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HEALTH INFORMATION EXCHANGE: A PATH TOWARDS IMPROVING THE QUALITY AND VALUE OF HEALTH CARE FOR PATIENTS

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED FOURTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING HEALTH INFORMATION EXCHANGE, FOCUSING ON A PATH TOWARDS IMPROVING THE QUALITY AND VALUE OF HEALTH CARE FOR PATIENTS

JUNE 10, 2015

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C O N T E N T S

STATEMENTS

WEDNESDAY, JUNE 10, 2015

HEALTH INFORMATION EXCHANGE: A PATH TOWARDS IMPROVING THE QUALITY AND VALUE OF HEALTH CARE FOR PATIENTS

WEDNESDAY, JUNE 10, 2015

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10:09 a.m., in room SD–430, Dirksen Senate Office Building, Hon. Lamar Alexander, chairman of the committee, presiding.

Present: Senators Alexander, Roberts, Burr, Scott, Cassidy, Murray, Casey, Whitehouse, Warren, Franken, Bennet, and Murphy.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Senate Committee on Health, Education, Labor, and Pensions will please come to order. Our hearing today is on how to improve the exchange of health information. Senator Murray and I will each have an opening statement. Then we'll introduce our panel of witnesses. After our witness testimony, Senators will have 5 minutes of questions for the witnesses.

We're here today to outline our plans to conduct an intensive review of electronic health records. To save a little time, I'm going to summarize my comments and put my entire statement in the record.

I have these things I'd like to say as we begin. There is a great deal of bipartisan interest in this subject. Senator Murray's staff and my staff have been meeting with experts almost every day, the staff of our committee members have been meeting once a week, and Senator Murray and I have been working with Secretary Burwell and other members of the Administration on this. They understand the importance of it.

Here's what we're talking about. The Meaningful Use Program, as it's called, began in 2009 to encourage 491,000 physicians who serve Medicaid and Medicare patients and almost 4,500 hospitals to begin to adopt and use electronic health records systems, and 456,000 of those physicians have received some sort of Medicare or Medicaid incentive payment.

All hospitals and most physicians that tried were able to meet the early requirements. So far, the government has paid out about $30 billion in these incentive payments. The stage 2 requirements have been so complex that only about 11 percent of eligible physicians have been able to comply so far, and just about 42 percent of eligible hospitals.

The next step in the program is penalties for doctors and hospitals that don't comply. This year, according to a CMS statement recently, 257,000 physicians who serve Medicare and Medicaid patients have already begun losing 1 percent of their Medicaid reimbursements, and 200 hospitals may be losing more than that.

Our committee's goal is to identify the five or six steps that we can take, working with the Administration, to improve electronic health records. It is a technology that has great promise, but through bad policy and bad incentives has run off track.

To put it bluntly, physicians and hospitals have said to me that they are literally terrified of the next implementation stage of electronic health records, called Meaningful Use 3, because of the complexity and because of the fines that will be levied. Our goal is—my goal, anyway, is before that phase is implemented, we can work with physicians and hospitals and the Administration to get the system back on track and make it a tool that hospitals and physicians can look forward to using to help their patients instead of something they dread.

Today we will start a series of hearings that we will hold this summer to address various possible solutions. Senator Murray and I are announcing the next two hearings in the series, which will be chaired by different members of our committee, to examine solutions to the problems we identify.

The first hearing is on the burden physicians face with these systems. I have asked Senator Cassidy, who is a physician himself, to chair that hearing.

The second hearing is on the question of whether you and I control information about our healthcare, and I have asked Senator Collins to chair that hearing.

The full committee held its first hearing on Meaningful Use on March 17. Today, we'll set the table for this series of hearings by discussing how we can solve problems.

The Precision Medicine Initiative that President Obama has proposed, which we are working on and which I strongly support, will only work the way it's supposed to work if electronic health record systems work the way they're supposed to work. The systems can help to assemble and understand the genomes of the 1 million individuals required for the Precision Medicine Initiative. And, second, if we want to make genetic information useful to doctors when they write prescriptions, we'll need to get things in order.

According to medical economic surveys recently published, about 70 percent of physicians say their electronic healthcare record system hasn't been worth it. They are spending more time taking notes than taking care of patients, and they are spending a lot of their own money on systems that have to comply with government requirements.

Today we have invited experts representing various perspectives—medical informatics, a records system vendor, a health system chief information officer, and the perspective of the patient—so we can hear these recommendations. I am especially interested to hear from our witnesses the recommendations they have to improve the system.

We're fortunate that a report was published in late May by the American Medical Informatics Association offering several strate-

gies. They include simplifying and speeding documentation, refocusing regulation, increasing transparency, fostering innovation, and supporting person-centered care delivery.

I look forward to our witnesses' recommendations, their thoughts on the report I just mentioned, and also specific advice on how we can make improvements as rapidly as possible.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you very much, Chairman Alexander. Thank you to all of our witnesses for being here today. I'm especially pleased to have a thought leader from Washington State with us, Dr. Payne, who I'll introduce shortly.

Thank you for taking the trip today and for everything you are doing in Washington State to make our healthcare system work better for families and patients.

As I've said before, I really believe strongly that when it comes to our healthcare system, we really need to keep building on the progress we've made so far. We need policies that continue to make healthcare more affordable, not less; expand coverage to more families instead of taking coverage away; and improve the quality of care patients receive.

I'm really pleased our committee is focusing on improving our Nation's health IT infrastructure, because effective health information technology is essential to improving quality and cost of care. I'm especially pleased that this is a shared, bipartisan priority.

Members on both sides of the aisle have some great ideas for ways we can move forward on these issues. I know that Acting Assistant Secretary Dr. Karen DeSalvo also sees this as a top priority as she moves into her new role.

I'm very hopeful we will be able to reach an agreement on some ways to strengthen health IT in our country, because while we have come a long way in a short time, there is a lot more to do.

Over the last few years, our healthcare system has made significant gains in terms of adopting electronic healthcare records. Today, 78 percent of physicians use some form of electronic health records, compared to just 18 percent in 2001.

The HITECH Act that passed in 2009 was a big part of that transformation. I truly appreciate the work that so many doctors and hospitals have done to bring our healthcare system into the 21st century and improve the value and quality of care patients receive. This is really making a difference.

In my home State of Washington, for example, Virginia Mason Medical Center now has more than 100,000 patients who are able to look up their own health information through Virginia Mason's medical record. Virginia Mason is also helping patients and their doctors keep in touch in more efficient ways.

Every week, doctors at Virginia Mason exchange more than 15,000 secure emails with their patients. That means patients can get more of their questions answered without making an appointment or being put on hold. It means they are more empowered to work with their doctors to find the treatment that is best for them.

Without question, there is a lot more we need to do to build on this progress. Many physicians across the country are facing a

Medicare payment reduction this year because they are struggling to meet requirements for the use of electronic health records.

I'm very interested in speaking with our witnesses today about the major gaps that still exist when it comes to interoperability, because this problem is preventing doctors from sharing information in a secure, efficient way. As we find ways to help doctors share information across systems developed by different vendors, we also need to continue helping patients stay informed about and involved in their own care.

During our last hearing on health IT, Dr. Angela Kennedy of Louisiana Tech University shared a story that really showed how big a difference electronic health records can make for patients. She explained that when she takes her adopted daughter Grace to the doctor, she is always quick to note that she does not know her daughter's biological family medical history.

Last year, the importance of having these kinds of records became very clear when, after Grace failed to respond to allergy treatment, genetic testing revealed that she had a rare form of cystic fibrosis. Without access to accurate, thorough medical records or the ability to correct errors in medical records, Grace's illness, one that is usually identified right after birth, was not diagnosed until she was 11 years old.

As Dr. Kennedy's story makes clear, strengthening our health IT system is absolutely critical to making sure patients get the care they need. There are a few steps I will be especially interested in looking at as we continue this effort.

I know the Meaningful Use provision has caused a lot of frustration among physicians. We need to do more to both set high standards and ensure providers have the support and flexibility they need to reach them.

We should make sure that systems developed by different vendors and used by different doctors are able to speak to each other. That way, families like Dr. Kennedy's will not have to spend countless hours tracking down and comparing documents from different sources. Providers will have quick, easy access to information about patients' unique medical needs.

We also need to continue supporting the development of a network of networks so providers have many options for trustworthy information sharing, and they don't have to reinvent the wheel every time they need to exchange information with a new facility. Similarly, we should look for ways to make it easier for providers to shop for electronic records systems and vote with their feet when one isn't working.

And, finally, as electronic health records become more integral to our healthcare system, we need to look at ways to ensure security that stands up to our 21st century challenges.

These and other steps would go a long way toward improving our health IT infrastructure and making our health care system work better for the patients and families we serve.

As I said before, I've been truly pleased by the great ideas and interest that we have seen so far in this, and I want to thank all of our committee members who are so willing to work with us on this and for the hard work that everyone has already put in.

I look forward to our efforts on this, Mr. Chairman, and I'm hopeful that we can reach some bipartisan agreements on this really critical topic.

The CHAIRMAN. Thank you, Senator Murray.

I'm pleased to welcome our witnesses, and I'll ask Senator Murray and Senator Burr to introduce the first two.

STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Mr. Chairman. I thank you and the Ranking Member for holding this hearing, and I want to welcome Craig Richardville from Carolinas HealthCare System in Charlotte, NC.

Craig, thank you for being here and sharing your expertise with us today.

Mr. Richardville is the vice president and chief information officer overseeing all of the systems for information services and strategies for the Carolinas HealthCare System, a network of more than 900 healthcare locations. Mr. Richardville also lends his expertise to a number of organizations focused on health IT, including serving as a Fellow with the Healthcare Information Management System Society and the American College of Healthcare Executives, as well as chairman of the Premier Healthcare Alliance Member Technology Improvement Committee.

Prior to joining Carolinas Healthcare System in 1997, Mr. Richardville spent 12 years with Promedica Health Systems.

I want to thank Craig for being here and lending his expertise to this very, very important hearing.

Senator MURRAY. Mr. Chairman, thank you. I'm really pleased to have a witness today who has come all the way across the country from Washington State. Dr. Thomas Payne is the medical director of IT Services for UW Medicine at the University of Washington. He's an Associate Professor of Medicine, an Adjunct Associate Professor in Health Services, Biomedical Information, and Medical Education at the University.

He's also an attending physician in general internal medicine at the University of Washington Medical Center and Harborview Medical Center. Prior to his current position, he led the installation of the Veterans Administration CPRS electronic medical record at VA Puget Sound in Seattle, and he's also the author of over 60 articles in this field, including the recent EHR 2020 Task Force report which he wrote as board chair-elect of the American Medical Information Association.

Dr. Payne, thank you so much for all you've done. We really look forward to the information you have to share with us today.

The CHAIRMAN. Thank you, Senator Murray.

Our third witness will be Ms. Christine Bechtel from Olney, MD. She's a long-time consumer advocate and the president of Bechtel Health, a mission-driven organization focused on accelerating innovation in patient and family engagement and patient-centered care. She serves as chair of the Consumer Workgroup of the Health IT Policy Committee, a Federal advisory committee.

Our final witness is Mr. Neal Patterson from Kansas City, MO. Senator Roberts was here to introduce him to me, so I'll introduce him to the other Senators. Mr. Patterson is Chairman of the Board

and CEO of the Cerner Corporation, a company he co-founded in 1979. He has led Cerner to invest more than $4 billion in the research and development of health information technology. Today, Cerner's systems are in use at more than 18,000 healthcare facilities in over 30 countries.

Dr. Payne, why don't we begin with you and go down the line. If each of you could summarize your remarks in 5 minutes, we have lots of Senators who would like to ask you questions.

Dr. Payne.

STATEMENT OF THOMAS H. PAYNE, M.D., FACP, FACMI, BOARD CHAIR-ELECT, AMERICAN MEDICAL INFORMATICS ASSOCIATION, MEDICAL DIRECTOR, IT SERVICES, UW MEDICINE, UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE, SEATTLE, WA

Dr. PAYNE. Good morning, Chairman Alexander, Ranking Member Murray, and distinguished members of the committee.

My name is Dr. Thomas Payne. I am the medical director of IT Services at UW Medicine and the University of Washington School of Medicine, and I am chair-elect of the AMIA board of directors. The American Medical Informatics Association represents more than 5,000 doctors, nurses, clinicians, researchers, and other informatics professionals who develop, implement, and study ways to manage information for patients, professionals in their clinical practice, public health, and in clinical research.

It is an honor to appear before you this morning alongside this distinguished panel. My comments will focus on positive, near-term action items policymakers can take to capitalize on the increased adoption of electronic health records and utilize an expanding trove of health data to improve the quality and the value of healthcare for Americans.

Recommendations, which I will describe in my comments, are derived from a recent report published by a multidisciplinary task force chartered by the AMIA board of directors. The EHR 2020 Task Force was established to develop recommendations on how we, as a Nation, can resolve challenges related to EHRs, challenges this committee has examined and will continue to examine through a host of recent hearings. This report was developed over the course of 12 months by a very diverse group of informatics professionals representing a broad range of perspectives.

Broadly, the report's 10 recommendations fall into four categories, which I will briefly summarize as a need to, first, improve documentation requirements and functionality to empower patients so that all members of the care team can contribute their perspectives and information; second, refocus regulations so that patients and their caregivers can derive the most benefit from a networked healthcare ecosystem; third, increase transparency to improve usability and safety of EHRs; and, fourth, foster innovation so that we can build toward the next generation of EHRs and realize the benefits of the learning healthcare system.

Congress can and should play a vital role toward encouraging better EHR usability, improved interoperability, and more meaningful patient engagement. For example, relatively simple steps could be taken to improve documentation requirements, such as en-

couraging regulatory guidance that clearly delineates who is and who is not eligible to enter data into the record for compliance and reimbursement purposes.

A more impactful and coordinated undertaking would be to include the refinement and adoption of standards meant to integrate clinical data from patients, medical devices, and other sources into the EHR. Longer term, Congress should develop policies that require CMS to revisit the entire billing and coding system that drives documentation for reimbursement and compliance purposes.

Congress should also continue to promote broad adoption of alternative payment models, such as value-based purchasing, so that reimbursement is contingent on outcome-oriented measures, supported by less prescriptive and more flexible requirements for documentation.

Documentation and the burdens associated with it are only one piece of a larger, more complex puzzle. The EHR 2020 Task Force also recommended that policymakers refocus the varied set of regulations and policies shaping the development of the health IT market and its use within healthcare.

The simple message resonating among the Tasks Force's recommendations: slow down regulation to accelerate progress. Ensuring CMS does not rush to get to the next stage of Meaningful Use, but rather works to help the private sector accelerate optimization of the tools and regulations that are already in place; reorienting ONC's certification program to test true interoperability by testing how systems both send and receive information are among the key steps HHS should take in the near term. Should the regulatory pressure continue, stakeholders may look to Congress to intervene.

While these steps will help the private sector make advancements toward more interoperable, safer health IT systems, Congress would engender genuine and lasting impact by enabling all patients to have their medical record, not just a summary of their record, available in standardized, machine-readable formats. It is unconscionable that in 2015, with the widespread adoption of electronic health records, a patient must still print and scan their medical record when they change to a new physician.

The future of healthcare will be characterized by an electronic, transportable record of care that provides customized views depending on what the care team needs to deliver and according to patient preference. The record will have the ability to incorporate data from different sources, including patient-generated data, population data, and community context, into an EHR.

Should this committee take up legislation during this or the next Congress, you should focus on the areas described in the EHR 2020 Task Force report. If so, I am confident that we can turn the page from frustrations of today's technology to realize the promise of a truly integrated, modern healthcare experience for all patients and their care providers.

A more detailed explanation of the recommendations and a copy of the EHR 2020 Task Force report will be submitted as part of the written record.

Thank you.

[The prepared statement of Dr. Payne follows:]

PREPARED STATEMENT OF THOMAS H. PAYNE, M.D., FACP, FACMI

SUMMARY

Recommendations, which I will describe in my oral and written comments, are derived from a recent report published by a multidisciplinary Task Force chartered by the AMIA board of directors. The EHR 2020 Task Force was established to develop recommendations on how we, as a Nation, can resolve challenges related to EHRs—challenges this committee has examined through a host of recent hearings. This report was developed over the course of 12 months by a diverse group of informatics professionals representing a wide range of perspectives.

Broadly, the report's 10 recommendations fall into four categories, which are briefly summarized as a need to:

1. Improve documentation requirements and functionality to empower patients so that all members of the care team can contribute their perspectives and information;
2. Refocus regulations so that patients and their caregivers can derive the most benefit from a networked healthcare ecosystem;
3. Increase transparency to improve usability and safety of EHRs; and
4. Foster innovation so that we can build toward the next generation of EHRs and realize the benefits of the "learning health system."

The steps Congress should take to help encourage better EHR usability, improved interoperability and meaningful patient engagement should focus near-term activities on **Reducing documentation burdens for clinicians** by clarifying regulatory ambiguity and supporting adoption of standards meant to integrate clinical data from patients, medical devices and other external sources of data with the EHR. Second, Congress should **unleash the potential for every patient to enrich the learning health system** by requiring vendors to give patients an electronic copy of their entire record, not just a summary, and require that such information is available in machine-readable formats. Policy development in this area will leverage existing requirements of HIPAA and generate a host of positive externalities to facilitate health information exchange among patients and their caregivers while fueling an ecosystem of modern applications and research. Third, Congress should **streamline the Federal health IT certification program** so that the process is more flexible, more transparent, focuses on clinically relevant functionality, and tests for true interoperability.

Finally, Congress should embrace the notion of **slowing down regulation to accelerate progress** on EHR usability, interoperability and innovation. Federal regulators should not rush to get to the next stage of meaningful use, but should instead work to help the private sector accelerate optimization of the tools and regulations that are already in place.

The recommendations developed by AMIA's 2020 Task Force are inclusive of a diverse group of informatics professionals and we think they are sensible, feasible and will capitalize on the progress made to-date. In combination, these recommendations represent the most important work Congress can engage to help turn the page from our current State problems. Lawmakers have a vital role in determining the next evolution in EHRs, and AMIA stands ready to support Congress in this important work.

Good afternoon, Chairman Alexander, Ranking Member Murray, and distinguished members of the committee. My name is Dr. Thomas Payne. I am medical director of IT Services at UW Medicine and the University of Washington School of Medicine, and I am chair-elect of the AMIA board of directors. The American Medical Informatics Association represents more than 5,000 doctors, nurses, clinicians, researchers and other informatics professionals, who develop, implement and study ways to manage information for patients, professionals in their clinical practice, public health and clinical research.

It is an honor to appear before you today, alongside this distinguished panel. My comments will focus on positive, near-term action items policymakers can take to capitalize on the increased adoption of electronic health records, and utilize a burgeoning trove of health data to improve the quality and value of healthcare for Americans.

Recommendations, which I will describe in my comments, are derived from a recent report published by a multidisciplinary Task Force chartered by the AMIA board of directors. The EHR 2020 Task Force was established to develop recommendations on how we, as a Nation, can resolve challenges related to EHRs—challenges this committee has examined through a host of recent hearings. This re-

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1. Improve documentation requirements and functionality to empower patients so that all members of the care team can contribute their perspectives and information;
2. Refocus regulations so that patients and their caregivers can derive the most benefit from a networked healthcare ecosystem;
3. Increase transparency to improve usability and safety of EHRs; and
4. Foster innovation so that we can build toward the next generation of EHRs and realize the benefits of the "learning health system."

Congress can and should play a vital role toward encouraging better EHR usability, improved interoperability and more meaningful patient engagement. For example, relatively simple steps could be taken to improve documentation requirements, such as encouraging regulatory guidance that clearly delineates who is and who is not eligible to enter data into the record for compliance and reimbursement purposes. A more impactful and coordinated undertaking would include the refinement and adoption of standards meant to integrate clinical data from patients, medical devices and other external sources into the EHR. Longer term, Congress should develop policies that require CMS to revisit the entire billing and coding system that drives documentation for reimbursement and compliance purposes. Congress should also continue to promote broad adoption of alternative payment models, such as value-based purchasing, so that reimbursement is contingent on outcome-oriented measures, supported by less prescriptive and more flexible requirements for documentation.

Documentation—and the burdens associated with it—are only one piece of a larger, more complex puzzle. The EHR 2020 Task Force also recommended that policymakers refocus the varied set of regulations and policies shaping the development of the health IT market and its use within healthcare. The simple message resonating among the Tasks Force's recommendations: slow down regulation to accelerate progress. Ensuring CMS does not rush to get to the next stage of meaningful use, but rather works to help the private sector accelerate optimization of the tools and regulations that are already in place; reorienting ONC's certification program to test true interoperability by testing how systems both send AND receive information are among the key steps HHS should take in the near-term. Should the regulatory pressure continue, stakeholders may look to Congress to intervene.

While these steps will help the private sector make advancements toward more interoperable, safer health IT systems, Congress would engender genuine and lasting impact by enabling all patients to have their medical record, not just a summary of their record, available in standardized, machine-readable formats. It is unconscionable that in 2015, with the widespread adoption of electronic health records, a patient must still print and scan their medical record when they change to a new physician. The future of healthcare will be characterized by an electronic, transportable record of care that provides customizable views and varied amounts of context depending on what the care team needs to deliver care, and according to patient preference. The record will have the ability to incorporate data from different sources, including patient generated data, population data and community context into an EHR. Once the complete medical record is available in an electronic form, patients can more fully participate in clinical research, precision medicine, and other activities in which they control who can use their data. The first step toward this future is to enable patients to have access to their entire record in a computable, electronic form, not just a summary of their record. The electronic standards are ready, and this is perhaps the single, most important work Congress can engage to help turn the page from our current State problems.

Should this committee take up legislation during this or the next Congress, and should you focus on the areas described in the AMIA EHR 2020 Task Force report, I am confident that we can turn the page from the frustrations of today's technology to realize the promise of a truly integrated, modern healthcare experience for all patients and their care providers.

A more detailed explanation of recommendations and a copy of the EHR 2020 Task Force report will be submitted as part of the written record.

Thank you.

The remainder of my comments will detail the action items policymakers can take to improve the quality and efficiency of care delivery, optimize patient safety, and improve interoperability of health IT.

Recommendation 1: Improve documentation requirements and functionality to empower patients so that all members of the care team can contribute their perspectives and information.

For the last two decades, documentation requirements for reimbursement and compliance purposes have increased dramatically in healthcare. Rather than diminish the burdens associated with documentation, as information technology has done for countless other industries, EHRs have magnified the amount of time physicians and nurses spend away from the bedside, increasing their workload and contributing to worsened professional satisfaction. Because EHRs are expected to serve the dual purpose of capturing data for clinical and billing purposes, as well as envisioned to fulfill a myriad of quality reporting requirements, EHRs do not inherently promote sensible workflows. Quite the contrary, in many cases EHRs dictate workflows to users in order to generate reports and satisfy documentation requirements, creating a classic "tail wagging the dog" situation.

