaking for Stage 3.[25] We applaud CMS for listening to stakeholder concerns about the speed of implementation of the program.

Misplaced Focus on Use of Technology Within Silos Rather Than Interoperability

Unfortunately, the program as laid out by CMS and the Office of National Coordinator for Health IT continues to focus less on the ability of disparate software systems to talk to one another and more on providing payments to facilities to purchase new technologies. We have seen this focus demonstrated in the following ways:

- The sequencing of regulations from the Office of National Coordinator for Health IT and CMS does not give providers a realistic timeframe during which to achieve meaningful use, despite the fact that the Office of National Coordinator for Health IT and CMS say that the meaningful use program is an important step on the path to interoperability.

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[23] "Stage One of Meaningful Use." Centers for Medicare and Medicaid Services. Last modified September 20, 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Meaningful_Use.html

[24] "Stage Two of Meaningful Use." Centers for Medicare and Medicaid Services. Last modified November 28, 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage_2.html

[25] Vaidya, Anuja. "CMS to Delay Stage 3 Meaningful Use Requirements." *Becker's Hospital Review*, March 7, 2013. http://www.beckershospitalreview.com/healthcare-information-technology/cms-to-delay-stage-3-meaningful-use-requirements.html

- CMS' failure to systematically and clearly address meaningful groundwork for interoperability at the start of the program could lead to costly obstacles that are potentially fatal to the success of the program.

The current approach to implementing the HITECH Act places a priority on pushing money out the door to get technology into doctors' offices and hospitals, but fails to ensure that technology will be used for its intended purpose. David J. Brailer, the former health information czar under President George W. Bush, warns the approach used to advance the use of EHRs has suffered from a "colossal strategic error" by creating a "race to adopt" mentality that lacks the forethought of pushing toward real interoperability.[26]

Rushing Through Stages of Implementation Does Not Allow Adequate Time to Ensure Meaningful Use, a Necessary Step to Interoperability

CMS currently has an aggressive, one-size-fits-all implementation schedule to achieve meaningful use, which does not account for the different abilities of providers to comply with the requirements. For example, some technologically integrated suburban hospitals are being held back from using more advanced capabilities, while small, rural physicians' offices are being overwhelmed by one-size-fits-all requirements.

Stage 1 requirements are effectively applied uniformly and on the same timeline to all providers across the country. This one-size-fits-all requirement ignores the fact that different providers and hospitals had vastly different capabilities at the onset of Stage 1 and overlooks the unique differences between rural solo practitioners, hospitals, older providers, specialty practices, and smaller practices.[27,28] CMS envisions Stage 1 as the initial gateway on the path to meaningful use. However, if the Stage 1 requirements hinder the ability of providers to take the first step due to unachievable aims, meaningful use becomes that much more difficult to achieve.

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[26] Abelson, Reed and Julie Creswell. "In Second Look, Few Savings From Digital Health Records." *New York Times* January 11, 2013. http://www.nytimes.com/2013/01/11/business/electronic-records-systems-have-not-reduced-health-costs-report-says.html?_r=0

[27] Moukheiber, Zina. "Government Should Slow Down Race to Implement Electronic Health Records." *Forbes* January 17, 2013. http://www.forbes.com/sites/zinamoukheiber/2013/01/17/government-should-slow-down-race-to-implement-electronic-health-records/

[28] Letter from American Medical Association to Office of the National Coordinator for Health Information Technology, January 14, 2013. http://www.ama-assn.org/resources/doc/washington/stage-3-meaningful-use-electronic-health-records-comment-letter-14jan2013.pdf

In the final rule for Stage 1, CMS stated it "expect[s] to update the meaningful use criteria on a biennial basis, with Stage 2 criteria by the end of 2011 and the Stage 3 criteria by the end of 2013."[29] While CMS modified this timeline by delaying Stage 2 by one year and recently announced a delay of Stage 3 rulemaking, the aggressive deadlines may not allow enough time to ensure that all providers are truly gaining *meaningful* use of their EHRs. If providers are not able to achieve meaningful use of their new technologies, they will not be in a position to share electronic records with other providers at the interoperability stage. This dynamic threatens to waste the funds spent on the technology as well as undermine the potential of the cost-savings and improved quality care that come from interoperability. Even worse, on top of this, providers will be penalized for not all reaching a common milestone.

Stage 2 and 3 Rules Lack the Benefit of Appropriate Data Review

On September 4, 2012, CMS released the final rule for Stage 2 of meaningful use of EHRs following an announced one-year delay in implementation.[30] CMS published this regulation without fully understanding both the strengths and weaknesses of the incentive program during Stage 1. Moreover, CMS released interim Stage 3 requirements and sought comments regarding Stage 3 of meaningful use on November 26, 2012, well before the end of Stage 1.[31] Within a six-month period, CMS implemented Stage 1, published a final rule for Stage 2, and began seeking feedback for Stage 3. At a time when reports continue to be released questioning the effectiveness of EHR adoption, it is imperative that CMS conduct appropriate data review before accelerating into Stage 2 and Stage 3.[32] It was prudent of CMS to heed stakeholder input and delay Stage 3 rulemaking because in order for the HITECH Act to be successful, it may be necessary for the administration to recalibrate their goals and reengage stakeholders to ensure their concerns are addressed and stakeholder insights are applied.

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[29] Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule. 75 Fed. Reg 44314, July 28, 2010. http://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17207.pdf

[30] Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2; Final Rule. 77 Fed. Reg 53968, September 4, 2012. http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf

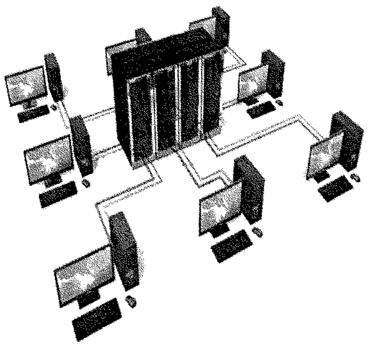
[31] Office of the National Coordinator for Health Information Technology; Health Information Technology; HIT Policy Committee: Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records, 77 Fed. Reg. 7044, November 26, 2012. http://www.gpo.gov/fdsys/pkg/FR-2012-11-26/pdf/2012-28584.pdf

[32] Ryan, Andrew M., et al. "Small Physician Practices In New York Needed Sustained Help To Realize Gains In Quality From Use Of Electronic Health Records." *Health Affairs* 32.1 (2013): 53-62.

A number of stakeholders have expressed concerns about the speed of implementation. According to a letter to CMS from the American Hospital Association, evidence indicates "the digital divide is widening, with large and urban hospitals reaching much higher rates of adoption than smaller and rural facilities."[33] Placing an advanced hospital system in the same pipeline as a rural solo practitioner has created problems in providing realistic timelines for all hospitals and providers. Stage 3 proposed rules should address how gaps in provider abilities to achieve interoperability will be addressed.

Lack of Initial Focus on Interoperability Has Created Obstacles to the Success of the Program

Achieving meaningful use occurs when a provider meets established federal requirements within the silo of that physician's office or hospital. While mastering the use of information within a hospital or physician's office is critical, more attention needs to be paid to ensuring a path to interoperability has been clearly established.



To date, the lack of unified, well-specified standards is a chief impediment to achieving interoperability. According to a survey and report published by the *Bipartisan Policy Center* and *Doctors Helping Doctors Transform Health Care*, more than 70 percent of clinicians said that a lack of interoperability was what kept them from electronically sharing information.[34] We recognize that the Health IT Standards Committee is actively pursuing the goal of unified standards, but we believe more emphasis should be placed on unified standards as a part of the EHR certification process. We are concerned that a lack of established interoperability standards from the beginning has resulted in vendors using vastly different terms, methods, and approaches to designing their health IT systems. This significant variation increases the likelihood that these systems will be unable to talk to and understand one another.

Given the requirements of Stage 2, the leap required from Stage 2 requirements to interoperability between unaffiliated health care systems that operate different software systems is unlikely to be accomplished by Stage 3. This dynamic raises serious concerns about the future of the program and requires the Office of the National Coordinator for Health IT and CMS to develop a workable plan to achieve interoperability.

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[33] American Hospital Association. "Letter to Acting Administrator Marilyn Tavenner on Stage 2 Notice of Proposed Rule Making," April 30, 2012. http://www.aha.org/advocacy-issues/letter/2012/120430-cl-cms0044p.pdf

[34] *Accelerating Electronic Information Sharing to Improve Quality and Reduce Costs in Health Care*. Bipartisan Policy Center Health Information Technology Initiative, October 2012. http://bipartisanpolicy.org/sites/default/files/BPC%20Accelerating%20Health%20Information%20Exchange_format.pdf

II. Misuse of EHRs May Actually Increase Health Care Costs

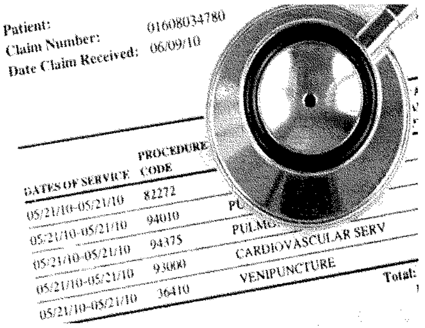
Recent evidence indicates that, contrary to initial projections, health IT as currently being used may unfortunately increase health care spending. For years, the arguments for adopting EHRs have focused on the promise of reduced costs to taxpayers and patients, as well as increased efficiency and quality in health care.[35] However, recent evidence indicates the push towards EHRs could instead increase utilization of unnecessary, more costly procedures, and, consequently, increase overall health care spending, which results in higher costs for patients and taxpayers. This means that the current health IT policy may be headed in exactly the wrong direction. We want to ensure the path of the program will produce a positive long-term return on investment of taxpayer dollars in EHRs.

