S. HRG. 116–434

IMPLEMENTING THE 21ST CENTURY CURES ACT: MAKING ELECTRONIC HEALTH INFORMATION AVAILABLE TO PATIENTS AND PROVIDERS, PART II

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING IMPLEMENTING THE 21ST CENTURY CURES ACT, FOCUSING ON MAKING ELECTRONIC HEALTH INFORMATION AVAILABLE TO PATIENTS AND PROVIDERS

MAY 7, 2019

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C O N T E N T S

STATEMENTS

TUESDAY, MAY 7, 2019

IMPLEMENTING THE 21ST CENTURY CURES ACT: MAKING ELECTRONIC HEALTH INFORMATION AVAILABLE TO PATIENTS AND PROVIDERS, PART II

Tuesday, May 7, 2019

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

The Committee met, pursuant to notice, at 10:05 a.m., in Room SD–430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

Present: Senators Alexander [presiding], Burr, Cassidy, Romney, Braun, Murray, Casey, Baldwin, Murphy, Kaine, Hassan, Jones, and Rosen.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Committee on Health, Education, Labor, and Pensions will please come to order. Senator Murray and I will each have an opening statement, then we will introduce the witnesses, and after that, Senators will each have five minutes of questions.

Let me just—let me say at the beginning, what I may repeat both in my statement and questions, my major concern is to remind the administration of the advice that my piano teacher used to give me before a recital. She would say, Lamar, play it a little slower than you can play it. You are less likely to make a mistake. And that is pretty good advice, and as I look back at our experience with Meaningful Use 3 and the large amount of data that we are dealing with here, in summary my view is that you are on a good track. Both in the Obama and the Trump administrations, you have worked hard to try to get on the right track here and implement the 21st Century Cures law that we passed. That I appreciate very much, and I appreciate the extension of time for a comment period.

But I want to say to Senator Murray and other Senators who are here that over the next two years we may want to continue to have, in an informal way, discussions with you about how we are doing, and I think it is much better for you to have on your tombstone, they got us where they wanted us to go instead of they try to go too fast and made it difficult for us. So we will say more about that. In 1991 the National Academies urged the adoption of electronic health records to improve patients' care. However, for many patients and many doctors, electronic health records made care more complicated.

No one knows this better than Dr. Kelly Aldrich who is the Chief Clinical Transformation Officer at the Center for Medical Interoperability in Nashville and whose husband Eric experienced a life-threatening emergency that could have been prevented if his electronic health records had been interoperable. Eric woke up one morning with a splitting headache. He went to see his primary care doctor. He sent Eric to the hospital for a CT scan. The results of that prompted an MRI. Usually the hospital's electronic medical records sends the results of the MRI directly to Eric's primary care doctor but in this case, the results were never sent so 12 hours after test, Eric's doctor called the hospital and learned that Eric had a tumor so large it was causing his brain to swell and shift, putting him at risk of seizures, permanent brain damage, and possibly death. Eric, however, assuming no news was good news was already 500 miles away on a fishing trip to Louisiana. Eric went to the Tulane Medical Center, which had to do another MRI because they could not obtain Eric's original test results because the two hospitals use different electronic medical record systems. Eric flew back to Nashville where he had to have yet another MRI before entering surgery. He spent several weeks recovering in the ICU.

At multiple points during this traumatic experience, the lack of interoperability between electronic health care records caused a life-threatening delay of care, redundant tests, higher costs, and additional pain. This is the second hearing on the proposed rules implementing the Electronic Health Information Provisions in the 21st Century Cures Act. Improving electronic health records is important to this Committee on both sides of the aisle. In 2015 while working on Cures, we realized that our electronic health record system was in a ditch.

The Committee held six bipartisan hearings in the midst of the 21st Century Cures discussions on how to improve interoperability and form a working group that recommended provisions in Cures to ban information blocking, which is when some obstacle is in the way of a patient's information being sent from one doctor to another. And this year the Committee is working on legislation to lower the cost of healthcare. 50 percent of what we spend on healthcare is unnecessary, according to Dr. Brent James of the National Academies. Electronic health records that are interoperable can prevent duplicative services, like Eric's repeated MRIs, and reduce what doctors and hospitals spend on administrative tasks.