The EHR 2020 Task Force concluded that much of the information relevant to the diagnosis and treatment of a patient could more effectively be entered by other members of the care team, captured automatically by devices or other information systems or captured and entered by patients themselves. Further, the Task Force noted that moving away from the current evaluation and management (E/M) billing structure would free EHR developers to support more novel methods to collect important data. In order to help the care team get back to the bedside, Congress should:

- Encourage regulatory guidance clearly delineating who is and who is not eligible to enter data into the record for compliance and reimbursement purposes;
- Adopt standards meant to integrate clinical data from patients, medical devices and other external sources with the EHR;
- Encourage and support Federal agencies, such as AHRQ, NIH, NLM, NSF and NIST to study alternative approaches to documentation using different media and data sources to identify more efficient documentation;
- Finally, Congress should support and encourage further adoption of alternative payment models, such as value-based purchasing, so that reimbursement is contingent on outcome-oriented measures, supported by less prescriptive and more flexible requirements for documentation. This will focus attention on documenting outcomes and clinically relevant information (rather than processes and procedures), and will speed the adoption of better ways of capturing and documenting clinical care.

Recommendation 2: Refocus regulations so that patients and their caregivers can derive the most benefit from a networked healthcare ecosystem.

Over the last 5 years, the Federal Government has been much more proactive in shaping the market for health IT and informatics. The Federal Government's centerpiece legislation, the HITECH Act, has driven significant efforts by public and private stakeholders, resulting in undeniable gains for the public good. The CMS EHR Incentive Program has enabled a remarkable rise in the adoption of EHRs and ONC's certification program has provided a long-overdue framework to identify, harmonize and drive the adoption of health IT standards across the fractured healthcare landscape. The impact of HITECH is undeniable, but so too are the burdens associated with compliance—and not just to meaningful use, but a host of other programs dependent on the use of IT and informatics tools. The growth in adoption and use of health IT has not been without its challenges.

Following completion of meaningful use Stage 1 and adoption of the 2011 Edition of Certified EHR Technology, many developers struggled to produce upgraded versions—2014 Edition CEHRT—and many providers struggled to meet Stage 2—more rigorous—requirements for meaningful use. Seeing these challenges, policymakers turned to a flurry of regulatory responses with exceptions, flexibility, and extended attestation periods. The challenges faced by healthcare stakeholders has also led to proposed legislation to increase flexibility in the program. These changes suggest that the EHR incentive programs should take a different approach to leverage the gains already made and prevent further erosion of the program. Further, the Federal Government needs to refocus the wider set of health IT and informatics policies across agencies and programs.

The EHR 2020 Task Force recommended Federal health IT regulations focus on (1) clarifying and simplifying MU regulations for providers and vendors; (2) improving data exchange and interoperability; and (3) Reducing duplicative quality measurement while prioritizing patient outcomes over new functional measures.

CLARIFY AND SIMPLIFY MU REGULATIONS FOR PROVIDERS AND VENDORS

In order to provide vendors with clarity on how to meet the MU certification criteria, ONC provides precise instructions for each MU functional objective. The advantage of this approach is that vendors know with certainty how to qualify for MU certification. An unintended consequence is that vendors believe their customers must follow the workflow they programmed into the certified function and built into the automated calculation of the MU threshold determination. This predetermined workflow built into EHR products significantly affects usability of the products, often in a negative way. The goal of certification should be to assure that standards are consistently used in vendor products, in how systems interact with each other, and how quality is measured. Properly used, standards can lead to *more* flexibility as best of breed and modular products allow customization. The certification program, however, has led to preprogrammed workflows that are intended only to meet the conditions of certification, and not the needs of health care providers. Near-term action items for Congress include:

- Ensuring CMS does not rush to get to the next stage of MU, but rather works to help the private sector accelerate optimization of the tools and regulations that are already in place;
- Create flexibility in the certification program by encouraging vendors to develop testing methods that focus on demonstrating a functional capability instead of adherence to a predetermined, prescriptive test procedures.

IMPROVE DATA EXCHANGE AND INTEROPERABILITY

New certification requirements should focus on technical requirements that will improve interoperability and data exchange, support better quality measures, and provide for safer and more secure care. To do this Congress should:

- Engage with HHS to ensure that ONC's certification program tests not just conformance to the standards, but true interoperability. This means testing both how systems send information and making sure that they are flexible in how they receive information.
- Require that health IT vendors provide all patients with their entire medical record in a standards-based computable format.

REDUCING DUPLICATIVE QUALITY MEASUREMENT WHILE PRIORITIZING PATIENT OUTCOMES

Quality measurement and reporting has become the primary focus of many FTEs within any given healthcare system due to a proliferation of quality reporting programs, such as the Physician Quality Reporting System (PQRS) Program, Inpatient Quality Reporting (IQR) Program, meaningful use quality reporting requirements and a host of quality reporting regimes applied by State-level health officials or private-sector insurers and accreditation bodies. Many, if not most of these quality reporting requirements befall providers simultaneously and call for slightly different specifications of quality measures, rendering multiple uses of the same measures impossible. As Federal legislators look to quality measures as the basis for future reimbursement models and consumer comparison efforts, Federal regulators are looking to require submission of electronic clinical quality measures, which are incomplete and inaccurate without the addition of manual abstraction with current EHR systems.

The EHR 2020 Task Force recommended that quality measurement should focus on outcomes that are consistent with national priorities while also being relevant to patients, their communities and clinicians' specialties. And, again, working with payers and other stakeholders to develop payment alternatives that depend less on documentation and more on quality and value is likely to promote EHR innovation and uses that support these goals. In order to reduce duplicative quality measurement and prioritize patient outcomes over functional measures, Congress should:

- Develop a special committee dedicated to harmonizing quality measurement across Federal, State and private sector stakeholders.
- Encourage development of accurate, complete and reusable electronically specified electronic CQMs, by building quality measures from a consistent set of data "building blocks".
- Study the value of complex versus simple quality measures, and use the results of those studies to simplify data collection and quality measure calculations. Complex quality measures will lead to complex data collection requirements, and simple, high quality measures may achieve the same goal at a lower cost.

Recommendation 3: Increase transparency to improve usability and safety of EHRs.

Currently, purchasers of EHRs often do not have visibility into how applications work. This lack of transparency inhibits an effective, competitive marketplace. Those choosing EHRs need clear knowledge of what commercial EHR systems offer and, importantly, what workflows are incorporated into their use for frequent tasks such as creating notes, entering data, reconciling medications, responding to decision support, and extracting data for reports or research—so they can make more informed choices.

However, transparency in how EHRs perform during certification conformance testing is only one aspect of transparency. Users of health IT also need transparency in how systems perform after they're deployed in a live environment. Moreover, patients and their care providers should have a clear understanding of the safety performance of health IT and informatics tools. In order to improve usability and safety and to foster innovation, health care organizations, providers and vendors should be fully transparent about unintended consequences and new safety risks introduced by health information technology systems, including EHRs, as well as best practices for mitigating these risks. In order to create the most transparent market for health IT, Congress should:

- Encourage ONC to modify its certification program to streamline the certification process—as outlined previously in my comments—and better convey the process by which developers program common functionality and frequent tasks;
- Make all the results of testing and how each vendor satisfies the certification requirements open to the public for review. This should include not just summaries, but videos, screen shots and details of the workflow used to satisfy the certification requirements;
- Move forward with recent Food and Drug Administration Safety and Innovation Act (FDASIA) report recommendations to develop a public-private Health IT Safety Center that would promote health IT as an integral part of patient safety with the ultimate goal of assisting in the creation of a sustainable, integrated health IT learning system; and
- Encourage a more inclusive "culture of safety," by affording similar safe harbors to vendors that are afforded to providers that participate with Patient Safety Organizations (PSOs).

Recommendation 4: Foster innovation so that we can build toward the next generation of EHRs and realize the benefits of the "learning health system."

Given the complexity of our healthcare system, the incomplete State of several national efforts to modernize care, harness health data and empower patients, a clinician could be forgiven for being overwhelmed. But the future is bright and the possibilities are great. As a Nation, we are closer than any other point in history where every patient encounter could present an opportunity for patients and clinicians alike to contribute to our understanding of health care and participate in research and clinical trials. This is the essence of the learning health system.

In addition to enabling the incorporation of research knowledge into practice to support evidence-based medicine, EHRs can enable evidence generating medicine thereby creating a virtuous cycle of rapid evidence generation and evidence-based care delivery, an essential element needed to create a learning health system and to advance precision medicine.

Although we don't know what the next generation EHR will look like, we know that it will likely be very different than the systems that we have now. If we want to have the same successes that we've seen in the internet, we need a stable base of standard building blocks that allows us to create new technology to benefit patients. Unfortunately, there is a disconnect between the promise of what we can do and the real-world infrastructure required to actually make it operational and scalable.

In order to foster innovation so that we can build toward the next generation of EHRs and realize the benefits of the learning health system, Congress should:

- Support the adoption of standards for connecting different systems together, such as Application Program Interfaces (APIs),
- Require standards that allow patients to have a copy of their entire medical record, not just a summary as previously described;
- Fund research on how to best capture data, integrate data and design new user interfaces utilizing the best computer and human-computer interaction science available; and
- Support innovation in precision medicine by making it easier to get information out of the electronic health records and into the hands of patients who wish to participate in precision medicine.

We know that the IT sector has in many other domains driving significant economic development and job growth. We believe the same is possible in Health IT, but we must create the innovation ecosystem that will allow everyone, not just the largest companies thrive in the expanding marketplace.

Together, we are confident these recommendations will improve the landscape for better, more usable EHRs that will lead to greater interoperability, more engaged patients and improved clinical outcomes. Congress can take tangible steps toward the improved future of health IT by reducing documentation burden, requiring vendors to give patients an electronic copy of their entire record, and by streamlining certification so the process is more flexible and transparent. These actions will enable advances in population health, precision medicine and capitalize on the progress made to-date.

Lawmakers have a vital role in determining the next evolution in EHRs, and AMIA stands ready to support Congress in this important work.

The CHAIRMAN. Thank you, Dr. Payne.

Mr. Richardville.

STATEMENT OF CRAIG D. RICHARDVILLE, MBA, FACHE, SENIOR VICE PRESIDENT AND CHIEF INFORMATION OFFICER, CAROLINAS HEALTHCARE SYSTEM, CHAIR, PREMIER HEALTHCARE ALLIANCE MEMBER TECHNOLOGY IMPROVEMENT COMMITTEE, CHARLOTTE, NC

Mr. RICHARDVILLE. Thank you, Chairman Alexander, Ranking Member Murray, and the members of this committee, for your leadership in holding this hearing today, and to you, Senator Burr, for your gracious introduction.

I appreciate the opportunity to testify today on behalf of Carolinas HealthCare System and the Premier Healthcare Alliance, where I serve as chair of Premier's Member Technology Improvement Committee.

Carolinas HealthCare System is one of the largest health systems in the country. We have a diverse network that includes more than 900 care locations, 3,000 physicians and ACPs, 39 hospitals, behavioral health centers, home healthcare, nursing homes, hospice, and palliative care. In 2014, we touched the lives of 11 million patients living throughout North Carolina, South Carolina, and northeast Georgia.

Premier is a leading healthcare improvement company, uniting an alliance of approximately 3,400 hospitals and 110,000 other providers to transform healthcare.

Improving health information exchange and achieving true interoperability is one of the key challenges of our time, especially given the drive from volume-based care to value-based care, to increase the quality, efficiency, safety, and well-being of our citizens. As this committee has heard earlier this year, the current HIT ecosystem continues to be challenging for healthcare providers due to the lack of interoperability among various HIT systems.

Efficient, easy to use, and the integration of health information is foundational to advancing and providing excellent care in this country. The cost to build, test, and maintain those integrations and interfaces is significant. At Carolinas HealthCare System, we have had success in these integrations. To date, we've integrated more than 125 different systems into our EMR.

More than the impact on providers and hospitals is the impact on the patients that we serve. In order to truly engage our patients in the management of their care and to give them the tools that

they need to manage and understand their health status, we must provide them with this clinical information.

Take, for example, a patient who has diabetes and other chronic conditions. This patient may be receiving care from multiple providers who are documenting their care in multiple systems. In order that the care be coordinated, up-to-date, and based on reliable current information, providers need to have the information readily available.

The lack of easy exchange of this data amongst all providers and patients is the challenge. The goal should be to design and implement a secure HIT ecosystem that enables an easy exchange of health information.

To accomplish this, we ask for a combination of congressional leadership and administrative actions that promote policy principles that further open health IT infrastructures. These include:

Governance: Private-public partnership on HIT interoperability governance should be established to provide clear rules of the road.

Functional standards: The governance mechanism should focus on the development of functional data and transport standards in key areas including patient identifiers, terminologies, clinical data query language, security, open APIs, and clinical decision support algorithms as well as business practices and policies.

Measures: Transparent and public measures of interoperability should be developed in collaboration with the Federal Government.

Transparency: Secure data should flow freely and easily.

Compliance enforcement: The Federal Government should be enabled to enhance its enforcement tools to ensure functional data and transport standards and measures are compliant in vendor partners through its certified technology programs.

The impact of having true interoperability achieved through the functional standards, metrics, and innovative technologies, such as open and secure APIs, would be transformative in terms of care, efficiency, safety, and patient engagement.

Let's go back to our patient with diabetes. With a more robust and open system, the patient could securely send to his or her provider daily glucose readings from a mobile device. Those readings would be easily posted and translated to a care management system where a coordinator is monitoring for fluctuations.

During the visit, either in person or a virtual visit, the physician sees all the data from the patient and the various clinical systems. This allows the provider to understand not only today's clinical data, but also the information that the patient voluntarily shares from outside the office.

Thank you again on behalf of the providers at Carolinas HealthCare System and Premier Healthcare Alliance members and the patients that we serve for this considerable transformative work that you are doing for the benefit of the communities that we serve.

[The prepared statement of Mr. Richardville follows:]

PREPARED STATEMENT OF CRAIG D. RICHARDVILLE, MBA, FACHE

SUMMARY

Chairman Alexander, Ranking Member Murray and members of the Senate Health, Education, Labor, and Pensions (HELP) Committee, I appreciate the oppor-

tunity to testify today on behalf of Carolinas HealthCare System and the Premier healthcare alliance, where I serve as the chair of Premier's Member Technology Improvement Committee (MTIC), which consists of member CIOs that advise Premier's leadership and the Board on health information technology (HIT) matters.

HIT INTEROPERABILITY IS FOUNDATIONAL TO IMPROVING QUALITY AND VALUE OF HEALTHCARE TO PATIENTS

As this committee heard earlier this year, the current market incentives are not aligned with open exchange of necessary healthcare data in cost-effective ways. The sharing of data that sits in software systems across the care continuum is not only technically complex, it also is expensive. Data resides in many systems, not just electronic medical records. Registration, billing, lab, pathology systems, medical devices, sensors and monitors, to name just a few, all have vital data that can and should be integrated and accessible across the care spectrum, no matter what the underlying software system is.

More than the impact on providers and hospitals is the impact on the patients we serve. In order to truly engage our patients in the management of their care and to give them the tools they need to manage and understand their health status, we must provide them with this clinical information.

PATHWAY TO ACHIEVING INTEROPERABILITY

The goal should be to design and implement a secure HIT ecosystem that enables an easy exchange of health information in timely and cost-effective ways. To accomplish these goals, we ask for a combination of congressional leadership and administrative actions that promote policy principles that further open health IT infrastructures. In creating these structures, we need clear rules of the road for providers and vendors alike through establishment of functional data and transport standards and methods to measure and test functionalities, with enhanced enforcement tools for regulatory bodies to drive compliance in the marketplace.

- *Governance*: Private-public partnership on HIT interoperability governance should be established to provide clear rules of the road on interoperability. This should be done in consultation and coordination with Federal agencies, such as HHS and ONC, and the private sector. Providers, vendors, patients and payers should be consulted. The government entities should provide regular reports to Congress and the Administration on current standards development status as well as ready to market timelines and assessments for their applications.
- *Functional data and transport standards that promote interoperability and innovation*: The governance mechanisms should focus on the development of functional data and transport standards in key areas including: patient matching, terminologies, clinical data query language, security, open application program interfaces (APIs), and clinical decision support algorithms as well as business practices and policies.
- *Public interoperability and cost efficiency measures*: Transparent and public measures of interoperability should be developed in collaboration with the Federal Government, including HHS and ONC, and standard-setting bodies in consultation with the private sector and be required as part of ONC's certified technology program.
    - These measures should be validated and tested in terms of functional standards, processes, and their maturity for application in the marketplace in a timely way, and within specific use case scenarios.
    - Measures should include business and implementation approaches that deliver functional interoperability outcomes and include operational processes and implementation practices.
    - Measures should also include assessment of cost efficiency metrics achieved through incorporating innovative technologies, such as existing API, which is an open source code that enables third party applications to exchange data.
- *Transparency*: Data should flow freely and easily. Determinants of transparency should include:
    - Availability of "free" (no cost) export of publishable EHR domains.
    - Prohibition of specific fees for access to necessary data through API or other functional standard callable methods.
    - Publication of technical instructions on how to interact with APIs, interface standards or other callable methods. These should be published either publicly or broadly to any authorized third party.
    - Technology and devices that generate health information be required to publish clinical data to any other authorized consuming applications, including

EHR/EMRs, to create interoperability. Consuming applications' ability to develop methods to ingest information from other HIT assets, including devices, should adhere to current and future medical device interoperability standards.

• *Enforcement of functional data and transport standards and measures of HIT interoperability*: The Federal Government should be enabled to enhance its enforcement tools to ensure functional data and transport standards and measures compliance of vendors through its certified technology program.

Chairman Alexander, Ranking Member Murray and members of the Senate Health, Education, Labor, and Pensions (HELP) Committee, I appreciate the opportunity to testify today on behalf of Carolinas HealthCare System and the Premier healthcare alliance, where I serve as the chair of Premier's Member Technology Improvement Committee (MTIC), which consists of member CIOs that advise Premier's leadership and the Board on health information technology (HIT) matters.

To start, I applaud the leadership of Chairman Alexander and Ranking Member Murray for holding this important hearing today. This is a vital topic, important to the well-being of our citizens and our Nation.

Carolinas HealthCare System is one of the largest health systems in the country. We have a diverse network that includes more than 900 care locations, 3,000 physicians and advanced clinical practitioners, 39 hospitals, behavioral health centers, home health care, nursing homes, hospice and palliative care. For 11 consecutive years, we have been named one of America's Most Wired Hospitals by Modern Healthcare. We are the only health system in North or South Carolina to have received HIMSS Analytics Stage 7, the highest level, for adoptions of electronic medical record (EMR) technologies in both outpatient and inpatient settings. We also are a member of Healtheway, a founding member of Carequality and being certified for the national eHealth Exchange. Just last month, Carolinas was named by Forbes magazine as one of the Nation's best employers.

Our mission is clear—to create and operate a comprehensive system to provide healthcare and related services, including education and research opportunities, for the benefit of the people we serve. In 2014, we had more than 11 million patient encounters, touching the lives of those that live throughout North and South Carolina and northeast Georgia. Each day, our 60,000 teammates dedicate themselves to providing the best medical care possible. Much of the care they deliver each day is extended, buttressed and enhanced by the advances in technology.

Premier, Inc. is a leading healthcare improvement company, uniting an alliance of approximately 3,400 U.S. hospitals and 110,000 other providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, advisory and other services, Premier enables better care and outcomes at a lower cost. Premier, a Malcolm Baldrige National Quality Award recipient, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide.

HIT INTEROPERABILITY IS FOUNDATIONAL TO IMPROVING QUALITY AND VALUE OF HEALTHCARE TO PATIENTS

Despite its potential, the current HIT ecosystem continues to be challenging for healthcare providers because of a lack of interoperability between systems. Cost-effective, efficient, and easy to use and integrate health information is foundational to advancing and providing excellent care in this country. Patients and care providers are missing opportunities to improve people's health and welfare when information about care or health status is not easily available. It is critical for us, all of us, to fully use and leverage the health data that is vital to improving patient care. Doing so will help us discover and develop better treatments while improving safety and quality in the delivery of that care.

As this committee heard earlier this year, the current market incentives are not aligned with open exchange of necessary healthcare data in cost-effective ways. The sharing of data that sits in software systems across the care continuum is not only technically complex, it also is expensive. Data resides in many systems, not just electronic medical records. Registration, billing, lab, pathology systems, medical devices, sensors and monitors, to name just a few, all have vital data that can and should be integrated and accessible across the care spectrum, no matter what the underlying software system is. The difficulty in achieving this has an impact not only in care quality but also in cost.

The cost to build interfaces and test and maintain those interfaces is not insignificant. At Carolinas HealthCare System, we have been successful with many of these integrations. In order to meet the needs of our patients across our geographies and throughout the care continuum, we have interfaced with more than 125 systems to get data into our EMRs. One critical factor to our success has been with our patient matching biometric program which uses palm vein scanning. Patients scan their palms, and we are able to match them to the data in many of our systems, ensuring that the right information about the right patient is available. Using this system, which 99 percent of our patients do voluntarily, results in less than .11 percent failure rate. That means 99.9 percent of our patients are correctly matched in our systems. The national average for this is 8 to 10 percent, while a best practice is 5 percent.

Achieving this integration has not been easy or inexpensive. Today, in order to build the bridges that connect disparate data sets necessary to provide comprehensive and informed decisions or care, providers must either pay their original system vendors thousands and sometimes millions of dollars to custom code linkages so they can "talk" to other systems, or they often find paper-based workarounds that are fraught with potential for both errors and wasted resources and expense.

The costs of sharing this critical data among other health systems is not just in dollars. It creates an environment of inefficient use of some our most valuable resources, our people. Having care providers faxing or mailing information to other providers is not the best use of these highly skilled clinical people.

More than the impact on providers and hospitals is the impact on the patients we serve. In order to truly engage our patients in the management of their care and to give them the tools they need to manage and understand their health status, we must provide them with this clinical information. Take for instance a patient who has diabetes and other chronic conditions. This patient may be receiving care from multiple physicians who are documenting their care in multiple systems. In order that the care be coordinated, up to date and based on reliable current information, those physicians need to have the information readily available when they are making clinical decisions. The lack of easy exchange of these data amongst all providers and the patient is the challenge.

PATHWAY TO ACHIEVING INTEROPERABILITY

The goal should be to design and implement a secure HIT ecosystem that enables an easy exchange of health information in timely and cost-effective ways. The system should promote collaboration among all stakeholders, from patients to providers to vendor partners and payers. We need a system of standards that focuses on improving healthcare quality, efficiency, safety, affordability and access through government and market incentives, while encouraging innovation and competition.