Electronic Health Recodes May Facilitate "Code Creep"

Medical codes are used by providers and hospitals to communicate to a payer, such as Medicare or private health insurance, the nature of the care that was provided to the patient. The codes are assigned a dollar value, and higher acuity care for sicker patients is reimbursed at a higher rate. According to a number of articles recently reported in academic journals and the media, the use of EHRs may be driving up costs via a phenomenon referred to as "code creep."[36,37]

For example, one form of code creep was highlighted by the *New York Times*: "Some [electronic health record systems] can automatically generate detailed patient histories, or allow doctors to cut and paste the same examination findings for multiple patients – a practice called cloning – with the click of a button or the swipe of a finger on an iPad, making it appear that the physician conducted more thorough exams than, perhaps, they did."[38]

Despite conventional wisdom that the wide adoption of health IT would decrease unnecessary tests and imaging as physicians had better electronic access to records, other early evidence actually suggests the opposite. Health IT may have increased the likelihood that duplicative, unnecessary care, such as redundant testing or procedures, will be done. According to a study published in the *Journal of the American Medical Association*, data



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[35] *Health Information Technology: Can HIT Lower Costs and Improve Quality?* RAND Health, 2005. http://www.rand.org/content/dam/rand/pubs/research_briefs/2005/RAND_RB9136.pdf/

[36] Schulte, Fred, et al. "How doctors and hospitals have collected billions in questionable Medicare fees," *Washington Post* September 15, 2012. http://articles.washingtonpost.com/2012-09-15/national/35496252_1_data-codes-medicare

[37] Abelson, Reed, and Julie Creswell. "In Second Look, Few Savings From Digital Health Records." *New York Times* January 11, 2013. http://www.nytimes.com/2013/01/11/business/electronic-records-systems-have-not-reduced-health-costs-report-says.html?_r=0

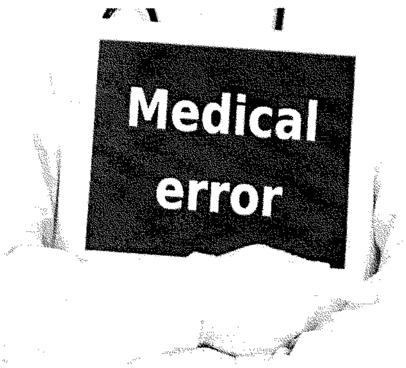
[38] Abelson, Reed, and Julie Creswell. "In Second Look, Few Savings From Digital Health Records." *New York Times* January 11, 2013. http://www.nytimes.com/2013/01/11/business/electronic-records-systems-have-not-reduced-health-costs-report-says.html?_r=2&

indicates an increase in use of clinical services when providers use electronic heath records.[39] In fact, some have attributed a portion of Medicare's increased billings over the last five years to the significant increase in EHR systems.[40]

Code creep can occur in nearly any health care setting that is reimbursed according to medical codes, and it may be unintentional. Some medical providers emphasize that the use of EHRs simply makes it easier to do the necessary documentation that satisfies the requirements for higher reimbursement codes.

While there is currently a lack of conclusive data that can authoritatively answer all relevant questions about the code creep phenomenon, it is clear CMS is not doing enough to address the issue. In the fall of 2012, when congressional staff questioned a CMS official about the possibility of code creep, the high-ranking CMS official effectively said CMS could not confirm that code creep is occurring for at least two years because of the lag in collecting and analyzing data and that consequently no agency actions were needed at the time to prevent unnecessary billing. When staff pressed the official on the wisdom of waiting two years—half of a presidential term—to determine if there is indeed code creep, the official merely demurred about the need for better data and the possibility of future adjustments in Medicare payments. While we appreciate caution, with the Medicare program facing insolvency it is unacceptable for CMS to wait for two years on this potential threat to Medicare. Sooner rather than later, CMS needs to evaluate the Medicare claims data for code creep.

"Cloned" or Copied Records Can Increase Medical Errors



Unfortunately, health IT adoption may have a negative impact on patients that is actually far graver than unintended financial impacts. There is a growing body of evidence that indicates some providers may simply copy and paste information in medical records, which represents a significant increase in the risk of medical errors by potentially including inaccurate, old, or out-of-date patient information in a patient record that can jeopardize patient safety and increase costs.[41] Similarly, others have raised the issue that some health IT applications actually perpetuate cloning records – coping key data from one EHR to another. While it is not inherently wrong for a provider to be able to incorporate standard protocols or care practices into an EHR, any kind of automated cut-and-paste process increases the likelihood of errors or omissions – errors which could even be life-threatening.

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[39] Palen, Ted E., et al. "Association of Online Patient Access to Clinicians and Medical Records With Use of Clinical Services." *Journal of the American Medical Association* 308.19 (2012). http://jama.jamanetwork.com/article.aspx?articleid=1392562

[40] Abelson, Reed, et al. "Medicare Bills Rise as Records Turn Electronic." *New York Times* September 21, 2012. http://www.nytimes.com/2012/09/22/business/medicare-billing-rises-at-hospitals-with-electronic-records.html

[41] Stokes, Trevor. "Copying Common in Electronic Medical Records." Reuters January 7, 2013. http://www.reuters.com/article/2013/01/04/us-electronic-medical-records-idUSBRE9030IJ20130104

The ability to quickly and easily generate documentation data deserves careful scrutiny as both a benefit and a risk of increased use of health IT. Without proper oversight it is especially concerning, particularly in light of the way the Medicare system currently uses claims data instead of patient outcome-based information to reimburse providers and monitor global changes in clinical patterns and practices. More needs to be done to ensure that the software programs that are sold by government-endorsed vendors and paid for by taxpayer dollars are held to the highest standards and promote the ultimate end goal of safely and effectively sharing health information.

While some analysis suggesting increased health care costs due to EHRs pre-dates the implementation of Stage 1 of the program, we believe this only further underscores the need for more rigorous data analysis of Stage 1 before moving forward into Stages 2 and 3.

III. Insufficient Oversight Has Put Taxpayer Money at Risk

Inspector General Recommends Additional Oversight of Self-Attestation

One of the key program vulnerabilities of the current HITECH program is that providers simply self-report to CMS that they have met meaningful use criteria in order to receive federal funds. This is a startling lack of program integrity. In few other government programs can an applicant simply claim eligibility without offering some documentation. This would be like an individual claiming to have won the lottery but not being required to produce the winning lottery ticket in order to collect the payout.

A recent report by the Department of Health and Human Services Office of the Inspector General (OIG) confirms this is a key program vulnerability, and the report heavily criticizes CMS's inability to effectively monitor eligible providers as they self-attest to meet the meaningful use requirements.[42] The OIG reviewed documents submitted to CMS from providers and hospitals and analyzed the data to ensure it met program requirements. In its report, the OIG warned that, due to several program factors, it is very possible CMS may have paid providers who are not actually achieving meaningful use requirements.[43] In fact, the report's authors are aware of a handful of cases anecdotally where providers self-attested for meaningful use payments but were not eligible, based on the program's criteria. These cases have been referred for further investigation.

At a time when the EHR incentive program is providing billions of taxpayer dollars in payments to providers and hospitals, it is unconscionable that CMS has not yet taken sufficient steps to ensure only eligible providers receive payments. It is essential that proper oversight is in place not only to ensure meaningful use of EHRs through the three stages, but also to prevent those providers or hospitals that are not meeting the required standards from receiving incentive payments from CMS.

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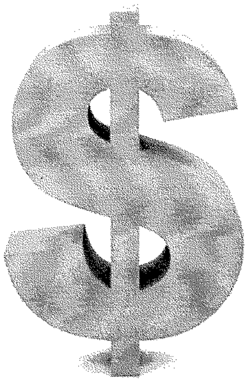
[42] Department of Health and Human Services Office of Inspector General. *Early Assessment Finds That CMS Faces Obstacles in Overseeing the Medicare EHR Incentive Program.* November 28, 2012. https://oig.hhs.gov/oei/reports/oei-05-11-00250.pdf

[43] Department of Health and Human Services Office of Inspector General. *Early Assessment Finds That CMS Faces Obstacles in Overseeing the Medicare EHR Incentive Program.* November 28, 2012. https://oig.hhs.gov/oei/reports/oei-05-11-00250.pdf

Taxpayer "Dollars Spent" Is an Insufficient Metric of Success

One of the most alarming findings in the OIG report is CMS' response that, despite the OIG's warning, it does not agree that more pre-payment review of eligibility is necessary since it could delay incentive payments.[44] Oversight into fraud and abuse vulnerabilities in EHRs continues to be a priority for the OIG, as indicated in its Fiscal Year 2013 work plan.[45]

CMS and the Office of the National Coordinator for Health IT said they disagreed with the OIG recommendation due to concerns about delays in incentive payments to providers and hospitals, and a closer review of the data confirms that CMS may be overly focused on getting payments out the door. In fact, it appears the metric used to measure the success of the EHR program is simply a "cash out the door" measure: federal taxpayer dollars paid to providers.