In March, the Office of the National Coordinator in the Center for Medicare and Medicaid Services issued two rules to implement the electronic health records provisions in the 21st Century Cures Act. First, the rules to define information blocking so it is more precisely clear what we mean when one system, hospital, doctor, vendor, or insurer is purposefully not sharing information with another. Second, the rules require that by January 1, 2020, for the first time, insurers must share a patient's health care data with a patient, so their health information follows them as they see different doctors.

Third, all electronic health records, and there might be an example of going too fast. This rule may not be final until the end of this year, then this information must be shared by January of next

year. Fourth, all electronic health records must adopt publicly available standards for data elements known as application programming interfaces are APIs—we will hear a lot about APIs today—two years after these rules are completed. Last month, we heard from those who use electronic health records. So here is what they had to say.

First, I ask our witnesses at that hearing if these were good rules and all four said, yes, the intent and the goal of the rules is correct. Mary Greeley, President of Healthcare Leadership Council said, "interoperability is not simply desirable, it is absolutely necessary. These rules represent an important and perhaps groundbreaking first step for true, national interoperability." Also asked our witnesses what one change they would make to improve the rules and Dr. Greeley cautioned about not rushing implementation saying, "we don't want to prevent moving ahead or progress, but I think we also have to be very cognizant of the challenges that providers and others are facing trying to do this complex work."

In 2015, I urged the Obama administration to slow down stage 3 of Meaningful Use, which incentivize doctors and hospitals to adopt electronic health care records. The administration then did not slow down implementation and looking back, the results would have been better if it had. The best way to get where you want to go is not by going too far too fast. I want to make sure we learned lessons from implementing Meaning Use stage 3, which in the words of one major hospital in Tennessee was, terrifying.

I am especially interested in getting where we want to go with the involvement of doctors, hospitals, vendors, insurances, with the fewest possible mistakes and the least confusion. We do not need to set a record time to get there with an unrealistic timeline. Because these are complex rules, I asked CMS and ONC to extend the comment period. I am glad to see they have done so, and I want to thank our witnesses for allowing more time to comment. We also heard concerns about ensuring patient privacy. If the 21st Century Cures Act is successfully implemented, patients should be able to get their own health data more easily and send it to their own healthcare providers. Patients may also choose to send that data to third parties like an exercise tracking app on their smartphones, but this raises some new questions about privacy and questions I am not sure have been answered.

Lucia Savage, Chief Privacy and Regulatory Officer at Omada Health said, "I think the Committee is rightfully concerned about privacy and security. None of this will matter if the consumers don't have confidence and their doctors don't have confidence that the consumers have confidence." Dr. Christopher Rehm, Chief Medical Informatics Officer at LifePoint Health in Brentwood, Tennessee reminded us at the hearing that these rules are, "not about the technology, it is about the patient, their care, and their outcomes."

I look forward to hearing from the administration today about how they plan to implement these rules.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Thank you very much, Mr. Chairman. In the decades, as Congress passed the HITECH Act to help spread better use of healthcare technology, we have made tremendous progress.

Back in 2008, just one in twenty hospitals used electronic health records and today we have seen that statistically flip entirely, one in twenty hospitals have not adopted electronic health records. We saw the impact of that shift nationally when electronic health records played an important role in understanding how the water in Flint, Michigan was putting families in danger. And healthcare providers have seen the impact of that shift in their work as electronic health records have helped them identify health problems sooner so patients can get preventive care to stay healthy, avoid duplicative tests or medication errors, and identify treatments that might be counterproductive based on a patient's medical history or current prescriptions. But for all the promise of electronic health records, we have also seen the serious danger to patients when health IT systems failed to live up to high standards of quality.

From the man in California who suffered brain damage after his diagnosis was delayed when a hospital software could not properly interface with the lab, to the women in Vermont who died of a brain aneurysm that might have been caught if a software problem had not stopped the order for the test that she needed. Families' lives depend on making sure we get this right, which is why I was glad Congress, and this Committee in particular, was able to take action in the 21st Century Cures Act to address some of the biggest challenges we face, and why I am eager to hear today from our witnesses about how the Office of the National Coordinator for Health Information Technology is implementing the steps that we passed.

While HITECH required certified electronic health record products to meet technical standards intended to make good information more accessible for care providers, a 2015 ONC report detailed how instead of making information easy to access and share, many organizations engaged in information blocking, intentionally setting up barriers between their systems and other systems like exorbitant fees whenever someone sent, received, or even searched for a patient's information, contracts that restricted people's ability to access and share their own health information, and systems built in ways that made sharing information needlessly complicated.