At Carolinas, for instance, we care for more than 60,000 people with diabetes. Continuing to manage their care through today's methods is not optimal. The shift from volume-based care, where we are paid for the numbers of things we do or the number of patients we see, to value-based care where we are compensated for the quality of the care, leads us to this new care delivery model. Population health programs like we are implementing at Carolinas will advance the delivery of this value-based care where providers and patients are linked and partners in the care.

To accomplish these goals, we ask for a combination of congressional leadership and Administrative actions that promote policy principles that further open health IT infrastructures. In creating those structures, we need clear rules of the road for providers and vendors alike through establishment of functional data and transport standards, and methods to measure and test functionalities, with enhanced enforcement tools for regulatory bodies to drive compliance in the marketplace. These include:

- *Governance*: Private-public partnership on HIT interoperability governance should be established to provide clear rules of the road on interoperability. This should be done in consultation and coordination with Federal agencies, such as HHS and ONC, and the private sector. Providers, vendors, patients and payers should be consulted. The government entities should provide regular reports to Congress and the Administration on current standards development status as well as ready-to-market timelines and assessments for their applications.
- *Functional data and transport standards that promote interoperability and innovation*: The governance mechanisms should focus on the development of functional data and transport standards in key areas including: patient matching, terminologies, clinical data query language, security, open application program interfaces (APIs), and clinical decision support algorithms as well as business practices and policies.

• *Public interoperability and cost efficiency measures*: Transparent and public measures of interoperability should be developed in collaboration with the Federal Government, including HHS and ONC, and standard-setting bodies in consultation with the private sector and be required as part of ONC's certified technology program.

- These measures should be validated and tested in terms of functional standards, processes, and their maturity for application in the marketplace in a timely way, and within specific use case scenarios.
- Measures should include business and implementation approaches that deliver functional interoperability outcomes and include operational processes and implementation practices.
- Measures should also include assessment of cost efficiency metrics achieved through incorporating innovative technologies, such as existing API, which is an open source code that enables third party applications to exchange data.

• *Transparency*: Data should flow freely and easily. Determinants of transparency should include:

- Availability of "free" (no cost) export of publishable EHR domains.
- Prohibition of specific fees for access to necessary data through API or other functional standard callable methods.
- Publication of technical instructions on how to interact with APIs, interface standards or other callable methods. These should be published either publicly or broadly to any authorized third party.
- Technology and devices that generate health information be required to publish clinical data to any other authorized consuming applications, including EHR/EMRs, to create interoperability. Consuming applications' ability to develop methods to ingest information from other HIT assets, including devices, should adhere to current and future medical device interoperability standards.

• *Enforcement of functional data and transport standards and measures of HIT*: The Federal Government should be enabled to enhance its enforcement tools to ensure functional data and transport standards and measures compliance of vendors through its certified technology program.

Let's go back to our patients with diabetes. With a more robust and open system, the patient could send to his or her care provider, their daily glucose readings from their mobile device. At Carolinas, they soon will do that through MyCarolinas Tracker, which integrates data from 60 consumer-based medical devices. Those readings would be easily posted and translated in a care management system, where a coordinator is monitoring for fluctuations. In the meantime, the coordinator is scheduling the patient for a check-up with the physician. Before the patient goes in for the visit, they log in to look at the latest lab and test results on them. During the visit, the physician sees all the data from the patient and all the data from the clinical systems in the EMR. The physician can also view when the patient had an ER visit at another hospital while on vacation. This allows the physician to understand not only today's clinical data, but also the life of the patient outside of the office visit.

The technology is now available to realize the goals of what the Institute of Healthcare Improvement calls the Triple AIM—improve the health of the population served, improve the experience of each patient, and improve the affordability of the care.

Thank you again for the opportunity to testify today. As this committee continues its work on improving HIT infrastructure and data exchange, we urge the Members to require HIT interoperability as foundational to facilitate research, storage and use of health data to advance patient care, quality and safety, while reducing costs. Thank you on behalf of the providers at Carolinas HealthCare System and Premier healthcare alliance and the patients we serve for this considerable transformative work you are doing for the benefit of the communities we serve.

The CHAIRMAN. Thank you, Mr. Richardville.

Ms. Bechtel.

STATEMENT OF CHRISTINE BECHTEL, M.A., ADVISOR, NATIONAL PARTNERSHIP FOR WOMEN AND FAMILIES, CHAIR, HEALTH IT POLICY COMMITTEE CONSUMER WORKGROUP, PRESIDENT, BECHTEL HEALTH, OLNEY, MD

Ms. BECHTEL. Good morning, Mr. Chairman, Ranking Member Murray, and distinguished committee members. I'm Christine Bechtel. I'm a consumer advocate, and I'm an advisor to the National Partnership for Women and Families. Thank you for having me here today.

As you've just heard, the healthcare system is struggling to foster the kind of exchange that will drive better care and smarter spending. We're making progress, but many organizations still treat health data as a close-hold business asset when it should be treated as a public good.

I'm here to talk about how consumers can be a force for change. The role of consumers in healthcare is changing rapidly, thanks to emerging information technologies, evolving economic incentives, and rising consumer expectations.

If we harness these forces, consumers can play a major role in beginning to dramatically reshape the way we share information in healthcare today. Simply put, if I can gather my data electronically from all of my healthcare entities that hold it, use a safe and secure app to store it, then I could share it with any one of my healthcare providers for my care or for other purposes, like precision medical research.

As the only one present at all of my healthcare encounters, I can potentially amass more data more quickly and more comprehensively than any single healthcare entity can today, because I know where it is, and I have a legal right to it.

We're close to achieving this vision. Both the policies and the technologies exist, but we aren't there yet, and my personal experience demonstrates that we have work to do.

Eight weeks ago, I tried to gather my health records from the patchwork of providers that hold it, and I started with my primary care practice. Because the practice participates in Meaningful Use, I should have been able to download my data directly from the patient portal. Unfortunately, the portal was broken, and the practice had no plan to fix it.

Instead, I asked for an electronic copy of my record, which I now have a legal right to under HIPAA. The practice was unaware of my right, and they had no established process for complying. I had to drop off a copy of the Federal register to demonstrate my right, and then the staff had to work through how to meet my request.

After a lot of back and forth, they put two files on this lovely CD–ROM, and I physically went to the office to pick it up. The process took about 2 weeks, and then once I looked at the CD's contents, I learned that the files alone aren't very useful. I researched and I downloaded an app, as anybody would, to display my medical record in a way that I could understand.

This simple medical records request was a lot of work. Most consumers will not have the resources or the expertise to persist as I did. They should, because my experience produced results. My doctor's office is now changing their process so that all patients can have an electronic option when they want it.

If consumers writ large can do what I did, if they can really ask for and demand their health information right now, then I believe that this can enable systematic change. To do that, there are several actions that we need to take in the next 12 months to make this process easy, private, and secure.

Good news—none require legislation, but a little nudge from Congress would certainly help. There's more detail in my written testimony. In summary, we need to start by raising consumer awareness and provider awareness about our rights to our electronic health information and the use of patient portals for downloading health data. HHS has many mechanisms for doing this.

We should also use the Federal EHR certification program to create the capacity for EHRs to receive consumer-generated data and make it easy for providers to analyze it and act on it.

Next, we need to preserve the Meaningful Use patient access requirement, including the requirement that a small percentage of patients use their online access at least once. We can argue over the exact percentage, but the fact remains that CMS's proposal to drop this threshold to just a single patient will completely undermine efforts to make consumer access to healthcare data the norm.

Finally, we do need advancements in consumer privacy. Consumers don't realize that once they download their data from a provider into an app, most often, HIPAA no longer protects them.

We need to do three things in the short term. One is to encourage HHS to finalize best practice guidance for app developers on privacy and security. The Federal Trade Commission can enforce voluntary best practices for those who adopt them.

Second, we need to incentivize more app developers to use ONC's model PHR notice for consumers. That's a Personal Health Record notice, and it enables quick and easy comparison of otherwise complex privacy policies.

Finally, we should shorten the timeframe for meeting medical records requests under HIPAA to less than 30 days. When the data is digitally available, the law should not give us a basis for delay.

The challenge before us is simple and straightforward, and success, I believe, is within reach. The steps I outlined will move us toward the day when consumers no longer have to use the sneaker net, where we walk our medical records around from doctor to doctor, and instead leverage the internet to drive quality, value, and patient-centered care.

Thank you.

[The prepared statement of Ms. Bechtel follows:]

PREPARED STATEMENT OF CHRISTINE BECHTEL, M.A.

Our health care system is struggling to foster the kind of exchange that will truly drive better care and spending. But consumers can be a force for change. Namely—if consumers could leverage their legal rights and gather data electronically from all of the health care entities that hold it, then use a safe and secure app to store it, it would enable us to share that data with health care providers and give them a much better view of health and care. Yet my own personal experience does not bear this out. My simple medical records request required multiple trips to the doctor, several aggravating phone calls, legal and technical knowledge, and persistence. Most consumers won't have the resources to persist and succeed. My case is not unique; it illustrates the challenges of our current system.

There are a range of actions we can take over the next 24 months to achieve change. A little nudge from Congress can help:

- Better educate consumers about their legal rights and about the use of patient portals for downloading and using health data. HHS has many mechanisms for doing so, including the Office of Civil Rights (OCR).
- Develop and disseminate tools to help consumers understand how/where/what and what format to request, what to do with the data, where to securely store it, and how to navigate roadblocks along the way. Make the data request process frictionless for consumers.
- Work through HHS to educate providers about how to meet the demand for digital health information.
- Use the Federal EHR certification program to create the capacity for EHRs to incorporate consumer-generated data and make it easy for providers to analyze and act on.
- Finalize the proposal to include open Application Programming Interfaces (APIs) in the Federal EHR Certification program. APIs will help break down information silos in health care.
- Preserve the Meaningful Use view/download/transmit requirement: both the requirement that the technology is in place, and the requirement that a percentage of patients use it at least one time during the reporting period. Regardless of whether the number is 5 percent or something else, CMS's recent proposal to drop this threshold to just a single patient will completely undermine efforts by consumers who want to have and use their data. Requiring providers to actively engage with a percentage of patients is an essential mechanism for changing consumer expectations and enabling consumers as a force for change.
- Privacy protection—consumers want and support greater online access, and consumers also care about privacy. We must encourage ONC, FTC and OCR to finalize best practice guidance on protecting privacy and security for app developers (most of whom are not covered by HIPAA). The FTC can enforce voluntary best practices for those who adopt them.
- Incentivize more app developers to use ONC's model PHR notice for consumers. It enables consumers to quickly and easily compare privacy policies across apps, including whether or not the developer sells consumer data for marketing or to employers and/or insurance companies.
- Shorten the timeframe for meeting records requests under HIPAA from 30 days. Patients should have the data as soon as doctors do, and where digital records make that possible, the law should not provide a basis for delay.
- Require providers to offer an ongoing data feed so patients don't have to submit requests again and again. There are technical standards that already enable this.
- Establish that it is willful neglect to deny a patient access (or even claim HIPAA precludes it), unless the provider in good faith is relying on one of HIPAA's exemptions.

Good morning Mr. Chairman, Ranking Member Murray and distinguished committee members. I'm delighted to be with you today to talk about driving progress toward quality and value through health information exchange.

The notion of "health information exchange" has been around for decades, and we have tried many approaches. Yet our health care system is struggling to foster the kind of exchange that will truly drive better care and smarter spending. Entrenched payment policies that do not reward better health outcomes or coordinated care continue to hold us back. We are making progress, but many health care organizations today still treat health data as a close-hold business asset, when it should be treated as a public good.

I'm here to talk about how consumers can be a force for change.

We know that consumers want health information technology (IT). According to a nationwide survey released by the National Partnership in December, patients overwhelmingly believe that electronic health records (EHRs) are essential to making sure providers have timely access to information that can help avoid medical errors and repeat tests.[1] Consumers also want and use online access to their own health information, largely through patient portals. Almost 9 in 10 patients who have such access use it, and it has a significantly positive impact on patient engagement, better care and improved outcomes. Notably, individuals who use patient por-

[1] Engaging Patients and Families: How Consumers Value and Use Health IT. National Partnership for Women & Families, December 2014. *www.nationalpartnership.org/patientsspeak*.

tals with some frequency are dramatically more likely to say it motivates them to improve their health.

We also know that the role of consumers in health care is changing rapidly, facilitated in part by these emerging technologies, along with evolving economic incentives and rising consumer expectations.

These forces are converging, positioning consumers as a potentially potent force for change that can dramatically reshape the way we share and use information in health care—if we can make the process of downloading, managing and sharing health information easy, private and secure.

What does it take to unleash this consumer potential? Let's look at how our system works today. In my case, I have a primary care physician (PCP) who uses an EHR. I also have a high-deductible health plan, which means that I often seek out care from places that have published price lists and are convenient—like a web-based service that, earlier this year, allowed me to "see" a doctor online on a Sunday morning for just $49. As a result, health care data about me exists in several different places—with my doctors, my health insurer, MinuteClinic, my web-based doctor service, and more. This is not usual for most Americans—all of us have data spread across a patchwork of providers and systems.

Few if any of these systems talk to each other, which means that no single provider can see a complete picture of my care. So how can I, and the millions of consumers like me, become a force for change that drives health information exchange in the marketplace?

If I could gather my data electronically from all of the health care entities that hold it, and use a safe and secure app to store it, then I could share it with any one of my health care providers, giving them a much better view of my health and my care.

The fact is, as the patient, I am the only one present at all of my health care encounters—so I can potentially amass more data, more quickly and more comprehensively than any single health care entity can today, because I know where it all is. And, in theory, I know how to get it. If I have the data, I can spot errors, avoid repeat tests, detect fraud, help facilitate coordinated care, and much more. I can be the curator of my own health record, sharing it where and when it is needed to improve my care, and for other important purposes like research into precision medicine.

We are close to achieving this vision; both the policies and the technologies exist. But we aren't there yet. I learned this the hard way when I requested my data from my PCP 8 weeks ago. Because the practice participates in Meaningful Use, I should have been able to download my data directly from the patient portal. That is due to an important Federal requirement that stipulates patients must be offered online access to view, download or transmit their health information to a third party. Unfortunately, the patient portal was broken and the practice had no plan to fix it.

I decided on another approach that few consumers—and it turns out, few providers—know about. Under the HIPAA amendments made by the HITECH law, I now have a legal right to an electronic copy of my health information. I can exercise this right with any covered entity that holds data about me, as long as they can produce the data electronically. And if they have a Meaningful Use-certified EHR, they can. So I asked my PCP's office for an electronic copy of my health record.

After convincing them that I wasn't trying to change doctors and just wanted my record electronically, they told me they "don't do that;" they only offer paper copies. I told them about my legal right to an electronic copy since they have a certified EHR, and they again simply said they don't do that.

I returned a few days later with a copy of the Federal Register, demonstrating my legal right under HIPAA to an electronic copy. Over the course the following week, and many phone calls back and forth, the practice staff figured out how to meet my request. They created a text file, and a second file in a format called CCR, which stands for Continuity of Care Record, and placed both files on a CD–ROM that they left at the front desk for me to pick up.

I quickly learned that having my record on a CD-–ROM wasn't very useful. I could read the text file (once I bought an external CD–ROM drive), but text files aren't very actionable. So I did what anyone would when faced with a problem—I downloaded an app. The app used the CCR file to summarize and display my medical record in an organized way that I can understand.

This simple medical records request was a big hassle—it caused a lot of friction even though I was simply requesting information to which I am legally entitled—information that is an essential part of my health and care. It required multiple trips to the doctor, several aggravating phone calls, legal and technical knowledge, and persistence. Most consumers won't have the resources to persist and eventually succeed.

My case is not unique, and it illustrates the many challenges of our current system:

• Many providers and their staff members don't know we have a right to an electronic version of our records.
• They don't have workflows to accommodate it—for example, their medical records request forms don't ask if the patient wants paper or an electronic copy.
• Consumers don't know about this right. And if we do, we don't know the best ways to ask for the data—that we should avoid PDFs in favor of structured data, and what our options are to get structured data. Many also don't know about their ability to download data via their portals.
• Most of us don't know what to do with the data once we get it. Which app should we use? What are that app's policies and practices on privacy and security? We also don't know that once we download data from my doctor, hospital or other covered entity, and upload it into an app like a Personal Health Record (PHR), that data is no longer covered by HIPAA unless the app developer is itself a covered entity. That means the developer could sell my identifiable health information.
• And finally, to drive heath information exchange, EHRs need to be capable of ingesting data from consumers, and making it actionable.

These are challenges, to be sure, but they can be addressed in the very near term. And if we overcome them, the potential of consumers to unravel the knot that binds our health data in silos is enormous. If consumers can make a concentrated tug on the rope and demand their data, starting right now, it can enable systemic change.

To do that, we need to take the friction out of the process for consumers. There are a range of actions we can take in three broad areas over the next 24 months to achieve change. The good news is that none require legislation. They can all be done by administrative action, by the private sector or with public-private collaboration. However, a little nudge from Congress can help:

1. Equip consumers with the tools and awareness they need to exercise their rights to their digital health data.

• Better educate consumers about their legal rights, and about the use of patient portals for downloading and using health data. The U.S. Department of Health and Human Services (HHS) has many mechanisms for doing so, one of which is the Office of Civil Rights (OCR). OCR has a Web page to help consumers understand and exercise their privacy rights. Content should be updated to emphasize electronic requests over paper-based ones.
• Develop and disseminate tools to help consumers understand how/where/what and what format to request, what to do with the data, where to securely store it, and how to navigate roadblocks along the way.
• Make the process of requesting data easier. How can we automate it? A small group of leading experts, consumer advocates and former policymakers are catalyzing action in this area right now. Developers are working on tools such as the Vocatus tool, which enables consumers to request their health data online. Others are working to fix problems with patient portal download features.

2. Give providers the tools and incentives to make consumer use of digital data the norm in health care.

• Work through HHS to educate providers about how to meet the demand for digital health information—through patient portals and through other means of downloading data such as Blue Button (which Medicare and the Veterans Administration already use), or the Direct protocol—a secure email link between patients and providers.
• Use the Federal EHR certification program to create the capacity for EHRs to incorporate consumer-generated data and make it easy for providers to analyze and act on.

3. Advance Federal policies that enable consumers to routinely request, download and use their own health data in private, secure and valuable ways. Focus on two areas.

1. First, support policies that drive more information sharing by:
   - Finalizing the proposal to include open Application Programming Interfaces (APIs) in the Federal EHR Certification program. APIs will help break down information silos in health care.
   - Preserving and strengthening the Meaningful Use view/download/transmit requirement, most commonly met by offering patient portals which deliver functions patients want like secure messaging with their providers, online medication refills and data downloads. We must preserve both the requirement that the technology is in place, and the requirement that a percentage of patients use it at least one time during the reporting period. Regardless of whether

the number is 5 percent or something else, CMS's recent proposal to drop this threshold to just a single patient will completely undermine efforts by consumers who want to have and use their data. Requiring providers to actively engage with a percentage of patients is an essential mechanism for changing consumer expectations and enabling consumers as a force for change.

2. Second, privacy protection—there is no question consumers want and support greater online access to their own health information. Consumers also care about privacy. Now that health data is increasingly accessible in digital form, an app market is rapidly emerging, bringing with it both benefits and risks. We need to enable the market *and* protect consumers who are using apps to manage their data.

To do so, we should:

- Encourage the Office of the National Coordinator (ONC), the Federal Trade Commission (FTC) and OCR to finalize and widely disseminate best practice guidance on protecting privacy and security for app developers. Under its existing authority, the FTC can enforce voluntary best practices for those who adopt them.
- Ask the public and private sectors to come together and explore how to evaluate apps on a range of aspects, including privacy, security and usability. My own research into the privacy policies and data sharing practices of the apps I considered for my record required hours of reading and the ability to decipher a lot of legalese. We should incentivize more app developers to use ONC's model PHR notice for consumers. It enables consumers to quickly and easily compare privacy policies across apps, including whether or not the developer sells consumer data for marketing or to employers and/or insurance companies. But it should be promoted much more aggressively by the Federal Government.
- Shorten the timeframe for meeting records requests under HIPAA from 30 days. Patients should have the data as soon as doctors do, and where digital records make that possible, the law should not provide a basis for delay.
- Require providers to offer an ongoing data feed, at least where it is feasible, so patients don't have to submit requests again and again. There are technical standards that already enable this.
- Establish that it is willful neglect to deny a patient access (or even claim HIPAA precludes it), unless the provider in good faith is relying on one of HIPAA's exemptions.

If all that sounds technical, the challenge before us really is quite simple and straightforward. More than that, success is within reach. By taking some of the steps I have outlined, we can make it possible for consumers to finally stop being the "sneaker net"—patients who have to walk our records around to different doctors—and start leveraging the Internet to drive quality, value and patient-centered care.

The CHAIRMAN. Thank you, Ms. Bechtel.

Mr. Patterson.

STATEMENT OF NEAL L. PATTERSON, MBA, COFOUNDER, CHAIRMAN, CHIEF EXECUTIVE OFFICER, CERNER CORPORATION, KANSAS CITY, MO

Mr. PATTERSON. Thank you, Senator Alexander and Senator Murray. This is a privilege and a pleasure, and I was told yesterday it would be fun to testify. This is my first.

Just to give you a quick thumbnail of Cerner, there's about 21,000 Cerner associates around the world. I had the privilege of being the co-founder of it in 1979. The first thing I want to do is thank you for the opportunity to be born in such a great country that a poor farm boy from Oklahoma that went to a land-grant college actually could go and create something that is significant.

It was pure fortune that I found the intersection of healthcare and IT. That is the world I live in. I wake up every morning and I go to sleep thinking about that. I think it is the most—I think information technology is the greatest lever we have to change our healthcare system. I also have the privilege of basically agreeing

almost wholeheartedly with everything that has been said here today.

My lift is relatively small. My biggest challenge as an entrepreneur is to talk within 5 minutes, and the clock is running.

We have a huge opportunity. We've invested as a country to digitize the entire content of the most important and largest sector of our economy. That's healthcare. Information technology is the biggest lever to create change.

We are, I believe, at the dawn of a new era, and I think there is huge opportunity for it to be a golden era. There are significant things, though, in front of us that are barriers to realizing all of those benefits, and the fact that you are having these hearings, the fact that you are as informed as you are about the issues, I think is a very, very good deal.

One thing that we say at Cerner about healthcare is that healthcare is too important not to change, and also healthcare ultimately becomes personal. My wife has stage 4 cancer since 2007. I have my version. My version of this with Jeanne are bags and bags, and you continuously update these. You do go to see doctors that are outside of the organization, and you need all that information in those bags.

I think it is a crime. I think that—I shouldn't say crime here. I think it is a failure of all of us to have in 2015 the fact that Jeanne carries bags to her doctors' appointments where she's going to see a new doctor or a specialist if she wants specific opinions. We have to fix that.