But as OIG noted, the entire purpose of reviewing applications before payments are made is to prevent the waste of taxpayer dollars on payments to ineligible providers. Thankfully, even though other Health and Human Services agencies are ignoring the issue, oversight into fraud and abuse vulnerabilities in EHRs will continue to be a priority for the OIG this fiscal year.

There are other indications a "cash out the door" metric may be an overly important metric for senior officials at CMS. In the opening session of the 2012 Office of the National Coordinator for Health IT Annual Meeting, Farzad Moshashari, National Coordinator for Health IT, highlighted how much money has been spent and suggested it was the measure of success of the EHR program. He recognized the CMS staff who have helped facilitate the "$9 billion" that has been provided to states that "had the highest proportion of eligible [providers] paid."[46]

Additionally, during the meetings of the Health IT Policy Committee, the program metrics discussed are the number of providers participating in the meaningful use program and how much has been paid out in incentive payments.[47] Those metrics fail to capture the true goal -- provider progress toward interoperability.

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[44] Department of Health and Human Services Office of Inspector General. *Early Assessment Finds That CMS Faces Obstacles in Overseeing the Medicare EHR Incentive Program.* November 28, 2012. https://oig.hhs.gov/oei/reports/oei-05-11-00250.pdf

[45] U.S. Department of Health and Human Services Office of Inspector General. *Work Plan for Fiscal Year 2013.* https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf

[46] 2012 Office of National Coordinator of Health IT Annual Meeting, "The Year of Meaningful Use: Leaders of the ONC State MU Acceleration Challenge." December 12, 2012. http://www.healthit.gov/oncmeeting/webcast/

[47] November and December 2012 Health IT Policy Committee, Update from CMS on Medicare and Medicaid EHR Incentive Program PowerPoint, November 7 and December 5, 2012.
http://www.healthit.gov/sites/default/files/hitpc_11_07_12mediincentive_0.pdf;
http://www.healthit.gov/sites/default/files/12_5_12_hitpc_medicare_medicaid_incentives.pdf

Too often in Washington, D.C., politicians and bureaucrats pretend that spending more is doing more. But topline spending is not the most effective measure of the program's success. Giving more providers more money incentivizes the purchase of government-approved health IT systems, but it does not guarantee true interoperability. Reimbursing providers to create technological silos where data is stovepiped is contrary to the goal of creating a system where information about patients can be shared seamlessly between unaffiliated providers.

Insufficient Oversight of Government-Funded Contractors Poses Obstacles to Interoperability

There have been concerning anecdotal reports about a few EHR vendors who use EHR contracts to effectively block or require increased resources for the exchange of data from competitors. The practice essentially only allows the sharing of data between EHRs that originated from the same vendor, effectively locking out data-sharing from other vendors. This dynamic creates patient-safety concerns and can be a barrier to interoperability when data is restricted to one set of providers.

Unless CMS takes strong steps to detect, monitor, and prevent such practices for certified vendors, taxpayers may be subsidizing the purchase of systems that undermine the program's goals by purposely blocking information-sharing with other software from other vendors.

Additionally, physician stakeholders have raised concerns that some of the 2,000 currently certified EHR vendors may not re-certify and will thus no longer offer EHR services. In that event, providers may face difficulties transferring patient data to a new EHR system.[48] Mitigating steps should be taken by CMS and the Office of the National Coordinator for Health IT to ensure interoperability and data sharing.

We are interested in hearing more about this problem from both stakeholders and the administration and how to address it to achieve interoperability.

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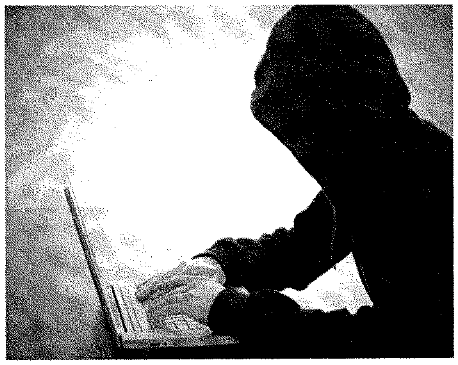
[48] Letter from American Medical Association to Office of the National Coordinator for Health Information Technology, January 14, 2013. http://www.ama-assn.org/resources/doc/washington/stage-3-meaningful-use-electronic-health-records-comment-letter-14jan2013.pdf

IV. Long-Term Questions on Data Security and Patient Safety Remain

In 2011, ONC asked the Institute of Medicine (IOM) to evaluate patient safety and privacy concerns regarding electronic health records and identify steps that can be taken to address these concerns.[49] As stated in the IOM's report, academic and research literature about health IT and patient safety is inconclusive thus far.[50] This is likely due to a lack of comprehensive and comparable data for EHRs.

Being proactive in anticipating and planning for patient safety concerns is a critical part of the long-term success of EHRs. Providers unsure about protecting the security of patient data will be more likely to opt out of EHR programs. Additionally, patients will be less likely to engage with their EHR if they feel their information is not secure or care is negatively affected. If unaddressed, these issues could seriously undermine the program.



We recognize that CMS and the Office of the National Coordinator of Health IT face a difficult challenge in ensuring federally incentivized EHRs are sufficiently secure and patient information is protected. However, federal agencies and health care providers are not immune to data security breaches. In 2011, for example, information about 20,000 emergency room patients from a California hospital was posted on a commercial website for nearly a year.[51] Additionally, an OIG report published recently revealed neither entity was doing enough to implement necessary security measures to protect sensitive patient information within their own offices.[52] If data security and patient privacy have proved to be a challenge within the Office of the National Coordinator for Health IT and CMS within the last two years, it is reasonable to assume that providers and stakeholders may face similar challenges.[53]

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[49] Institute of Medicine. *Health IT and Patient Safety: Building Safer Systems for Better Care*. November 2011. http://www.iom.edu/~/media/Files/Report%20Files/2011/Health-IT/HealthITandPatientSafetyreportbrieffinal_new.pdf

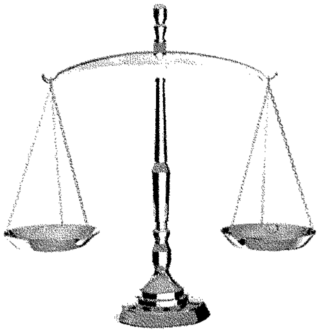
[50] Institute of Medicine. *Health IT and Patient Safety: Building Safer Systems for Better Care*. November 2011. http://www.iom.edu/~/media/Files/Report%20Files/2011/Health-IT/HealthITandPatientSafetyreportbrieffinal_new.pdf

[51] Sack, Kevin. "Patient Data Posted Online in Major Breach of Privacy." *New York Times* September 8, 2011. http://www.nytimes.com/2011/09/09/us/09breach.html?pagewanted=all&_r=0

[52] Department of Health and Human Services Office of Inspector General. *Early Assessment Finds That CMS Faces Obstacles in Overseeing the Medicare EHR Incentive Program.* November 28, 2012. https://oig.hhs.gov/oei/reports/oei-05-11-00250.pdf

[53] Lewis, Nichole. "Federal Agencies Fail Health IT Security Audits." *Information Week*. May 18, 2012. http://www.informationweek.com/healthcare/security-privacy/federal-agencies-fail-health-it-security/229502471

Problems with data entry, computer programming errors, and other unforeseen complications can affect the security of patient data and have the potential to jeopardize patient safety. Improper access to EHRs by unauthorized agents also poses a threat to the security of patient information. The OIG shares our concerns with ensuring adequate information technology control standards to protect patient information and plans to continue to monitor this risk.[54]



Patient Safety Concerns Must Be Balanced With Burdens on Providers

No system is completely invulnerable to criminals or reckless actors who do not follow protocols. As systems become more secure, they may be less useful to providers and patients. Therefore, concerns about the security of patient information need to be balanced against the burdens placed on entities that are responsible for the safekeeping and disclosure of the data. It is unclear if HHS has properly considered the safety and security issues, much less the burden, to date.

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[54] U.S. Department of Health and Human Services Office of Inspector General. *Work Plan for Fiscal Year 2013.* https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf

V. Questions Remain About Long-Term Sustainability of the EHR Program

In addition to our concerns about interoperability, costs, oversight, and security, we have an even more basic concern that the $35 billion effort will be wasted if providers are not able to comply with requirements or maintain the health IT system over the long-term. HITECH was included in a controversial, rushed legislative environment and enacted in the midst of an already complicated and increasingly burdensome regulatory landscape. Multiple overlapping reporting and regulatory burdens will make it difficult for providers to stay abreast of developments and direct the majority of their time to patient care.

The pressure on providers will only further increase when incentive payments turn into penalties. At that point, it will be even more challenging for many providers to maintain health IT systems, which will need to be constantly monitored, managed, and upgraded to keep up with changing technologies.

These long-term risks are even more pronounced for solo practitioners and other small- to medium-size offices that do not have the benefit of achieving economies of scale and spreading their acquisition and maintenance costs over a larger pool of patients. For example, one study of ongoing EHR costs for small and solo practices estimated that the ongoing costs to maintain an EHR system averaged over $8,000 per provider per year.[55] Providers are already facing large payment changes and administrative costs due to changes in federal policy and regulations.

