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IMPLEMENTATION OF THE 21ST CENTURY CURES ACT: ACHIEVING THE PROMISE OF HEALTH INFORMATION TECHNOLOGY

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE IMPLEMENTATION OF THE 21ST CENTURY CURES ACT: FOCUSING ON ACHIEVING THE PROMISE OF HEALTH INFORMATION TECHNOLOGY

OCTOBER 31, 2017

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C O N T E N T S

STATEMENTS

TUESDAY, OCTOBER 31, 2017

IMPLEMENTATION OF THE 21ST CENTURY CURES ACT: ACHIEVING THE PROMISE OF HEALTH INFORMATION TECHNOLOGY

TUESDAY, OCTOBER 31, 2017

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

The Committee met, pursuant to notice, at 2:34 p.m., in room 430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

Present: Senators Alexander [presiding], Cassidy, Young, Murray, Casey, Franken, Bennet, Baldwin, Murphy, Warren, Kaine, and Hassan.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Senate Committee on Health, Education, Labor, and Pensions will please come to order.

I want to congratulate my Democratic colleagues for being on time. I've issued reprimands to the Republicans, but probably with no effect.

This afternoon we're holding a hearing entitled, 'Implementation of the 21st Century Cures Act: Achieving the Promise of Health Information Technology'. Senator Murray and I will each have an opening statement, then we'll introduce our panel of witnesses. After our witnesses, Senators will each have 5 minutes of questions.

Last December I said that, for the second consecutive year, President Obama has signed a 'Christmas miracle' into law. That was his term for what we did in 2015. It was the Every Student Succeeds Act, the law fixing No Child Left Behind. Last year, it was the 21st Century Cures Act, which Majority Leader McConnell called 'the most important legislation Congress passed last year'.

This is the first hearing on the implementation of what we call Cures, which this Committee worked hard on and almost every single member contributed to. We hope it will help virtually every American family by taking advantage of breathtaking advances in biomedical research.

But as I have often said when we began hearings on the Every Student Succeeds Act, a law is not worth the paper it's printed on if it is not implemented properly. I intend to ensure that Cures is also implemented properly, the way Congress wrote it, and today is the start of that oversight.

This hearing is focused on the health IT provisions in Cures. We will have additional implementation hearings in December on the sections of Cures dealing with research, development, and approval of innovative treatments, cures and medical devices, and on the reforms to the mental health programs.

As we worked on Cures, we learned that in order for most areas of the bill to succeed, it was essential that electronic health care records systems work properly.

For example, the precision medicine initiative that was so important to President Obama aims to assemble 1 million genomes to help doctors tailor treatment to patients. But most of that information the head of the National Institutes of Health, Dr. Francis Collins, is trying to collect, will flow through electronic health care records.

The more we looked into these systems, the more we realized our Nation's system of electronic health care records was in a ditch.

Since 2011, we have spent $37 billion incentivizing doctors and hospitals to install electronic health care records systems through the meaningful use program in Medicare and Medicaid.

A well-respected hospital told me that Meaningful Use Stage I was helpful, Stage II was difficult, Stage III was terrifying, in their words. On top of that, doctors and hospitals were being asked to adjust to a new system of Medicare and Medicaid reimbursements.

So I recommended slowing down the implementation of Stage III to get it right, and working with doctors and hospitals to get it right, which the previous administration declined to do.

In 2015, a family doctor in Kingsport, Tennessee explained to the New York Times the problems that he and others face with electronic health records systems saying, "We have electronic records at our clinic, but the hospital, which I can see from my window, has a separate system from a different vendor. The two don't communicate. When I admit patients to the hospital, I have to print out my notes and send a copy to the hospital so they can be incorporated into the hospital's electronic records."

The exchange of information between electronic health records systems is called interoperability. In the case of the doctor from Kingsport, and many others, this exchange of information does not always happen easily, or at all.

This Committee eventually held six hearings in 2015. We didn't set out to do that, but when we stumbled into the problem with electronic records we found ourselves holding six hearings looking at ways to improve electronic health records and formed a bipartisan working group that made recommendations that were included in the final Cures legislation.

The goal of the health IT provisions in Cures was to make it easier for patients to access their health records and for doctors and hospitals to get the information they need to treat patients.

The law set clear deadlines for the Administration to meet, and today I would like to hear how implementation of those provisions is going.

Are doctors spending less time on administrative tasks and more time with patients?

Are doctors and hospitals better able to understand before purchasing an electronic health records system how well it shares information with other systems?

What has been done to discourage information blocking, which is when there is some obstacle getting in the way of health records being sent to another medical provider, like one clinic refusing to send information to another, or one record system not exchanging information with another?

What tools have been given to local provider networks, hospitals, and doctors to help them achieve interoperability with other health providers?

What has been done to ensure patients know they have a right to access their own health care records?

What steps have been taken to help doctors ensure they are looking at the record of the patient in front of them and not another patient's record?

There is also a role for the private sector to play. In a country where 2 million people fly every day, taking for granted how easy it is to make and change flight reservations on different airlines, we should be able to use the genius of our private sector to make sure electronic health records are working.

While some regulations are useful, we should be careful to leave plenty of room for the game-changing innovation in electronic health records that we've seen in so many other sectors of our economy.

One such effort is the Center for Medical Interoperability, a group of non-profit, for-profit, and university-based hospitals that is headquartered in Nashville.

Their idea is that, all together, they have a large enough purchasing power to tell the makers of electronic health record systems they want systems that work properly and that are able to communicate with each other. If the systems don't work properly and communicate with each other, these purchasers will find products that do.

In February 2016, former CMS Administrator Andy Slavitt joined me at the Center for Medical Interoperability in Nashville. Both of us were impressed with what we saw. I was glad to see these hospitals coming together to work out a solution in the private sector to help with interoperability.

Electronic health records are a critical piece to the success of the 21st Century Cures legislation. I look forward to hearing what steps the Administration has taken to implement the provisions this Committee helped to enact into law.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Thank you very much, Chairman Alexander. I, too, am very glad we are continuing our work on ways to improve the health and well-being of families across the country.

Today's discussion really picks up on a series of hearings that we held last Congress to improve health IT for patients and families, doctors and hospitals, and for our Nation's larger health care infrastructure.

This is an area where I am very glad we found common ground, explored common sense steps, and built on some of the great work that has already been done.

Here's why this is so important, and here's why we are here today.

Whether it's coordinating care between providers, being able to look up your own health care information online, or using patients medical records to catch a dangerous interaction between medicines, a strong health IT infrastructure is critical to building a health care system that works for patients and families and puts their needs first.

Now, as we've talked about, we have made some progress.

Hospitals and providers have made great strides over the last few years when it comes to adopting health IT.

Today, physicians use electronic health records more than ever before. Health care organizations are continuing to share and use electronic health information.

But we do have more work to do. Fortunately, because of your efforts, Mr. Chairman, Members on this Committee, and the overwhelming majority of the Senate, we now have an important tool at our disposal to better advance this work. Of course, that is the 21st Century Cures Act, something I know we all are proud of.

Along with all Cures does to tackle our hardest-to-treat diseases, confront the opioid epidemic, strengthen mental health care, and advance medical innovation, this legislation helps make improvements to help empower patients and providers with more and better information to help drive treatment and improve health outcomes.

So, I look forward to talking today about this and how we can best utilize and build on Cures.

First of all, that means making sure this Administration is implementing Cures in the way Congress intended, and that includes strong investments so that patients and families actually see the benefits of this law.

Quite frankly, that has been an issue with this Administration. I won't go into all of the reasons why, but I am concerned, for one, that President Trump has asked Congress to slash ONC's operating budget. That certainly will not help our efforts today.

I am also concerned the President didn't include anything in his proposed budget for information blocking, requested by ONC and the Office of the Inspector General, which helps certify and protect health information.

So those are two examples, but it does speak to a larger concern.

I hope that, just as we came together to pass Cures, we can work across the aisle to make sure the agencies involved have access to the funding they need in order to make this a success.

Now, to be clear, we have seen this Administration continue the work started by the Obama administration to support the development of a framework for trusted exchange of health information, which Senators Baldwin and Hatch worked together to include in Cures. That will help make sure that providers and networks don't have to reinvent the wheel every time they need to exchange information with a new facility.

That is very encouraging, and I want to make sure they keep at it and that we keep moving in the right direction so that we continue to engage stakeholders to find the best path forward and implement critical new conditions for certification of health information technology.

Fortunately, we have great witnesses here today, and we appreciate all of you coming today. I look forward to all of you sharing your expertise with us.

Last, I would just acknowledge all the work our colleagues on both sides have done and are doing when it comes to health IT.

Like all of you, I am very hopeful we can do more to ensure electronic health records are accessible to patients and families so they are able to stay engaged in this effort.

I will have questions for the witnesses, but thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray, and thank you for your leadership in passing the 21st Century Cures Bill, which the Majority Leader called the most important bill last year.

I would say to the witnesses before they begin what I said to the witnesses from the Obama administration. We have our differences on this Committee, but in this area we've got a lot of common goals, and our purpose is to create an environment in which you can succeed toward those goals. So I would encourage you not to think of us as adversaries, and we won't always agree, but think of us as wanting to create an environment in which you can succeed, and if during the hearing or afterwards with our staff you think of ways that we can do that, I hope you'll be specific about it.

The first witness is Dr. Jon White. He is the Deputy National Coordinator for Health Information Technology in the Office of National Coordinator for Health Information Technology—that's a pretty big title—also known as ONC. That's the lead entity within the Department of Health and Human Services on issues related to health information technology. He's provided leadership over all those programs.

Next we'll hear from Dr. Kate Goodrich. She is from the Center for Medicare and Medicaid Services. She's Director of the Center for Clinical Standards and Quality and Chief Medical Officer at CMS. She oversees the implementation of the Electronic Health Record Incentive program, also known as meaningful use, and the implementation of the quality provisions of the Medicare and CHIP Reauthorization Act.

Last we will hear from Mr. James Cannatti. Mr. Cannatti serves as Senior Counselor for Health Information Technology in the Office of the Inspector General at Health and Human Services. In the Cures Act, the Office of Inspector General was given new authorities to investigate and take enforcement actions against acts of information blocking or the blocking of the flow of patient data or electronic health information.

We welcome, again, our witnesses. If you could summarize your remarks in 5 minutes, that will leave more time for questions from the Senators.

Dr. White, let's begin with you. Welcome.

STATEMENT OF JON WHITE

Dr. WHITE. Thank you very much. Good afternoon, Chairman Alexander, Ranking Member Murray, and distinguished Committee Members. I appreciate the opportunity to speak with you today about the Office of the National Coordinator for Health Information Technology's progress in implementing provisions of the 21st Century Cures Act.

I am grateful to Congress and particularly to this Committee for your vision and your thoughtful leadership in passing this important and bipartisan law. We agree with Congress that health IT must be more interoperable, that it should be easier to use for everyone, and that information must flow seamlessly and without unreasonable blocking, and I know the National Coordinator, Dr. Don Rucker, shares this view.

I've worked with health IT as a family physician and as a public servant for a long time, so I'm familiar with a variety of health IT perspectives. While the Nation has made significant progress in digitizing health information, important work remains, particularly around interoperability, clinician burden, and information blocking.

Indeed, ONC has been concerned with these issues in recent years, and I'd like to share with you some of the work that we led in the years prior to the passage of the Cures Act.

In 2015, ONC outlined a 10-year plan for interoperability in the Shared Nationwide Interoperability Roadmap. We released the Federal Health IT Strategic Plan, developed in partnership with over 35 Federal entities, and we submitted a report to Congress on information blocking. We included application programming interfaces, or APIs, as part of the 2015 edition Health IT Certification Criteria, and we partnered with the innovation community through various prize competitions to advance patient matching, patient privacy, and API security. Last month we provided administrative flexibility for certification, which has downstream benefits to the clinicians using EHRs.

To provide focus and clarity for ONC stakeholders around our interoperability goals, we're concentrating on three framing questions. The first is about the patient. Can patients access their medical data in a secure, straightforward, and consumer-friendly way?

The second is about institutional accountability. Can payers assess the quality and value of the care they purchased, and can clinicians provide outstanding care for entire populations?

The third guiding question is how do we operationally define an openly published API that makes information available to the right people without special effort, language that may be familiar to you?

Today, under the National Coordinator's leadership, ONC is deeply engaged in supporting the implementation of the Cures Act, specifically the provisions in Title 4. ONC will work with the HHS Secretary to establish a goal, a strategy, and recommendations to reduce regulatory or administrative burden. We understand that clinicians face real challenges in using health IT, and it's a priority to get that right.

We work closely with CMS on this effort and have engaged with dozens of stakeholders to identify the important issues. We've also met with stakeholders representing medical specialties to better understand how health IT can best help them meet the needs of

their patients. ONC has begun to implement the trusted exchange provisions outlined in the Cures Act. The resulting Trusted Exchange Framework and Common Agreement, or TEFCA, will be a critical component of nationwide, network-to-network exchange of health data and our charge to support nationwide interoperability.

We've held two to three initial public meetings on the TEFCA and had one round of public comments, and we intend to release a draft of the TEFCA for public comment by the end of the year.