Interoperability is high on my list, both professionally and personally, to fix. From the role, I guess—what's your role as government in interoperability? I hold up this card. This is my ATM card. I'm old enough to basically remember when that was issued by my bank, and I had to use the bank's machine.

I'm old enough to remember that I was so excited when I could go to other banks in other cities. As long as I had a network—my card had the network that was on the machine—I could get money out of it, and today, we go—my youngest son just flew last night to Sri Lanka, and he will get currency out of an ATM machine there.

We, as an industry, are behind around access to information, enabling the person, the patient, to have that. I believe industry should solve that. I think all of my associates up here believe that, too. It takes, frankly, my part of the industry to solve that, and we have to work together to do that.

That has not happened to date. I'm moderately optimistic it will happen. I commit—I will do everything I can to make that happen so that we collaborate as an industry, and our networks that we build as companies, where we have our clients connected—that those private networks connect, and it will work like the ATM, I hope, by the end of this decade, so that you can expect to go to any physician anywhere in the country, and they can push one button and the relevant part of your lifetime record would appear on that screen.

I think what you—one other quick thought on your role. Make sure when you do regulations and you do legislation that you put rounded edges on it. One of the issues with Meaningful Use is it

was defined specifically, and physicians felt like they had to follow the specifics every time for every patient, and, in reality, that was not—and they felt like they had to do it, and their assistants could not do it.

We need thoughtful regulations coming from here. Thank you very much.

[The prepared statement of Mr. Patterson follows:]

PREPARED STATEMENT OF NEAL L. PATTERSON, MBA

Dear Chairman Alexander, Senator Murray, and members of the HELP Committee, thank you for inviting me to share my ideas about how to improve health information exchange for the benefit of every American. I appreciate your openness to ideas and action from the private sector as well as administrative and legislative change.

My name is Neal Patterson. I am co-founder, chairman and CEO of Cerner. We are a leading health information technology company with a projected $4.7 billion in revenues in 2015. We will spend more than $650 million on research and development in 2015. We employ 21,000 associates who operate in more than 30 countries worldwide.

The intersection of health care and IT is one of the most important in modern society. Every citizen touches and depends on both.

I appreciate the opportunity to share Cerner's perspective on what can be done to create a more interoperable health system. We believe that every individual has a right to access their complete health record, regardless of where it's located or what system contains the data. It is immoral for any organization to block the flow of information that could help individuals—and their providers—make better-informed decisions about their care.

In other industries beyond health care, from retail and entertainment to banking to manufacturing and distribution, information technology has wrought massive change and materially improved our lives. It is not simply the efficiencies of IT. When things are digitized, they change.

Digitizing content drives transformation. Digital music recording paved the way for file sharing and iPods to change our music collections. The movement of news online changed how quickly we receive the news. ATM cards changed how we bank. Social media has enabled political mobilization against dictatorships. The second-order effects of content digitization are profound.

You don't always see these effects coming. They happen when data liquidity allows innovators to use information in new ways.

In health care, HITECH and Meaningful Use are not perfect, but they are helping move health care onto a digital platform. As a society, we may be closer than we think to a golden era when science, intelligence and insights from big data can become a natural, unforced part of health care.

Two qualities are important to enable this type of transformation. Health IT platforms must be open, and they must be interoperable.

The quality of being open is what allows independent developers to build "apps" and extensions that work with existing health IT platforms. After years of little movement, our industry is finally making real progress toward being open to outside development. It will fuel an entrepreneurial wave of novel health IT apps and services that will address particular needs of providers and patients.

For all the progress and promise, however, our current efforts are insufficient if they still serve a bunch of disconnected digital silos. Current health IT systems lack true interoperability, and the lack of true interoperability is failing patients. Without it, we risk missing the moonshot transformation that has positively changed other industries and lives.

My wife has been fighting breast cancer since 2007. I have her permission to share her story. She has had procedures in the last 8 years ranging from mastectomy, radiation and chemo to brain surgery and genome sequencing. Her diagnostic and treatment journey has taken her to multiple providers, and her records have wound up in more than 20 different health organizations' EHRs. Everyone has a *piece* of Jeanne's record, but no one has the whole picture.

Because there is not widespread interoperability, Jeanne carries printed copies of her records around in shopping bags. Each record she carries represents a phone call, a wait in a line at a records desk, a fax or a photocopy. The burden of assembling those records is what she calls the "train wreck."

It's, of course, not just cancer patients who live this reality. It's almost all people with chronic conditions who have to see specialists—and people who move—and people who rely on emergency rooms for their care. In reality, everyone in the chamber today has experienced this issue. In the United States, the average person has seen 18 different doctors. If you're over 65, the number increases to 28.[1] It doesn't matter if the records are across the country or across the street. If the systems are not interoperable, the result is the same.

Here is my litmus test and vision for real, patient-centered, true interoperability. It is when you as a patient can go to a new doctor who hasn't seen you, sign your name electronically giving your consent, and then the doctor can click a button in the EHR and compile what is most relevant from your lifetime record that you want to be shared, pulling information from many places. We actually are quite close to being able to realize this vision, and the issues in realizing it are largely not technical ones.

Over the past decade, there has been some good progress on interoperability. Standards have progressed that define how and what information is shared to whom and when. Governance and privacy standards are also progressing. We are members of Carequality, an industry coalition focused on governance. I think Congress's recent focus and sensitivity to the behavior of data blocking (intentional or inadvertent) is a good thing. There are current efforts to create the concept of "semantic interoperability," which is extremely powerful and has the potential to unleash enormous innovation that will interact with the EHR platforms. But it is my testimony that, while this progress is good and necessary, it will not realize the vision I shared above. I want Jeanne's doctors to have access to her full lifetime record. That vision requires a system for national patient identification, for record location tracking and for patient-driven consent.

There is a tendency to use isolated interoperability success stories as the poster children for progress and defense of the status quo. Some regard largely single-vendor networks or "intra"-operability as equivalent to interoperability. It's a form of progress, but it's not the same, because your records and Jeanne's records are not all on one vendor's system. They're spread out across every vendor in the industry. It's just not enough. If we remain satisfied with this progress, patients could wait decades to see real interoperability. It will leave too many patients carrying too many bags for too long.

As a health IT industry, the electronic health record community has grown up alongside each other—Meditech, Cerner, Epic, McKesson, Allscripts and many others. We were out conquering the map. Each of us has had our own version of building our core capabilities. Competition has been healthy, and it has driven a lot of innovation. But too often these competitive instincts led to technological silos.

Outside of health care, there are plenty of examples where competing business interests, spurred by consumer pressure, came together to solve interoperability problems. Apple and Android phones can talk nationwide. The Verizon network connects with the Sprint Network. My Microsoft Outlook email communicates seamlessly to Google Gmail. My ATM card works at nearly every machine worldwide. Government may have helped, but industry played the biggest role.

In 2013, in an effort to augment the standards and governance work playing out in Washington, our industry sought to take on a set of big issues that are impeding true interoperability and data liquidity. Along with some other vendors, we created a non-profit called CommonWell with an eye toward addressing three barrier issues to true patient-centered interoperability: patient identification, record location and patient-driven consent. CommonWell invited all electronic health record vendors to come together.

To solve for the needs of patients, we wanted an approach that was national in scale. The service it offered had to be available at a very low, utility-like cost to providers. And it goes without saying that it had to safeguard privacy and the trust of individuals and providers.

Achieving this level of interoperability in health care requires a virtuous cycle of product innovation and standards development and evolution. It also requires all the players in the industry to agree that patient-centered interoperability needs shared networks between vendors, not just a trickle of individually negotiated connections. Waiting around to fulfill the next request to connect two hospitals to each other or to a local HIE meets the letter of the law. But getting to full interoperability requires active cooperation among all the vendors, and their acceptance that once technological silos are eliminated, they will have to compete on innovation, quality and cost. We do not have this yet in health IT, but this kind of dialog at the national level has a chance of creating real change.

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[1] Practice Fusion survey conducted by GfK Roper, 2010.

What we do have is CommonWell, a non-profit vendor-to-vendor network, national in approach, which providers and hospitals can access on behalf of individual patients. It is open to the entire industry, and its members include Allscripts, Athenahealth, Brightree, Cerner, Evident (formerly CPSI), Greenway, McKesson, Medhost, Meditech, Merge Healthcare, Sunquest, and other companies—which includes every major acute care EHR company in the industry with the exception of one. Cerner is committed to any effort to advance true interoperability, and the CommonWell network is in my opinion our industry's best cooperative effort so far. I have made it clear that if someone establishes another open network that has a reliable method of patient identity management, record location tracking and patient-driven consent, it will also have my support and participation.

As for Washington's role, it must be clear to all that the policy of this country is true interoperability. The Office of the National Coordinator (ONC) must continue pressing its framework for interoperability, convening, facilitating and evolving important standards work. Vendors and providers must enable sufficient transparency around data sharing to allow keeping a watchful eye on behaviors in our industry. Congress should not be afraid to act. Whether intentional or unintentional, behaviors that restrict patient choice, throw up roadblocks to true interoperability, or use control over data to further market share should be challenged. None of us have a perfect record, and we can all do better.

The subject of interoperability can quickly become blurred into an alphabet soup of acronyms, nomenclature, standards, governance and use cases—so much so that we lose the point. In the end, you will know it when *you* see it. It's when you can go to your doctor and they can push a button and assemble the relevant parts of your lifetime record that you want to be shared with your doctor.

We all can cite how the rising cost of health care is consuming more of our resources as a family, community and country. I am convinced that information technology is the single greatest lever for creating value in health care by eliminating waste, variance, error, delay and friction. It can put a system into health care.

We have a chance to deliver a golden era of health care. It's a system where consumers not only have a right to their data, but also have the ability and the financial incentives to mobilize it in pursuit of better health.

We have a chance to make Jeanne's shopping bags a thing of the past.

I look forward to working with the industry, as well as members of the committee, to advance that vision.

The CHAIRMAN. Thank you, Mr. Patterson, and thanks to all the witnesses. We'll now begin a round of questions. I'll call on the Senators in the order they were here at 10 a.m. Senator Murray after me, and then Senator Burr, Senator Warren, Scott, Casey, Cassidy, Bennet, Franken is the order that I have.

Dr. Payne, in March, the department released proposed rules for Stage 3 of Meaningful Use and the 2015 edition of the Certification Program for Electronic Health Record Technology. The comment period ended in May, and we expect the Administration to release the final rules this fall. Meaningful Use 3 will go into effect in 2018. Parts of 2015 certification could go into effect later this year.

A hospital that should know what it's doing has told me it's terrified by Meaningful Use 3. Do you think that it would be a good idea to delay some or all of these proposed rules until Congress and the Administration have a chance to work on the five or six things that seem to be the biggest impediments to making our electronic healthcare records something people look forward to instead of dreading?

Dr. PAYNE. Thank you for the question. The answer is yes. We think Stage 3 needs some improvements. There are many elements to it. A good example of an improvement would be that it tests whether a vendor conforms to a standard, but it doesn't test whether the vendor systems are truly interoperable.

We should be sure that the record can be sent and that it can be received and used. The certification program also needs to be

improved so it can make certain that both the sending and receiving is possible. Some of the standards in it are in a draft state.

The CHAIRMAN. My question is do you think it should be delayed or not, in part or in whole?

Dr. PAYNE. We think it should be delayed until it's improved.

The CHAIRMAN. Mr. Patterson, in your comments earlier, you seem to think that physicians are being asked to do some things, or they think they're being asked to do some things that's not necessary for them to do. Senator Cassidy is going to chair a special hearing on physician documentation.

As I understand your position, you feel that physicians—there is some documentation that physicians certainly should do. There are other things that an aid could do. To some extent, the billing system has gotten mixed up with the electronic healthcare records and made it even more onerous on physicians. Is that a fair summary?

Mr. PATTERSON. I would agree with your summary.

The CHAIRMAN. Would you be able to suggest to us or perhaps to Senator Cassidy's work the specific things that you think doctors should do and other things that others shouldn't do—or aren't necessary for them to do, and how we might change the regulations or the law to make that clear?

Mr. PATTERSON. Yes. We certainly can provide some followup to that in writing.

To give you an example, meds reconciliation, I think, as written and the intent of the regulation is that the physician is to do the meds reconciliation. I think that's appropriate in many cases, but that was—but I think in many cases, that function could be done by a nurse or an aid to the physician under their supervision. They review the work and basically accept it. That's the, if you will, rounded corners, rounded edges on the regulation.

The physician's time is one of and if not the most critical resource inside of the healthcare system, and then the person they're serving—the patient's time is the other part of that. We need to preserve the physician's time with the patient, and I think, current state, we have impacted that amount of time that they can spend negatively.

The CHAIRMAN. Mr. Richardville, all of you have mentioned the importance of having agreed upon standards by the various participants in healthcare, and it's critical to enabling real interoperability, the kind of ATM card that Mr. Patterson talked about. To what extent would you propose that the Federal Government get involved in mandating or otherwise requiring health information technology standards to be adopted?

Mr. RICHARDVILLE. A couple of points, and thank you for the question. There are current initiatives out there today that help promote—that are trying to promote some of this interoperability—Carequality, CommonWell, Epic Care Everywhere, Argonaut—and there are successful——

The CHAIRMAN. My question is on standards. To what extent should the Federal Government get involved?

Mr. RICHARDVILLE. Well, I think what the Federal Government needs to do is to come in from a governance perspective and help define what those rules of the road are so that these organizations can all abide by those rules. I think, as Senator Murray talked

about, that the ability for the network of networks, which is similar to Neal's point, like the Cirrus network that connects the ATMs, would be a viable opportunity for the healthcare industry.

If those rules are set up——

The CHAIRMAN. Do you want the Federal Government figuring out the standards?

Mr. RICHARDVILLE. No.

The CHAIRMAN. Or do you want it encouraging the development of standards developed by private industry?

Mr. RICHARDVILLE. Encouraging the development of—I think it's a multidisciplinary team of payers, patients, vendor partners, and providers that should get together and develop what those standards are. We do need regulation to help define what the timelines are, the aspects of defining what those rules of the road are that we all need to play into so we can participate in a very multidisciplinary approach and allow that network of networks to develop.

The CHAIRMAN. Thank you.

Senator Murray.

Senator MURRAY. Thank you. Our hearing today is focused on health IT because of its potential to improve the quality and value of healthcare for our patients. Health IT can support research that unlocks innovative new treatments. It can support better coordinated care at critical times like when a patient is being discharged from a hospital. To achieve any of those objectives, patients themselves need to be engaged in this work.

Ms. Bechtel, I want to ask you: How does health IT enable better partnerships between patients and families and their doctors?

Ms. BECHTEL. Health IT does quite a lot to enable those partnerships. It lends a lot of transparency, so I can see what's in my medical record. I can correct errors. I can add to it and complete information. It also helps me engage more in not just managing my care, but in managing my own health. There's a lot of data that shows us the many ways, from reading my physician's notes to looking at lab results, that health IT really supports and enables that.

I think the one thing that is essential to also think about—and this is going to point back to Senator Alexander's question about delaying Stage 3. There are aspects of patient engagement that we would give up if we delayed Stage 3 wholesale. I just want to note that we would also, ironically, give up requiring a greater percentage of doctors to share information electronically, not just with patients but with other doctors.

We would also lose a technical fix that would help us to unlock the data that is currently siloed in patient portals. It's called an API, an application programing interface, where we would be able to download that. We would give up some gains on patient-generated health data.

I just want to recognize that wholesale delay of Meaningful Use Stage 3 should be very thoughtfully considered in light of the items that we would impact, give up, that I know we all support.

Senator MURRAY. OK. Great.

Dr. Payne, in your testimony, you talked about enabling patients to receive an electronic copy of their entire medical record, that that would have the most genuine and lasting impact on smoothing

the flow of electronic health information. I'm really proud that in our home State of Washington, including the University of Washington, we are pioneering the Open Notes Project, which is working to give patients access to the visit notes written by the doctors and nurses that Ms. Bechtel just talked about.

Talk a little bit about how enabling patients to access and download their entire electronic record would improve the flow of information.

Dr. PAYNE. Well, just as the Open Notes Project makes sense, we think that providing access to the entire record also makes sense, and it's the right thing to do. The notes are very important, but elsewhere in the record are also pieces of information that are very important and that are still today very difficult for people to access.

If we set the standard that the record that is truly the right of the person to see is available to them, they will have other benefits beyond just reading the notes. We think there will be innovation that will be based on having access to the entire record that we don't see today. We think it is the logical next step, now that we have a good deal of the Nation's health record in electronic form, that the person who owns it has a right to see it.

Senator MURRAY. Well, in order to make sure that patients and clinicians have better access to electronic health information, we need to make sure that no one is deliberately blocking it.

Mr. Patterson, I'm glad that in your written testimony you agree. We need to prohibit data blocking. HHS tells us that it can be difficult to distinguish between contract terms and pricing policies that are normal business practices and those that are designed to deliberately block information.

In your view, can you share with us how vendors and providers deliberately block data?

Mr. PATTERSON. The word, deliberate, is a bit caustic from the way I think it actually happens today. I think their historic practice is we're not to share data. I think business strategies get in the way, and business models get in the way, saying, "I'm better off if I don't share it."

In my written testimony, I frankly, if it's you or your loved ones, and that information is vital, I consider it immoral for people to block that data and force us to carry it in bags. I think we're just crossing over into a new era. I think, as I said earlier in my oral comments, your asking that question, is extraordinarily powerful, and I think you should continue to talk about it.

We individuals, the citizens, the people who are served by the health system—those are our records, and I think you should pass a law that says we should have a copyright to that—we should have a legal standing in that information, because too many times, healthcare thinks it's theirs. They should have a copy, too. They produced it. It's a part of their—they have all kinds of reasons for that record.

But when it's digital, I can have my copy, too. I think it happens. It happens from a historical practice point of view. We need to change those practices or we're never going to get rid of the bags.

Senator MURRAY. Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. I should repeat that one of our next hearings this summer is on precisely the subject of who controls my data and how do I get hold of it. Senator Collins is going to chair that hearing for the committee.

Senator Burr.

Senator BURR. Mr. Richardville, why is this so hard?

Mr. RICHARDVILLE. Great question. There are actually multiple factors that makes interoperability difficult. First and foremost, it's technically complex. You have a varied amount of different systems that have different rules of the road that they're participating in, and we're expected to try to connect that information that they're producing together.

Second, in terms of prioritization, when you look at the incentives, especially those that came out through Meaningful Use, a lot of the investments that healthcare providers had to make—it was not one of the top incentives. When you have limited resources, looking to try to achieve things that you need to have done—those are things that kind of fall a little bit more down to the bottom of the list.

Senator BURR. What's your definition of interoperability, and is your definition different than anybody else on this panel?

Mr. RICHARDVILLE. I hope it's not different. My definition of interoperability is the open, free exchange of secured data between providers and patients, utilizing health information technology systems as the road to provide that kind of activity.

Senator BURR. Let me throw it out to any of you. Why would a provider not want to make a patient's information available to a patient?

Ms. BECHTEL. Well, I can tell you that when I asked for my health record electronically, I first had to convince them that I wasn't trying to leave the practice. They have real endowed business reasons, because of the way we pay for healthcare in a fee-for-service environment, to try to hold my data as a business asset so it's not as easy for me to actually go get an office visit somewhere else.

From a consumer perspective, it makes it much more challenging for me. Yet every piece of data says that if you give me my data, and you give me access to it, it actually increases my loyalty to the practice. Other folks may have comments.

Mr. RICHARDVILLE. You know, at Carolinas HealthCare System, our motto is patient first always. For us to engage and involve the patient in everything that we do is part of how we are able to move forward and progress.

The only thing that I would say in addition to what Ms. Bechtel has said is that sometimes some of the language and some of the data structures that are put in place may be difficult for a patient or a consumer to digest without some easier way to translate that into meaningful pieces that they can then absorb.

Senator BURR. Dr. Payne.

Dr. PAYNE. One friendly amendment to Craig's definition—I would add that interoperability includes the ability to use the information when it is exchanged. There are many ways to exchange information, some of which leave it dormant. If we make the ex-

change occur in a way that it's useful for its intended use, that's an important element of interoperability.

Senator BURR. Mr. Patterson.

Mr. PATTERSON. To have true interoperability nationally or get close to the ATM card functionality, there's really three things that have to be in place. One is there has to be an identification. When you're going to send Neal Patterson's record from physician to physician, provider to provider, there has to be an identifier of Neal. We do not have a national identification system in this country. It's a subject that's been discussed a lot, and it's one that's basically been tabled.

In today's world, we can solve that as an industry without you doing anything. But it has prohibited, because to curate who I am on the other receiving side is a lot of work. We lack a functionality around identification.

We lack a functionality—there's no place that knows where my records are, other than me, and, frankly, that's—you know, Jeanne has been to 35 different places. I can figure it out, but it's a—so we don't have a system that says where my records are.

And third, we really need a consent—everybody is very afraid—providers are very cautious of letting records out because HIPAA has some very stringent penalties in there around sharing information, patient information. We need a consent system.

Senator BURR. It's a shared feeling. We're scared about opening up HIPAA to try to tweak it, because it may become more cumbersome and more onerous.

Let me just say this to all of you. If you will think about, when you leave here, anything else that we might need to look at from a provider's standpoint that's a disincentive to sharing information, so that we know what we're up against as we begin to look at legislation, as regulators begin to look at regulations, I think therein holds the key.

If we're just down to an economic decision, Ms. Bechtel, I think we can find a trigger for that.

I've got to believe that there's more than that, and I think it revolves around interoperability in some way, shape, or form. It may be what they chose to put their electronic medical records in and their inability to merge that into something else.

I think that we're going to find things that are out there that maybe, by themselves, you wouldn't look at and say, "Here's the problem," but, collectively, they probably contribute greatly to this inability.

I thank the chair.

The CHAIRMAN. Thank you, Senator Burr.

Senator Warren.

STATEMENT OF SENATOR WARREN

Senator WARREN. Thank you, Mr. Chairman. So far, the Federal Government has invested $30 billion in electronic health records, in part because sharing health information between doctors can improve patient care. It's still the case that the health record systems can't always match a particular scan or test result to the right person, and mismatches can be very dangerous. As more patient information is stored electronically and as doctors exchange more health

records with other doctors, the risk of mismatching patient information goes up.

We've got at least two studies that I know about on this. A 2008 Rand Corporation study estimated that even with database management software and personnel that were dedicated to preventing such mistakes, hospitals mismatch patient information about 8 percent of the time. A 2012 study conducted by the Council of Health Information Management Executives found that one in five physicians encountered mismatched information that put a patient at risk during the previous years.

I would like to start—Mr. Richardville, can you explain to us what tools Carolinas HealthCare used to solve this problem?