Incentives for Compliance to Be Replaced by Penalties for Noncompliance

As the EHR incentive program continues to progress, long-term uncertainty for physicians is still a problem that needs to be addressed as physicians fear the looming penalties. In 2015, physicians and hospitals will begin incurring penalties in the form of decreased Medicare reimbursement for not meeting meaningful use requirements. While it is true EHR adoption has been increasing nationwide, research suggests that most physicians who have already applied for incentive payments or intend to apply for them are not gaining meaningful use under CMS's regulatory standards.[56] This means that initial estimates overestimated providers in compliance, leaving many more providers out of compliance than originally thought.

To avoid a penalty, those who participated in the EHR incentive program in 2011 and 2012 must demonstrate meaningful use for a full year in 2013, the final year of Stage 1 of meaningful use, to avoid

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[55] Menacehmi, Nir, and Taleah H Collum. "Benefits and drawbacks of electronic health record systems." *Risk Management and Health Care Policy* (May 2011): 47-55. http://www.dovepress.com/benefits-and-drawbacks-of-electronic-health-record-systems-peer-reviewed-article-RMHP

[56] Hsiao, Chun-Ju, and Esther Hing. "Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United States, 2001-2012." Centers for Disease Control and Prevention. December 6, 2012. http://www.cdc.gov/nchs/data/databriefs/db111.pdf

the penalty beginning January 2015.[57] Furthermore, these providers must then continue to show meaningful use of EHRs every subsequent year in order to avoid future penalties.

According to the Government Accountability Office, participation for 2011, the most recent year data is available from an entity outside of the U.S. Department of Health and Human Services, shows that participation in the program is low. As noted in the table below, less than 40 percent of hospitals are participating in the Medicaid program and less than 20 percent participate in the Medicare program. Even with an increase in participation before 2015, one could project a scenario where more than a third of all hospitals are penalized.

	Medicaid	Medicare
Number (percentage of eligible)	1,964 (39)	761 (16)
Median payment	$613,512	$1.7 million
Total payments	$1.7 billion	$1.3 billion

Source: GAO[58]

Reports continue to be published regarding the difficulties that established eligible providers and those in smaller practices are having in achieving meaningful use of EHRs. Accordingly, we are concerned about CMS's rigid timeline and insufficient flexibility for providers who face these specific circumstances.[59,60] In its final rule for Stage 2 of meaningful use, CMS acknowledged various reports regarding these difficulties, but did not seek to provide relief from these burdens.[61]

Long-Term Sustainability of EHR Systems Is Questionable Due to Other Financial Pressures on Providers

At a time when the CMS Actuary has projected that future reductions in Medicare reimbursements may produce negative Medicare margins for providers, we are concerned that eligible providers will also be unable to sustain their EHR systems.[62] Continued maintenance and upgrades of EHR hardware and software systems will require massive investments in information technology infrastructure. However, it is unclear if providers will be able to dedicate the necessary resources for these types of investments in the near future. The unstable financial climate for hospitals and other providers undermines the future sustainability of EHR systems. This issue is intricately tied into concerns about the careful balance that must be struck between data security for patient privacy and the burdens imposed on providers.

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[57] Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule. 75 Fed. Reg 44314, July 28, 2010. http://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17207.pdf

[58] Number and Characteristics of Providers awarded Medicaid Incentive Payments for 2011. Government Accountability Office, December 13, 2012. http://www.gao.gov/products/GAO-13-146R

[59] Hsiao, Chun-Ju, et al. "Most Physicians Were Eligible For Federal Incentives In 2011, But Few Had EHR Systems That Met Meaningful Use Criteria." *Health Affairs* 31:5 (2012): 1-8.

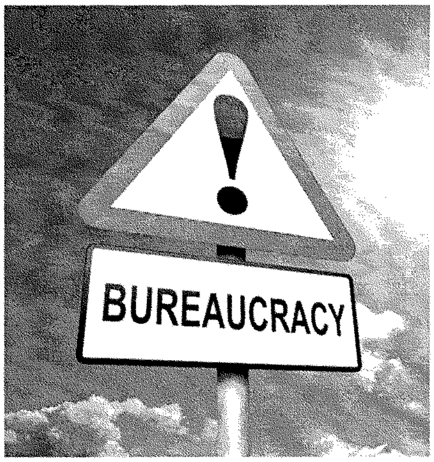
[60] Decker, Sandra L., et al. "Physicians In Nonprimary Care And Small Practices And Those Age 55 And Older Lag In Adopting Electronic Health Records Systems." *Health Affairs* 31:5 (2012): 1108-1114.

[61] Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2; Final Rule. 77 Fed. Reg 53968, September 4, 2012. http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf

[62] CMS Actuary's Estimated Financial Effects of the Patient Protection and Affordable Care Act, As Amended. April 22, 2013. http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/downloads/PPACA_2010-04-22.pdf

Multiple Health IT Programs Create a Challenging Regulatory Landscape That Affects Providers' Ability to Satisfy Federal Requirements

As previously noted, health IT policy is governed by a complicated patchwork of overlapping federal legislation and standards. Federal laws and standards are implemented through CMS, the Office of the National Coordinator for Health IT, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, and the National Institute of Standards and Technology, among others. Additional entities working on standards include the Health Information Security and Privacy Collaboration, which is developing a national privacy and security framework, the Health Information Technology Standards Panel, a public-private effort to develop standards for the certification of health IT products, and the National eHealth Collaborative, a public-private advisory body to make recommendations on health IT adoption and usability. The multiplicity of actors and entities has created a confusing, complicated system of requirements that providers must navigate in order to avoid mandated penalties for noncompliance. These compliance burdens are largely not in sync and create a tangle of requirements that may be well-intentioned, but will likely be opaque and confusing to stakeholders. Moreover, these panels need sufficient time to learn from each stage, develop appropriate recommendations, and give vendors and providers time to update and respond to the new demands. This speaks to the concern that the pace of implementation prior to CMS's announcement of a delay in Stage 3 rulemaking did not allow for this type of thoughtful approach.



Serious Program Vulnerabilities Demand Consideration; CMS Decision to Delay Appropriate

Based on a range of objective data, it is clear that the current payment structure of the EHR incentive program does not provide enough oversight or safeguards to ensure the proper stewardship of taxpayer dollars. Moving rapidly through the three stages without providing clear and proper oversight of the EHR incentive program is a short-sighted approach. It prevents CMS and the Office of the National Coordinator for Health IT from studying findings reported by eligible providers and hospitals to ensure the long-term success of the HITECH Act.

We seek comments on whether it would be in the best interest of CMS, the Office of the National Coordinator of Health IT, vendors, providers, taxpayers, and other stakeholders to hit "pause" while reexamining the current procedures put in place to safeguard and ensure meaningful use of EHRs prior to forging ahead with Stages 2 and 3. We are not alone in our concern on this issue. For example, the American Medical Association and other health care stakeholders have asked CMS and the Office of the

National Coordinator of Health IT to hire an outside entity to evaluate the incentive program's performance before quickly rushing into future stages.[63,64]

We are pleased CMS has effectively announced such a pause by delaying promulgating Stage 3 regulations and seeking to work with stakeholders. We seek comments on what steps CMS needs to take before implementing Stage 3.

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[63] Conn, Joseph. "AMA Calls for Outside Evaluation of Electronic Health Records Incentives." *Modern Healthcare* January 14, 2013. http://www.modernhealthcare.com/article/20130114/NEWS/301149961

[64] Conn, Joseph. "HIMMS, ACP also weigh in on Stage 3 MU." *Modern Healthcare* January 16, 2013. http://www.modernhealthcare.com/article/20130116/NEWS/301169956