We have already closed the previous two Federal Health IT advisory committees, and we'll open that new health IT advisory committee established by the Cures Act, holding our first meeting this winter.

We're also working to implement the information blocking provisions in Title 4. Information blocking is a complex issue with significant implications for patients and the industry. It's important to distinguish inappropriate practices for information blocking from appropriate ones like protecting patient privacy and security. So we're working closely with our Federal colleagues, including the HHS Office of the Inspector General. We're also working with the Agency for Health Care Research and Quality to include health IT developers as protected participants in patient safety organizations, and with the HHS Office for Civil Rights to support patient access to their health information.

As we look ahead, effortless access to and use of their medical data will improve the ability of patients to shop for their care. As authorized by the Cures Act, we're working to support a modern information economy and a competitive marketplace by improving the ease with which clinicians, patients, and their caregivers can securely send and receive medical information. These pro-competitive steps will allow new business models and software applications to flourish.

Importantly, we believe that computational ownership or access to and use of electronic data by patients and payers, not just clinicians, can set a floor for increased market competition in health care. ONC will use the tools provided by Congress through the Cures Act to tackle today's challenges of interoperability, usability, and information blocking.

We look forward to working with you to achieve our shared vision. Thank you again for the opportunity to speak before you today, and I look forward to your questions.

[The prepared statement of Dr. White follows:]

PREPARED STATEMENT OF JON WHITE

Chairman Alexander, Ranking Member Murray, and distinguished Committee Members, thank you for the opportunity to appear today. My name is Dr. Jon White, and I am the Deputy National Coordinator for Health Information Technology. On behalf of Dr. Rucker, the National Coordinator, I appreciate your invitation to discuss our progress with the implementation of 21st Century Cures Act (Cures Act).

The Office of the National Coordinator for Health Information Technology (ONC) was established by Executive Order in 2004. Today our mission is to improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most. In 2009, ONC was statutorily established by the Health Information Technology for Economic and Clinical Health (HITECH) Act as part of the American Recovery and Reinvestment Act, or "Stimulus Bill."

The HITECH Act provided important resources and infrastructure needed to stimulate rapid nationwide adoption and use of electronic health record (EHR) systems. In the 8 years since the HITECH Act was enacted, we have seen dramatic progress in the use and adoption of health IT. Today, 97 percent of hospitals and three-quarters of office-based physicians use health information technology (health IT)[1] that has been certified under the ONC Health IT Certification Program (Certification Program).

ONC initiatives like the Regional Extension Centers, the Certification Program, and terminology standardization, as well as the Centers for Medicare & Medicaid Services (CMS) Medicare and Medicaid EHR Incentive Programs under the HITECH Act, and the Quality Payment Program (QPP) under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), have accelerated health IT adoption across many care settings. As ONC stated to this Committee in 2015, the Nation is on the path to a digital healthcare information system. We thank the Committee for its leadership in the enactment of the bipartisan Cures Act and look forward to implementing the Act's health IT provisions.

My career has been dedicated to improving health and healthcare quality through the use and sharing of electronic health information. In my 15 years as a family physician, I have worked in a variety of settings with multiple health IT systems. At ONC, I advance key National Coordinator and Administration priorities, and provide executive direction and leadership for all ONC programs and policies. Before my service at ONC, I was Director of Health IT at the Agency for Healthcare Research and Quality (AHRQ) where we established hundreds of health IT projects in 48 states. These included research, demonstration, and implementation projects on a variety of applications such as telemedicine and e-prescribing. I have worked with Federal partners, including CMS and the Department of Veterans Affairs, and state and local government, as well as key clinician, patient, and policy stakeholders to advance health IT progress.

Despite gains in health IT adoption, important work remains. ONC's highest priorities improving interoperability, reducing clinician burden, and addressing information blocking—are central to recasting our healthcare system. In recent years, ONC has focused on advancing data liquidity among clinicians, patients, and their caregivers; addressing information blocking; and advancing developers' move to interoperable systems that are easy to use for clinicians. In 2015, ONC outlined a 10-year plan to achieve nationwide interoperability, "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap."

That year we also released the Federal Health IT Strategic Plan 2015–2020, developed in partnership with over 35 Federal entities that use and support the use of electronic health information and designed to support and align important changes across the Federal health landscape. In April 2015, we submitted a report to Congress, "Report on Information Blocking,"[2] which was the first time the government issued a formal report on the problem of information blocking. Information blocking is the act of providers and EHR vendors knowingly and unreasonably engaging in business practices that interfere with electronic health information exchange (HIE). Since we submitted the Report, additional studies and experience have confirmed that information blocking persists and is a serious impediment to interoperability.[3] Recognizing these concerns, Congress included provisions in the Cures Act that provide a robust response to the information blocking problem. We are working closely with our Federal partners to implement these provisions.

We have also kept pace with the specific needs of the health IT community and the clinicians and patients they serve. In support of industry innovation and requests, we updated our Certification Program to support greater transparency around developer product capabilities and even the types of costs users can incur. We have considered industry developments around technology in our work and included application programming interface (API) capabilities as part of the 2015 Edi-

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[1] Office of the National Coordinator for Health Information Technology (December 2016). 2016 Report to Congress on Health IT Adoption.*https://www.healthit.gov/sites/default/files/2016—report—to—congress—on—healthit—progress.pdf. Accessed October 2017*

[2] ONC, Report to Congress on Health Information Blocking (Apr. 2015), *https://www.healthit.gov/sites/default/files/reports/info—blocking—040915.pdf*[hereinafter "congressional Report"]

[3] *See, e.g.,* Julia Adler-Milstein and Eric Pfeifer, *Information Blocking: Is It Occurring And What Policy Strategies Can Address It?*, 95 Milbank Quarterly 117, 124-25 (Mar. 2017), available at:*http://onlinelibrary.wiley.com/doi/10.1111/1468–0009.12247/full*; Martin Gaynor, Farzad Mostashari, and Paul B. Ginsberg , Making Health Care Markets Work: Competition Policy for Health Care, 16-17 (Apr. 2017), available at:*http://heinz.cmu.edu/news/news-detail/index.aspx'nid=3930*; Diego A. Martinez et al., A Strategic Gaming Model For Health Information Exchange Markets, Health Care Mgmt. Science (Sept. 2016).

tion Health IT Certification Criteria. Published APIs, or doorways to the data, are a critical component of our connected future. Mobile applications use APIs to connect us with the life tasks we complete each day—from seamlessly banking online, to ordering dinner and rides on our smartphones. APIs, when securely linked with health IT, hold the same promise for patients and clinicians with regards to their ability to readily access health information without special effort.

ONC works closely with the health IT community in a number of ways and looks forward to expanding these types of engagements. For example, we have partnered with the innovation community through various prize competitions under the America COMPETES Act[4] to better understand patient matching, patient privacy, API security, and how information can flow to the patient. 1A[5] We also approved two alternative testing methods administered by stakeholders in the private sector[6],[7].

Today, under the National Coordinator's leadership, ONC is deeply engaged in supporting the implementation of the Cures Act, specifically the provisions in Title IV. Looking ahead, ONC is committed to the critical role we play to advance health IT usability and interoperability that supports coordinated care and reduces clinician burden. We continue to engage with our Federal partners, including CMS, and with external stakeholders to better understand and find ways to address the regulatory and administrative burdens identified by stakeholders related to the use of EHRs. I would like to express particular gratitude for my colleagues at CMS who have taken several concrete steps to address clinician burden in their programs head-on. As outlined in section 4001(a) of the Cures Act, ONC will establish a goal, develop a strategy, and provide recommendations with respect to the reduction of regulatory or administrative burdens, such as documentation requirements, relating to the use of electronic health records. With CMS, we have established four working groups which address (1) EHR Reporting; (2) Documentation, Administrative, and Reimbursement Models; (3) Health IT and User-Centered Design; and (4) Non-Federal Payers (State/Private) and other Government Requirements, and are engaging with relevant stakeholders in each area.

We also have other efforts underway to reduce the regulatory burden on health IT developers. ONC now allows health IT developers to self-attest to certain functionality-oriented certification criteria to which most had previously been tested in the past in order to focus more on interoperability testing. Additionally, we allow ONC-Authorized Certification Bodies to use discretion in their randomized surveillance of certified health IT in the field, thus reducing the potential of unnecessary productivity impacts on clinicians. These two steps preserve the integrity of the Certification Program while at the same time improving its efficiency and overall impact on the industry.

We have met with stakeholders representing medical specialties, including pediatrics and long-term care, to better understand how health IT can best help them meet the needs of their patients, as outlined in section 4001(b) of the Cures Act. We are working to implement the conditions of certification and maintenance in section 4002. We are also working with AHRQ regarding the treatment of health IT developers as providers with respect to patient safety organizations, as outlined in section 4005(c), and with the HHS Office for Civil Rights (OCR) to identify effective means to, for example, promote convenient patient access to health information, as outlined in section 4006. We are also working to implement the information blocking provisions in Title IV, in close coordination with all of our Federal partners, including the HHS Office of the Inspector General (OIG), CMS, OCR, and the Federal Trade Commission (FTC).

We agree with Congress that health IT must be more interoperable, that it should be easier to use for everyone, and that information must flow seamlessly—that is, without unreasonable impediment—while still respecting individual privacy rights and applying strong security protections to the information. Transaction costs to move health information within Federal programs alone are considerable. For example, in FY'2016 the Social Security Administration Office of Disability Determination received medical records from healthcare organizations costing about $180 million and consultative exams costing about $391 million for a total cost of about $571 million.

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[4] America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act

[5] *https://www.oncprojectracking.healthit.gov/wiki/display/TechLabI/ONC+Challenges+and+Winners*

[6] *https://www.healthit.gov/buzz-blog/healthit-certification/step-diversify-certification-programs-testing-portfolio/*

[7] *https://www.healthit.gov/buzz-blog/interoperability/onc-health-certification-program-approves-himssimmunization-integration-program-iip-testing-method/*

Frictionless access to and use of medical data will increasingly improve the ability of patients to shop for care. As authorized by the Cures Act, we are working to support a competitive marketplace by improving the ease with which clinicians, patients, and their caregivers can securely send and receive medical information. These pro-competitive steps include combating information blocking and will allow new business models and software applications to flourish.

It should be noted that increased interoperability is also important to the payers who purchase most of our medical care and who often have difficulty accessing data they need for reimbursement decisions. Computationally open APIs provide the data liquidity that artificial intelligence and machine learning are dependent upon to realize their full potential in healthcare (that can be used consistent with the privacy and security requirements of the Health Insurance Portability and Accountability Act of 1996 regulations).

There are many potential avenues for us to work to advance interoperability. To provide focus and clarity for ONC stakeholders, we are concentrating on three framing questions. The first is about the patient: can patients access their medical data in a secure, straight-forward, and consumer-friendly way? The second is about institutional accountability: can payers efficiently assess the quality and value of the care purchased, and can clinicians efficiently and effectively provide care for entire populations? The third guiding question is how to operationally define an open API without special effort.

Most patient data is held by clinicians and EHR vendors, so what do open APIs at the clinician and at the vendor level look like? The Cures Act requires that the use of these APIs be "without special effort," so we are looking at advancements in the health IT community to help understand the full opportunities presented by APIs. ONC is leading efforts to bring these modern data standards to healthcare working with the Health Level Seven standards organization and key developers of Fast Healthcare Interoperability Resources (also known as FHIR) interface technology.

APIs provide one avenue to interoperability, especially for patients and payers. Regional and commercially initiated interoperability networks provide another route to interoperability. To date, these have focused exclusively on facilitating communications between certain groups of clinicians for the purpose of treatment (though often behavioral health and substance use treatment information is not exchanged) but not payment or healthcare operations purposes. ONC has initiated efforts to implement the "trusted exchange" frameworks and common agreement provisions outlined in section 4003(b) of the Cures Act. We held two public listening sessions with stakeholders across the health IT spectrum and completed one round of public comment to gain insight from stakeholders on the policies and practices the Trusted Exchange Framework and Common Agreement (TEFCA) should address. The TEFCA will be an integral component of nationwide network-to-network exchange of health data and a critical part of our charge to support nationwide interoperability. ONC will hold one more listening session before we release draft materials for public comment.

As in the past, ONC is committed to serving as a coordinator and convener of most participants in the health IT field. As part of our implementation of the Cures Act, ONC has worked closely with the HHS Secretary's office to wind down the previous two health IT Federal advisory committees and to stand up the new Health IT Advisory Committee called out in the Cures Act, as outlined in section 4003(e). To select new committee members, we have worked closely with Members of Congress and the Government Accountability Office. The new charter has been finalized and we anticipate meetings will commence this winter.

We are excited about our work underway to advance Congress's goals in the Cures Act, however it is important for me to share with you what ONC has not been able to advance at this time. Due to competing priorities, at this time ONC is unable to move forward with implementation of Section 4002(c), which calls for a transparent process to develop reporting criteria as part of an "EHR Reporting Program" for certified health IT.

ONC recognizes the importance of working with our Federal partners, Members of Congress this Committee included and external stakeholders such as patients, clinicians, health IT developers, and payers. ONC has a primary role in implementing the health IT provisions in the Cures Act. We are excited to work with Congress and our stakeholders to make health information more accessible, decrease documentation burden, and support EHR usability while simultaneously accelerating innovation and competitive healthcare markets.