Mr. RICHARDVILLE. Yes. CHS on many pieces are on the forefront of innovation. What we looked at several years ago and was the first, actually, to bring into the country was a biometric palm vein scanning system. It actually scans the veins in the palm. It's not a palm print, but it's the veins, like a snowflake, in the palm. We have that at all of our locations. We've had that for many years.

Since then, when you quantify like the 8 percent, our medical record number duplicator error rate is .11, which is 80 times better than the average that you talked about. At least within our system, we've been able to mitigate that issue.

As we try to match across the systems, I'm not saying that that is the answer for others. I think there's probably other successes in the country, and we need to put those heads together and see if there is a way that we can expand that across.

Senator WARREN. Let me ask the question about, then, among systems. Mr. Patterson, in your written testimony, you discussed CommonWell, an alliance of health IT companies that connects health records that are managed by different vendors. What has CommonWell done to avoid the mismatches? We've got between systems here.

Mr. PATTERSON. Right. In broad terms, CommonWell allows you to create an account that is used for—and you, as an individual, create it. You say, "Here's what consent I give to share my information, and here is my identification." It's like having your Google email account, and you are controlling that account as the person.

Senator WARREN. This is done patient by patient.

Mr. PATTERSON. Patient by patient at enrollment. Once you have that account—obviously, to start your first email account, there's a process to it. Once you have your identification, then information can be sent and moved. CommonWell has solved the identification problem on a voluntary basis.

Craig's solution is much more precise and elegant, but I do not think we can implement that nationally. I'm not going to—you'll have to have a hearing on that. That's much more precise.

Also CommonWell basically provides the software—we have near 30 members of CommonWell. All of us as software companies agree to also—when we record the fact that there is information about a person under that ID in our records at these locations. We solve the record location issue.

Senator WARREN. Carolinas HealthCare and CommonWell and others around the country are all working to prevent patient

matching errors within their own systems. There are obviously limitations on what you can do alone.

Mr. Patterson, I'd like to ask you: What can Congress or the Office of the National Coordinator of Health IT do to help scale individual efforts to reduce matching errors and at the same time to protect patient privacy?

Mr. PATTERSON. The ability to have an identifier that we all share would be an enormous help in reducing the risk and improving the value to patients. If it were possible for it to be simple to do and accurate, then it would happen more often, and I think patients would benefit enormously from that.

In the absence of such an identifier, algorithms that help us do the next best thing, which is to use existing information to make sure that we know who the person is when the information is sent or received, would also be very helpful. Much work has already been conducted in this arena.

It is a complex and very important question, and I'm glad that you are focusing on it. We also have people who come to us in our trauma center who are unconscious, unable to tell us who they are. It is a risk to them and requires enormous effort on the part of our staff to be sure we know who this is as we provide care to them in the safest way we can.

Senator WARREN. Thank you. You know, accurately matching health information to the correct patient record is critical for the safety and the effectiveness of electronic health records. I look forward to seeing more research in this area. I hope that industry and government can work together to find a solution that keeps patients safe and that protects their private health information.

Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.

Senator Cassidy, I've already noted that you'll be chairing a hearing for the full committee. I think Senator Whitehouse may serve as the ranking member for that hearing on physician documentation. We appreciate your willingness to do that.

STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. Thank you.

Mr. Patterson, you mentioned in your testimony semantic interoperability. Is that a challenge? Because it sounds like once you go through CommonWell, and you have this kind of ID that I volunteer and it goes to others, that there should be some sort of way to communicate. How much of an issue is that?

Mr. PATTERSON. Dr. Payne would be probably the subject matter expert on it. I'm very impressed—so there is work on standards to create the next level of interoperability. In my testimony, I call that semantic interoperability. It's one thing to move safely information about ourselves. For it to be consumed by the physician, if we can understand what's in that record and it can be worked into the——

Senator CASSIDY. Simply, as Ms. Bechtel said, not necessarily as a pdf but rather structured so I can follow blood pressure over time with some chart relative to medicine.

Mr. PATTERSON. Right.

Senator CASSIDY. That would somehow structure it between records.

Mr. PATTERSON. Yes, you've got it near—you are perfect on that.

Senator CASSIDY. Thank you.

Mr. PATTERSON. And that's a huge deal.

Senator CASSIDY. Will you talk to my wife about that and extrapolate the other things?

[Laughter.]

CommonWell, you mentioned in your testimony that all major players except one are participating in CommonWell. Who is the major player not participating in CommonWell?

Mr. PATTERSON. Epic is not participating in CommonWell.

Senator CASSIDY. Senator Murray asked about business practices, or somehow that developed in the conversation—is it deliberate or is it business practices. The effect is the same, that data is not—I feel like Epic is the elephant in the room.

It was implied in your testimony that a business practice which does not allow sharing somehow furthers their business model. If you want to share data with another Epic hospital, you have to have Epic, and they have such a market share that people will migrate. That's my opinion, but is that a fair opinion? Is that defensible?

Mr. PATTERSON. That would be my experience, that they would use that as a marketing technique.

Senator CASSIDY. Again, as Senator Murray——

Mr. PATTERSON. I might add that I believe—and I hope Epic will join CommonWell and that we work together as an industry. The only way this is going to get solved is that we work together.

Senator CASSIDY. I accept that totally. On the other hand, sometimes we set this up—I say Congress—giving billions of dollars, and now a major player is not participating in a common effort to create the sort of structured data that Ms. Bechtel would find so useful and that you agree would be a nice way to do it. We need to have them come to say it.

But that is a problem, and I say that as a physician who shakes my fist at the computer because I can't get the data that I need as I am seeing a patient. Let me ask, and I'll open this up. What can we legislate that would—if people don't want to come forward voluntarily—we can say you've got to—it's hard to say you have to participate in CommonWell, because CommonWell may become something different.

Mr. PATTERSON. Right.

Senator CASSIDY. Yet I have a sense that you prefer the private sector to be the setter of the standards as opposed to a Federal agency. Really, it may be that we have to have a Federal agency that says, "We shall solve these problems by this deadline or else we shall prescribe." Do you have opinions on that? Is that what's required?

Dr. Payne?

Dr. PAYNE. I think one move that we as a nation and Congress could take is to move toward reimbursement for value, for quality. If that movement accelerates, there will be a big drive for interoperability.

Senator CASSIDY. That just may be a big drive to continue business practices which say,

> "Listen, if you want to play, you've got to play with me because I'm the big guy on the block, and so, therefore, I'm the only person that can give you everything."

Dr. PAYNE. I think it would also be a strong incentive for industry, but also provider organizations, to use standards that exist now for interoperability. We should do a better job with interoperability——

Senator CASSIDY. I'm not sure you're answering my question. My question is: Do we have to be more coercive than we are now in order to crack it open?

Mr. Richardville.

Mr. RICHARDVILLE. I would say, Senator Cassidy, several things. One is I do think congressional action is needed so we can set up what I would call functional standards that we can all play by. I also think that the measures of the outcomes that was referred to needs to be part of it. Most importantly, is the enforcement. Make sure that compliance takes place as we start doing this.

In addition to what Neal Patterson talked about and with CommonWell, I do think there are a handful of other integrative efforts that are going on in play. We at Carolinas HealthCare System actually—one of the unique systems that we actually have—Cerner, Epic, McKesson, Allscripts within our system, and we've built a core competency of interoperability with our health information exchange to actually change information within our system with different vendor partners that we work with.

Senator CASSIDY. Does it cost you per transaction, or can you do that without charge?

Mr. RICHARDVILLE. It is not per transaction. It's per member. We pay based upon the number of people who actually participate in it. For us, as we have more physicians come into that, we actually pay based upon the people that consume and participate in our health information——

Senator CASSIDY. That's interoperability with a charge.

Mr. RICHARDVILLE. It's interoperability with a charge based upon usage.

Senator CASSIDY. OK. I yield back. Thank you.

The CHAIRMAN. Thanks, Senator Cassidy.

Senator Casey.

STATEMENT OF SENATOR CASEY

Senator CASEY. Thank you, Mr. Chairman.

I want to thank the panel for your testimony and for helping us to better understand and, we hope, figure out a complex problem.

I wanted to start this morning with children. We have over many years developed programs that enhance children's health insurance, whether it's in the Children's Health Insurance Program or Medicaid or otherwise. We often don't ask, I think, an essential question, which is—just as we do in the context of protecting the environment, we say, "What's the environmental impact of a particular policy?" or the environmental impact, more particularly, on a project.

We should ask the same question in the context of children: What will be the impact on a child or children if we take this step with regard to healthcare and, in this case, with regard to healthcare records? I wanted to start in a very particular way.

Dr. Payne, you've heard child advocates say for a long time that children are not small adults. We need to make sure that we have strategies and approaches to children's health insurance that may not be applicable or transferable from the strategies for adults.

In particular, I wanted to highlight immunizations, so critical to pediatric healthcare and also providing a great public health benefit. Access to immunization records is necessary to ensure that children receive the recommended vaccinations at the appropriate time.

What can you tell us in the context of this discussion with regard to the fundamental question, which is ways that having electronic health records that are interoperable—how can that improve access to immunizations?

Dr. PAYNE. That's a great question and a great example of the benefit of interoperability. In our report, we addressed just that issue, that there are a growing number of registries for children's immunizations, because children, as do adults, move from city to city, and those registries contain the record of their immunizations. Most importantly, the record tells us what they have not received so that we can make sure that they do receive it.

The challenge here is that the information in those registries is not flowing seamlessly into the electronic health records that the pediatrician or family doctor would use to look to see what's needed next. That's an example of where improved use of existing standards or refined standards would help children in a very direct way. This is an important preventative care measure, and we should make sure we use it every time it is appropriate for a child's health.

Senator CASEY. I want to open it up to the panel, if anyone else has any comments on this, and I'll have a followup for Dr. Payne. Anyone on the panel?

Ms. BECHTEL. Sure. I think this is a terrific use case for the kind of consumer demand for their health information that I was describing earlier. I think as moms and caregivers can begin to get and request an electronic copy of their health information from their doctor, they can begin to catalog those things, and, at least, until we fix the standards and fix the registries, I can build a comprehensive list of my immunizations. I can share that with my provider. I can manage that. I can set alerts when things are due.

It really enables me as a caregiver to have a much more complete picture of my child's health, including immunizations. Enabling that kind of consumer demand, that pulling on the rope right now, would be a really essential strategy to make very quick progress in the short term.

Senator CASEY. I appreciate that.

Mr. PATTERSON. I might add that immunizations is a very good example of something where IT creates a lot of value. Immunizations at birth—you know for the next 7 years when, approximately, immunizations need to be done. The systems should know what—not just help document what is happening. It should know what

isn't happening, and it should be able to then report back to the pediatrician, report to the family that these events need to happen.

There's just too much reliance on well-intended—and the systems are increasingly getting smarter—would need to get smarter. That's a great example of population health.

Senator CASEY. I appreciate that. I'm almost out of time. Maybe for a fuller answer to this question, I'll start with Dr. Payne—or I should say a fuller answer from everyone. It might be better just to put it in the record.

I wanted to ask, in the context of transparency, what can we do more broadly now—not just with regard to children, but more broadly—to increase transparency as it relates to electronic health records? If you can give a short answer, and everyone else can put it in writing if that's all right so I don't get the chairman upset.

Dr. PAYNE. I think you can highlight its importance and its value and encourage other regulatory bodies to embrace it.

Senator CASEY. Thanks very much.

The CHAIRMAN. Thanks, Senator Casey.

Senator Franken.

STATEMENT OF SENATOR FRANKEN

Senator FRANKEN. Thank you, Mr. Chairman.

I'm co-chair of the bipartisan Senate Rural Health Caucus, and I've had a lot of roundtables around Minnesota—I think about 30 between me and my staff having roundtables. At practically every roundtable, they bring up this issue of health records, electronic health records. In rural America, we have a lot of small providers, and one of the issues is the up front cost.

I guess this is for Mr. Patterson, since you're in this business. Even those who can afford the initial investment are often sort of—end up with the most basic out-of-box product because they don't have the resources or the influence to demand a custom tailored solution from vendors.

Are there ways that EHR vendors like Cerner can structure their sales models to help lower or eliminate the up front cost of implementing a new EHR system?

Mr. PATTERSON. You're talking to an old farm boy, and rural health is actually on my, if you will, professional bucket list to fundamentally make a difference in. We have been very aggressive in using kind of shared services and shared domains to create as low price points as we can to get out into critical access in smaller facilities. It's been, frankly, fairly successful, both from the client side and from our side. Yes, they're on very thin budgets, and I started that—they get advantages of very sophisticated technologies.

My wife's brother, who is still the farmer down there in Oklahoma, unnecessarily died from sepsis. I went to the local healthcare community and said that didn't need to happen, and sepsis is a predictable condition. That community now has an intelligent set of algorithms looking over the entire community and identifying the people that look like they're on a path to become septic, and it has fired over 60 times this year. It would have saved his life.

They need, really, everything we talk about. You've got to create business models and get low price points.

Ms. BECHTEL. Senator, if I might, I think one of the things we haven't really addressed—yet it plays a huge role in all of the challenges that clinicians and other providers are facing—is the fact that we don't actually pay for and reward the kind of care that clinicians can deliver when they're enabled by health IT and by an interoperable system.

Senator FRANKEN. Sure.

Ms. BECHTEL. The up front costs would be worth it, as they were for the banking industry, right? If we were able to start paying for coordinated care, paying for health outcomes, paying for better patient experiences, I think it would drive this discussion in a far different direction. The banks didn't struggle with standards for 30 and 40 years as we have in healthcare, right? We didn't actually talk ever about bank IT.

Senator FRANKEN. Well, this is supposed to lead to savings. This is supposed to lead to coordinated care. This is supposed to lead to value. I think the next questioner has some thoughts about that. Senator Whitehouse does.

I want to talk about interoperability. Why, why, why can't the VA and the Defense Department become interoperable? This is just a mystery to me. A lot of resources have been spent trying to do this. Does anybody have any thoughts on that?

Mr. RICHARDVILLE. Senator, if I could just make a couple of comments, I do think that the lack of the standards, functional standards, in place that allows this transport of data back and forth between systems is difficult. It is expensive. You talked about the EHR with the rural facilities. We look at interoperability. It's just as expensive and complex to try to connect them to other care providers when they do referrals back to other complex organizations. Until we actually have the government action in place to help us to have the functional standards, the measures, and the compliance to take place, we're going to have this difficulty in this country.

Senator FRANKEN. These are two government entities that are dealing with the same population. If they can't get it together, I don't understand how we're supposed to be optimistic about us setting standards. I'm out of time.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Franken.

Senator Whitehouse.

STATEMENT OF SENATOR WHITEHOUSE

Senator WHITEHOUSE. Thank you, Chairman.

This is such an important issue, and Chairman Alexander and Ranking Member Murray have embarked on a committee-wide process to take a look at health information technology and information exchange. I would invite each of you, in terms of what a law student would call issue spotting, to feel free to send in to us the list of issues you think our process should be sure to be addressing, even if you haven't had the chance to get to it in this hearing. I know that we would be interested in that.

My particular concern comes from my Rhode Island experience. Many years ago when I was the attorney general in Rhode Island, I established an organization called the Rhode Island Quality Institute, and we embarked on, first, electronic prescribing and then

electronic health records, and now full-on health information exchange through a nonprofit organization called CurrentCare which has been very effective in terms of how broadly it has reached out and connected all the providers, connected with the Epic system in both of our major hospital chains. It's been quite good.

Here's my concern. We've spent an enormous amount of money on Meaningful Use. Most of that has gone to end users, subsidizing the machinery on the doctors' desks. We kind of take a bank shot off of that back into the information exchange piece by defining Meaningful Use in ways that require things to happen.

For a lot of those providers, the healthcare providers, they don't really have a big say in whether or not there's a statewide health information exchange in their State. They just have to sort of live with the consequences of whatever their world is.

Rhode Island has worked really hard to get the health information exchange up and going. I think they've done a terrific job. I believe that they've won every available grant every single time that there's been one available. Even with all of that, they've had such a heavy load to carry. It's like this little donkey trying so hard at the head of the pack with all these burdens of solutions that have to be achieved, and the Federal Government kind of over there in the next field throwing billions at Meaningful Use and not paying as much attention as it should to those States and those localities—it's not always a full State—that are really trying to get the exchange piece right.

If you're going to have health information exchange, I think there has to be an exchange. Maybe it can happen in the cloud. I think it works a lot better if there's actually an exchange, and I'd love to hear your thoughts on how, as we reconsider a Meaningful Use 2.0 or try to reboot this issue—how should we be focusing on exchange?

The easy way to do it is to give money to big systems, and then they exchange data within the system, and a CEO gives a rule, and everybody complies. It gets harder when you're doing it by State, and you've got a whole bunch of people together. I think that's where we have to end up, is with cross-corporate exchange, and it seems to me that that is something that needs direct attention, not just the attention of conditions being put on Meaningful Use.

If you could take that right down the line, starting with Dr. Payne, I'd appreciate it.

Dr. PAYNE. I agree with your premise that we're really after health information for its being used, and exchange makes that happen. I think one element that would really help with exchange would be to include the patient in that so that they get the entire record, because we will not be able to anticipate all the uses they might have for that.

I think also that for critically ill patients who need exchange of information, such exchanges as you described in your region would be incredibly helpful. There are other solutions, also. I'll be brief. We have much more information we can provide because we agree with you that that is really how we're going to get the best use out of these systems that we've invested so much in.

Senator WHITEHOUSE. Mr. Richardville.

Mr. RICHARDVILLE. Yes, thank you. I would make two points. One is we talked earlier about the patient match or the patient ID. We have to solve that problem. It's a foundational component of exchanging information back and forth in between providers.

And second is how we do it. We have to do it in a very cost-effective way. Today, it's onerous and it's very expensive, and many cannot afford to do what some other systems have been able to do. For me, it would be kind of moving toward the open API, a more innovative type of technology, to allow you to freely share information back and forth.

Also, it allows innovation from other companies who actually have access to that as well, and they can start generating apps and other things for patients and others, but it can also consume the data from the different EMRs that we've all installed and put together. Those would be the two components.

Senator WHITEHOUSE. Ms. Bechtel.

Ms. BECHTEL. I couldn't agree more. Far as I understand it, ONC has invested about $570 million in State health information exchanges, so that pales in comparison to the Meaningful Use price tag. No question about it. They have tested a couple of different models, one, of course, that looks a lot like—suspiciously like Rhode Island's.

Also is consumer-mediated exchanges I testified to earlier. This is certainly an area where I think Congress could help invest in developing the infrastructure further.

Senator WHITEHOUSE. Mr. Patterson.

Mr. PATTERSON. Finally, I might be a bit contraire in here, but I think you all pioneered some real meaningful work in Rhode Island. You implied, though, in your statements there's not a fundamental business model for the exchange. It has to either be financed through grants and/or through the healthcare providers that are exchanging information.

The people that are actually benefiting from the information aren't actually funding that. It did not solve all of the fundamental—so you still are curating an identification—identification is still an issue, and it's part of the cost of you running it.

What we're saying is through standards—and then get the software manufacturers—people who make software and sell into these marketplaces—and if CommonWell is not the answer, show it—I think we need a national system, because you've got boundaries. You've got water on one side but you've got boundaries on the other side, and people are transient. We need a national approach to this and one that is sustainable.

Senator WHITEHOUSE. Chairman, thank you for the hearing. I think this is very helpful and constructive, and we clearly—I think one thing that the witnesses will all agree on is that we have work to do.

The CHAIRMAN. Well, thank you, Senator Whitehouse. I mentioned earlier that I thank Senator Cassidy, who I've asked—and you, who Senator Murray has asked, who will chair a hearing on physician documentation later, and that will be an important part of what we do.

Senator Murray, do you have any final comments?

Senator MURRAY. I don't have any additional questions. I just want to thank all of our witnesses for being here today. I think this is really a critically important conversation. I think we all know that effective health information technology is really essential to improving quality and the cost of care.

We've got to find a way, and the best way, for providers and patients to share information securely and efficiently in order to get people the best care possible. I'm really glad that we're making this a bipartisan priority on this committee and doing the work that I think is so important to get us to a better place. Thank you.

The CHAIRMAN. Thank you, Senator Murray. This has been very helpful. I think you can see that we're pretty committed to this, given the amount of time we're spending on it, and that we're working in a bipartisan way, not just among ourselves, but with the Administration.

Of course, the best way to solve whatever problems exist are, first, for the community to do it itself, for the industry to do it itself; second, for the Administration to be able to do it; and, third, we might have to pass a law. In my view, those are the steps of preference.

Just so I can get it clear, Mr. Patterson, you held up an ATM card. Would you say this is the goal, that a patient-centered electronic medical system—that the goal is that I would have the ability to have all my medical information on a card? If we started from there and worked back to where we are today, would that be the way to think about this? Or am I simplifying it too much?

Mr. PATTERSON. I think it is the goal, but it's the fact that the real information about what my bank account is isn't on that card. We have to have a way of identifying ourselves in accessing highly critical information at almost any point, any time.

The way the ATM system works—that card does not have your bank balance on it. That bank balance is somewhere—I don't want to say in the cloud, but it is on a database. If you're in France, you're not going to get——

The CHAIRMAN. If the card works, the bank needs to know my bank balance.

Mr. PATTERSON. That's what I'm saying. I'm just saying your bank balance isn't on the card.

The CHAIRMAN. What I'm really trying to get at is there are different ways to approach this. One way to approach it is from the point of view of what you do, or the point of view of what each of you do. The other way to think about the whole thing, it seems to me, would be to start with this and work back to all the other issues that there are.

Mr. PATTERSON. I don't disagree with that. At least, it should work as simple as that.

The CHAIRMAN. As I'm hearing you, what you're saying—and I think Senator Cassidy's comment was an important one, and I haven't made my mind up about this yet. Do we need to do something to cause to happen here what needs to happen, for example, standards for all the people who do what Mr. Patterson does, to work together?

My very strong bias is that the less we have to do, the more efficient it will work. The ATM card probably doesn't work because of

a law that Congress passed. The terrific airplane reservation system that we enjoy every day probably doesn't work because of anything we did, and if we had done it, it probably wouldn't work as well.

What we need to know from you is what are the things that we have to do to get you to do it? That is the question, and we don't have to know that today. It sounds like standards is one of those. My bias is that we are better as enablers rather than mandaters—the government is, and that the more we have to mandate, the less successful we're likely to be.

Senator WHITEHOUSE. Mr. Chairman.

The CHAIRMAN. Yes, Senator Whitehouse.

Senator WHITEHOUSE. Can I address your point just for one moment?

The CHAIRMAN. Sure.