Conclusion

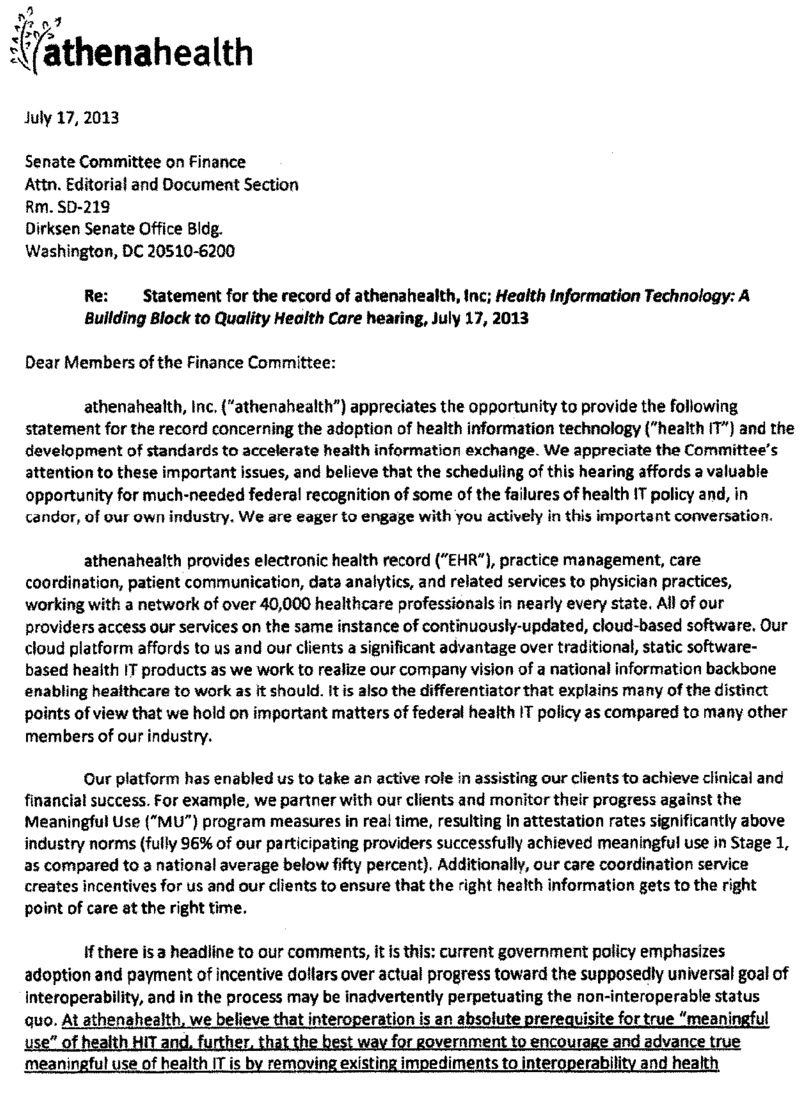
Transformations in health IT will significantly change how health care is provided in this country. Americans want to search for medical information online, check drug interactions or symptoms with their smart phones, and e-mail their doctors. Physicians can now access digital records of a patient even if they are in another city, state, or country. Clinical notes are recorded with increasing speed and ease, and other transformations offer the promise of increased efficiency, reduced costs, and improved quality of care.

However, the details of federal law and regulation may be inadvertently incentivizing unworkable, incoherent policy goals that ultimately make it difficult to achieve interoperability. Congress, the administration, and stakeholders must work together to "reboot" the federal electronic health record incentive program in order to accomplish the goal of creating a system that allows seamless sharing of electronic health records in a manner that appropriately guards taxpayer dollars. Fulfilling the goal of increasing efficiency in the health care system; reducing costs for payers, providers, and patients; and improving quality of care for patients is a challenging task. In order to succeed, the following implementation deficiencies must be addressed:

- **Lack of Clear Path Toward Interoperability**
- **Increased Costs**
- **Lack of Oversight**
- **Patient Privacy at Risk**
- **Program Sustainability**

We present this white paper in an effort to initiate a dialogue with the administration and the stakeholder community. The purpose of this paper is to foster cooperation between all stakeholders – including providers, patients, EHR vendor companies, and the Department of Health and Human Services – to address the issues raised in this white paper, evaluate the return on investment to date, and ensure this program is implemented wisely.

COMMUNICATIONS



athenahealth

July 17, 2013

Senate Committee on Finance
Attn. Editorial and Document Section
Rm. SD-219
Dirksen Senate Office Bldg.
Washington, DC 20510-6200

Re: Statement for the record of athenahealth, Inc; *Health Information Technology: A Building Block to Quality Health Care* hearing, July 17, 2013

Dear Members of the Finance Committee:

athenahealth, Inc. ("athenahealth") appreciates the opportunity to provide the following statement for the record concerning the adoption of health information technology ("health IT") and the development of standards to accelerate health information exchange. We appreciate the Committee's attention to these important issues, and believe that the scheduling of this hearing affords a valuable opportunity for much-needed federal recognition of some of the failures of health IT policy and, in candor, of our own industry. We are eager to engage with you actively in this important conversation.

athenahealth provides electronic health record ("EHR"), practice management, care coordination, patient communication, data analytics, and related services to physician practices, working with a network of over 40,000 healthcare professionals in nearly every state. All of our providers access our services on the same instance of continuously-updated, cloud-based software. Our cloud platform affords to us and our clients a significant advantage over traditional, static software-based health IT products as we work to realize our company vision of a national information backbone enabling healthcare to work as it should. It is also the differentiator that explains many of the distinct points of view that we hold on important matters of federal health IT policy as compared to many other members of our industry.

Our platform has enabled us to take an active role in assisting our clients to achieve clinical and financial success. For example, we partner with our clients and monitor their progress against the Meaningful Use ("MU") program measures in real time, resulting in attestation rates significantly above industry norms (fully 96% of our participating providers successfully achieved meaningful use in Stage 1, as compared to a national average below fifty percent). Additionally, our care coordination service creates incentives for us and our clients to ensure that the right health information gets to the right point of care at the right time.

If there is a headline to our comments, it is this: current government policy emphasizes adoption and payment of incentive dollars over actual progress toward the supposedly universal goal of interoperability, and in the process may be inadvertently perpetuating the non-interoperable status quo. At athenahealth, we believe that interoperation is an absolute prerequisite for true "meaningful use" of health HIT and, further, that the best way for government to encourage and advance true meaningful use of health IT is by removing existing impediments to interoperability and health information exchange ("HIE") in current policy, regulation, and law. Government is no better able or equipped than the private sector to predict the evolution of technology and innovation, or to prescribe and/or mandate specific means and conditions to enable the eventual seamless exchange of information in healthcare. Instead, government rules and actions should be focused much more on desired outcomes—including actual interoperation between vendor platforms—and less on specific prescriptions as to how those outcomes are to be met.

In our view there are three actions that government stakeholders could take in short order to make significant progress towards the shared goal of truly "meaningful use" of health IT:

(1) Focus and realign MU incentives and tighten the definition of "meaningful use" to end de facto government subsidies for technologies that do not (and often cannot) help achieve those goals.

Taxpayer dollars that enable the purchase of obsolete technology that cannot interoperate or contribute to cross-platform HIE, and that must be replaced in few years, are wasted taxpayer dollars. Taxpayer dollars that subsidize the purchase of cutting edge technology that is deliberately designed to be unable to interoperate with other platforms are, likewise, wasted dollars (if interoperability is in fact the goal motivating the expenditure). Surely no policymakers intended the MU incentives program to subsidize technological dinosaurs with federal dollars, just as nobody intended MU dollars to fund proprietary information silos, locking doctors, patients, and information into closed systems and driving up costs. But both of these unintended consequences are happening, and both are impeding progress toward interoperability. CMS and ONC should focus the impact of subsidies by tightening the definition of "meaningful use" to require actual interoperation (an outcome, as opposed to merely theoretical "interoperability") between vendor systems, while avoiding specific prescriptions that could inadvertently hamper innovators as they work to achieve this goal.

We disagree with much of our industry on the advisability of repeated delays in implementation of the successive stages of the MU program. In our view, government should resist calls made by technological laggards and those using technology to consolidate market share to slow MU timelines and lower standards. To advance interoperability and achieve HIE exactly the opposite—aggressive timelines and high, outcomes-focused standards—are necessary. The experience of athenahealth's provider clients provides strong support for this position.

Last year, 96% of athenahealth clients that enrolled in the MU program successfully attested, compared to the national average of only about 40%. athenahealth's data, which closely tracks each attestation metric to ensure actual achievement, shows that practices of all sizes, whether solo doctors or large multi-specialty groups, are equally successful in attesting for MU (in fact, the small practices tend to outperform the larger ones). Approximately 30% of athenahealth clients who have attested to MU to date only began using athenahealth's EHR the same year in which they were successful. As these numbers demonstrate, the current MU measures are in fact relatively easy to meet, assuming the correct technological tools are leveraged. Virtually anyone who has visited a doctor or a hospital will confirm that health IT lags years behind the rest of the information economy, and in most contexts the best tools are not yet used. Slowing down is not the way to catch up.

Of course, any one-size-fits-all environment must ensure that the one size is the right size. Unfortunately, the current MU program is entirely focused on functionality-based measures, as opposed to measuring true outcomes, and the program will therefore continue to be in some ways a waste of taxpayer funds until fundamental changes are made.

Federal dollars spent on MU incentives is not an accurate measure of success of the MU program; it may, in fact, be exactly the opposite. athenahealth believes in the power of free markets. We do not advocate for government action intended to disadvantage our competitors in the health IT marketplace. If, however, the over-arching goal of federal health IT policy is to spur creation of a framework for true interoperation in healthcare, then at a minimum government should stop subsidizing technologies that either cannot support achievement of that goal or—worse—that deliberately undermine the likelihood of its achievement.

(2) Support modernization of the Anti-Kickback Act and the Stark Laws to encourage payment reform and to enable a true, functioning market for the exchange of health information.

Policymakers frequently acknowledge the fact that in order for a major sea change in any learned behavior to occur, there needs to be a financial incentive for that behavior to change. What are federal incentive payments to spur EHR adoption, after all, if not acknowledgement of that truth? But temporary, targeted incentives can only motivate so much change. Government cannot (and should not) subsidize desired behaviors in perpetuity.

To incentivize systemic, lasting health information exchange, government must enable a functioning market for health information by allowing the custodians/curators of data to charge a fair market fee to deliver to recipients exactly the information that is needed, in the form requested. Where a functioning market for information exists, standards for the interoperable exchange of that information follow—in finance, insurance, even auto parts—but not in healthcare.