Health IT holds great promise to increase more effective and efficient care. Importantly, we believe that computational ownership, or access to and use of, electronic data by patients and payers (not just clinicians) can set a floor for increased market

competition. The Cures Act encourages new approaches and business models for healthcare, and ONC will use the tools provided by Congress through the Cures Act to tackle today's challenges of interoperability, usability, and information blocking. We look forward to working with you to achieve our shared vision. Thank you again for the opportunity to speak before you today and I look forward to your questions.

The CHAIRMAN. Thank you, Dr. White.

Dr. Goodrich, welcome.

STATEMENT OF KATE GOODRICH

Dr. GOODRICH. Thank you. Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to discuss the Centers for Medicare and Medicaid Services efforts to implement the health information technology provisions of the 21st Century Cures Act. We appreciate your leadership in enacting this important law, and CMS is working closely with our colleagues in the Office of the National Coordinator and HHS Office of Inspector General on its implementation.

In addition to my roles at CMS as the Director of the Center for Clinical Standards and Quality and Chief Medical Officer, I continue to practice medicine as a hospitalist on weekends. This gives me an on-the-ground perspective of how the work we do at CMS is succeeding or failing. From this vantage point I see both the promises and the pitfalls of health IT and electronic health records.

I regularly see anywhere from 20 to 30 patients on a weekend. Prior to the adoption of health IT, I spent at least 2 hours writing out, by hand, separate orders for each patient. Today, with just a few clicks, I can complete that same work in less than one-quarter of the time, which allows me to spend more time with my patients.

At the same time, though, I can tell you that there are still too many burdens on clinicians, and we are a long way from true interoperability. Far too often, I still need to call, fax, copy, or manually enter information into a health record, a process which could and should be much more efficient.

Additionally, as the caregiver for my mother, an 80-year-old Medicare beneficiary, I've been with her when her geriatrician doesn't have access to her records from an appointment with a specialist that we saw just a few weeks or months ago. I use these perspectives to help guide me and my CMS colleagues as we implement recent laws that encourage the adoption of health IT.

CMS, by law, has implemented two key programs to encourage hospitals and clinicians to adopt and effectively use certified EHR technology, the Medicare and Medicaid EHR Incentive Program, and the Advancing Care Information component of the Quality Payment Program, or MACRA. Congress created these programs to encourage hospitals and clinicians to adopt and meaningfully use EHRs. While these programs have helped clinicians to procure and begin to use these technologies, we are far from the goal of interoperability.

As we travel the country and meet with doctors and nurses on the front lines, CMS leadership is hearing similar concerns from these stakeholders. The implementation of the 21st Century Cures Act provides an opportunity to look at what's working, what's not working with regard to policies surrounding health IT, and at CMS

we are taking a hard look to make sure we are meeting the needs of clinicians and patients.

For example, as directed or required by the 21st Century Cures Act, CMS has adopted and proposed for clinicians a specific hardship exception for hospitals and clinicians whose EHR technology becomes decertified, to recognize the difficulty health care providers face when the software that they have invested in becomes decertified.

Earlier this year CMS implemented and proposed for clinicians an exception to the 2017 and 2018 Medicare payment adjustments for clinicians who furnish 75 percent or more of their covered professional services in an ambulatory surgical center. We've clarified our policies so that a physician may now delegate some of the EHR documentation requirements to another person as long as the physician signs and verifies the documentation, which gives physicians more time facing their patients and less time facing the computer. CMS is publicly hosting data that shows the percentage of hospitals and eligible professionals delineated by state who have demonstrated meaningful use of certified technology in the EHR incentive programs.

Like the situations with my mother and with my patients demonstrate, health information should be available and securely and effectively shared when and where it is needed. CMS anticipates referring any cases of information blocking it becomes aware of to the OIG for further investigation, as required by law.

In addition, CMS now requires clinicians to attest that they have not knowingly and willfully limited or restricted the compatibility or interoperability of their certified EHR technology as part of the quality payment program.

As a practicing physician, every time I meet with patients, I want to be able to give them the best care efficiently and effectively. However, far too often, I still encounter obstacles to achieving true interoperability and the full promise of health IT.

CMS is looking to drive patient-centered care in all of our programs. We are listening to stakeholders and committed to using data-driven insights, meaningful quality measures, and technology that empowers patients and their clinicians to make decisions about their health care.

The enactment of the 21st Century Cures Act has provided CMS with another opportunity to pursue flexibility and reduce burden on providers and patients while helping to spur the adoption of promising technologies. We appreciate the Committee's ongoing interest and commitment to this important work, and look forward to continuing to work with you. Thank you.

[The prepared statement of Dr. Goodrich follows:]

PREPARED STATEMENT OF KATE GOODRICH

Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to discuss the Centers for Medicare & Medicaid Services' (CMS) efforts to implement the health information technology (health IT) provisions of the 21st Century Cures Act.[1] CMS is committed to partnering with healthcare providers and stakeholders to harness the potential of health IT, while

[1] Public Law No. 114–255: *https://www.Congress.gov/114/plaws/publ255/PLAW–114publ255.pdf*

reducing burden on providers and ensuring high-quality care for their patients. CMS is working closely with our colleagues in the Office of the National Coordinator for Health Information Technology (ONC) and the Department of Health and Human Services Office of Inspector General (HHS-OIG) to implement this important law.

While health IT holds promise in helping clinicians communicate and in empowering patients with access to their health information, as a practicing physician, I can personally attest to the work that remains before we fully meet this promise. Electronic Health Records (EHRs) can be an important source of information and data, but the need to input data can interrupt the face-to-face time I have with my patients. CMS is hearing similar concerns from clinicians across the country. We have heard that there are too many quality programs, technology requirements, and other measures, like meaningful use measures, that get between the clinician and the patient. Clinicians have difficulty getting the data they need for reporting quality measures directly from the EHR, which should be a seamless process. Some patients struggle to access their information online. In my experience, everyone practicing medicine wants to provide the best care possible for patients, and far too often it seems the on-the-ground reality of EHRs fall short of what was envisioned. We have a long way to go before EHRs are truly interoperable, allowing clinicians, like me, to easily access health information about our patients when other providers they see use different systems.

CMS, by law has implemented two key programs to encourage hospitals and clinicians to adopt and effectively use certified EHRs: the Medicare and Medicaid EHR Incentive Programs (as established by the American Recovery and Reinvestment Act of 2009[2]) (for clinicians and hospitals) and the Quality Payment Program and its Advancing Care Information category (as established by the Medicare Access and CHIP Reauthorization Act of 2015[3] (MACRA)) (for clinicians). These programs are intended to encourage hospitals and clinicians to adopt and meaningfully use EHRs. While these programs have helped clinicians procure and begin to use these technologies, we are far away from the goal of interoperability, in which these systems can effectively communicate.

At CMS, we are taking a hard look at what is working and what is not working, as well as what is duplicative, and what we may be missing to help us move in the right direction and more fully realize the promise of EHRs without placing unnecessary requirements on clinicians. CMS is committed to simplifying our programs, especially for small, independent, and rural practices, while ensuring fiscal sustainability and high-quality care.

CMS is reducing burden and increasing flexibility for hospitals and clinicians through our payment policies, rulemaking, and other interactions with providers. CMS has included Requests for Information (RFIs) as part of our annual Medicare payment rulemaking process to obtain feedback on positive solutions to better achieve transparency, flexibility, program simplification, and innovation. This feedback will inform the discussion of ways to reduce burden in program requirements. Through these RFIs, CMS is starting a national conversation about improving the healthcare delivery system, how Medicare can contribute to making the delivery system less bureaucratic and complex, and how CMS can reduce burden for clinicians, providers, and patients in a way that increases quality of care and decreases costs—thereby making the healthcare system more effective, simple, and accessible while maintaining program integrity.

Promoting Health IT with the 21st Century Cures Act

Congress has helped to further streamline EHR adoption and use efforts with the enactment of the 21st Century Cures Act, which charges HHS with addressing some of the obstacles to realizing the promise of health IT. The implementation of this law will help to continue the adoption and use of health IT, while eliminating unnecessary requirements, and making it easier for clinicians to do what they do best: care for patients. CMS is supporting ONC's work to establish a goal for the reduction of regulatory or administrative burdens relating to the use of EHRs as well as a strategy and recommendations for meeting the goal, as required by the 21st Century Cures Act. Working closely with the ONC, CMS is looking at opportunities for improvement, particularly related to timelines, flexibility, decreased burden, and clearly defined requirements.

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[2] Public Law No. 111–5: *https://www.Congress.gov/111/plaws/publ5/PLAW–111publ5.pdf*

[3] Public Law No. 114–10: *https://www.Congress.gov/114/plaws/publ10/PLAW–114publ10.pdf*

Electronic health information should be available and securely and efficiently shared, when and where it is needed, to support patient-centered care, enhance health care quality and efficiency, and advance research and public health. To implement the 21st Century Cures requirement for the Office of the Inspector General to investigate claims of information blocking by health information technology vendors, health information exchanges or networks, or health care providers, CMS anticipates referring any cases of information blocking it becomes aware of to the OIG. In addition, MACRA required clinicians to show that they have not knowingly and willfully limited or restricted the compatibility or interoperability of their certified EHR technology when they attest to how they used EHR technology for the purpose of the Quality Payment Program. CMS issued a rule that implemented this requirement for all clinicians in November 2016. [4]

CMS is also examining the opportunities presented by telehealth and telemedicine technology. CMS will produce a report on the populations of Medicare beneficiaries who would most benefit from expansion of telehealth and other information that can help inform future congressional policymaking on the future of telehealth in Medicare as requested by the 21st Century Cures Act.

CMS has also begun work to establish a provider digital contact information index, another requirement of the 21st Century Cures Act, which will provide digital contact information for health professionals and facilities. This index is intended to improve the exchange of electronic health information between different providers and facilities and CMS is working with our colleagues at the ONC to ensure that this directory is useful to providers who want to contact each other and stakeholders.

Promoting Health IT though Flexibility and Alignment

In addition to implementing important provisions of the 21st Century Cures Act, CMS is using the opportunity presented by the creation of the Quality Payment Program to help reduce burden on clinicians using EHRs. The Quality Payment Program [5] includes certain aspects of three separate programs, including the Medicare EHR Incentive Program (often called "meaningful use") for physicians, into one program designed to reward clinicians for providing high quality care. The Quality Payment Program brings significant changes to how clinicians are paid within Medicare, so CMS is continuing to take implementation slowly to ensure that clinicians can easily participate and that patients are put first. CMS is using stakeholder feedback to find ways to streamline the programs to reduce clinician burden. For example, we proposed to implement a variety of participation options, including a virtual group participation option. CMS is carefully reviewing the comments we received on the Quality Payment Program proposed rule released in June 2017 [6], and this Administration will continue to listen to stakeholders and take steps to support clinicians and patients by alleviating burdens and allowing them to focus on improving health outcomes.

In addition, CMS has taken the following specific steps in the last year to reduce burden and improve flexibility through our proposed and final policies related to EHRs.

. Improved Flexibility. For the EHR Incentive Program, CMS adopted for the 2018 reporting period [7], and for the Quality Payment Program, it proposed for clinicians for the 2018 [8] performance period, policies that allow hospitals and clinicians to use various versions of certified EHR technology. For example, some clinicians may use the 2014 Edition while others may use the 2015 Edition, or a combination of the two. This increased flexibility encourages hospitals and clinicians to participate in the programs even if they haven't upgraded their software to the latest certified version. CMS continues to encourage clinicians and hospitals to migrate to the implementation and use of EHR technology certified to the 2015 Edition so they may

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[4] Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician Focused Payment Models Final Rule (CMS—5517—FC)—*https://www.gpo.gov/fdsys/pkg/FR–2016–11–04/pdf/2016–25240.pdf*

[5] *https://qpp.cms.gov/*

[6] CY 2018 Updates to the Quality Payment Program Proposed Rule (CMS—5522—P)—*https://www.gpo.gov/fdsys/pkg/FR–2017–06–30/pdf/2017–13010.pdf*

[7] Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician Focused Payment Models Final Rule (CMS—5517—FC)—*https://www.gpo.gov/fdsys/pkg/FR–2016–11–04/pdf/2016–25240.pdf*

[8] CY 2018 Updates to the Quality Payment Program Proposed Rule (CMS—5522—P)-*https://www.gpo.gov/fdsys/pkg/FR–2017–06–30/pdf/2017–13010.pdf*

take advantage of improved functionalities, but we recognize that depending on their circumstances, some hospitals or clinicians may need more time to make these updates.