Senator WHITEHOUSE. I think that having the card and having a mechanism by which the individual patient has access to their data is one of the important goals that we need to achieve. I think we also need to achieve the goal for the patient who is unconscious, who is very elderly and perhaps at the end of their life, who is perhaps not at their full mental capacity, to have the data system work, even when the patient is not a participant.

I think we've all had the experience, either ourselves or with loved ones, of being in a hospital and having to be there at the bedside to help manage what's going on just in that hospital, just for that patient. I think there are two goals. One is the ownership and command of information by the patient themselves, and the other is a system whose information support will take care of that patient even when they are alone and incapable and eliminates a lot of the confusion and misinformation that bedevils modern complex practice.

The CHAIRMAN. Dr. Payne mentioned that example, and I see what—Ms. Bechtel, I wonder if you are thinking something.

Ms. BECHTEL. I am, always. How did you know? I think that, conceptually, you're right. The challenge is I have two ATM cards and three credit cards in my purse. My bank card isn't linked across the data systems. What is, though, is Mint, right, Mint.com, where I can connect it to all of my accounts. We still do need the electronic—the systems to connect to each other.

I think you're fundamentally right, which is this is my electronic health record right now, and I can add to it in this particular version. It's not particularly secure. You saw Neal grabbing it earlier, and I hope I don't lose it today. The concept that I described around how consumers can ask for, aggregate, and hold their health information, at least in the near term, would start to unlock that data and enable me to share it with the providers who do need it and who can rightly have access to it.

Mr. RICHARDVILLE. Senator, if I could add to the comment, I do think that where we're moving toward, or where we'd like to move toward, is truly changing the culture of how health and care is looked at by the patients and by other consumers, and really move that to be part of your daily life. One aspect of doing that, like we've all done with our smart phones and with apps, for those that have those—and it keeps growing and growing—is that open API

infrastructure that allows people like Mint.com and others to grab that information and present it back to the patient or back to the provider.

The action that we need is to help support us to move this so this becomes part of the rhythm of life. You wake up every day. You check your email. You check your texts. You check your Facebook. You need to check your health status, and this is part of what we want to try to incorporate as we continue to move toward the value-based system of prevention.

The CHAIRMAN. Dr. Payne, everyone else has had a last word. Would you like to?

Dr. PAYNE. I would just add that innovation can help in coming up with ways to solve this problem. I agree with your approach that we want to have something we can work toward that's practical, and the way to come up with that is probably to leverage the ideas of people who are not at this table and maybe not even a health IT at the moment, but are clever people who can help us solve that problem. Our report encourages the development of innovation to help solve some of these problems.

The CHAIRMAN. Senator Murray, anything else?

Senator MURRAY. No.

The CHAIRMAN. Thanks to all of you. It seems to me a couple of unresolved questions that I'll be looking for answers to are, No. 1, to followup on Senator Cassidy's point, to what extent do we need to use coercion to cause things to happen so that you can do what needs to be done? And, No. 2, I take the point about delay of the Meaningful Use 3 regulations. There's probably some downside to that.

For something that seems to have as much resistance right now and as much need to improve, human nature tells me that it may be better to step back a little bit on at least some parts of the rules and work with physicians and vendors and hospitals and take some advice about how to improve things, and then once they're better, to accept and go forward. We want to do this as rapidly as we can. We don't want to lose the impulse to cause people to do this.

At the same time, the more important thing, I would think, is to make sure that we get it done in a way that causes patients, doctors and hospitals to look forward to the experience of this system rather than to dread it. If you have, after you leave, specific suggestions about these parts of the regulations that absolutely not be delayed, these parts might be delayed while we continue to work together to try to improve them, that would be very helpful.

The hearing record will remain open for 10 days. Members may submit additional information if they would like.

The next hearing will be Achieving the Promise of Health Information Technology: What Can Providers and the U.S. Department of Health and Human Services Do To Improve the Electronic Health Record User Experience? That's the one which the shorthand name would be physician documentation, and Senator Cassidy and Senator Whitehouse will chair that. Senator Whitehouse will be the ranking member on that hearing.

Thank you for being here today. The committee will stand adjourned.

[Additional Material follows.]

ADDITIONAL MATERIAL

JULY 14, 2015.

To: Alicia Hennie, Health Policy Advisor, Sen. Alexander (R–Tenn.); Colin Goldfinch, Health Policy Advisor, Sen. Murray (D–Wash.)

From: Jeffery Smith, Vice President Public Policy, AMIA

Re: Strategies to improve interoperability of health IT through changes to certification and adoption incentives

This memo outlines ways to amend and enhance Federal health IT policy to further widespread interoperability. Recommendations focus on ONC's Health IT Certification Program and potential changes to CMS's incentive structure for meaningful use and other value-based reimbursement programs.

ONC HEALTH IT CERTIFICATION PROGRAM

As part of the HITECH Act, the Office of the National Coordinator (ONC) for Health IT established a health IT certification program to help "ensure that health IT conforms to the standards and certification criteria adopted by the Secretary of Health and Human Services."[11] The Federal health IT certification program is meant to provide assurances to users that the technology meets certain capability, functionality and security requirements adopted by HHS, and provides assurance that the products are interoperable (the systems can exchange information and use that information for a specific purpose once it's received). As the Federal Government's only policy lever to impact the technical development of information technology in healthcare, ONC's Certification Program should be seen as vital pathway to improve interoperability, usability and patient safety.

Recommendations

- Improve interoperability through more robust testing.
  - Require interoperability testing on *both* the sending and receiving of data.
  - Incorporate exception handling into EHR certification.
  - Develop C–CDA guidance and tests to support exchange.
- Contract for—or otherwise solicit—testing methods from developers and other stakeholders.
  - This is a current policy option, but ONC has had limited success engaging with others to help develop testing methods.
  - Without more "skin in the game" vendors may continue to "develop to the tests" that government policymakers design.
- Force transparency into obfuscated market.
  - Require additional information to be submitted for, or captured during, certification testing, and make these publicly available. This includes:
    - Establish greater transparency and uniformity on UCD testing and process results.
    - Screen shots and/or video of workflow configurations.
    - Screen shots and/or video of exception handling with data provided by testing body, *not* the developer.
    - Participation in on-going interoperability testing with an ONC–ACB or other entity, as designated by the HHS Secretary.
  - Require ONC–ACBs to conduct post-market surveillance through *in situ* testing.
    - This will require resources and agreement on how to test, which will require stakeholder buy-in.
    - This is in keeping with anti-information blocking efforts.
  - Promote pathways and protocols for users of certified technology to report information blocking.
- Provide regulatory clarity and certainty to an emerging market.
  - Support ONC efforts around the Standards Advisory and regular updates to Certified Health IT Editions.
    - This supports policies already underway at ONC, but will require ongoing leadership when the inevitable pushback comes.

[11] ONC Health IT Certification Program, "About the ONC Health IT Certification Program," *http://bit.ly/1FLG7ip* accessed June 11, 2015.

- Make ONC develop a multiyear—3- or even 5-year—Edition development plan.
  - This would be similar to a vendor's product development plan and it would help vendors know what to expect long before its officially proposed as part of a regulation.
  - An example might be a certification for LTPAC or behavior health, improvements to quality measure report generation, etc.
- Limit the scope of ONC certification to areas with a "demonstrated need".
  - This will help assuage fears that ONC will start certifying everything in health IT and it would create an opportunity to define some kind of rationale identifying circumstances when certification would be more harmful than helpful.

CMS INCENTIVES: MEANINGFUL USE AND OTHER VALUE-BASED PAYMENTS

Should ONC make substantive improvements to its certification program, it will not have the intended impact unless there are continued incentives (positive and negative) to drive further adoption of health IT and to compel continued upgrades of certified health IT technology. While we acknowledge that financial incentives are not the domain of Senate HELP, we felt it was important to complete the logic model of how to improve interoperability from a policy and program perspective.

Recommendations

- Provide relief to a highly regulated sector of the economy.
  - Prohibit CMS from issuing a final Stage 3 rule until at least 60 percent of EHs and EPs are successfully demonstrating Stage 2 (as defined in an upcoming rule—expected August 2015).
- Provide incentives rather than deadlines.
  - Sunset MU penalties and make CMS incorporate MU "status" as part of reimbursement updates ala MACRA/MIPS.
    - This provides long-term sustainability in incentive to participate in the program; without which all other policy levers are substantially weakened.
    - Hospitals are not impacted by MACRA and so their market basket update would be a good candidate to make this happen.

RESPONSE BY THOMAS H. PAYNE, M.D., FACP, FACMI, TO QUESTIONS OF SENATOR ALEXANDER AND SENATOR MURRAY

SENATOR ALEXANDER

Question 1a. Many stakeholders have suggested that the health information technology industry could come up with many solutions to the problem of interoperability on its own. However, so far, we are stuck with a system that does not work even though the government has spent over $30 billion.

What areas would be best determined by private industry? What areas should the government decide, if any?

Answer 1a. **Overview:** Americans benefit when their health information is available when and where needed. To get there, the private sector should be responsible for developing technical standards to support interoperability that have consensus across stakeholders. The government should help convene stakeholders, support pilots and enforce adherence to standards—their use in certified products, their implementation in provider settings and their application toward the widespread use of "open" EHRs.[1] The government should also continue to create and integrate incentives for use of health IT as part of evolving alternative payment models. Further, the government should conduct a full review of Federal and State privacy laws, harmonizing legal inconsistencies, correcting misinterpretations and prosecuting bad actors who inhibit exchange or improperly disclose information.

Detail: The current state of interoperability cannot be addressed solely by the health information technology (health IT) industry. As you and your committee have heard, the lack of interoperability—the ability of two or more systems to exchange data and *use that data to care for patients once exchanged*—is a multifaceted problem. Numerous technical, business and cultural barriers have converged to inhibit

[1] Sittig DF, Wright A, J Am Med Inform Assoc 2015;0:1–3. doi:10.1093/jamia/ocv060.

the free flow of information in healthcare and nothing short of on-going public-private collaboration will change this current State of challenges.

Policymakers should focus their efforts on refining the mechanisms and policy levers already at their disposal and consider augmenting those levers with new ones. Specifically, the Federal Government's primary policy lever when it comes to interoperability is the Federal Health IT Certification Program and health IT adoption incentives. Certification has the potential to produce harmonized technology that conforms to foundational standards upon which developers can innovate and augment technology for their customer's needs. This has always been the goal of the Federal certification program, but only recently has it been possible.

Prior to 2012, there was no national conversation, nor agreement, on standards prerequisite for interoperability: namely, content standards, vocabulary standards and transport standards. Prior to 2014, and perhaps even true to this date, the technology bundle containing these standards—the 2014 Edition of Certified EHR Technology (CEHRT)—had not been widely adopted, as required for Stage 2 of meaningful use (MU). Also, prior to 2014, no hospital or physician had met the objectives for Stage 2, which included process requirements to exchange health information across care delivery settings and technology platforms. According to the most recent data available from the Centers for Medicare & Medicaid Services (CMS) only 36 percent of hospitals and 10 percent of eligible professionals have met the requirements of Stage 2, using the 2014 Edition of CEHRT.[2] Moreover, 91 percent of hospitals and 82 percent of professionals chose to defer the requirement to send a summary of care record at transitions of care, which is the process requirement in MU Stage 1, preceding the most straightforward "interoperability requirement" in Stage 2 to electronically send a summary of care record at transitions of care.[3] In other words, the ecosystem of technology and processes which would demonstrate interoperability to a degree worthy of $30 billion in taxpayer investment is highly underdeveloped and the vast majority of providers do not even practice the processes laid out in regulation that would move data from place to place. This is true even without considering the business and policy barriers that inhibit interoperability.

I will not go into detail here, but as it pertains to your question, Congress should continue efforts to change Medicare & Medicaid fee-for-service reimbursement by helping CMS develop, evaluate and scale alternative payment models. Changing how we pay for care can lead to great advances in interoperability. Congress should also reassess Federal & State privacy laws—with broad input from patients, providers, researchers and the informaticians who support them.

In my testimony, I mentioned the need to,

> "streamline the Federal health IT certification program so that the process is more flexible, more transparent, focuses on clinically relevant functionality, and tests for true interoperability."

The practical application of this phrase is provided in a memo developed by AMIA staff, and included as *an enclosure* to this response, but I would reinforce the notion that to improve interoperability, Congress should focus on improving ONC's certification program, especially as it relates to testing for interoperability, and reconsider ways to incentivize further adoption and continued upgrade of certified health IT technology.

Finally, Congress should embrace the notion of "slowing down regulation to accelerate progress on EHR usability, interoperability and innovation." Federal regulators should not rush to get to the next stage of meaningful use, but should instead work to help the private sector accelerate optimization of the tools and regulations that are already in place. Again, the *enclosed memo* goes into more detail, but I reiterate my previous statement that Stage 3 rules not be finalized in haste. I believe it is imperative that Congress keep MU requirements, with penalties for noncompliance, in place over the near and mid-term. The forthcoming "meaningful use modifications" rule has proposed a number of changes to help streamline and simplify participation.[4] These changes would apply to the current program year through to 2018 and they will give providers a stationary set of requirements while technology optimization and workflow enhancements occur.

Question 1b. Does the government need to set deadlines or otherwise encourage industry to make decisions?

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[2] Centers for Medicare & Medicaid Services, "May 2015 CMS HITPC Report," *http://go.cms.gov/1MhJ924* (accessed July 9, 2015).

[3] Ibid.

[4] Centers for Medicare & Medicaid Services, Notice of Proposed Rulemaking (CMS 3311P) *http://go.cms.gov/1HqJNqV*.

Answer 1b. **Overview:** Deadlines are not as impactful as providing strong incentives.

Detail: Both positive and negative government incentive programs have been successful in converting health information from paper to electronic form. This was necessary for interoperability, but not sufficient. There have also been encouraging efforts for greater interoperability in the private sector, such as CommonWell Health Alliance,[5] the Sequoia Project[6] and others. However, the vast majority of work—and all of the regulatory consequences—of exchanging and using healthcare data falls to hospitals, physicians, clinics, and other providers. And few are happy with the result we've achieved to-date. Today, the best way to ensure data can be used at the point of care across settings is to have a single EHR vendor across all settings. This single-system approach is counter to prevailing trends in technology, which allow for substitutability and modularity. The most successful utilizers of information technology know that diversity is far preferable than expecting one system to do all functions well. But adherence to common standards is prerequisite for a diverse ecosystem to work.

As an example of the current state, there are enormous national meetings for customers of EHR vendors. There is no comparable meeting devoted to interoperability across EHR vendor products, or in caring for patients whose health records are dispersed. The unspoken message is that the simplest route to interoperability is to use one vendor, but this does not fit how Americans live and receive health care. And this is where government can help.

Incentives should be changed so all government-certified EHR vendors whose products are used to care for Medicare/Medicaid beneficiaries work together to have the same rapid advance in interoperability that we have seen in EHR adoption. This doesn't mean government creates interoperability. It means government moves the market toward rapid rise in interoperability.

New incentives are not needed, nor are heavy-handed penalties. The recently passed MACRA may provide a template for incentives that can be long-lasting and impactful. For physicians participating in the Merit-based Incentive Program System (MIPS) meaningful use penalties will sunset in 2018, and participation in MU will constitute ¼ of a composite score that will determine a physician's reimbursement rate. This dynamic provides a pay increase for successful participation in MU, which is significant because there are very few—if any—incentive dollars left from the HITECH Act in 2018. For physicians participating in MIPS who fail to meet meaningful use requirements, they forego the possibility of obtaining a full increase in payment, but it does not necessarily translate to a penalty, or a negative payment adjustment.

Congress should look at this model and determine if a similar approach can be used with hospitals and clinicians not participating in MIPS. Increases to hospitals' market basket update, or additional funds for ACOs, bundled payments, et cetera, could be leveraged to encourage participation. Nonparticipation will not be penalized, yet money will be "left on the table," so to speak. Key to this recommendation is adjusting the meaningful use "all or nothing" paradigm where providers must meet all requirements or receive no incentives/full penalties. Such flexibility will be needed to keep providers engaged in the *only Federal Government program* that dictates use of modern information and communication technology in healthcare.

Likewise, Congress needs to examine ways to incentivize—or compel—interoperability between and among competing EHR developers as a business imperative, rather than just pressuring providers and care delivery system.

Question 2a. If you could change all or parts of the rules for Stage 2 and 3 of Meaningful Use and the 2015 certification rule, what would you change?

Are there particular parts that should be delayed and others that should go forward? What changes would you make to them?

Answer 2a. On the macropolicy level, the "Stage 2 modifications" rule, issued by CMS April 10, 2015, should be finalized as soon as possible and it should be finalized largely as proposed. The certification rule, likewise should be finalized on schedule and according to general consensus received through the open commenting process. Stage 3 meaningful use rules should not be finalized until 2018—at the earliest—or until 60 percent of EHs and EPs are demonstrating Stage 2 as modified. This dynamic keeps provider requirements set for a time where technology and workflows can be optimized to deliver on the promise of modern communication and information technology. It also allows for ONC to move forward with updates to cer-

[5] *http://www.commonwellalliance.org/*.
[6] *http://sequoiaproject.org/*.

tified technology to incorporate fixes to known "bugs" or to accommodate emerging national standards.

On the program design-level, participation in meaningful use cannot continue 365-days per year *ad infinitum*. Much-needed downtime for upgrades, bug fixes and workflow re-design is necessary during any, and most likely every, year. For this reason, and for related reasons of patient safety, CMS should not require 365-day EHR reporting periods, but something closer to 180-days or 270-days. Likewise, more flexibility needs to be built into the program by removing the "all or nothing" construct. Especially as the program is integrated into MIPS, there are rational policy changes that could allow for this to happen because meaningful use becomes part of a composite score dictating reimbursement. A rudimental example could be that if a physician meets 80 percent of MU objectives, they receive 80 percent of the available meaningful use points that are part of the composite score.

On the program content-level, it will be difficult for various stakeholders to agree on all the necessary program components. Meaningful use was developed with broad input from various stakeholders and because of this, it has requirements important to many groups of health professionals and patient advocates. The problematic areas of the program are well-documented—patient action requirements, such as patient portals and secure messaging and summary of care requirements for transitions of care are among the most often cited. Despite the challenges associated with these objectives, they have strong support from different segments of the stakeholder community, and they have illuminated technical, cultural and business barriers that are signals of progress. We would not be as cognizant of our "interoperability problem" without the requirement that data be exchanged and used after transitions of care—or at least we would not know the extent of the challenge.

Question 2b. Do you think that the proposed rules will make health information technology better? If so, which parts?

Answer 2b. The degree to which MU and the Federal health IT certification program have advanced the ecosystem for health IT cannot be overstated. The regulations have served as an important catalyst and the work to develop and implement them has enabled the entire sector to evolve at an incredibly fast rate. We can't exchange health information electronically if it is on paper. The proposals in question will undoubtedly have a positive impact on the health IT landscape, but they will also engender more disdain unless they are implemented properly—at a pace the industry can handle and with flexibility to accommodate a dynamic system.

Specifically, the Stage 2 modifications rule will make several changes to remove topped-out measures and provide a single definition for all providers beginning 2015. Keeping the requirements steady for a period of 3 to 5 years will give providers time to optimize the technology they have and developers the time to innovate on the versions already deployed. Lowering the patient action thresholds, while controversial, is the right step absent a more nuanced conversation over how to encourage—and measure—patient engagement.

ONC's 2015 Edition Certification rule contains many proposals that should improve the State of health IT, including:

- A proposal to expand the ONC Health IT Certification Program to additional types of care and practice settings;
- An expansion of existing surveillance efforts of health IT under the ONC Health IT Certification Program, where ONC–ACBs (authorized certification bodies) would conduct annual randomized in-the-field surveillance;
- A significant expansion of health IT developer transparency and disclosure requirements for certified health IT;
- Expansion on the 2014 Edition transitions of care criterion by using updated C–CDA standard and requiring capabilities to detect valid and invalid C–CDA documents;
- Enhanced requirements for data portability to facilitate the accessibility and exchange of data; and
- A new requirement that health IT would have to demonstrate that an API responds to data requests for any one, and for all, of the data referenced in the Common Clinical Data Set (CCDS). This criterion would rigorously assess a product's C–CDA creation performance (for both C–CDA version 1.1 and 2.0) when presented for certification for exchange capabilities.

The net-effect of these changes should be more usable, safer and more interoperable health IT. However, passing a regulation with these changes does not ensure these outcomes. Developers must build technology that performs these functions in a way that corresponds with how care is delivered; providers must adopt, implement, test, train and use the technology as its intended and a large share of providers must do this before the impacts will be noticeable.

Question 2c. Are there any parts of the proposed rules that you think would make health information technology worse? If so, which parts?

It may be premature to know which parts of the proposed rules will make HIT worse, but there are a number of proposals that necessitate close watch; that will be very difficult to operationalize and scale; or that will create stress on an already-stressed system. For example, the Stage 3 proposed requirements to incorporate patient-generated health data and requirements related to "clinical information reconciliation" fall across several of the aforementioned categories. There are well-documented use cases where PGHD or reconciliation have added value and safety to care, but these are domains with little experience and immature standards.

SENATOR MURRAY

In your testimony, you suggest that in order to,

> "see the same success that we've seen in the internet, we need a stable base of standard building blocks that allows us to create new technology to benefit patients."

You also note that these "building blocks" will support the development of new electronically specified clinical quality measures to help streamline and improve Medicare's quality incentive programs.

Question 1. How would these building blocks allow for the development of better measures and streamlined processes for reporting electronically specified measures? Could they help align reporting requirements across quality reporting programs and accelerate interoperability between electronic health records and registries?

Overview: Congress is well-positioned to help advance quality measurement in healthcare by moving toward outcomes-based clinical quality measures (CQMs) and by supporting technical improvements to CQMs produced in the digital age. Given Federal plans to accelerate toward reimbursement based on value and outcomes, rather than volume, now is the right time to think systematically about quality measurement. This means simplifying the process, streamlining the number, and harmonizing the types of CQMs required for public reporting. Alignment of CQMs across programs is largely a policy issue; whereas the need to generate accurate and complete CQMs, and accelerate interoperability between EHRs and registries is a technical one.

In order to accelerate development of quality measures to improve Medicare's quality incentive programs, and to improve interoperability between EHRs and registries, policymakers must take three important steps: (1) review and adopt a national format standard for common data elements (CDEs) used to generate CQMs; (2) simplify quality measures by rethinking exclusion criteria for CQMs and (3) improve the quality of data in CQMs by encouraging broader adoption of up-to-date EHRs.

Detail: Similar to the internet, there are foundational "building blocks" that support flexible, standards-based interoperability. For health IT there are five building blocks that we need to facilitate standards-based exchange of information and streamlined interoperability:

1. Standardized Meaning
2. Standardized Format (or structure)
3. Standardized Transport
4. Standardized Security
5. Standardized APIs or services

Standardized meaning

Standardized vocabularies and terminologies like SNOMED and ICD–10 allow a computer to understand that "heart attack" and "myocardial infarction" are the same concept, because they have the same standardized code. MU provides for four major vocabularies—LOINC for lab tests, RxNorm for medications, SNOMED for problem and symptom descriptions and ICD–10 for billing diagnoses. These should be used for all quality measures and registries so that the vocabularies are the same as those used in EHRs.