Like the industry's prevalent technology, the current conception of market dynamics in healthcare remains far behind the times. Under laws intended to prevent self-dealing in referrals, specifically the Anti-Kickback Act and the Stark Laws, a fee paid for quality information could be deemed a "kickback." As a result, virtually nobody curates the vast stores of electronic patient data that we are steadily amassing (including in government-supported Health Information Exchanges (HIEs), and nobody leverages the power of that data to reduce costs, increase efficiency, and improve care—because nobody is allowed a financial incentive to do so. That needs to change.

Today, though referring providers have a supply of patient health information and providers receiving referrals have a demand for that information, lack of clarity under the Anti-Kickback and Stark laws discourage transaction-based payment models for care coordination between referring and receiving providers.

As a result of the legal prohibition on paying for the value inherent in curated information, referring providers have no incentive to send curated information regarding the patient to the receiving provider. This makes it more likely that the receiving provider will duplicate tests and services (or hand the patient a clipboard) that could have been eliminated if previous data and test results were shared through electronic information exchange.

If transaction-based payment models were expressly permitted by law the development of an open and sustainable market for HIE would follow, allowing providers to pay for the benefit of the information they receive. The success of such models has been demonstrated in other spaces, such as finance and the internet, where standards for information exchange developed quickly once an open market for exchange was established. Again, health IT lags the rest of the information economy; government should remove impediments to catching up.

A functioning, two-sided market for HIE would not only spark a revolution in such exchange, it would also fund itself with nary a taxpayer dollar required, much less wasted.

(3) Promote technologies, such as web-based platforms, that can help to quickly realize the goals of health reform.

There exists a common misconception that the imperatives of innovation and other policy goals, such as quality, efficiency, safety, and security, must be balanced, as if these objectives were mutually exclusive. To the contrary, athenahealth believes that innovation must be promoted to achieve higher levels of safety and security within health IT. For that reason, we encourage government to promote innovative technologies, such as web-based platforms, while simultaneously ending its subsidy of outdated technology that cannot deliver the levels of innovation needed to realize the goals of health reform, or that deliberately contravene those goals.

Outdated, static software based technologies simply cannot achieve the goals of the MU program or the broader aims of health reform. Innovative technologies, such as web-based platforms, have the power to truly transform our health care system in the same way that they have revolutionized information technology and fueled an explosion in the seamless, secure sharing and exchange of information across the rest of our economy.

When every user of an information network is on the same cloud platform, there are significant advantages with respect to interoperability, data security, and patient safety, and even fraud detection:

- Because uniform interoperability standards do not yet exist, cloud platforms create economies of scale for users. The same interface infrastructure can be used across entire client bases, whereas static software requires that separate interfaces be built between every installed instance of that software—a costly proposition that, again, is obsolete in most other segments of the economy.
- This economy of scale principle also applies to data security, because cloud vendors extend the benefit of world class data security experts and infrastructure to every user of their system, allowing even solo doctors to have the same data security as large health systems.

- Because changes can be made to web-based software and implemented across thousands of users instantly, cloud vendors can be much more responsive to patient safety issues than vendors of static software.
- The data collection and analysis that is an inherent characteristic of a cloud-based platform provides cloud vendors with real time insight into client billing patterns that simply cannot be achieved by static systems. We disagree with the notion that technologies designed and implemented to create efficiencies and reduce administrative workload can or should properly be blamed for deliberate misuse by human beings who are, in the end, responsible for deliberate acts of fraud whether committed using a pen and paper or a sophisticated billing application. However, we strongly believe that information technology can be used to detect and prevent irregular billing or outright fraud.

We are fully committed to achieving true, widespread interoperation between vendor platforms, which is why even as we work to achieve our corporate vision of a national health information backbone, we are a founding member of the CommonWell Health Alliance, an independent, not-for-profit trade association focused on creation and promotion of standards to support cross-platform interoperation.

In closing, we at athenahealth are extremely appreciative of the attention that the Finance Committee continues to pay to the important federal policy issues that currently impact and in some ways steer the health IT industry. We believe that there are serious and costly deficiencies in the current MU program, but also that the program is achieving worthwhile results and should be improved rather than ended. The prescriptions set forth above are the result of months of internal analysis of our own results, conversations with countless of our care provider clients, and dozens of interactions with policymakers (including staff in your offices). We look forward to continuing to engage with you on these important issues, and appreciate the opportunity to provide our comments.

Sincerely,

Dan Haley
Vice President, Government and Regulatory Affairs
athenahealth
311 Arsenal Street 2R
Watertown, MA 02472

HRBA
Health Record Banking Alliance

From: William A. Yasnoff, MD, PhD, President, Health Record Banking Alliance
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To: Senate Committee on Finance
Date: July 17, 2013
RE: Health Information Technology: A Building Block to Quality Health Care (Hearing on Wednesday, July 17, 2013) – Statement for the Record

The Health Record Banking Alliance (HRBA) is a non-profit 501(c)(6) membership organization with the goal of establishing accurate, secure, and comprehensive health records that can be accessed and authenticated by both patients and their health care providers under the control of the individual patient. We advocate for community repositories of electronic health records (health record banks) as an effective and sustainable health information infrastructure solution, support programs that provide assistance to communities building health record banks, and advocate for necessary legislation and regulation consistent with community health record banks (see http://www.healthbanking.org for additional information). HRBA members include national, state and community health information exchange organizations, health information providers, physicians, and vendors interested in health information technology, exchange, and services.

We are submitting this statement for inclusion in the record of the Committee hearing held on 7/17/13, "Health Information Technology: A Building Block to Quality Health Care." Our focus is on an effective and feasible approach to rapidly advancing health information technology. We appreciate the opportunity to provide our perspective and look forward to working collaboratively with the Committee to implement improvements in policies and programs to accelerate the development of an effective health information infrastructure for the nation.

Thank you for your consideration.

William A. Yasnoff, MD, PhD
President, Health Record Banking Alliance

Executive Summary

A. Purpose of health IT (HIT)

The purpose of HIT is to improve the quality and efficiency of healthcare through the availability of comprehensive electronic patient records when and where needed.

B. Health Information Infrastructure (HII) Challenges

The key challenges to achieving the goals of HIT are privacy, stakeholder cooperation, availability of all medical record data in digital, interoperable formats, and financial sustainability. We describe an approach that overcomes these challenges, meets the objectives, and is feasible to implement.

C. Health Record Bank (HRB) Approach Solves Problems

A Health Record Bank (HRB) is an organization that stores and protects copies of personal, private health information, including both medical records and additional data that optionally may be added by the patient. The patient controls who may access which parts of the information in his or her account. When patients seek care, they give permission for their health care provider to access some or all of their up-to-date health records. When care is complete, the new records from that encounter are securely deposited into the HRB and securely stored for future use under the patient's control.

The HRB approach solves the problems of privacy (through ongoing patient control), and stakeholder cooperation (since the patients request their own records, the HIPAA regulations require every stakeholder to provide them electronically if available in that form). It also can facilitate all digital interoperable information by paying providers for deposits (required to be in standardized form) from their EHRs and also supplying no-cost Internet-accessible EHRs to outpatient physicians who do not yet have them. Financial sustainability can be achieved through a combination of revenue sources including optional apps for patients, advertising to patients, and research use of the data with patients' permission (including identified records with specific patient consent).

D. Actions needed

1. Fund large-scale HRB demonstration projects

Congress should immediately allocate at least $50 million to competitively fund at least three large-scale HRB demonstration projects. Properly structured, such projects could be fully functional within six months after initiation.

2. Finalize regulations enabling patient access to lab data

CMS should finalize the draft regulations that allow patients to request and directly receive their lab results in electronic form. This will promote patients' access to and control of this critical information.

3. Help HIEs convert into HRBs

ONC should also provide assistance to existing HIEs that wish to convert to HRBs. This conversion requires: 1) engagement with consumers; 2) development of value-added services for consumers; and 3) organizational realignment to ensure consumer trust. A collaborative effort to address these issues among HIEs could rapidly lead to effective transitional strategies.

I. Current Problems with Health Information Infrastructure (HII)

A. Goal

The overarching purpose of health information infrastructure (HII) is to assure the availability of comprehensive electronic patient information when and where needed, allowing providers to have comprehensive and current compilations of a patient's health data upon which to base clinical decisions. This would also allow clinical decision support to be integrated effectively with information delivery so that both clinicians and patients could receive reminders of the most recent clinical guidelines and research results. This would avoid the need for clinicians to have superhuman memory capabilities to assure the effective practice of medicine, and enable patients more easily to adhere to complex treatment protocols and to be better informed. Patients could also review and add information to their compiled records and thereby become more active participants in their care. In addition, the availability of comprehensive compiled records for each patient would enable value-added services, such as immediate electronic notifications to patients' family members about emergency care, as well as patient-authorized queries in support of medical research, public health, and public policy decisions.

B. HII Requirements

An effective HII requires both EHR adoption and the capability to aggregate each patient's records into a coherent whole.

1. Electronic Health Record (EHR) adoption

It is self-evident that health information cannot be electronically exchanged unless the information is in digital form. The information also must ultimately be structured and codified to maximize its value. While creating digitized electronic images of paper records for transmission may be a potentially useful interim "publish and subscribe" strategy, it will not facilitate the processing necessary to automatically integrate records from multiple sources over time. Therefore, universal EHR adoption is necessary to enable a fully functional HII.