- Increased Alignment Between Programs. It can be challenging for hospitals and clinicians to comply with the differing requirements of multiple programs. Whenever possible, CMS has looked for ways to align the programs relevant to EHRs, including aligning the clinical quality measure requirements. As an example, under the Quality Payment Program, the Medicare clinical quality measure requirements have been aligned to eliminate any duplication in reporting. Clinicians can choose to report quality measures through their EHR system; however, if another reporting mechanism better meets their needs for reporting measures, such as a qualified clinical data registry, they can choose that mechanism to report. [11]
- Exception for clinicians in small practices. Additionally, in response to concerns raised by small and rural providers, CMS has also proposed a new category of hardship exceptions for small practices (15 or fewer clinicians). [12]
- Clarifying Documentation Requirements. CMS has also implemented 21st Century Cures requirements by clarifying our policy that a physician may delegate some of the EHR documentation requirements to another person as long as the physician signs and verifies the documentation. [13] This allows physicians to spend more time with patients and less time in front of a computer.
- Hardship Exceptions for Decertified EHR Technology. CMS has granted timely requests for hardship exceptions from the Medicare EHR Incentive Program for hospitals and clinicians with EHR vendor issues. As directed by the 21st Century Cures Act, this year we adopted [14] (and proposed for clinicians [15]) a specific hardship exception for hospitals and clinicians whose EHR technology becomes decertified to recognize the difficulty health care providers face when the software they have invested in becomes decertified.
- New Advancing Care Information (ACI) Exception for Clinicians Who are ASC-Based. CMS has implemented the 21st Century Cures Act provisions requiring an exception to the 2017 and 2018 Medicare payment adjustments for clinicians who furnish 75 percent or more of their covered professional services in an ambulatory surgical center [16].
- Promote Transparency. CMS has implemented the 21st Century Cures Act provision by publicly posting data online that shows the percentage of hospitals [17] and eligible professionals [18], delineated by state, who have demonstrated meaningful use of certified EHR technology in the Medicare and Medicaid EHR Incentive Programs.

Looking Forward

As CMS looks to drive patient-centered care in all of our programs, we are listening to stakeholders and committed to using data driven insights and meaningful quality measures and technology that empowers patients and clinicians to make decisions about their healthcare. While recognizing that we have a long way to go to make health IT truly interoperable, the enactment of the 21st Century Cures Act has provided CMS with another opportunity to pursue flexibility and reduce burden on providers and patients, while helping to spur the adoption of promising tech-

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[11] Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician Focused Payment Models Final Rule (CMS—5517—FC)—*https://www.gpo.gov/fdsys/pkg/FR–2016–11–04/pdf/2016–25240.pdf*

[12] CY 2018 Updates to the Quality Payment Program Proposed Rule (CMS—5522—P)-*https://www.gpo.gov/fdsys/pkg/FR–2017–06–30/pdf/2017–13010.pdf*

[13] For more information see: *https://questions.cms.gov/faq.php—faqId=20477*

[14] Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates—Final Rule (CMS—1677—F)—*https://www.gpo.gov/fdsys/pkg/FR–2017–08–14/pdf/2017–16434.pdf*

[15] CY 2018 Updates to the Quality Payment Program Proposed Rule (CMS—5522—P)-*https://www.gpo.gov/fdsys/pkg/FR–2017–06–30/pdf/2017–13010.pdf*

[16] Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates—Final Rule (CMS—1677—F)—*https://www.gpo.gov/fdsys/pkg/FR–2017–08–14/pdf/2017–16434.pdf*

[17] *https://dashboard.healthit.gov/quickstats/pages/FIG-Hospitals-EHR-Incentive-Programs.php*

[18] *https://dashboard.healthit.gov/quickstats/pages/FIG-Health-Care-Professionals-EHR-Incentive-Programs.php*

nologies. We appreciate the Committee's ongoing interest and commitment to this important work, and look forward to continuing to work with you.

The CHAIRMAN. Thank you, Dr. Goodrich.

Mr. Cannatti, welcome.

STATEMENT OF JAMES A. CANNATTI, III

Mr. CANNATTI. Thank you. Good afternoon, Chairman Alexander, Ranking Member Murray, and other distinguished Members of the Committee. Thank you for the opportunity to appear before you today. I am pleased to be able to discuss OIG's role in the implementation of the health IT provisions of the 21st Century Cures Act. My testimony today will focus on OIG's new information blocking authorities provided under Section 4004 of the Cures Act.

In general terms, information blocking is a practice that inappropriately impedes the flow or use of information. The availability of information when and where it is needed is a critical element of a high-functioning health care system.

OIG's mission is to protect the integrity of HHS programs and the health and welfare of program beneficiaries. Information blocking can pose a threat to patient safety and undermine efforts by providers, payers, and others to make our health care system more efficient and effective.

For example, when pertinent information is not available in a patient's record, a physician may inadvertently prescribe a contraindicated drug. Although an area of concern for some time, OIG historically had no authority that allowed us to investigate or take enforcement action based solely on acts of information blocking. Rather, we looked to leverage existing authorities, where possible, to hold wrongdoers accountable.

With the passage of the Cures Act in December 2016, Congress empowered OIG to directly address the problem of information blocking. The statute requires rulemaking to carve out certain reasonable and necessary activities that do not constitute information blocking for purposes of the law. Within the Department, ONC has been tasked with that rulemaking.

ONC's final rule will provide a legal basis that OIG will use to assess conduct during our investigations and our enforcement activities. In the meantime, OIG has been preparing for effective, efficient, and fair enforcement. Our goal is to protect patients and the health care system by stopping information blocking. We aim to leverage our new authorities to change behaviors in the industry. We believe that this can best be accomplished through a combination of clear rules of the road for those who want to comply with the law and targeted enforcement against those who choose to break it.

The Cures Act information blocking prohibition covers a broad spectrum of conduct and arrangements. It covers everyone from large electronic health IT providers and developers to individual physicians, and the information blocking landscape is complex. It combines highly technical issues with a breadth of business arrangements. Stakeholder engagement is critical to developing a deep understanding of this complex landscape.

To date, we have held more than a dozen stakeholder meetings with representatives from a wide cross-section of the health care

and technology communities. The insights gained from stakeholders will help us as we begin enforcement.

We have also engaged with our partners, including ONC, CMS, the HHS Office for Civil Rights, and the Federal Trade Commission. We have provided and will continue to provide technical assistance to ONC, and we are working to formalize processes for sharing complaints, referrals, and other information within HHS.

The Cures Act provided important new authorities that enhanced the government's ability to address the problem of information blocking. OIG is working diligently, alongside our HHS partners, and with input from stakeholders, to prepare to enforce. We aim to deter information blocking, hold wrongdoers accountable, promote the integrity of HHS programs, and benefit the public.

Thank you for the opportunity to testify on this important issue. I look forward to answering your questions.

[The prepared statement of Mr. Cannatti follows:]

PREPARED STATEMENT OF JAMES A. CANNATTI, III

Good afternoon, Chairman Alexander, Ranking Member Murray, and other distinguished Members of the Committee. I am James Cannatti, Senior Counselor for Health Information Technology for the Office of Inspector General (OIG), U.S. Department of Health and Human Services (HHS or Department). Thank you for the opportunity to appear before you to discuss OIG's role in the implementation of the health information technology (health IT) provisions of the 21st Century Cures Act (the Cures Act). My testimony today will focus on our new information blocking investigative and enforcement authorities provided under Section 4004 of the Cures Act.

Information Blocking Harms Patient Care and Our Health Care System

In general terms, information blocking is a practice that inappropriately impedes the flow or use of information.[1] The availability of information when and where it is needed is a critical element of a high-functioning health care system.

OIG has long acknowledged the importance of the appropriate flow of information, subject, of course, to privacy and security protections. In fact, OIG has highlighted the issue for the past several years in our annual list of Top Management and Performance Challenges facing the Department.[2] Addressing the negative impacts of information blocking is consistent with OIG's mission to protect the integrity of HHS programs, as well as the health and welfare of program beneficiaries.

Information blocking can pose a threat to patient safety and undermine efforts by providers, payors, and others to make our health care system more efficient and effective. For example, when pertinent information is not available in a patient's record, a physician may inadvertently prescribe a contraindicated drug causing the patient to become ill. Further, when results are not shared between providers, patients may be subjected to duplicate tests. Beyond unnecessarily exposing patients to risks associated with the tests,[3] payors and patients incur unnecessary costs for the duplicative services. Information blocking also threatens the significant investment taxpayers have made in encouraging the adoption and use of technologies like electronic health records (EHRs).

OIG's Approach to Information Blocking Before the Cures Act

Historically, OIG had no authority to investigate or take enforcement action based solely on acts of information blocking. Rather, the concept arose for us in the context

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[1] Section 4004 of the Cures Act added a specific definition of information blocking for purposes of the statute. That definition is codified at Section 3022(a) of the Public Health Services Act, 42 U.S.C. § 300jj–52(a).

[2] For 2016, OIG identified 10 top management and performance challenges, including one entitled "Health Information Technology and the Meaningful and Secure Exchange and Use of Electronic Information." OIG's 2016 Top Management and Performance Challenges Facing HHS is available at:*https://oig.hhs.gov/reports-and-publications/top-challenges/2016/*.

[3] Some tests pose greater risks than others; for example, some tests may be more invasive or expose the patient to higher levels of radiation than other tests.

of the application of the Federal anti-kickback statute (the Anti-Kickback Statute)[4] to arrangements in which one party, such as a hospital, provides an EHR system to another party, such as a physician group practice. These "donation" arrangements were designed to facilitate and promote broad adoption of EHRs. Questions arose about the need for safe harbor protection for some of these donation arrangements. In 2006, OIG issued a final rule establishing a safe harbor that protected certain EHR donation arrangements and required, among other conditions, that donated EHR software be interoperable (the EHR safe harbor).[5] Our goal was to "promot[e] the adoption of interoperable [EHR] technology that benefits patient care while reducing the likelihood that the safe harbor [would] be misused by donors to secure referrals" from those receiving the technology.[6] As with all safe harbors, we attempted to strike a balance—endeavoring to include safeguards that minimize potential fraud and abuse risks, without impacting the positive benefits of the underlying arrangements. In the case of the EHR safe harbor, one of the key safeguards prohibited donors and certain other parties from taking actions to limit or restrict the use, compatibility, or interoperability of donated EHR systems.

Although we did not use the term "information blocking" at the time, the EHR safe harbor conditions included concepts that align closely with the Cures Act prohibition on information blocking. We were concerned that information blocking would serve as a method of locking in or steering referrals, conduct prohibited by the Anti-Kickback Statute. Over time, our concerns about this risk grew. Moreover, Congress, HHS, and other stakeholders began raising additional concerns about information blocking. Accordingly, we issued a policy reminder in 2015 to again warn the industry about the impact of information blocking on potential safe harbor protection, and we went so far as to restate our position that EHR donation arrangements involving information blocking would be suspect under the Anti-Kickback Statute.[7]

The Cures Act Empowers OIG to Directly Address Information Blocking

With the passage of the Cures Act in December 2016, Congress gave OIG new authorities that will allow us to address the issue of information blocking more directly—beyond those limited circumstances in which the conduct is a part of a larger kickback scheme. The Cures Act added section 3022(b)(1) of the Public Health Services Act,[8] which granted OIG specific authority to investigate claims that certain parties (health information technology developers, health care providers, and others) engaged in information blocking as defined in section 3022(a). Further, subsection (b)(2) established penalties for those engaged in information blocking. For developers and certain other parties, the penalties take the form of civil monetary penalties not to exceed 1 million dollars per violation.[9] For health care providers, the Cures Act directs OIG to refer such parties to "the appropriate agency to be subject to appropriate disincentives. . . ."[10]

OIG's information blocking authorities under the statute are directly tied to the definition of information blocking in Section 3022(a). That definition contemplates rulemaking to identify "reasonable and necessary" activities that would not constitute information blocking for purposes of the Cures Act. Within the Department, our colleagues at the Office of the National Coordinator for Health Information Technology (ONC) have been tasked with that rulemaking, which will address the definition of information blocking within the meaning of Section 3022 and will provide the legal basis that OIG will use to assess conduct during our investigations and enforcement actions.

OIG Is Preparing for Effective, Efficient, and Fair Enforcement

OIG has been readying for effective, efficient, and fair enforcement. Our goal is to protect patients and the health care system by stopping information blocking. We aim to leverage our new authorities to change behaviors in the industry. We believe this can best be accomplished through a combination of clear rules of the road for

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[4] 42 U.S.C. § 1320a–7b(b).
[5] 71 Fed. Reg. 45110 (Aug. 8, 2006); 42 C.F.R. § 1001.952(y). We most recently modified the EHR safe harbor at the end of 2013. 78 Fed. Reg. 79208 (Dec. 27, 2013).
[6] 78 Fed. Reg. 79208 (Dec. 27, 2013).
[7] OIG Alert, OIG Policy Reminder: Information Blocking and the Federal Anti-Kickback Statute (Oct. 6, 2015), available at:*https://oig.hhs.gov/compliance/alerts/guidance/policy-reminder–100615.pdf.*
[8] 42 U.S.C. § 300jj–52.
[9] Section 3022(b)(2)(A) of the Public Health Services Act, 42 U.S.C. § 300jj–52(b)(2)(A).
[10] Section 3022(b)(2)(B) of the Public Health Services Act, 42 U.S.C. § 300jj–52(b)(2)(B).

those who want to comply with the law and targeted enforcement against those who choose to break it.