Standardized Format

MU has adopted a number of document-centric ways to standardize information that include a patient care summary or a transitions of care document. However, two additional standardized formats are needed: (1) A standardized format for granular data that can be used to build quality measures and new kinds of documents; and (2) a standardized format for unstructured data so that patients can share their entire medical record in an electronic format. Both of these play an important role in improving quality reporting.

Standardized Transport and Security

These standards are typically drawn from fundamental building blocks that support the internet and the WWW. In healthcare, we should leverage these mechanisms like email and Web page interactions, or secure ways to encrypt data or authenticate users, but not develop specific transport or security standards .

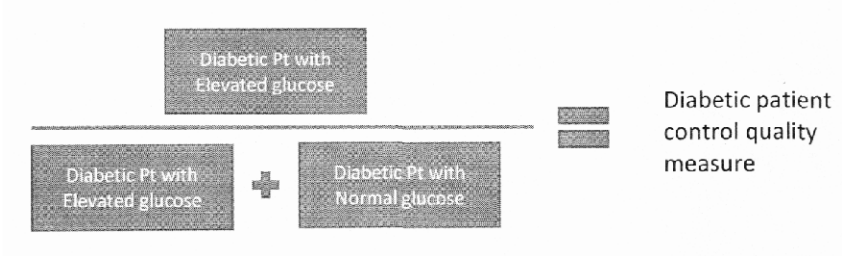
Standardized Services, such as Application Programming Interfaces (APIs)

APIs provide very specific channels or connections between two systems. These are useful to connect systems, but cannot substitute for a full export of a medical record for a patient to access their information.

By focusing development on format standards that are more data-centric and less document-centric, different pieces of medical data can be used in modular ways. Perhaps no better example of this is quality measurement. Development of granular data standards would most certainly yield positive benefits for quality measurement reporting, measure specification alignment and facilitate interoperability of EHRs and registries.

Quality measures are made up of three kinds of information: (1) Meta-data; (2) a data value; and (3) a formula. The meta-data describes what the quality measure is, when it was developed, who developed it, and other provenance data. Data value, includes the actual values for things like lab test result, medication, or problem list, for example. Finally a formula is needed to calculate the quality measure; for example a formula to identify all patients with diabetes who have an elevated HbA1C.

If one had a granular data element that defined diabetes (all patients with a problem list that had a SNOMED code for diabetes) and defined what an "elevated HbA1C level" is, one could identify those patients who need more help caring for their diabetes. In the diagram below, each of the boxes represents a granular data building block that are reusable.



This approach is generalizable. If there was a national common data element structure that used standardized vocabularies, the same structure could be used to describe the data values in a quality measure, the data values in a registry, and the data values in the electronic health records. This common format would accelerate interoperability for granular data elements, and provide a fundamental building block for other initiatives such as precision medicine and decision support.

Candidate standards for common data elements (CDE) currently exist. For example, a CDE standard was developed through the standards and interoperability framework at ONC (*http://hl7.org/fhir/2015May/sdc.html*), and has been balloted through HL7 as a FHIR resource; however the standards has yet to be adopted by Federal agencies. Such a format standard, if adopted nationally, would be an important step toward accelerating quality reporting programs, registry and EHR interoperability.

Once there was a common format standard for granular data elements, additional work to agree on the standardized meaning would be greatly accelerated. Domain experts in medicine and quality assessment can focus on reaching agreement on the definitions of data elements, knowing that once an agreement is reached on the definitions, the technical format will allow for rapid adoption and use for quality measures, registries, and EHRs.

Last, I would urge Congress to use the upcoming development of the MIPS as an opportunity to focus more work toward simplifying quality measures in healthcare. Many measures have tens of hundreds of data elements that are of dubious quality and that complicate the user interface and documentation requirements for clinicians. Each additional data element creates additional cost and complexity while adding only marginal value. One source for this problem is a proliferation of exclusion criteria, which are highly variable across programs and CQM specifications. We would do better to have quality measures with simple, but high-quality data.

Question 2. How would you recommend that clinicians and HHS identify these building blocks, and what process should be used to translate them into quality measures?

Answer 2. The Federal Government has a process to develop and maintain quality measures, and this process has gone through several evolutions since EHRs were used to generate quality measures. The unfortunate truth is that the current process is still new and still evolving, and I fear that it will need further modification and improvement before it will yield the intended results. This means dedicated resources are needed and the process must include individuals with deep clinical and technical expertise.

Generally speaking, the National Quality Forum (NQF) and CMS have worked to "regularize" a process to identify areas of quality measurement and update those quality measures over time. Through the Measure Applications Partnership (MAP) HHS has convened multiple stakeholders to guide "the selection of performance measures for Federal health programs," to provide "a coordinated look across Federal programs at performance measures being considered." [7] This effort has been developing recommendations since 2011 and has played an important role in helping define core measures for Medicaid populations, including adults, children and dual eligible beneficiaries. However, work related to eMeasures or eCQMs (measures generated by EHRs) is still on-going with little demonstrable success, due to a lack of aforementioned building blocks. The original notion was to "retool" paper-based measures as electronically generated measures. This approach has been largely abandoned and now most eCQMs are *de novo*, or newly constructed. The foundational problem is that some data needed to complete eCQM specifications are not currently captured by EHRs, or not captured in a way that can be used to generate quality measure reports.[8] [9]

As is often the case in the regulator-regulated relationship, requirements developed by the regulators are often incomplete because regulators have little direct exposure to the regulations they develop. In this instance, measure developers, technology developers and government regulators are not required to gather/input data necessary to generate eCQMs—clinicians gather these data at the point of care, often in ways unreflective or disjointed from clinical workflows. This has contributed to poor usability in EHRs and incomplete quality measures.[10]

One potential approach would provide dedicated resources to quality measure experts, inside and outside government, developers and clinicians to develop measures consistent with realistic clinical workflows. Bringing together clinical and technical expertise could then help inform the process already developed by CMS and the NQF MAP. Stated simply, measure developers and EHR developers must incorporate the views of practicing clinicians and their workflows. However, without a granular data standard, as outlined above, we will continue to have little success measuring quality as a "byproduct" of care delivery.

CAROLINAS HEALTHCARE SYSTEM,
July 13, 2015.

Hon. LAMAR ALEXANDER, *Chairman,*
Health, Education, Labor, & Pensions Committee,
U.S. Senate,
Washington DC, 20510.

Hon. PATTY MURRAY, *Ranking Member,*
Health, Education, Labor, & Pensions Committee,
U.S. Senate,
Washington DC, 20510.

DEAR CHAIRMAN ALEXANDER AND RANKING MEMBER MURRAY: Thank you for the opportunity to testify on behalf of Carolinas HealthCare System and the Premier

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[7] National Quality Forum, Measure Applications Partnership, *http://bit.ly/1dW7VJq* (accessed July 10).

[8] Amster A., Jentzsch J., Pasupuleti H., Subramanian K "Completeness, accuracy, and computability of National Quality Forum-specified eMeasures," J Am Med Inform Assoc, *http://dx.doi.org/10.1136/amiajnl-2014-002865* 409–16, October 2014.

[9] Garrido T., Kumar S., Lekas J., et al, "e-Measures: insight into the challenges and opportunities of automating publicly reported quality measures" J Am Med Inform Assoc, *http://dx.doi.org/10.1136/amiajnl-2013-001789* 181–84 Jan. 2014.

[10] Parsons A., McCullough C., Wang J., Shih S., "Validity of electronic health record-derived quality measurement for performance monitoring," J Am Med Inform Assoc, July 2012 *http://bit.ly/1HqDUtK.*

healthcare alliance at the "Health Information Exchange: A Path Toward Improving the Quality and Value of Health Care for Patients" hearing on June 10, 2015. Attached are my responses to the Questions for the Record posed by the Chairman and the Ranking Member.

Sincerely,

CRAIG RICHARDVILLE,
Senior Vice President & Chief Information Officer,
Carolinas HealthCare System,
Chair, Premier Healthcare Alliance,
Member, Technology Improvement Committee.

RESPONSE BY CRAIG D. RICHARDVILLE, MBA, FACHE, TO QUESTIONS OF SENATOR ALEXANDER AND SENATOR MURRAY

SENATOR ALEXANDER

Question 1. Many stakeholders have suggested that the health information technology industry could come up with many solutions to the problem of interoperability on its own. However, so far, we are stuck with a system that does not work even though the government has spent over $30 billion.

What areas would be best determined by private industry? What areas should the government decide, if any?

Does the government need to set deadlines or otherwise encourage industry to make decisions?

Answer 1. Despite its potential, the current HIT ecosystem continues to be challenging for healthcare providers because of a lack of interoperability between systems. Cost-effective, efficient, and easy to use and integrate health information is foundational to advancing and providing excellent care in this country.

As this committee heard earlier this year, **the current market incentives are not aligned with open exchange of necessary healthcare data in cost-effective ways.** The sharing of data that sits in software systems across the care continuum is not only technically complex, it is also expensive and time-consuming to integrate. Data resides in many systems, not just electronic medical records. Registration, billing, lab, pathology systems, medical devices, sensors and monitors, to name just a few, all have vital data that can and should be integrated and accessible across the care spectrum, no matter what the underlying software system is. The difficulty in achieving this has an impact not only in care quality but also in cost.

Despite the challenges, significant strides have been made with digitizing health information in the last 6 years. More than 80 percent of eligible providers and more than 90 percent of hospitals have begun the work to digitize their patient health data. Still, achieving necessary data integration to move forward has not been easy or inexpensive. Today, in order to build the bridges that connect disparate data sets necessary to provide comprehensive and informed decisions or care, providers must either pay their original system vendors thousands and sometimes millions of dollars to custom code linkages so they can "talk" to other systems, or they often find paper-based workarounds that are fraught with potential for both errors and wasted resources and expense.

In order to achieve the goal of having data that is secure, accessible and actionable by providers and patients, one of the key prerequisites is creation of patient matching systems. It is imperative that for the patient data to be interoperable we have a rational and effective method to match the right data to the right patient. A patient matching system is also foundational to interoperability. This goal of a secure HIT ecosystem that enables an easy exchange of health information in timely and cost-effective ways could be achieved with foundational work in patient matching.

To accomplish these goals, we ask for a combination of congressional and administrative actions that promote policy principles that further open health IT infrastructures. In creating those structures, we need clear rules of the road for providers and vendors alike through establishment of functional data and transport standards, and methods to measure and test functionalities, with enhanced enforcement tools for regulatory bodies to drive compliance in the marketplace. These include:

• ***Establishing governance:*** A private-public partnership on HIT interoperability governance should be established to provide clear rules of the road on interoperability. This should be done in consultation and coordination with Federal agencies, such as HHS and ONC, and the private sector. Providers, vendors, patients

and payers should be consulted. The government entities should provide regular reports to Congress and the Administration on current standards development status as well as ready to market timelines and assessments for their applications.

• ***Identifying functional data and transport standards that promote interoperability and innovation:*** The governance mechanisms should focus on identifying and setting the development of functional data and transport standards in key areas including: patient matching, terminologies, clinical data query language, security, open application program interfaces (APIs), and clinical decisions that support algorithms as well as business practices and policies.

• ***Focusing on public interoperability, cost and quality:*** Transparent and public measures of interoperability should be developed in collaboration with the Federal Government, including HHS and ONC, and standard-setting bodies in consultation with the private sector and be required as part of ONC's certified technology program.

- These measures should be validated and tested in terms of functional standards, processes, and their maturity for application in the marketplace in a timely way, and within specific use case scenarios.
- Measures should include business and implementation approaches that deliver functional interoperability outcomes and include operational processes and implementation practices.
- Measures should also include assessment of clinical quality and cost efficiency metrics achieved through incorporating innovative technologies, such as existing APIs, which are open source codes that enable third-party applications to exchange data.

• ***Encouraging transparency:*** Data should flow freely and easily. Determinants of transparency should include:

- Availability of "free" (no cost) export of publishable EHR domains.
- Prohibition of specific fees for access to necessary data through API or other functional standard callable methods.
- Publication of technical instructions on how to interact with APIs, interface standards or other callable methods. These should be published either publicly or broadly to any authorized third party.
- Requiring technology and devices that generate health information to publish clinical data to any other authorized consuming applications, including EHR/EMRs, to create interoperability. Consuming applications' ability to develop methods to ingest information from other HIT assets, including devices, should adhere to current and future medical device interoperability standards.

• ***Enforcing functional data and transport standards and measures of HIT:*** The Federal Government should be enabled to enhance its enforcement tools to ensure functional data and transport standards and to measure compliance of vendors through its certified technology program. Enforcement also can be encouraged through measurement and adherence to Meaningful Use standards.

Question 2. If you could change all or parts of the proposed rules for Stage 2 and 3 of Meaningful Use and the 2015 certification rule, what would you change?

Are there particular parts that should be delayed and others that should go forward? What changes would you make to them?

Do you think that the proposed rules will make health information technology better? If so, which parts?

Are there any parts of the proposed rules that you think would make health information technology worse? If so, which parts?

Answer 2. **Given the complexity of the objectives proposed under Stage 3, we believe meaningful use of EHRs can only be achieved if and when data captured in various EHRs and other data systems are interoperable.** Being able to fully leverage the robust clinical and health data in various disparate systems is essential not only to deliver efficient, high-quality, and patient-centered care but also to provide patient access and engagement. The data is digitized. Now it needs to be shared freely and easily. The HIT assets within the current ecosystem continue to be challenging for healthcare providers; however, due to the lack of interoperable HIT infrastructure as market incentives are not aligned with the open exchange of necessary healthcare data in cost-effective ways. As a result, data is locked in proprietary software systems.

As we have commented to CMS on the proposed rules for Stage 3, without an interoperable HIT infrastructure in place first, the increased thresholds for the various objectives proposed under Stage 3 will be challenging for providers. While we applaud the optional measures utilizing APIs to meet

some of the objectives proposed, we have requested that CMS minimize and keep consistent the baseline compliance thresholds when it comes to most of the objectives and patient access and engagement provisions in particular. More specifically:

• ***Calendar Year Reporting Period for 2015 CEHRT.*** Under the CMS proposed rule, the EHR reporting period for all providers, including eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs), would be a full calendar year, beginning with calendar year (CY) 2017. In particular, for the first year in which the 2015 edition of certified EHR technology (CEHRT) must be used and Stage 3 meaningful use requirements met, providers would have a full CY 2018 EHR reporting period.

We strongly oppose requiring a full calendar year reporting requirement for the first year of Stage 3, whether that first year occurs in 2017 (by a provider's choice) or in 2018 (as required under the proposed rule). It is unrealistic to expect all providers to adopt a new edition of CEHRT and initially meet the full array of Stage 3 meaningful use requirements for an entire year, whether or not they have previously been able to satisfy Stage 1 or Stage 2 EHR meaningful use requirements. We, therefore, urge CMS to allow for a 90-day reporting period for the first year. We argued for similar treatment for 2015 and CMS has recently, and somewhat belatedly, proposed to provide this recommendation. We believe it would be a serious mistake to fail to give providers the flexibility to use a 90-day reporting period for the first year in which they adopt the 2015 Edition of CEHRT to meet Stage 3 requirements.

• ***Objective 4: Computerized Order Entry.*** Objective 4 focuses on computerized provider order entry (CPOE) for medication orders, laboratory orders, and diagnostic imaging orders. The proposed objective calls for such orders to be directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant who can enter orders into the medical record per State, local, and professional guidelines. CMS emphasizes that a layperson is not qualified to perform functions associated with order entry, and that medical staff whose organizational or job title, or the title of their credential, is other than medical assistant may enter orders if these staff are credentialed to perform the equivalent duties of a credentialed medical assistant by a credentialing body other than their employer.

Providers' primary concern with this proposed objective is the demand that medical staff member credentialing be conducted by an entity other than the staff person's employer. In the case of providers, that would mean that a hospital would be unable to credential such individuals, even though hospitals are in the regular business of credentialing members of their medical staff. **We see no additive value to imposing such external credentialing costs and burdens on the Nation's hospitals and we strongly oppose this aspect of the CMS' proposal.**

• ***Objective 5: Patient Electronic Access to Health Information.*** Objective 5 focuses on providing access for patients to view online, download and transmit their health information (e.g., through a portal), or retrieve their health information through an API, within 24 hours of its availability.

Provider's primary concern with this proposed objective is the unrealistic timeframe for making the information accessible, moving from the current Stage 2 requirements of 4 business days for EPs and 36 hours post discharge for hospitals to 24 hours for all providers. We believe this is unrealistic from a workflow perspective and also risks forcing information to become accessible before its content can be adequately assessed for accuracy and before actions can be taken by the provider to educate or prepare the patient, if this is necessary. Since the thresholds for the objective are being increased and since **CMS is interested in having near-identical requirements for both EPs and hospitals, we urge adoption of the same four business day timeframe for all providers.**

In contrast to our concerns regarding timeframe, **we heartily endorse CMS' proposal to offer providers** *the option* to use an API-based mechanism to provide patient access to their health information, in addition to the existing option of viewing online, downloading and transmitting such information. To enable this option, however, it will be essential for CEHRT vendors be required to provide open and functional standard APIs that will enable secure applications to facilitate the exchange of information. We encourage CMS to look beyond data in EHRs and also consider the growing usage by patients and consumers of tools where they store, track and can share their own health data with providers.

• ***Objective 6: Coordination of Care through Patient Engagement.*** Objective 6 focuses on provider use of the communication functions of CEHRT to engage with patients and their authorized representatives about the patient's care. For this objective, providers would be expected to attest to the numerator and denominator of

all three proposed measures and successfully meet the threshold for two of these three measures. Proposed measure 1 would, for example, require that more than 25 percent of all unique patients discharged from the hospital inpatient or emergency department during the EHR reporting period view, download or transmit to a third party their health information or access their health information through the use of an ONC-certified API that can be used by third-party applications or devices. Similarly, proposed measure 2 would require hospitals to send a secure message using the electronic messaging function of CEHRT to more than 35 percent of such unique patients. Proposed measure 3 would also require hospitals to incorporate into the CEHRT patient-generated health data or data from "a non-clinical setting" for more than 15 percent of such unique patients.

We have concerns with Objective 6, especially its proposed increase in percentage thresholds. First, in the case of measure 1, we believe it would be unfair to providers to hold them accountable for patients' ability and willingness to electronically access their health information, especially given the proposed 25 percent threshold. CMS itself notes that median hospital performance for Stage 2 (for a related measure) is only 11 percent. Additionally, CMS has recently proposed to change the Stage 2 threshold for this measure so that providers would be able to meet the measure if at least one patient views, downloads or transmits his or her health information to a third party.

Given all the other changes being contemplated for Stage 3, and given CMS' proposed change for Stage 2, **we urged CMS to adopt a 5 percent threshold for Stage 3, which is the threshold previously finalized under Stage 2 for the comparable measure.** This would more realistically recognize that the patient populations served by providers vary widely in terms of their medical literacy, their access to computers and other technologies, their desire to access their health information under various scenarios, and even their interest in doing something they have never done before: electronically access their health information (that is, be early adopters of a new option). We would also note that the current broadband availability exclusion is inadequate, especially as measure thresholds increase; some providers have indicated that the current exclusion does not apply to their locale even though a significant proportion of their patient population do not have ready access to computers and/or the Internet. In addition, CMS also needs to recognize that some patients with multiple chronic conditions who are receiving care from multiple providers during an EHR reporting period may have no interest or need to access information from all of these providers. For all of these reasons, **a 25 percent threshold for measure 1 would be unrealistic. Providers need more experience with electronic patient access to health information to better understand which patients take advantage of and value such accessibility before being able to provide advice regarding a threshold greater than 5 percent.**

We also consider proposed measures 2 and 3 for this objective to be extremely problematic. We do not believe these measures should apply to hospital inpatients or to individuals presenting themselves to hospital emergency departments. We do not understand CMS' objective in requiring emails to be sent to patients after their discharge from the hospital or emergency departments. The issue with hospital-based providers being held accountable for sending secure messages is that it does not acknowledge how that care differs from an ambulatory setting and how care is delivered through hospitals. Patients often are cared for by hospitalists and then when the patient is discharged, care is returned to the patient's primary care provider. Oversight and coordination of care happens with the primary provider.

Further, a 35 percent threshold for measure 2, which is a new measure, is unrealistic. Similarly, we do not believe that hospitals should be expected to incorporate patient-generated data or information from "non-clinical" settings for patients' post-discharge from the hospital inpatient setting or emergency department. Thus, for hospitals, **we believe that only measure 1 should apply and only if a 5 percent threshold is adopted.** Even for EPs, we believe that measure 3 would be challenging, as this is a brand new concept and fails to recognize the diversity of patient health literacy and willingness or need to furnish patient-generated data.

• ***Objective 7: Health Information Exchange.*** Objective 7 focuses on the provision of a summary of care record when providers transition or refer their patients to another setting of care, retrieval of a summary of care record by providers receiving a transitioning or referred patient (or upon the first encounter with a new patient), and incorporation into the EHR of summary of care information from other providers using the functions of CEHRT. For this objective, providers would be expected to meet two of the three proposed measures. Measure 1 focuses on the creation and electronic exchange of summary of care records by the providers initiating a transfer or referral. Measure 2 focuses on the incorporation of electronic summary

of care documents by the receiving providers (or those seeing a new patient for the first time). And measure 3 would, for example, require hospitals to perform clinical information reconciliation for more than 80 percent of transitions or referrals received and for new patient encounters. This reconciliation could, for example, address the reconciliation of medication, medication allergy or patient problem lists.

We have significant concerns with Objective 7. For measure 1, our primary concern is the lack of adequate infrastructure for electronically exchanging summary of care documents with many providers likely to be on the receiving end of transitions of care or referrals, such as post-acute care providers. We do not believe it would be reasonable to hold hospitals accountable for other providers' inability to electronically accept a document. Thus, at minimum, the 50 percent threshold for measure 1 is unrealistically high.

In the case of measures 2 and 3, we oppose the application of these measures to patients who are not the subject of a transition of care or referral. We believe it is unrealistic, for example, to apply this requirement to first patient encounters in hospital emergency departments. In many cases, there will be no referring physician or even a physician of record, and no clinical information available to reconcile. Further, we believe that any such requirements would be extremely disruptive to emergency department workflows. These measures also presume the existence of an infrastructure that is capable of efficiently exchanging available information and such infrastructure does not currently exist in many or most cases.