2. Aggregation into comprehensive individual records

EHRs alone, even if adopted by all healthcare providers, are a necessary but not sufficient condition for achieving HII. Each EHR simply converts an existing paper "silo" of information into structured electronic form. These provider-based systems manage each provider's information on the patient in question, but do not have all the information that exists among the multiple providers for each patient. To achieve the goal of availability of comprehensive patient information, there must also be an efficient and cost-effective mechanism to aggregate the scattered records of each patient from all their various providers and over time. Major gains in quality and efficiency of care will be attainable only through HII that ensures the availability of every patient's comprehensive record when and where needed.

C. Challenges of EHR Adoption

While medication information and laboratory results are already predominantly electronic, patient records, particularly for office-based physicians, are not. The major obstacle to physician adoption of EHRs is not merely cost, as is often cited, but the very unfavorable ongoing cost/benefit ratios. Most of the benefits of EHRs in physician offices accrue not to the physician, but to other stakeholders. It is unreasonable to expect physicians to shoulder 100% of the cost of systems while receiving only a tiny fraction of the benefits.

D. Challenges to Aggregation of Individual Records

With rare exceptions, most existing HII systems have chosen an institution-centric approach to data storage, leaving patient records wherever they are created and using distributed health information exchange (HIE) to retrieve them when needed (Figure 1 below). Although records are not stored centrally, it is necessary in this architecture to maintain at least a central index of where information can be found for a particular patient; without such an index, finding information about each patient would require queries to every possible source of medical information worldwide -- clearly an impractical approach. When a given patient's record is requested, the index is used to generate queries to the locations where information is known to be stored. The responses to those queries are then simultaneously and immediately aggregated to produce the patient's comprehensive record. After the patient encounter, the new data is entered into the clinician's EHR system and another pointer (to that system) is added to the index so it will be queried (in addition to all the other known prior locations) the next time that patient's record is requested.

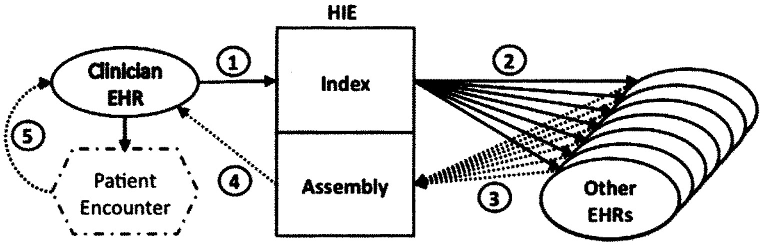

Figure 1. Institution-centric HII Architecture.

1. The clinician EHR requests prior patient records from the HIE; this clinician's EHR is added to the index for future queries for this patient (if not already present)
2. Queries are sent to EHRs at all known sites of prior care recorded in the HIE Index; patient consent is verified at each "other" EHR prior to release of information
3. EHRs at each known prior site of care return records for that patient to the HIE; the HIE must wait for all responses
4. The returned records are assembled and sent to the clinician EHR; any inconsistencies or incompatibilities among records must be resolved immediately
5. After the care episode, the new information is stored in the clinician EHR only

E. Current Path Will Not Be Successful

1. Measurement of progress

Labkoff and Yasnoff described four criteria for the quantitative evaluation of HII progress in communities: (1) completeness of information, (2) degree of usage, (3) types of usage, and (4) financial sustainability (Labkoff SE and Yasnoff WA. A framework for systematic evaluation of health information infrastructure progress in communities. *J Biomed Informatics* 2007;40(2):100-105). Using these criteria, four of the most advanced community HII projects in the U.S. achieved scores of 60-78% (on a 0-100 scale), indicating that substantial additional work was required before their respective HII systems could be viewed as complete. These measures or their equivalent should be used routinely by Congress and ONC to evaluate HII progress. Such evaluation would provide an objective ongoing assessment of the degree of completeness of HII systems in communities and, with aggregation, the nation.

2. Both key tasks not on trajectories towards success

While estimates vary, it is clear that the majority of office-based physicians still do not utilize EHR systems, despite Meaningful Use (MU) incentives. Furthermore, even the most optimistic estimates of EHR adoption predict that half of office-based physicians will still be using paper-based systems after the expiration of the incentive program.

The HIE approach to aggregating records has multiple serious flaws as described recently (Yasnoff W, Sweeney L, and Shortliffe EH. Putting Health IT on the Path to Success. *JAMA* 2013;309(10):989-91):

"1. *Complex and expensive.* It requires that all EHR systems be online 24/7 responding to queries, as well as implementation of new systems for real-time reconciliation of records from multiple sources. It is extremely difficult to accomplish without a unique patient identifier (which is both politically impractical and a privacy threat). Further, an expensive 24/7 network operations center must constantly monitor and ensure availability of all possible sources of information.
2. *Prone to error and insecurity.* A recent simulation study showed that, in comparison with a central repository, the institution-centric approach requires exponentially more transactions and is exponentially more likely to provide incomplete records because of EHR response failures (Lapsia V, Lamb K, and Yasnoff WA. Where should electronic records for patients be stored? *Int J Med Informatics* 2012;81(12):821-7). Decentralization of records also allows more security failure points.
3. *Increased liability.* Because patients have no opportunity to review or annotate data, the burden of data correctness falls on clinicians, institutions, and the HIE. Integration errors and an inability to propagate corrections to those who already received data further compound medical-legal risks.
4. *Not financially sustainable.* This is a widely acknowledged problem. Financial sustainability should not require clinicians and hospitals to underwrite costs (ultimately passed on to patients or insurers).
5. *Unable to protect privacy.* Leaving data at their source makes managing privacy preferences impossibly complex because patients would need to set and maintain permissions separately at each location providing care.
6. *Unable to ensure stakeholder cooperation,* because providing records is totally voluntary; requests for them are not from patients, leaving records incomplete and possibly misleading as a result.
7. *Unable to facilitate robust data searching,* e.g., for research and public health purposes. Because each record must be obtained from all sources and integrated each time it is needed, search becomes sequential, which is prohibitively inefficient. Even with high-speed systems, access to patient information is greatly facilitated by having that information in one place. For instance, although credit reporting systems are admittedly imperfect, they would be much less effective if they had to query all creditors when a report was needed, and it would be much more difficult for consumers to review or attempt corrections if records were not in a single location."

II. Health Record Bank (HRB) Approach Solves Problems

A. HRB Approach

A Health Record Bank (HRB) is an organization that stores and protects copies of personal, private health information, including both medical records and additional data that optionally may be added by the patient. The patient controls who may access which parts of the information in his or her account. When patients seek care, they give permission for their health care provider to access some or all of their up-to-date health records in the HRB repository. When care is complete, the new records from that encounter are securely deposited into the HRB for future use (Figure 2 below).

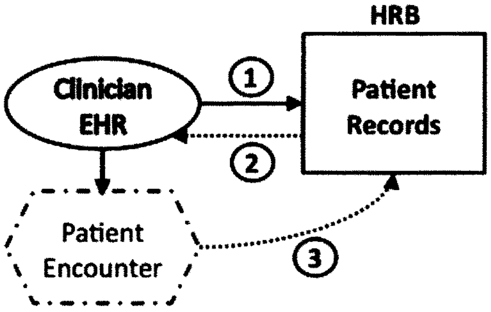

Figure 2. Patient-centric HII Architecture.
1. The clinician EHR requests prior patient records from the HRB
2. The prior patient records are immediately sent to the clinician EHR
3. After the care episode, the new information is stored in the clinician EHR and sent to the HRB; any inconsistencies or incompatibilities with prior records in the HRB need to be resolved or flagged before that patient's records are requested again (but not necessarily immediately)

(Note: This process is repeated whenever care is provided, resulting in the accumulation in the HRB of each patient's records from all sources)

The HRB approach solves the problems of privacy (through ongoing patient control) and stakeholder cooperation (because the patients request their own records, the HIPAA regulations require every stakeholder to furnish them electronically if available in that form). It also can facilitate the transition to all digital interoperable information by paying providers for deposits (required to be in standardized form) from their EHRs and also supplying no-cost Internet-accessible EHRs to outpatient physicians who do not yet have them. Financial sustainability can be achieved through a combination of revenue sources, including optional apps for patients, advertising to patients, and research use of the data with permission.

B. Privacy

Privacy is of overriding importance for HII. Clearly, health records are very sensitive - perhaps the most sensitive personal information that exists. In addition to our natural desire to keep our medical information private, improper disclosure can lead to employment discrimination. Furthermore, failure to assure the privacy of health records will naturally result in patients' unwillingness to disclose important personal details to their providers - or even to avoid seeking care at all. In addition to the contents of the records, the very existence of certain records (e.g., a visit to psychiatric hospital) is sensitive even if no other details are available. Therefore, extraordinary care must be taken to ensure so that health information is protected from unauthorized disclosure and use.

Assigning decision-making for disclosure of personal health records to anyone other than the patient or the patient's representative inherently erodes trust. In essence, the patient is being told, "we are going to decide for you where your medical records should go because we know what's in your interest better than you do." A patient may wonder why, if a given disclosure is in their interest, their consent would not be sought. Furthermore, failing to seek such consent inevitably leads to suspicion that the disclosure is in fact not in the patient's interest, but rather in the interest of the organization deciding that the records should be released. To address the trust issue, all decisions about release of patient records need to be entrusted to the patient (with rare exceptions, such as mental incompetence). Establishing trust is absolutely necessary for an effective and accepted HII. The HRB approach does this by assigning all record access decisions to the patient (or the patient's authorized representative). This need not be inconvenient or burdensome; patients' disclosure preferences may be indicated in advance and stored to avoid the necessity for specific patient approval of each access to their health records.