The Cures Act information blocking prohibition covers a broad spectrum of conduct and arrangements. It covers everyone from large electronic health IT developers to individual physicians. The information blocking landscape is complex. It combines highly technical issues and a breadth of business arrangements and scenarios. Stakeholder engagement is critical to developing a deep understanding of this complex landscape. That is why we began engaging with industry and other private stakeholders that expressed an interest in sharing their unique perspectives on information blocking. To date, we have held more than a dozen stakeholder meetings with representatives from a wide cross-section of the health care and technology communities. We have included our colleagues from ONC in these meetings to further coordination on this topic within HHS. The insights gained from stakeholders will help us as we implement an effective, efficient, and fair enforcement approach to the issue of information blocking.

We have also engaged with our Federal partners, including ONC, the Centers for Medicare & Medicaid Services, the HHS Office for Civil Rights, and the Federal Trade Commission. For example, we have provided technical assistance to ONC on enforcement-related issues in order to inform its policy formulation efforts. Additionally, we are working to formalize processes for sharing complaints, referrals, and other information relevant to information blocking enforcement efforts within HHS that build on existing efforts, where possible. These efforts are intended to ensure that we are prepared to leverage the new tools to curb information blocking.

Conclusion

Stopping information blocking is important for patients and the broader health care system. The Cures Act provides important new authorities that enhance the Government's ability to address this problem. OIG is working diligently, alongside our HHS partners and with substantial input from private stakeholders, to implement an enforcement approach that deters information blocking, holds wrongdoers accountable, promotes the integrity of HHS programs, helps protect the health and welfare of program beneficiaries, and benefits the American public.

Thank you for the opportunity to testify on this important issue. I look forward to answering questions.

[SUMMARY STATEMENT OF JAMES A. CANNATTI, III]

Information Blocking Harms Patient Care and Our Health Care System

In general terms, information blocking is a practice that inappropriately impedes the flow or use of information. It can pose a threat to patient safety and undermine efforts by providers, payors, and others to make our health care system more efficient and effective. Information blocking also threatens the significant investment taxpayers have made in encouraging the adoption and use of technologies like electronic health records (EHRs). Historically, OIG had no authority to investigate or take enforcement action based solely on acts of information blocking.

The Cures Act Empowers OIG to Directly Address Information Blocking

Through the Cures Act, Congress gave OIG new investigative and enforcement authorities that will allow us to address the issue of information blocking directly. OIG's new authorities are tied to the definition of information blocking in the statute. That definition contemplates rulemaking to identify "reasonable and necessary" activities that would not constitute information blocking for purposes of the Cures Act. Within the Department, our colleagues at the Office of the National Coordinator for Health Information Technology (ONC) have been tasked with that rulemaking, which will address the definition of information blocking within the meaning the law and will provide the legal basis that OIG will use to assess conduct during our investigations and enforcement actions.

OIG Is Preparing for Effective, Efficient, and Fair Enforcement

OIG has been readying for effective, efficient, and fair enforcement. Our goal is to protect patients and the health care system by stopping information blocking. We aim to leverage our new authorities to change behaviors in the industry. We believe this can best be accomplished through a combination of clear rules of the road for those who want to comply with the law and targeted enforcement against those who choose to break it. We have engaged industry and other private stakeholders that

expressed an interest in sharing their unique perspectives on information blocking, holding more than a dozen meetings to date. We have also engaged with our Federal partners, including ONC, the Centers for Medicare & Medicaid Services, the HHS Office for Civil Rights, and the Federal Trade Commission. We have provided, and will continue to provide, technical assistance to ONC, and we are working to formalize processes for sharing complaints, referrals, and other information relevant to information blocking enforcement efforts within HHS. The Cures Act provides important new authorities that enhance the government's ability to address the problem of information blocking. OIG is working diligently, alongside our HHS partners and with substantial input from private stakeholders, to implement an enforcement approach that deters information blocking, holds wrongdoers accountable, promotes the integrity of HHS programs, helps protect the health and welfare of program beneficiaries, and benefits the American public.

The CHAIRMAN. Thanks to all three of you.

We'll now begin a 5-minute round of questions.

Let me start with Dr. White and Dr. Goodrich on a subject that I expect you'll get some more sophisticated questioning about from Dr. Cassidy, but this is the subject of physician documentation.

There are about, I believe, 900,000 doctors in the country, and about 500,000 who use Medicare. Am I correct that the doctors who use Medicare are subject to the meaningful use rules and regulations that involve electronic health care records? Is that correct? It's about 500,000 doctors.

According to a 2016 study funded by the American Medical Association, for every hour a doctor spends with a patient, two additional hours are spent on electronic health records and desk work. According to a 2013 study by the Rand Corporation, electronic health records are the leading cause of physician dissatisfaction.

Does that sound right to you, Dr. Goodrich?

Dr. GOODRICH. I have read the same studies, and that is what we have certainly heard from the clinicians that we engage with through the implementation of our programs.

The CHAIRMAN. Dr. White, what about you? Do you think it's true that for every hour a doctor spends with a patient, two additional hours are spent on electronic health records and desk work?

Dr. WHITE. Not to be smart, but when they find out my job, usually that's the first thing they complain to me about. I will say that it is certainly an issue that we hear about frequently. When you consider studies like that, it's worth taking a look at the full breadth of the administrative tasks that any provider has to go through. Some of that is documentation. Some of that is other things, as well.

The CHAIRMAN. Let me keep going, since I've got 5 minutes.

That's two-thirds of a doctor's time spent on electronic records and desk work. If two-thirds is too much, what would be a reasonable goal? Do you have one in mind? Did some independent group ever set one? Did they say it should be 30 or 40, or not more than 50 percent?

Dr. WHITE. I'm not aware of a number specifically, myself.

The CHAIRMAN. Dr. Goodrich, have you ever heard of a number?

Dr. GOODRICH. I haven't heard of a number. I think the point here is that two-thirds is way too much time and we need to reduce that.

The CHAIRMAN. Well, I had a suggestion last year. Let me make it to you. In fact, as a result of this suggestion, we put it in the

law, or I put it in the law, we all did, and that was that the Secretary is to set a goal by December 13 of 2017, a year after the President signed it, of reducing physician documentation.

Now, part of reducing physician documentation is reducing it, and part of it is causing the 500,000 doctors who are subject to meaningful use to believe it's been reduced. I remember that Secretary Burwell, I kept complaining to her, as did other Senators, that the patient satisfaction surveys in hospitals were providing incentives for opioid prescriptions, and all the evidence she had said that wasn't true. But everybody believed it was true, and so she changed the procedures because she said perception has become reality.

It seemed to me an important part of reducing physician documentation and causing doctors to believe it has actually been reduced is to involve them in the process, which is why I suggested that meaningful use be delayed and that they be involved in coming to a conclusion.

Here is a suggestion I made. It may sound very simple. There may be a better one. But you're supposed to come up with a goal, or the Secretary is, by December 13. That's not very far away. My suggestion was that you say we read your report, the AMA report, that said you're spending two-thirds of your time on electronic health records and desk work. If that's true, then either we're not doing our job or you're not doing your job right, and let's work together to reduce that goal to X. That's the goal I was hoping the Secretary would set by December 13, and then involve the physicians in a collaborative process, taking a whole lot of steps to say what can we do to reduce the goal.

Now, you mentioned, Dr. Goodrich, that you've taken some steps, and you work on weekends, and you know what you're talking about. But don't you think it would be a good idea to involve the physicians in that way and say we're going to go from two-thirds to 40 percent over the next 3 years, or 50 percent, or 25 percent, and let them join you in doing that?

Dr. WHITE. This is such an important issue, and we really do hear about it frequently. So we agree with you completely that it's critical to address it, and we want to get it right.

We are very closely partnered with CMS. We work very tightly on this because it's such an important issue. We found four areas of focus that we think are high priorities to address. One is Federal reporting requirements for quality. A second is Federal documentation requirements, including billing. A third is issues of technology, including usability of the software and things like that. The final piece is other requirements like state-level requirements, public health requirements, and other third-party requirements.

We are meeting on a regular basis with key stakeholders, including physician groups, including hospital groups.

The CHAIRMAN. I'm going to cut myself off here or I'll be in trouble with my colleagues. But to me, a goal—those are the steps you're taking, but toward what goal? I think it helps to have a goal. If everybody thinks it's two-thirds and it ought to be something less, I think it would be wise to pick a number and then say join us in doing all these various things to reach that goal, and let us have hearings to see how you're doing.

Senator Murray.

Senator MURRAY. Thank you very much.

Dr. White, let me start with you. Your team is working to engage stakeholders in the implementation of the 21st Century Cures Act, which asks the Office of National Coordinator to develop or support a framework for trusted exchange of electronic health information across networks, and to develop new conditions for certification of health information technology. We had a number of Senators—Baldwin, Whitehouse, Cassidy, Hatch—who worked very hard on those policies, and those will advance interoperability so providers can provide more coordinated care and give patients access to their health information.

Both of those policies are due within the next year. Could you give the Committee an update on how those two priorities are proceeding, and also what you're hearing from stakeholders?

Dr. WHITE. Sure. We appreciate the chance to work on both of those situations. We both think they're very important.

On the trusted exchange framework and common agreement, we believe that ONC can act as a neutral party to work collaboratively with all the stakeholders and ensure that everyone who requires interoperability has a voice in that agreement. We've held two initial public meetings. We have a third one planned. We've had a round of public comments on the trusted exchange framework and common agreement. We're looking forward to getting their feedback. We are committed to getting a draft of that out by the end of the year for public review.

On the conditions of certification, again, there are a lot of important things to work on. We mentioned some of them earlier. That involves rulemaking, so I'm not at liberty to say where we are on that, but we have been busily addressing those, and we look forward to working with your staff and keeping you updated.

Senator MURRAY. So you'll meet the timeline.

I'm curious what you mean by what you're hearing from stakeholders as you go through it.

Dr. WHITE. Well, as you all know, there are several nationwide networks that address or try to achieve interoperability, and there are a number of frameworks and agreements between them, and all these folks are, again, working hard at this and have set up their frameworks and their agreements in certain ways. We've been working hard to understand the variation across those different approaches. They're often there for good reasons, but we sometimes find that some of the variations cause those networks to not be interoperable with each other, which is a challenge. So that's something that we're working hard to understand.

Senator MURRAY. Okay, thank you.

Mr. Cannatti, while you're here I wanted to ask you, last month the Office of the Inspector General reported that Medicare spent over $1.5 billion on just seven medical devices that were either recalled or failed prematurely, but it took the IG years to complete the report because providers are not required to document which device they use when they file a claim. So after a procedure there may be no way to find out what device was used, which can lead to waste in the health system and pose a serious threat to people's safety.

This is especially frustrating because FDA requires each device to carry what is called a unique device identifier, put in place to help us better track safety performance of medical devices. ONC has begun to address this by requiring medical records to include information on what device was used. But wouldn't it be easier to know which devices have safety issues if the device identifier was also in the claims data?

Mr. CANNATTI. Yes. Based on our work, without that information you could not rely solely on the claims data.

Senator MURRAY. Your report recommended that the device identifier be included in the next version of the CMS claims form. My staff's investigation into outbreaks of superbug infections linked to duodenoscopes recommended inclusion in the claims form to improve patient safety. Do you still think that's the right course of action?

Mr. CANNATTI. I do.

Senator MURRAY. Okay. Thank you. I really hope that CMS will work with the organization that develops the claims form and push it to include in the next edition. I think that's really important.

I just have a few seconds left. But, Dr. White, I wanted to ask you, the President's 2018 budget requested $38 million in budget authority for ONC's operating budget. That is a pretty significant cut from the $60 million you ultimately received in 2017. Given the work you have to do to implement Cures, what provisions of the bill will you not be able to carry out if this budget cut is enacted?

Dr. WHITE. So, under the current budget proposal, we are expected to meet all the requirements of the Cures Act, with the exception of the EHR reporting program and Section 4002. As you all know, there was $15 million that was authorized in the Cures Act but not appropriated for that.

Senator MURRAY. So what will you cut?

Dr. WHITE. So at this point, right now, we expect to be able to meet all the requirements of the Cures Act, but we will not be able to implement the EHR reporting program.

Senator MURRAY. Okay. Thank you.

The CHAIRMAN. Thank you, Senator Murray.

Senator Young.

Senator YOUNG. Thank you, Chairman.

Dr. White, I'm going to pick up on the Chairman's line of questioning about establishing goals. I spent a couple of years as a management consultant, and as you likely know, you have your techies who are system experts oftentimes, and you have those who do business process redesign and help tease out system requirements and try to come up with organizational efficiencies.

I don't intend to be prescriptive with respect to your project work, but I'll just say that it might be helpful to this Committee and to other stakeholders, as you establish clearer goals, to assign probabilities to achieving a certain amount of work by a certain amount of time. You have that hard aspirational goal out there, but that would give us I think a richer sense of how likely you are to accomplish this monumental task by certain dates. That's one thought from someone who has done a little of that.

With respect to information blocking, I thought Mr. Cannatti put it pretty concisely, "the practice of some providers electronic health

record vendors of inappropriately impeding information flow or use." So 21st Century Cures Act defines information blocking with respect to electronic health information. The Secretary, in fact, under that law is directed to identify practices that are not information blocking so that he or she can provide safe harbors and give clarity over the issue.