In sum, **for Objective 7, we believe that only measure 1 should apply to hospitals for Stage 3 purposes and only if a much more reasonable measure threshold is adopted. As infrastructure interoperability capabilities improve, we believe it would then be reasonable to reconsider the appropriateness of applying measures 2 and/or 3 in the hospital context for specified patient populations.**

• ***Objective 8: Public Health and Clinical Data Registry Reporting.*** Objective 8 focuses on active provider engagement with a wide range of public health agencies (PHAs) and/or clinical data registries (CDRs). As proposed, this objective would require EPs to meet three of five possible measures (with two of these measures able to count more than once if more than one PHA or CDR were involved), while hospitals would be required to meet four of six possible measures (with measure 6 focusing on electronic reportable laboratory result reporting).

With respect to Objective 8 and its many associated measures, we believe that the number of measures that need to be met by providers should be uniformly set at two, rather than the proposed three for EPs and the proposed four for hospitals. We recognize that the proposed rule includes a number of exclusions that would have the effect of reducing the number of measures that a given EP or hospital would need to meet, in some cases below the required three or four, but we believe that the proposed thresholds of three and four are too high given the current state of readiness and the lack of provider experience. While we understand that CMS views Stage 3 as the final stage, CMS also acknowledges that future changes to the objectives and measures are likely to be warranted for a variety of reasons. **Therefore, we believe that additional experience with provider reporting to PHAs and CDRs should precede any decision about the reasonableness of requiring provider reporting to three or more PHAs or CDRs.**

SENATOR MURRAY

Question 1. The private sector is beginning to make progress toward standards, including the development of Fast Healthcare Interoperability Resources (FHIR) that will promote the interoperability of health information technology. In your testimony, you note that, "the Federal Government should be enabled to enhance its enforcement tools to ensure functional data and transport standards." What enforcement mechanisms should be enhanced?

Answer 1. As this committee heard during the hearing, **the current market incentives are not aligned with open exchange of necessary healthcare data in cost-effective ways.** The sharing of data that sits in software systems across the care continuum is not only technically complex, it is also expensive.

The costs of sharing this critical data among other health systems is not just in dollars. **It also results in inefficiently using some of our most valuable resources—our people.** Having care providers faxing or mailing information to other providers is not the best use of these highly skilled clinical people.

Thus, the reform goals should be to design and implement a secure HIT ecosystem that enables an easy exchange of health information in timely and cost-effective ways. The system should promote collaboration among all stakeholders, from pa-

tients to providers to vendor partners and payers. We need a system of standards that focuses on improving healthcare quality, efficiency, safety, affordability and access through government and market incentives, while encouraging innovation and competition.

To accomplish these goals, we ask for a combination of congressional and Administrative actions that promote policy principles that further open health IT infrastructures. In creating those structures, we need a combination of clear rules of the road for providers and vendors alike through establishment of functional data and transport standards, and methods to measure and test functionalities, with enhanced enforcement tools for regulatory bodies to drive compliance in the marketplace. More specifically:

• **On standards,** we need functional data and transport standards with a focus on key areas including: patient matching, terminologies, clinical data query language, security, open application program interfaces (APIs), and clinical decision support algorithms as well as business practices and policies. Although FHIR is promising, we need government leadership to prioritize the need for functional data and transport standards that are necessary within a care context to enable adoption as they become market-ready.

• **On the enhancement of enforcement tools,** enforcement should focus on compliance by technology vendors and entities who choose to do business in the CEHRT marketplace. Through the ONC certified technology program, they should be required to demonstrate through testing results that they meet functional data and transport standards to validate that they meet the metrics for interoperability.

The Federal Government should be enabled to use its existing enforcement tools as well as be provided with additional tools to ensure compliance through the ONC certified technology program with impactful consequences for noncompliance. The provider consumers who suffer the consequences and disruption due to technology vendors or entities who fail to comply with the standards and metrics of interoperability should be provided with hardship exemptions from meaningful use penalties.

RESPONSE BY CHRISTINE BECHTEL TO QUESTIONS OF SENATOR MURRAY

Question 1. How would you recommend that the Department of Health and Human Services (HHS) leverage rulemaking to enhance patient engagement in health information technology products?

Answer 1. Thank you for the opportunity to expand on this essential issue. There are several ways in which rulemaking can advance patient and family engagement in health IT, as well as in their own care.

We recently launched the GetMyHealthData campaign, spearheaded by the National Partnership for Women & Families, in collaboration with Amida Technology Solutions; Code for America; Genetic Alliance; Health Data Consortium; and NATE.

What we have learned so far, unequivocally, is that most patients and most providers don't know about patients' right to an electronic copy of their records under HIPAA—an important provision of the HITECH law. What's more, many providers often don't refer patients to their own portal, which should be capable of permitting downloads of records if the provider participates in Meaningful Use. These problems are not caused by ill-intentioned or bad actors; these providers and their staff are simply unaware of the law and do not have a workflow designed to produce e-Copies.

To remedy this, and facilitate broader patient engagement, rulemaking can help:

• **Guidance from the Office of Civil Rights regarding the HIPAA right of access.** OCR should strengthen its guidance around this right, and conduct significant outreach and education efforts to providers and consumers.

• **The Meaningful Use program has been and continues to be a powerful lever for patient and family engagement.** Its power lies in the requirement to genuinely engage patients in using online access to their health data, as well as in new proposed requirements that facilitate care coordination. Specifically:

  • Stage 3 would also increase the percentage of patients, or authorized family caregivers, that use online access and secure messaging. Nationally representative data demonstrate beyond any doubt that electronic access to health information is a significant catalyst for engaging patients and families in their care: Almost 9 in 10 patients who have such access use it, and it has

a significantly positive impact on better care, better communication with providers and improved outcomes.[1]

- However, many patients today do not know that they have online access and can download their records, because they are not told by their providers. The requirement implemented in Stage 2 and continued in Stage 3 for providers to actively engage a percentage of patients to use their data is mission-critical in addressing these challenges and making consumers' use of their own data a reality.
- Stage 3 would also introduce Application Programming Interfaces (APIs) into Meaningful Use for the first time. These, and the health applications they make possible, could be a significant benefit to many patients and providers. APIs could give patients the ability to more easily download the data they need, in ways they find more useful, and incorporate the data into their comprehensive record, to be shared and used by primary care providers and others involved in the patient's care on an ongoing basis.
- A new requirement would also enable providers to not only send patients' health data electronically, but also to incorporate patients' health data sent by other providers.
- New abilities would also enable patients and caregivers to contribute information to their medical record that is specific and material to their care, including correcting errors in doctors' records.

Therefore, measures of patient electronic access and health information exchange must be left intact for Stage 3, and these aspects of Stage 3 cannot be delayed. Further, CMS's proposal for Stage 2 to reduce the required threshold for patients accessing their health data to just a single patient should not be finalized.

- **The EHR Certification rule** also offers an important opportunity to create the necessary technical ability to deliver on the policy promises outlined above. Through the Certification rule, the ability to download and transmit patients' own data, as well as the additional Stage 3 proposed requirements described above, will become feasible for providers using certified systems.
- **Alternative Payment Model (APM) rules** also offer an important opportunity to advance patient and family engagement via health IT. APMs should require the use of certified EHRs, as well as include at least Stage 2 of Meaningful Use as a basic requirement of qualification for participation in APMs.

Question 2. What would you identify as key short- and long-term objectives for patient engagement in the Health Information Technology for Economic and Clinical Health (HITECH) Act.

Answer 2. Short-term patient engagement objectives:

- **Accelerating health data access for consumers.** HITECH established in law the policies, technology standards and education outreach that permit and encourage patient electronic access to and use of health data. HITECH not only created the Meaningful Use program, but also created a new right of access to an electronic copy of one's health record. Also included in the Act was an education campaign focusing on health IT, privacy and this new right of access.
- **Reducing health disparities.** HITECH included a provision to advance standardized ways of collecting data on race, ethnicity, language and gender so these data may be used to reduce health disparities in the short term, and advance health equity in the long term.
- **Giving consumers a voice.** HITECH also established important Federal advisory committees with specifically designated consumer seats, in recognition of the essential role consumers and their advocates should play in Federal policymaking. Meaningful Use may not have had a priority focus on patient engagement without these consumer voices, and more consumer voices are needed as current policymakers consider the future of health IT policy, including interoperability and Meaningful Use.

Long-term patient engagement objectives: Based on the short-term objectives laid out in the HITECH law, it is clear that long-term objectives for patient engagement include:

- Making consumer **access** to data ubiquitous, seamless and easy to use.
- Advancing health **equity**, including equal access to health information for all individuals, in languages of their choice, as well as measures of quality that are

[1] National Partnership for Women & Families. (2014, December). *Engaging Patients and Families: How Consumers Value and Use Health IT*, from *http://www.nationalpartnership.org/research-library/health-care/HIT/engaging-patients-and-families.pdf*.

stratified by disparity variables (specifically race, ethnicity, language, gender, sexual orientation and gender identity).

• Achieving **patient- and family-centered care**, including care that is coordinated, affordable, planned, effective and efficient.

Thank you again for the opportunity to provide input. Please don't hesitate to contact me with any questions.

CERNER,
KANSAS CITY, MO 64117,
July 13, 2015.

Hon. LAMAR ALEXANDER, *Chairman,*
Senate HELP Committee,
428 Dirksen Senate Office Building,
Washington, DC 20510.

Hon. PATTY MURRAY, *Ranking Member,*
Senate HELP Committee,
428 Dirksen Senate Office Building,
Washington, DC 20510.

Hon. ORRIN HATCH,
Senate HELP Committee,
428 Dirksen Senate Office Building,
Washington, DC 20510.

Hon. TAMMY BALDWIN,
Senate HELP Committee,
428 Dirksen Senate Office Building,
Washington, DC 20510.

DEAR CHAIRMAN ALEXANDER, RANKING MEMBER MURRAY, SENATOR HATCH AND SENATOR BALDWIN: Thank you for the opportunity to testify at the June 10, 2015, HELP Committee Hearing entitled, "Health Information Exchange: A Path Toward Improving the Quality and Value of Health Care for Patients."

Please find attached my responses to your Questions for the Record.

I welcome any opportunity to discuss these questions or any others as you continue your very important work.

Respectfully yours,

NEAL L. PATTERSON,
Chairman and CEO.

RESPONSE OF NEAL L. PATTERSON TO QUESTIONS OF SENATOR ALEXANDER, SENATOR HATCH AND SENATOR BALDWIN

SENATOR ALEXANDER

Question 1. You have mentioned that there are four specific things that physicians complain about the most relating to the burden of documentation. You've also said that three of those four things could be shifted to other members of the care team to free up more physician time.

What do you think providers should continue to document and what do you think could be shifted to other members of the care team?

Answer 1. Capturing the patient's health history, present illness, and course of treatment through observations, evidence of medical decisionmaking, treatment plans and outcomes is critical for facilitating treatment and continuity of care, driving accurate coding to maximize revenue, and calculating a facility's quality of care indicators. These needs are not new—they existed in the paper world and are deeply embedded in the Fee-For-Service model.

Further confounding the automation of the clinical workflow through electronic health records is the effect of narrowly interpreting prescriptive regulatory requirements, resulting in workflows that have driven physicians to become highly trained, highly specialized data entry experts.

State licensure, State boards governing specific professions, Medicare conditions of participation, and hospital or practice policies dictate patient care activities dependent on physician involvement, as well as permitted activities for non-physicians, such as physician assistants and advanced practice nurses. Specific to Meaningful Use requirements, according to CMS FAQ10071, computerized physician

order entry (CPOE) is the only Meaningful Use objective that has limitations on who can perform the activities necessary for that particular objective to meet the measure—it must be performed by a licensed or certified provider with clinical knowledge.

What we have seen implemented at hospitals and physician practices, however, are complicated physician workflows that go beyond traditional approaches and attempt to address multiple objectives: e-prescribing (eRx), medication reconciliation, clinical summary, patient education, transition of care summaries (for which the physician must verify that the summary contains a problem list, medication list and medication allergy list), and patient portal.

I believe that government needs to "round the corners and smooth the edges" of regulations and provide guidance so that critical data can still be captured as part of the patient's record, yet care team members—including nurses and physician assistants—are able to proxy for physicians, particularly in the areas of medication reconciliation, orders, clinical documentation and discharge planning, *where exclusive physician responsibility for these activities is not required*.

The shift away from the Fee-For-Service payment model is a major step in the right direction. CMS could speed this process by relaxing the complex evaluation and management (E/M) documentation guidelines or by expressly allowing non-physicians to complete the aspects of that work that do not require physician judgment, but with physician final review. Further, Meaningful Use must not impose any additional requirements—either actual or perceived—that hospitals and physician offices should presume physicians must perform when State licensure and State medical and health professional board regulations allow non-physician roles to do so.

Question 2. Many stakeholders have suggested that the health information technology industry could come up with many solutions to the problem of interoperability on its own. However, so far, we are stuck with a system that does not work even though the government has spent over $30 billion.

What areas would be best determined by private industry? What areas should the government decide, if any?

Does the government need to set deadlines or otherwise encourage industry to make decisions?

Answer 2. EHRs should be built to be interoperable—to exchange critical information with providers and organizations across the patient's entire continuum of care. *Clinical data should always flow unimpeded to wherever it is needed for direct clinical care of the patient*.

It is true the industry has not yet "solved interoperability" for seamless exchange, yet we have made significant strides and learned valuable lessons.

- Standards alone will not create interoperability. Standards must be developed and tested by the private industry based on real-word use cases. Deployment and use of the standards must be to achieve a business purpose. *Government should continue to facilitate emergence of appropriate business drivers through changes in provider payment that reward managing care over a continuum, and perhaps other regulatory pressures if market forces prove to be inadequate. Government could also play a role in funding pilots and demonstrations of up-and-coming standards. Government should facilitate transparency around the degree of actual data sharing so that "data blockers" will be exposed to market scrutiny.*
- Nationwide interoperability requires an open network that has a reliable method of patient identity management, record location tracking and patient-driven consent.
    - The network must manage contractual and legal arrangements necessary to share health data, as well as deploy a governance mechanism to ensure the arrangements are followed. *Government could play a role in "blessing" material elements of such arrangements to reduce the amount of time needed to negotiate new relationships and to ensure that participants are comfortable that such an arrangement complies with appropriate regulations. The government could encourage and/or require public transparency of business practices, and provide enforcement mechanisms when a business entity falls short of its obligations.*
    - These networks require the active engagement and collaboration of their participating entities. They cannot be simply created by a legislative vehicle.
    - CommonWell Health Alliance is such a network.

The government should define the "what" and "when"—the U.S. health care stakeholders should define and achieve the "how."

Question 3. If you could change all or parts of the proposed rules for Stage 2 and 3 of Meaningful Use and the 2015 certification rule, what would you change?

Are there particular parts that should be delayed and others that should go forward? What changes would you make to them?

Do you think that the proposed rules will make health information technology better? If so, which parts?

Are there any parts of the proposed rules that you think would make health information technology worse? If so, which parts?

Answer 3. For more detailed responses to your questions, I have attached Cerner's responses to each respective proposed rule: Modification of Stage 2, Stage 3 and 2015 CEHRT.*

Two key points:

1. A wholesale delay of the Stage 3 timeline could create a major disruption in momentum of health IT adoption that could interfere with payment reform and advanced initiatives such as precision medicine. January 1, 2018, should remain as the start date for Stage 3; however, the final rules should proceed with a purposeful focus on requirements that advance interoperability and increase patient engagement.

2. ONC should propose certification criteria beyond what is necessary for Meaningful Use only at the point in time they are required by other Federal program requirements, and not presume a market role absent a Federal policy interest.

SENATOR HATCH

An HIT vendor change brings with it new challenges, including data collection and reporting, which are both part of Meaningful Use requirements, as well as patient safety issues. One hospital system in my State estimated that it could take as long as 19 months to safely transition EHRs.

Question 1. From your experience, can you tell us how long installing an EHR takes and give us a sense of all of the steps required? Please describe the timing and the complexity of the problem for a physician office, for a hospital, and for a multi-hospital system.

Answer 1. The answer varies based on organization size and profile. For example, we can have a stand-alone physician office live in 3 months. A single hospital system typically requires 14 months, as is our standard recommendation for a community-based health system; however, a larger, multi-facility health system could reasonably expect 18–24 months.

Most EHRs are highly configurable so they can meet the needs of a variety of different kinds of provider organizations. At a high level, steps accomplished in the implementation timeframe include:

- *Planning*: Project governance, organizational change management, resource allocation, current State assessment, definition of measurable project outcome.
- *Execution*: Executing the plan, defining future State (people, process, technology), building the configurable parts of the EHR, testing and training.
- *Conversion/System Adoption*: Includes post conversion assessment, adoption confirmation, outcomes measurements.

Question 2. In what ways would transitioning to a new HIT vendor interfere with a provider's ability to comply with Meaningful Use requirements? What considerations would ease the burden on providers looking to transition from one vendor to another? What are the merits of a hardship exemption from Meaningful Use penalties for such circumstances, and what other options would you suggest? What would be an appropriate amount of time for a hardship exception from Meaningful Use penalties for providers who transition vendors?

Answer 2. Even with a fairly seamless transition to a new system, the provider or hospital must be live on this new system for some time to reach productive use in the same (or improved) mode and manner experienced before. Expecting immediate par level results with a new conversion may not be realistic for at least a period of months.

The challenge of transitioning to a new technology is much greater than simple data migration—the provider/hospital must essentially re-implement and roll out all features. This likely requires process and workflow changes, database customization, education, and so on. Post implementation, a client may experience a re-adoption curve where performance levels may dip, or a dual system period with multiple reporting approaches.

Some measures allow for consideration of activity that occurs before, during or after the reporting period. That data may not be available to the new system, as

*Due to the high cost of printing, the attachment referred to have been retained in committee files.

the old system's mechanism may not be "translatable" for how the new system recognizes numerator credit, the data that was the basis of proof in the old may not be able to be converted, or it simply may be a process not available to the new. To that extent, any such functional measures need time to build that history for the activity data, which may require more than simple data conversation but actual new rounds of seeing existing patients to establish or re-establish that history.

In Cerner's experience dealing with technology transitions, one of our clients' biggest issues is related to the patient reminders objective for Stage 2 Eligible Providers (EPs). Fortunately, this issue would be addressed under the proposed Stage 2 Modification Rule. As way of example, however, on that measure, there is a requirement that the provider send patient reminders to 10 percent of patients that have had two or more encounters in the 24 months prior to the reporting period. If the provider switched vendors, pulling relevant data could be a potentially expensive and time-consuming process for that one measure.

Public health reporting may create another issue. If a provider/hospital is submitting on an ongoing basis for public health and then switches technologies, the rule is not clear as to whether there will be a new time to enter into "active engagement" again.

To help facilitate a technology transition, we suggest, at a minimum, a hardship exemption that avoids penalties. To support ongoing incentives, and/or in lieu of a hardship exemption, allowing the provider/hospital the ability to attest in good faith—without being judged strictly on measurement achievement—may also be a helpful option. So would allowing a temporary break in reporting, focusing on attestation when the provider is fully operational on the new system, but not necessarily the entire year. In general, regulatory measures that focus on "process" rather than "outcome" will be harder to transition to a new system. This is one reason why we favor focus on the "what" rather than the "how." If a new system has a better approach to certain processes, then those process changes should not adversely effect achievement of incentives.

SENATOR BALDWIN

Question 1. I am encouraged by progress made on vendor-developed exchanged networks, such as Epic's Carequality and Cerner's CommonWell. How many patients have opted in to CommonWell as of the date of this hearing? What percentage of hospitals and clinics using Cerner's EHR software are currently connected to CommonWell?

Answer 1. CommonWell Health Alliance, an open, industry-driven, vendor-led Alliance consisting of 29 health IT organizations including Cerner, concluded its yearlong pilot testing and began nationwide rollout of services in January 2015. Seventy-three facilities were connected and live on CommonWell services as of June 10 (the date of my testimony), with 5,000 facilities anticipated to be enrolled by years' end.

While CommonWell is in early deployment across the country, we are reporting promising patient adoption. As of June 10th, over 30,000 patients were actively enrolled in CommonWell, and active data exchange was occurring nationwide. We fully anticipate that growth in these numbers will accelerate as the national rollout expands, as new members extend services, and as provider utilization increases.

Specific to Cerner, 336 acute facilities using Cerner's EHR are currently enrolled in CommonWell services. This represents approximately 10 percent of Cerner's acute client base.

Of course, even as CommonWell adoption grows, we continue to support a number of interoperability activities, including connections to more than 130 HIEs and numerous point-to-point connections, many facilitated by Cerner's open, standards-based exchange network. All told, last month (June), we generated more than 7.7 million CCD records across our client base. Most were for consumption by non-Cerner systems.

If you have additional questions specific to CommonWell, I encourage you to contact: Jitin Asnaani, Executive Director, CommonWell Health Alliance. 617.396.4009; *jitin@commonwellalliance.org, commonwellalliance.org.*

Question 2. It is important that we support putting into place a national structure to enhance and connect existing networks so they can seamlessly and securely share patient records with each other. Therefore, it is critical to identify any barriers to participation in networks, as well as barriers that may inhibit connecting of networks. Do you see potential drawbacks in charging for the licensing or use of interoperability software? Does this create any barriers for participation?

Answer 2. The pricing of interoperability services is a great concern, particularly as we try to encourage a State of true nationwide interoperability. Point-to-point

interfacing has traditionally been very labor intensive and costly, and that is one of the reasons we saw a need for CommonWell. Interoperability should be free for patients, and priced like a public utility (like water or electricity) for provider organizations. As the beneficiary of all the public investment in health IT, it doesn't bother me if the industry/vendors have to pay a little more to make this happen.

It is Cerner's goal to provide interoperability services at a low cost to health care providers, and to engage in fair practices that do not financially penalize connections that flow outside of our own network to other vendors or other networks. We endeavor to embrace the notion of FRAND (fair, reasonable and non-discriminatory) pricing. A good example of FRAND pricing at work: when a Cerner client signs up for CommonWell, they pay a low, one-time setup fee, and that covers *all* their standards-based connections, whether those connections are to the CommonWell network or to organizations using non-CommonWell vendors such as Epic. Right now we don't have direct bridging between CommonWell and the entire Care Everywhere network, but we support unlimited connections to points inside that network. We believe that direct bridging of networks will follow. When that happens, our work will be easier, not harder.

Countless dollars have been spent as a nation on health information exchange networks, yet they rarely scale to all the venues where any given patient actually receives care. I believe the greatest barriers to participation in networks are associated to the creation of the networks themselves, not a result of connecting them. These are the exact frustrations—governance and data sharing agreements, patient identification, record location and consent management—that sparked the need for CommonWell to provide more services than simply bridging limited network infrastructures. In other words, problems within the networks themselves must be addressed—not just the efforts—and costs—necessary to connect them.

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

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