C. Stakeholder Cooperation

To ensure the availability of comprehensive patient records, all healthcare stakeholders that generate such records must consistently make them available. Assuring long-term cooperation of competing healthcare stakeholders in providing records is problematic. Indeed, only a handful of communities have succeeded in developing and maintaining an organization that includes the active participation of the majority of healthcare providers. Even in these communities, the system could be disrupted at any time by the arbitrary withdrawal of one or more participants. The unfortunate reality is that healthcare stakeholders are often quite reluctant to share patient records, fearing loss of competitive advantage.

Patient control, a key part of the HRB approach, addresses this issue by mandating healthcare stakeholder participation through the HIPAA Privacy Rule. It requires all providers to respond to patient requests for their own records (U.S. 45 CFR 164.524(a)). Furthermore, if patients request their records in electronic form, and they are available in electronic form, this regulation also requires that they be delivered in electronic form. Although not well known, this latter provision is included in the original HIPAA Privacy Rule (U.S. 45 CFR 164.524(c)(2)), and has been reinforced by HITECH. It is also being promoted by ONC's "blue button" initiative.

D. Ensuring Information in Standardized Electronic Form

While the MU incentives are helpful in promoting EHR adoption, they do not cover the majority of costs for physician EHR systems. This is particularly evident when including the substantial conversion costs related to reduced revenue from lost productivity during the transition from paper to electronic records. In addition, the MU incentives are one time only, while the costs of EHRs continue indefinitely for physicians. To encourage EHR adoption by the vast majority of practices, we believe it will be necessary to provide permanent reimbursement and/or other offsetting benefits to allow physicians to recoup their costs. At the very least, any proposed approach to building a sustainable HII will be more effective if it includes mechanisms that result in a favorable cost/benefit ratio for physician EHRs. These reimbursements also serve to ensure standardized data export to the HRB.

Hospitals also have not uniformly adopted EHRs. However, hospitals have a more substantial economic incentive to do so, since reducing their costs improves financial performance under the diagnosis-related groups (DRG) reimbursement system that pays a fixed amount for a specific condition. While it remains to be seen if the MU incentives for hospitals are sufficient to induce widespread EHR adoption, it appears that their effectiveness will be substantially greater than for office-based physicians. In addition, once patients are admitted to the hospital, coordinating their records is largely an internal problem that cannot be greatly aided by external HII. Furthermore, the large majority of healthcare encounters do not involve hospitals, and therefore HII should focus primarily on the outpatient environment.

E. Financial Sustainability

The most common approach suggested for long-term HII sustainability is leveraging anticipated healthcare cost savings. This is based on the substantial, growing body of evidence that the availability of more comprehensive electronic patient records to providers results in higher quality and lower cost care. Some of the best examples include large, mostly closed healthcare systems such as Kaiser, Group Health and the Veterans Administration, where the conversion of records into electronic form over time has been consistently associated with both cost savings and better care. While the case for HII reducing healthcare costs is compelling, the distribution and timing of those savings is difficult to predict. In addition, cost savings to the healthcare system may mean revenue losses to one or more stakeholders – clearly an undesirable result from their perspective. Finally, the allocation of savings for a given population of patients is unknown, with the result that organizations are reluctant to make specific financial commitments that could be larger than their own expected benefits. The unfortunate reality is that this path to financial sustainability has not been effective, as demonstrated by multiple HIE failures.

HRBs utilize a more promising path to financial sustainability of HII: utilizing the new value created by the availability of compiled, comprehensive electronic information held in a repository with access controlled by each patient. While it is widely recognized that this information will be extremely valuable for a wide variety of purposes, this option has remained largely unexplored.

Perhaps the largest potential HII revenue source is from innovative applications that rely on using the underlying information to deliver compelling value to consumers and other healthcare stakeholders. For example, HII allows the delivery of timely and accurate reminders and alerts to patients for recommended preventive services, needed medication refills, and other medically related events of immediate interest to patients and their families. It also would allow deployment of applications that assist consumers automatically with management of their chronic diseases. Utilizing new value to finance HII avoids the prediction and allocation problems inherent in attempts to leverage expected healthcare cost savings, with the added incentive that any such savings would fully accrue to whoever achieves them.

III. Actions Needed

A. Fund large-scale HRB demonstration projects

Congress should immediately allocate at least $50 million to competitively fund at least three large-scale HRB demonstration projects. Properly structured, such projects could be fully functional within six months after initiation. An RFP soliciting HRB proposals should be issued at the earliest possible time. Proposers should be required to show how they would successfully address the privacy, stakeholder cooperation, fully standardized and electronic information, and financial sustainability issues within a specific targeted population.

B. Assist HIEs in converting to HRBs

ONC should provide assistance to HIEs to convert their operations into HRBs. This would involve at least six steps:

1. Use data from the HIE for the HRB

Whatever data is already being collected or is available from providers by the HIE should be used for the HRB. Existing HIE interfaces should be kept in place. Those interfaces that use a "pull" approach of requesting data only when needed should be converted to a "push" methodology that transmits new data as it created. The Direct protocol already under development by ONC can be used here.

2. Add central repository (if not already present)

If the HIE does not already have a central repository to store data, this capability should be added. This allows patient information to be immediately available for provider use with a single query authorized by the patient. It also enables efficient searching of the data to facilitate value-added applications and research (see step 5 below).

3. Provide patients with access to and control of their own data

Patients should be engaged to enroll in the HRB to access their data and record their preferences for access to it, which can be stored for ongoing use (and modified by the patient at any time). A default set of preferences might for example allow use by all of a patient's current providers as well as bona fide emergency providers who certify the patient is present in an emergency situation. Patient enrollment should also include a standing, blanket request for medical records to be deposited in the HRB, thereby invoking the HIPAA requirement for all providers to supply such data.

4. Include patients in HRB governance

To facilitate the trust needed to operate a central repository holding comprehensive, aggregated digital patient records, patient representatives should be included in the governance structure. It may be appropriate for the HRB to be a separate organizational entity from the original HIE. The ideal governance arrangement has not yet been determined, and may vary depending on local circumstances. However, it is essential that patients' interests be directly represented.

5. Add new capabilities to generate revenue

The HRB should include the ability to deploy applications ("apps") to patients, advertising to patients, and generate anonymized aggregate reports of patient data for research and public health purposes. All of these activities should require the consent of the patient.

Examples of apps include 1) "Peace of Mind" Alerts -- automatic notifications to a patient's loved ones when a patient's information is accessed by emergency medical personnel; 2) Health and Wellness Alerts ("Prevention Advisor") -- reminders by email or text message of recommended preventive tests and procedures; and 3) Prescription Refill Alerts -- reminders by email or text message when prescriptions are due for renewal coupled with automatic refill requests to pharmacies. In addition, third-party vendors of health-related applications (*e.g.*, Health 2.0 firms) can integrate their "apps" into an HRB. While there are many creative and compelling ideas for such apps, most require the patient's medical information in order to be effective. Manual input and updating of that data is a huge disincentive for consumer adoption. By offering a direct connection to the HRB, consumers can select and use applications that automatically access their data on an ongoing basis, making them convenient and easy. Vendors will thus be able to benefit by deploying applications that can be rapidly adopted by large numbers of consumers. The HRB would retain a minority share (*e.g.*, 30%) of third-party application revenue, incentivizing vendors by allowing them to retain the bulk of their own revenue.

Advertising should not interfere with the basic access functions. Patients should be able to opt out of advertising by payment of a small annual fee (e.g., $5).

Aggregation of data into anonymized reports should include data only from patients who have agreed to such use. To encourage patients to allow this, a material portion of revenue generated from these reports can be shared on a pro rata basis with participating patients (patients who agree therefore would have "interest bearing" HRB accounts).

6. Use revenue to incentivize data deposits

Revenue generated from apps, advertising, and reports may be used to incentivize providers to deposit standardized electronic medical records in the HRB. Although such deposits are required on patient request under HIPAA, the reality is that the EHR systems that generate the data are costly and burdensome, particularly to outpatient physician practices. By paying for deposits, the HRB can incentivize higher levels of EHR adoption leading to more comprehensive patient records (which are much more valuable). Another option to accomplish this is for the HRB to provide no-cost Internet-accessible EHRs to outpatient physicians who do not already have them. Provision of EHRs and/or payments for deposits should also be conditioned on providers enrolling patients for basic HRB accounts (which could be free), as well as compliance with established data standards.

IV. Conclusion

A comprehensive health information infrastructure (HII) is a prerequisite for healthcare reform. In essence, healthcare must be "informed" before it can be successfully "reformed." While much progress toward HII has been made, the end goals still remain elusive. It is clear that we must try new approaches, which by definition are currently unproven.

As we have described, the HRB approach solves the critical problems that have stymied progress thus far. At this time, three key actions are needed: 1) Fund several large-scale HRB demonstration projects; 2) Finalize the regulations enabling patients to access their lab results; and 3) Assist HIEs to reconfigure their operations and organizations into HRBs.

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