Mr. Cannatti, you directly mention this in your testimony, that the Cures definition of information blocking contemplates rulemaking to identify reasonable and necessary activities that would not constitute information blocking, but there's been no rulemaking. So why hasn't there been a rulemaking, and when do you anticipate this rulemaking taking place, sir?

Mr. CANNATTI. So, we have been working closely with our colleagues at ONC. They are tasked with that, as you indicated. I would have to defer to them in terms of timing.

Dr. WHITE. First, thank you for the advice. They didn't teach me project management in medical school, but I've been learning it in the government.

Regarding rulemaking, the Cures Act——

Senator YOUNG. Thank you for your service.

Dr. WHITE. My pleasure, absolutely.

The Cures Act asks us to define what is not information blocking, and we're looking forward to doing that through rulemaking. As I said previously, because it's before the issuance of a Notice of Proposed Rulemaking, I can't say when. We're working very closely with stakeholders across the spectrum that will be affected by information blocking to understand instances in which it might be appropriate and in which it might not be appropriate.

Senator YOUNG. I appreciate maybe if you huddle up with the team and try to give us some estimate of when we can expect the rulemaking to begin.

Dr. WHITE. In general, we are always delighted to follow-up on a regular basis with staff, so I'm happy to.

Senator YOUNG. Thank you.

There's been some discussion of steps that are being taken—all of you have talked about steps you're taking to improve interoperability, reduce the clinical burden, and address information blocking. But what flexibilities are needed to be built into our health IT system so we can keep up with the latest technology developments?

We'll start with Mr. Cannatti.

Mr. CANNATTI. I think you raise a very important point. From an enforcement perspective, one of the things that's really important for that rulemaking, for the contours that ultimately set out the rules of the road, is to have sufficient flexibility to allow for adaptation to emerging trends or emerging technology. At the same time, it's important to have enough clarity so that both the regulated industry and the enforcers understand what it is that is prohibited and is not.

I know it can be a challenge, but it's really important to kind of strike that balance.

Senator YOUNG. Dr. Goodrich.

Dr. GOODRICH. The provisions around interoperability are primarily under the purview of my colleagues at ONC, but what I will say is that as a clinician it is very frustrating not to be able to see

all the information that I need to see when I have a patient right in front of me that I'm trying to take care of, especially in this day and age. So we are strongly supportive of the new tools and flexibilities that Cures has given the Department to be able to move forward on that.

Dr. WHITE. On the technological side, I'd offer the thought that really the industry has said application programming interfaces are the technical way to get at your data, and that includes both the standards for the data as well as the business rules under which that data can be accessed and by whom it can be accessed. So that's the technical side of things.

Then there's the business practice and policy side of things. This is an instance where the exchange framework and common agreement is not going to be something in a regulation. It's a voluntary agreement. So that's the kind of thing that moves fast enough, and business practice moves fast enough that you shouldn't commit that to a regulation. So again, we're looking forward to having that be a voluntary agreement.

Senator YOUNG. Well, thank you for your work. It's really important we get this right from my constituents perspective. Their ability to shop for health care is really going to be enhanced once this process plays out, so I really appreciate it.

The CHAIRMAN. Thank you, Senator Young.

Senator Bennet, if you'll excuse me, Senator Murray and I were talking and asking staff where is there a rule that says you can't tell us when you're going to start making that rule and when you're going to finish? We hadn't heard of that.

Dr. WHITE. Oh, I'm sorry. My counsel has told me that when we're engaged in rulemaking and we've already started, the official——

The CHAIRMAN. I thought there was a blackout period for comments, after you were waiting for comments.

Dr. WHITE. Right. So—and you may be able to help me out on this one.

[Laughter.]

Dr. WHITE. We started staff discussions about potential rules. That's been ongoing——

The CHAIRMAN. Why don't you go back to the counsel and say that we, in a bipartisan way, we'd like to know when you're going to start and when you're going to finish. If there's some law or rule that prohibits our knowing that, we'd like to know what it is.

Senator MURRAY. Is there a law?

Mr. CANNATTI. I'm not the expert on that. I don't know. We'll ask our counsels, too.

The CHAIRMAN. Thank you.

Senator Bennet.

Senator BENNET. Thank you, Mr. Chairman.

Let's say you started making a rule 60 days—no, I'm just kidding.

[Laughter.]

Senator BENNET. Thank you for having the panel, and it's a privilege to be on a Committee that actually passes legislation. I think we should be passing Alexander-Murray right now. That's not in front of us today.

In the discussion that we're having around interoperability and linking different electronic medical health records, it's important to focus on prescription drug monitoring programs. As all of you know, these data bases help physicians and other providers to monitor opioid use by seeing a patient's prescription history.

When I visited the University of Colorado emergency room not long ago in Colorado, actually the Commissioner of the FDA was with me when I went this past August. Their physicians demonstrated a new tool where the prescription records and the PDMP were tied into the hospital's patient records. Now that those two records speak to each other, that ER has the information it needs in one click, which means that 3 years ago about 20 percent of the patients were leaving the ER with a prescription for pain medication and that percentage has since dropped to 12 percent, and they believe that the advancement can drive that number even lower.

So I wonder—and I'll start, Dr. Goodrich, with you—how we can speed up interoperability between electronic health records and PDMPs as another tool to address the opioid crisis, and anybody else who would like to speak to it, I'm happy to have you do that.

Dr. GOODRICH. Absolutely. Thank you for the question. Interestingly, that is also a functionality that has recently been made possible in the health system that I work in, as well, and it has proven to have incredible benefit to be able to have that information at your fingertips about your patients.

We definitely believe—first of all, the opioid epidemic overall is a top priority of the Administration. In both the QPP, or the quality payment program—excuse me—and the EHR incentive program, we do require that clinicians and hospitals report on their prescribing practices. In addition, under the quality payment program, one of the things that we've put in place is that we can give clinicians credit under the improvement activity category if they access their state's PDMP when considering opioids for their patients or when working with patients who are already on opioids.

So again, we strongly support the work that ONC will be doing with stakeholders around enhancing interoperability. In terms of the actual activities under those sections, I would certainly defer to my colleague, but we're very supportive of that work.

Senator BENNET. Dr. White.

Dr. WHITE. Senator Bennet, thank you for the question. One of the ways in which health IT has become ubiquitous for those of us who get health care that you may have noticed is electronic prescribing. A large number of prescriptions are sent electronically now.

ONC's efforts in this area are focused on two things. One of them has been what you just mentioned, which is harmonizing the technical standards so that data that's in a prescription drug monitoring data base and in an EHR are one and the same and can be shared between them. That's work that we've undertaken for the past 2 years, and you're starting to see the fruits of that.

The other thing that we've done is we've worked with our colleagues at the CDC to translate their prescribing guidelines for responsible prescribing into clinical decision support that can be implemented in information systems so that when Dr. Goodrich goes to prescribe something, she's got the guidelines at her fingertips.

Senator BENNET. Thank you.

Dr. Goodrich, I have one other question. I only have about a minute left. In your written testimony you indicated that CMS is examining opportunities that telehealth presents, and you also noted that CMS is working on a report to describe which Medicare beneficiaries can benefit the most from expansion of telehealth. In Colorado, over 700,000 people live in rural areas, and by 2018 about 40 percent of them will be over the age of 65 and presumably covered by Medicare. So expanded telehealth and remote patient monitoring may be important tools for these Coloradans that have to travel long distances.

I wonder if you could give us what you're looking at in that regard.

Dr. GOODRICH. Absolutely, happy to. First of all, telehealth is very important to us, and we hear all the time from consumers and patients and providers how they would like to see telehealth expanded. We are working actively on the report, as is directed by Cures. We know it's a priority for this Committee, so we're working hard on that. We're looking at which types of patients may benefit from telehealth. We are, of course, looking at innovation center models that are utilizing telehealth and future models that could utilize telehealth. We're also looking at high-volume procedures and codes and diagnoses that may be well suited for telehealth, and also barriers to expansion of telehealth.

So we're excited to be doing this work and working hard to get the Committee the report that you've asked for.

Senator BENNET. Thank you.

Thanks, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Bennet.

Senator Cassidy.

Senator CASSIDY. Hey, you all, thank you for what you do. As a guy who occasionally still uses an electronic medical record, and as one of those people who if I caught you in the doctor's dining room would wear you out, thank you all for doing it.

I think I gather from what you're saying, though, that information blocking persists. Is that correct?

Dr. WHITE. Yes.

Senator CASSIDY. If it persists, it begs the question what are we doing about those who are persisting in blocking information. What are we doing? Do you have the tools? Because I thought we gave you those tools. If we did, are we using those tools to stop this?

Dr. WHITE. It does remain an issue of concern for us, and we do appreciate you giving us the tools to be able to address that. The process is laid out in the law. It starts with saying what is not information blocking, and we're going to work to do that. We're working very closely with our colleagues at OIG and the stakeholders, as I mentioned. Then once we've gone through that process—James, I'll let you speak about what you all might be doing.

Mr. CANNATTI. Absolutely. So, first, just to be clear, while we are not anticipating imposing penalties under the new authorities until after that rulemaking, we are looking at and assessing complaints that we receive, whether referred by ONC or through a hotline, to determine whether there might be other authorities to hold people who are engaging in prohibited conduct accountable.

We are currently engaged in preparing so that when the rulemaking is complete, we'll be ready to enforce. Once we're in the enforcement phase, we will go about that the same way we would with any CMP. We would investigate. We would leverage our investigators. We would issue subpoenas, gather information, weigh the evidence, and in the event that the evidence supported a violation, we would move through the penalty process.

Senator CASSIDY. So we're in a little bit of a holding pattern until all these rules are done, although you hope you have things that could otherwise encourage folks to comply.

Mr. CANNATTI. That's correct.

Senator CASSIDY. Now, in terms of publishing APIs, I actually read some very positive things about how this is progressing. A person who does third-party APIs said, "You've got to be kidding, I'm totally blocked out." There's a woman back home who sees patients but goes home and spends 4 hours every evening typing up her notes. I go to four different hospitals, I have four different interfaces. Why can't I have the same interface which made me so much more efficient when I was there? I wouldn't have to go home and type up notes for 4 hours. So that seems fairly straightforward.

Are the vendors publishing their APIs?

Dr. WHITE. One of the recent enhancements we made to the ONC website is the terms of developers' APIs. So right now you can go to healthIT.gov, pull up what's called the Certified Health IT Product List, and there is actually an API Terms button. You click on it and pick your vendor and you can take a look at the terms of use for that API.

Senator CASSIDY. Now, I didn't quite follow that, the terms of use. Usually that's something I click I agree to, and I would have no clue what it says.

[Laughter.]

Senator CASSIDY. Does the terms of use have adequate technical information so that I, as a programmer, could take my own widget or whatever it's called and, using this, be able to plug it in and take it between vendors products?

Dr. WHITE. Yes, if you're a programmer. Not if you're Dr. Cassidy, but if you're a programmer. That is under the 2015 additional certification rules. Of course, this passed after the 2015 edition was finalized. So we are taking a look at the new provisions and specifically talking about published APIs that make information available without special offer, and trying to figure out how best to implement that so exactly what you're talking about does not happen.

Senator CASSIDY. So, if I'm a programmer—I'm going to be dense. If I'm a programmer, I could log on, and I could see the terms of use, and I would be able to program to that terms of use to come up with something that my friend the neurologist, the pediatric neurologist could then somehow use to go between vendor and vendor and have the exact same form that she was filling out to improve her efficiency, yes or no?

Dr. WHITE. That's an approximate description, yes.

Senator CASSIDY. Okay. Dr. Goodrich, perhaps you'll weigh in on this. Whatever the advantages, one of the specific things that people complain about, physicians complain about EHRs, is the narrative. I mean, instead of the chief complaint is "my leg hurts," and

the history of the present illness is "fell out of a tree," it's now just gobs and gobs of information, oftentimes people cutting and pasting.

Similarly for review of systems, and the importance of this is that you bill for this. If you do a review of systems of the whole body, you just billed a lot more, and that's going to be done automatically, and oftentimes I find people are cutting and pasting review of systems, cutting and pasting physical exams when they've not done them. Frankly, it's Medicare fraud, I think. I don't know if there's been an audit to this.

You are a person who has become quite facile with these EHRs. You feel good about it. But do you find this is a problem, the absence of a narrative, the cutting and the pasting, the bloating of notes, and frankly, the over-billing to payers? If so, what do we do?

Dr. GOODRICH. Thank you for the question. This is definitely something that I have experienced in my clinical life, where you have essentially the same text day after day after day. So you can't really tell what's happening with the patient, if the care plan has been updated——

Senator CASSIDY. Because of cutting and pasting.

Dr. GOODRICH. Because of cutting and pasting.

Senator CASSIDY. It takes so long to do it. People are cutting and pasting because it takes so long to do it.

Dr. GOODRICH. Right, and I think what you're getting to are some of the issues I know my colleagues and I think a lot about, which is around the safety of health IT. I know ONC has done a lot of work in that area. So this is definitely something we're worried about.

As it relates to Medicare fraud, that is obviously something that's a high priority for us at CMS, to guard against Medicare fraud. So it's something that I think we definitely need to keep an eye on and work with our colleagues at ONC to get to a better way to be able to do documentation just generally, and also at an EHR.

Senator CASSIDY. I think that directly feeds into what Senator Alexander said, which is that you've got to make this so that physicians aren't so crunched for time that we're cutting and pasting.

Dr. GOODRICH. Yes.

Senator CASSIDY. Because even though you're good at it, for most physicians it's still a productivity killer. So you don't get the integral change, you just get a cut and paste, which is bad on several measures.

Dr. GOODRICH. Documentation is one of the things that we are taking a comprehensive look at, at CMS, as part of our burden reduction initiative for clinicians.

Senator CASSIDY. Thank you.

The CHAIRMAN. Thank you, Senator Cassidy.

Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

Electronic health records are a valuable resource to help healthcare providers share information about patients in real time, improve the quality of the data, and empower patients to be able to understand and track their own health care needs. But we all know that there are errors. A health record system doesn't always match the patient's health records to the right person. For exam-

ple, when somebody has the same name and the same birth date, they may get switched. Or human error in a lab might mean that they end up assigned to the wrong patient record. I understand these mismatches can be dangerous. They also can be very expensive.

Dr. Goodrich, you oversee efforts at CMS to ensure the quality in health care settings, and quality means, at least in part, accurate patient matching. So can you just say a word about what the dangers are to a patient when their medical records are not accurately matched in a medical setting, when there's a patient misidentification?

Dr. GOODRICH. Yes, absolutely. Unfortunately, I have witnessed actual harm to patients in my clinical practice that has been as a result of patient mismatching. So, as you point out, when one patient is mistaken for another because of an identical or similar name, we know this does happen. Patient mismatching can result in the wrong patient getting the wrong treatment at the wrong time, and that, of course, can lead to actual harm to patients and, of course, medical error.

It also can result, though, in inefficient care when incorrect tests or diagnostics are performed and the patient then needs a duplicative test later on once the mismatching is identified. So that, of course, can contribute to increased cost to the health care system.

Senator WARREN. So money and the fact that people can actually get hurt from this.

Dr. GOODRICH. Yes.

Senator WARREN. A 2012 survey found that 1 in 5 physicians encountered mismatched information that led to illness or injury at least once during the preceding year. Then a recent report showed that medical error, including patient misidentification, was the third leading cause of death in the United States.

Dr. White, you work on patient matching issues at the Office of the National Coordinator. Why is it that the health IT systems used by hospitals and doctors don't always accurately match patient records?

Dr. WHITE. You actually outlined two of the reasons that might happen. There might be a lot of Jon Whites that go to a given hospital, or Jon White might have mistakenly had more than one medical record number assigned to my name. So my CAT scan wasn't in the same place as my blood test.

Even though a hospital uses the same system, that doesn't always preclude you from having patient matching issues. We're actually quite encouraged by some of the modern approaches to matching people to their information. We're certainly taking a look at approaches like biometric identifiers and a couple of other different approaches. There is actually a very robust interest in the private sector. This is an issue that they really want to see solved. We've been very closely following the CHIME patient matching challenge with great interest, and we think there are going to be some good approaches on the near horizon to address the issue.

Senator WARREN. I'm very glad to hear this, that we're working on ways to address the shortcomings in the current system. It's part of the reason, though, that Senator Cassidy and I worked, along with Senator Hatch and Senator Whitehouse and Senator

Baldwin, on a provision in the 21st Century Cures Act that requires the GAO to produce a study on patient matching, and that's why all five of us sent a follow-up letter to GAO earlier this month reminding them of the urgency of this issue and requesting that they produce some clear recommendations for improving patient matching methods in their final report.

So I look forward to working with both of you to improve the safety and quality of our health information systems so patients can get the care they need. Thank you very much for your work, and let's get this done.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.

Senator Hassan.

Senator HASSAN. Thank you, Mr. Chair and Ranking Member Murray, for holding this hearing. Thank you to our witnesses for being here today.

I was very glad to see the topic of this hearing. I'm blessed with two children, one of whom happens to have very complicated medical needs, and at various times we've had as many as nine doctors and 20 medications. Ben is now 29, but especially early on in his life, I really felt like I was the walking medical record and that if I wasn't there with him, all sorts of heck could break loose just because there was a lot to keep track of and everybody had their own recordkeeping system, and sometimes the records made it to the next doctor in time, and sometimes they didn't, for the meeting. So I have seen the benefits as we have moved into the electronic age. I tried as Governor of New Hampshire to help move the process along, but clearly we have some work to do.

So I just wanted to explore really how we are going about implementing the charge in the 2015 Medicare Access and CHIP Reauthorization Act, which instructed HHS to develop metrics to measure the degree to which health providers across the country are able to achieve the widespread interoperable exchange and use of electronic health information.

Dr. Goodrich, I wonder if you can help walk us through this. What metrics did you adopt, and how are you using them to measure interoperability?

Dr. GOODRICH. I can speak to a couple of ways we're doing that. First of all, we do track the adoption of EHRs by rural providers and non-rural providers. I think what we have found is that the adoption rates by rural and non-rural are actually quite similar. So adoption rates have been fairly good for rural providers.

Having said that, we know that there are certainly still significant barriers to adoption by small practices and rural providers.

We also, in the meaningful use program, as well as part of the quality payment program, we have focused the measures on EHR use to really be about interoperability. So about 70 to 80 percent of the measures that clinicians must report on in hospitals really are focused on that exchange of health information from one person to another. We anticipate learning a lot more as those measures are implemented to understand where people are with interoperability.

The other thing I would note is that under MACRA, Congress gave CMS resources to have technical assistance provided specifi-

cally to rural providers and those in underserved areas and small practices. We awarded those contracts in February of this year, and as our contractors are going out into the field and working with these providers to help them with the quality payment program, what they're hearing is I definitely need some help in figuring out what the best EHR is for my practice that is affordable and that is going to meet my needs.

So I think we're also able to give those types of providers who may have increased barriers assistance to help them to get what they need so that they can really see the benefits of EHRs.

Senator HASSAN. Thank you. I'll echo the other Senators on the panel, it sounds like we have plans in place for making progress with metrics. We all want to get to the even better use of this. Coming from a state with a lot of rural providers and small providers, I know that they understand the potential benefits but, yes, they really do need this technical assistance to truly adopt.

Last—and in a second I'll yield back the remainder of my time—I just want to echo what Senator Bennet raised about the importance of prescription drug monitoring for all of us, but particularly in states that have been particularly hard hit by the opioid crisis and the need to make sure that we're sharing that information but also protecting patient privacy, as appropriate. I know you're all working on it, but I'll just add my voice to the chorus on that.

Thank you, and I yield the remainder of my time.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Baldwin.

Senator BALDWIN. Thank you.

I'm encouraged that we're continuing to focus on bipartisan work that can improve health care through the interoperability of electronic health records. Last year I worked with my colleague, Senator Hatch, to advance the development of a national structure for all health IT exchange networks to share at the basic level patient information with each other. Just like calling someone on a cell phone with a different network, it shouldn't matter what network your doctor belongs to in order to share basic data.

But we shouldn't reinvent the wheel. Much of the work has already been done for us, and the industry has made significant progress in creating a blueprint for this exchange. For one, Carequality is a network-to-network framework with a common agreement developed by a large coalition of stakeholders, nearly 300,000 providers over 23 vendors, including EPIC, which is based in my home State of Wisconsin. That number are using Carequality today. In fact, EPIC has exchanged nearly 3 million records with other networks through Carequality.

Dr. White, the 21st Century Cures Act requires the Office of the National Coordinator to develop or support a voluntary framework and agreement for the exchange of health information across networks. Importantly, the Office of the National Coordinator is also required to take into account and leverage the work of existing frameworks to avoid disruption. This means that we should not create an entirely new framework.

Can you please discuss how the Office of the National Coordinator plans to support the advancement of a trusted framework by partnering with and utilizing industry's work in this space? Can

you assure me that you will not be duplicating existing agreements?

Dr. WHITE. Senator, thank you for the question. The great news is that progress has been clearly made by the networks and the industry. There has been an acceleration of the work in the past 2 years with your and our focus on improving interoperability, and they've made great progress. I'm very glad to be able to report that.

That's why, as I said earlier, we've been focused on the areas of variation that exist between these networks and frameworks that we're finding can limit the ability of those organizations to connect with each other and support that nationwide interoperability that we all want and that we know we're trying to get at. We want to build on that great work.

Just to give you a quick example, when I say what are variations, one example is different policies on to what level users must be identity-proofed and authenticated in order to be able to access. So it's one thing if I have my iris scanned and give you a pint of my blood. It's a whole other thing if I've got a handwritten card that says "Dr. White". You need to have some agreement across those trust frameworks and common agreements to be able to trust each other, really is what it comes down to.

There are some areas where we believe we can provide some minimum requirements that enable and build trust between these organizations, and we think that we can be a neutral coordinator of the industry efforts to help ensure that no particular group is disenfranchised.

Senator BALDWIN. Input from a diverse set of health IT stakeholders, from vendors to patients during the development of this legislation, was truly invaluable in our process and to our bipartisan work, and I think it should continue to be integral to the Office of the National Coordinator's implementation. I've heard some frustrations from stakeholders in this process that the Office of the National Coordinator has not always followed the recommendations from its Health IT Stakeholder Advisory Committees and does not usually provide insight when the guidance isn't followed as to why that's the case.

Our legislation streamlined the work of these committees into one Health IT Advisory Committee and included specific areas of focus for its recommendation, and I'm running out of time. So maybe as a follow-up, in writing, Dr. White, can you please describe how the Office of the National Coordinator plans to increase transparency and how it utilizes stakeholder input, including sharing why or why not recommendations from this advisory committee are implemented?

Dr. WHITE. Would you like a brief answer, or would you rather I follow-up later?

The CHAIRMAN. Why don't you give her a brief answer and follow-up?

Dr. WHITE. Belts and suspenders.

We really appreciate and value the input of our advisory committees, and I'm pleased to tell you that I was the Chair of the Standards Committee for a couple of years. They're good folks and they give us great advice. We often do take their advice. They were ac-

tually integral for us for our response to the Zika crisis and a number of other situations.

On our website, healthIT.gov, in addition to making sure that our meetings are publicly open, that we webcast them so anybody can listen in to them and offer public comment, we're also working to ensure that our website, healthIT.gov, has full transparency of all the proceedings and all the recommendations that have been made. So we look forward to working with you and your staff.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Franken.

Senator FRANKEN. Thank you, Mr. Chairman. I apologize for missing so much of this hearing. I was just in a Judiciary hearing right now.

In 2015, the Government Accountability Office put out a report highlighting areas that would need to be addressed to advance efforts at nationwide interoperability. The report states that interoperability would move forward if providers saw value in their systems being interoperable, and specifically highlighted efforts to tie payments to quality and value rather than volume as a potential catalyst for more information sharing across providers. Basically, there hasn't been a strong business case for interoperability, but new payment reforms, including those focused on care coordination, offer a path forward.

Dr. Goodrich, in recent years the Department of Health and Human Services has advanced a number of policy reforms aimed at implementing these types of payment reforms, including accountable care organizations and bundled payments. Can you describe the specific way in which CMS is leveraging these new policy reforms which are focused on value rather than volume to promote the timely exchange of health information?

Dr. GOODRICH. Yes, thank you for the question. Over the last several years we've seen a fairly significant expansion of payments from Medicare coming through what we call alternative payment models, so these value-based payment arrangements that are directly tied to quality and value of care. We now have about 30 percent of payments from Medicare coming through these types of arrangements. As required under the MACRA legislation, for example, advanced alternative payment models that clinicians can participate in to basically reap extra rewards from the Medicare program if they perform well on these measures does require the use of certified EHR technology.

In addition, many of these payment models do directly incentivize those types of activities that are most important to patients like care coordination, like communication across providers. So there are direct incentives for those types of activities that are built into these models.

Senator FRANKEN. Does that seem to be helping?

Dr. GOODRICH. With interoperability itself?

Senator FRANKEN. Yes.

Dr. GOODRICH. I think it's probably a contributor. I think the problems with lack of interoperability are complex and multifactorial, and if it was just one thing we would have solved it by now. So I also believe that the Cures Act gives us as a department, and ONC in particular, some new tools to really move forward on that.

So I think value-based arrangements are an important piece of it, but they're not by themselves probably sufficient.

Senator FRANKEN. My State of Minnesota is working to develop a multi-level system of health information exchange. The state wants to move beyond the system that enables just the basic flow of health information for an individual payment for purposes of care coordination to a more expansive health information system that simultaneously allows for the flow of information for a larger patient population. The goal of this more expansive system would be to connect data to support community health and enable community advisors, social services, and other public health actors to use the data to address community health needs.

Dr. White, ONC is working to develop a national trusted exchange framework. From the conversations you've held thus far, would this framework be focused on promoting the flow of information solely at the individual level, or do you envision a framework that is expansive enough to allow for the exchange of information for entire patient panels as piloted in my state?

Dr. WHITE. This is about interoperability for all, interoperability for everybody. That's important for me as an individual, for the people for whom I care, for the people in my family, but it's also important for my community. So it's for both. You really have to be able to enable it for individuals, and every individual. But you've also got to be able to enable interoperability across a population for the right purposes.

Senator FRANKEN. In what ways do you think a national trusted exchange framework that provides clearer policies, standards, and services to stakeholders can better support communities' focus on solving community-level problems like the opioid epidemic?

Dr. WHITE. Well, it helps you set the rules of the road. It's everybody who agrees that they're operating from the same play book, essentially. Kate mentioned that this is complicated, so I'm not going to get into a lot of the details——

The CHAIRMAN. Another opportunity for a brief answer and a written follow-up.

[Laughter.]

Dr. WHITE. ——but it allows you to address some of that complexity in the agreement. If folks are voluntarily signing on to it, it helps them pull them to address those issues.

Senator FRANKEN. I look forward to the written follow-up.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Franken.

We have votes at 4. I think some Senators may want to ask additional questions. Before they do, let me just say, Dr. White, in addition to Senator Murray and me, the Congressional Research Service has never heard of a prohibition in the Administrative Procedures Act that would keep you from telling us when you're going to have a rule that defines what is information blocking and what isn't. So after you consult with your counsel, we would appreciate your letting us know when that rule is coming out.

Dr. WHITE. I'll have my counsel talk to your counsel.

The CHAIRMAN. Thank you. No, just give us the answer.

[Laughter.]

The CHAIRMAN. Now, Senator Murray, do you have additional questions?

Senator MURRAY. I just want to thank you for having this hearing. I think Senator Warren had one additional question. But I think this is a really important discussion. We have to focus on this if we want our health care system to work better.

I'm going to keep focused on making sure this Administration is implementing the 21st Century Cures Act as intended, and that the agencies involved have the resources they need to actually carry this out. So there's much work ahead of us, and I look forward to working with you on that.

The CHAIRMAN. Thank you, Senator Murray.

Senator Warren.

Senator WARREN. Thank you, Mr. Chairman. I appreciate a chance to ask another question.

I want to talk about medical devices. As you know, millions of people are living with some kind of medical device implanted in their bodies. Every year, about a third of a million Americans have surgery to get a pacemaker implanted. About a million hip or knee replacements are performed every year. We're talking about things like cardiac stents and IUDs and artificial disks and screws and defibrillators.

Patients going under the knife need to have confidence that they're getting a product that isn't likely to fail or get recalled and force them to have to have a second operation. But right now, doctors don't have the information available to tell which pacemaker has a failure rate of, say, one-tenth of 1 percent and which one has a failure rate that is ten times or even a hundred times higher.

So I want to follow-up on a question that Senator Murray asked about unique device identifiers. Mr. Cannatti, you work at the Office of the Inspector General for HHS, which recently released a report about Medicare's ability to track the performance of medical devices. What did you find about the cost to patients and to taxpayers when these devices fail prematurely?

Mr. CANNATTI. We found that CMS could not, from the claims form or information alone, determine that amount. In doing really advanced audit techniques, we were able to determine that over a 10-year period approximately $1.5 billion were paid for Medicare services related to the replacements, and that accorded to about $140 million in beneficiary, co-pay, and deductible liability.

Senator WARREN. That was just on one kind of product, right? Just cardiac devices, just seven of them.

Mr. CANNATTI. That's correct.

Senator WARREN. It was $1.5 billion, and another $140 million out of the pockets of the patients themselves.

So it seems that figuring out how to use safer devices and sorting out the safer devices from the less safe devices could save Medicare a lot of money and save consumers a lot of money and a lot of pain. That's why, back in 2007, Congress required that all medical devices be labeled with what's called a unique device identifier, basically a string of numbers and characters that tell the specific model and the specific manufacturer. But, of course, those data are valuable only if we actually collect them.

So, Mr. Cannatti, does the Medicare claim form that hospitals currently fill out include a line for the device identifier information that tells us what model of device failed and who made that device?

Mr. CANNATTI. No, it does not.

Senator WARREN. Does the HHS Inspector General support adding such a line to the claim form?

Mr. CANNATTI. We do.

Senator WARREN. All right. I was glad to see that the standards group in charge of updating the claim form added this line to the draft that it released a few months ago. So it looked like everybody was on board and this was about to happen. Last year, CMS also supported adding the device information to claims. But when the OIG report came out a few weeks ago, CMS said they were reviewing the policy. Then a few days later CMS put out a new statement saying the device identifiers on the claim form would "reduce Medicare costs by identifying poorly performing devices more quickly"—true—"and protect beneficiaries from unnecessary cost"—also true.

So, great. It looked like everybody was back on board. But then a few days after that, CMS put out another statement saying the policy is still under review and that the earlier statement was wrong.

So, Dr. Goodrich—you're the Chief Medical Officer at CMS—I'm hoping you can clear this up. Do you agree with the Inspector General's recommendation that adding device identifiers to the claim form would help reduce Medicare costs and protect beneficiaries from unnecessary cost and pain?

Dr. GOODRICH. First I want to say that we very much appreciate the work of the OIG and this Committee's interest in this issue. Patient safety as it relates to the devices is obviously very important to CMS. However, at this time, I don't have anything else to offer besides that because, as is customary for new administrations, we are still reviewing this policy.

Senator WARREN. So, all right. Let me just say, this should be a no-brainer. Your agency's own watchdog says you should do it. MedPAC says you should do it. Organizations that represent orthopedic surgeons, cardiac surgeons, thoracic surgeons, all say you should do this. Adding device identifiers to claim forms has bipartisan support in Congress. Senator Grassley and I have been pushing this now for years, and I'll be blunt, we're going to keep pushing on this. It is time for CMS to step up to protect patients and to protect the Medicare system.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.

Senator Baldwin, do you have other questions?

Senator BALDWIN. I have a remaining question. Thank you.

The CHAIRMAN. Sure.

Senator BALDWIN. I wanted to share a story about the La Crosse area of Wisconsin. La Crosse, Wisconsin has, I think, a unique story that illustrates the importance of provider and patient access to electronic health records. In that community, an astounding 99.4 percent of patients at the end of life have an advanced care plan that's easily accessible in their medical records thanks to an innovative program pioneered by Gundersen Health System. Easy access and usability of electronic health records for both patients and

providers is essential to that program's success and helps ensure that the most appropriate care is delivered at the right time.

But as we know, providers and patients continue to face some barriers such as navigating various standards, from meaningful use to patient privacy requirements, and also how to access your own medical record from your doctor.

So I want to ask both Dr. Goodrich and Dr. White if you could please update us on how ONC and CMS are working together to help reduce provider reporter burdens across programs and how you're educating providers to better share medical record data with patients.

Dr. WHITE. You know, it really starts with talking to doctors. We do that regularly and often. We're pleased to say we engage on a regular basis with representing doctors, representing hospitals, representing patients, representing communities, representing other users of health information. It really informs what we do, and it really helps us drive where we go.

They have said to us we clearly think this is important, that we need to have access to this information, and we've clearly heard some of the issues which have been well described here today.

I mentioned earlier I don't want to rehash some of the ways in which Dr. Goodrich's team and my team are taking a look at provider burden. We recognize that it's absolutely essential, whether it's the reporting burden, whether it's billing documentation, whether it's usability of software, whether it's other requirements that are being placed on providers. We need to identify what those issues are and drill down on them and make them better.

Dr. GOODRICH. So I would just add that reduction of burden on providers and beneficiaries is a top priority for CMS. We actually launched last week our Patients Over Paperwork initiative. So we are taking a very comprehensive and holistic look across CMS at our administrative requirements certainly as it relates to meaningful use, as it relates to quality measure reporting. Like Jon said, we are also spending a huge amount of time just listening to clinicians, listening to patients. Patients want to be at the table. They want to be part of the solutions.

We've been traveling the country, going into physicians' offices and talking to them so that we can really understand in a specific way their pain points and how our requirements impact their daily lives. We are taking this approach across all providers.

I will say we do have a particular focus on clinicians, as well as a focus on beneficiaries, because I would say, again as a caregiver for a Medicare beneficiary, it is a burden on patients when their doctors are facing away from them at the computer and when they cannot access their health care information.

So this is definitely a top priority for both of us.

The CHAIRMAN. Thank you, Senator Baldwin.

Thanks to all three witnesses.

I have two quick questions. Dr. Goodrich, Dr. White, this, according to Tom Friedman's new book, was invented in 2007 when Steve Jobs showed it to John Dore at a soccer game out in California, and it has transformed the world. It caused a lot of trouble, too. But that was 2007, 10 years ago. The electronic health care records law was passed 2 years later, in 2009. In my view, we spent $37 billion

on it, and Meaningful Use I was helpful, Meaningful Use II was difficult, and Meaningful Use III, people at Vanderbilt and Mayo, two of the biggest users of that kind of thing, say they're terrified by it, it was a big problem.

Now, we've talked about all that, but I wanted to make sure that in all of our regulatory and legal efforts we left plenty of room for the kind of genius that created this to solve the problems with electronic health care records. If 2 million of us can fly every day and we can use these things and all the things that Amazon and Google and those people do, we try to do this in the law.

I tried to resist putting too many mandates in the law about electronic health care records and interoperability specifically. That's why we're so pleased to see the Center for Interoperability in Nashville—and Andy Slavitt went down there. Dr. Goodrich, you were there when he went with me, and we were both surprised, actually, and impressed by what $100 million a year purchasing power might be able to do in terms of getting a common platform where everybody could talk to each other, both with devices and with data.

So my question is, do you share the same hope or zeal that I do in trying to make sure that we allow within our regulatory framework the opportunity for game-changing technology to solve many of these problems for us and make electronic medical devices work better for providers, doctors and patients?

Dr. GOODRICH. Absolutely. I think that's exactly what we would like to see happening. That's a great example. You're right, the Center for Interoperability, it's just amazing what they've done. So I think there are lessons to be learned from them and other stakeholders who have done some really innovative work in this space.

The CHAIRMAN. Dr. White.

Dr. WHITE. You know, I was in the room with you when you got the terrifying comment, and I didn't like it any better than you did. It haunts me to this day.

But here's what I'll say. I think you've given us the right tools, I really do. There was a really thoughtful process that went into the passage of this law. I think that what you've done is you've given us the ability to introduce the right amount of regulatory focus and reform, as well as the right amount of non-regulatory—for example, the trusted exchange framework and common agreement—that's going to allow us to work both with the developers in the private sector and the folks who need access to this information.

One of my children just started their second year of college halfway across the country, and they've got a medical condition. Ten years ago I couldn't have had access to their information on my device. Now, as soon as my child is seen, the note is there, the record is there. I can log in, I can talk with him, I can talk and make sure he's taking his medications. As a parent, it's made a world of difference. That's what I want to see across the health care delivery system.

The CHAIRMAN. My last words are more of a suggestion than a question, but I'm going to make it again, and it's redundant. Someone gave me a book when I was elected Governor about presidential leadership or executive leadership. There are three parts to

it. One, you see an urgent need. You develop a strategy to meet the need. Then you persuade at least half the people you're right. I found that to be very useful.

In the case of physician documentation, we would say the urgent need is that you've got two-thirds of the doctors who say they're spending two-thirds of their time on electronic health care records and desk work.

Now, you've listed a number of strategies that you've developed to try to change that. But the third part of executive leadership is persuading at least half the people you're right. If they don't believe that and you actually change it, you haven't made as much progress as you should.

If I were doing it—and I hate to say it that way, but I believe this. If I were doing it, I would call in the American Medical Association and the other physician groups and say we read your report, it says two-thirds of the time is being spent on this, what do you think it should be? Let's see if we can agree on a number. Just like a football field is 100 yards long, and a basketball goes this way, let's agree that over the next 3 years we ought to try to get it down to 50 percent, or 45 percent, and then let's work together to identify all the things that would do that, and let's announce on a quarterly basis or every 6 months what progress we've made, or lack of progress we've made. So then you actually do it, and they believe you're doing it. Or probably, if it's like most things, it's partly the fault of the regulators and partly the fault of the physicians who may not understand all the things they need to do.

So I guess what I'm urging you to do is set a number. I mean, if they think two-thirds of their time is being spent on that, pick another number and say let's get to that goal, and get there. What's wrong with that sort of executive leadership?

Dr. GOODRICH. I don't think anything is wrong with it. Our experience has absolutely been that when you want to improve, for example, quality of care, the way you do that is you set a goal, a time-bound goal, you get everybody to buy into it, and then you move toward it, and you're much more likely to achieve it.

So we'll certainly take that advice back as we are working with the clinician community on implementing that section of care around setting a goal and a strategy to meet the goal. We'll take that back.

The CHAIRMAN. Dr. White, any comment? We'll wrap up.

Dr. WHITE. I think it's sound advice. I look forward to taking it.

The CHAIRMAN. Well, I don't want your job, let me make that clear.

[Laughter.]

The CHAIRMAN. I think you've got a tough job, but I'd like for you to succeed. I think a clear goal for a period of time would be a helpful aspiration and would help.

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

Thank you for being here.

The Committee will stand adjourned.

[Whereupon, at 4:11 p.m., the hearing was adjourned.]

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