We have also seen how too many health IT vendors include gag causes to stop care providers from speaking out about the problems or the issues in errors that the encountered. We cannot afford to have bad actors who prioritize their bottom line over patients' best interest, who block information that is essential to patient care, and who prevent people from speaking out when they see something that could jeopardize someone's health because when systems cannot speak to each other and people can't speak up about problems they see, it is patients that get hurt. That is why in the 21st Century Cures Act, Congress moved to end information blocking and make clear when patients and their care providers need information, they should not be stopped by unnecessary, unreasonable barriers.

We then tasked ONC with clarifying what concerns, like privacy, safety, and security, would be grounds for reasonable exceptions. We also took steps to help ONC strengthen its certification program so they can require vendors seeking the Government seal of approval to swear off information blocking and gag clauses. The new conditions also call for open application programming interfaces, APIs, another step that will help make sure systems, developed by different vendors and used by different doctors, are able to speak to each other and patients have an easier time getting access to their medical records. These are important steps. I am looking forward to hearing today about how ONC is working to carry them out.

I am also eager to hear about how the Centers for Medicare and Medicaid Services is working on a parallel track to make claims data more accessible and prompt care providers to be better about sharing information. I hope during today's hearing we can also focus on how to make sure health information technology doesn't just work for providers, but for patients and that means tackling patient engagement and usability so patients who are looking for clear information about their health can find more than massive binders and unreadable PDFs and stacks of CDs.

We also need to make sure we are discussing what is required for all parties to be good stewards of the data people entrust them with and supporting the development of technology and best practices to keep people's personal information private and secure. This is only going to become more important as tech companies and others introduce new products, mobile applications, that empower people with their healthcare data, that are not covered by existing HIPAA protections. Patients should be able to expect tech companies are going to use their most sensitive information responsibly and give them the tools they need to be able to control how and when their information is disclosed.

Our objective should be to make sure tech companies are putting patients in the driver seat, not the other way around. So, I hope our witnesses will be able to speak to the importance of that as well. I look forward to continuing our bipartisan, Mr. Chairman, to help make sure health technology is informing and empowering patients and providers in a way that leads to better care and helps people live happier, healthier lives.

Thank you.

The CHAIRMAN. Thank you, Senator Murray. I think the witnesses can see by the attendance already today that this is of interest to a large number of Democrat and Republican Senators because we spent so much time with it in the 21st Century Cures Act. I am pleased to welcome our two witnesses today. I would like to ask you each to summarize your remarks in five minutes. The first witness, Dr. Don Rucker. He is the National Coordinator for Health Information Technology for the Office of the National Coordinator for Health IT within the Department of Health and Human Services. That is a big, long title. He has extensive experience with health information technology both in public service and the private sector, most recently serving as Clinical Professor of Emergency Medicine and Biomedical Informatics at the Ohio State University.

Next, we will hear from Dr. Kate Goodrich who testified before the HELP Committee in 2017 on the implementation of health information technology provisions in the 21st Century Cures Act. Dr. Goodrich is the Director of the Center for Clinical Standards and Quality and the Chief Medical Officer for the Centers for Medicare and Medicaid Services. Dr. Goodrich has over 20 years of clinical and quality standards experience both as a practicing physician and in several roles with the Center for Clinical Standards and Quality.

Dr. Rucker let us begin with you.

STATEMENT OF DON RUCKER, M.D., NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. RUCKER. Thank you. Chairman Alexander, Ranking Member Murray, distinguished Members of the Committee, thank you for the opportunity to testify. As an ER physician and electronic health records software developer for the last 30 years, I am deeply appreciative to Congress for the 21st Century Cures Act and the work to improve interoperability and reduce provider burden.

ONC's proposed Cures Act rule will help achieve Congress's vision for a patient's health information to be available to the patient and their clinicians whenever and wherever they need it. This rule can also unleash a wave of innovation that will make healthcare more efficient and affordable. The rule requires secure standards-based application programming interfaces that will allow patients to download their records to their phone and to do so at no cost. Moving patient charts to smart phone platforms will enable third-party app developers to build new business models of healthcare. Specifically, the proposed rule will require physician and hospital electronic record systems to allow patients to download their medical data to apps of the patient's choosing. App ecosystems have transformed many industries, including travel, entertainment, and shopping. An app ecosystem can do the same for healthcare.

However, the promise of standards-based APIs can only be realized if providers and their business partners actually share the clinical data. The practice of information blocking not only undermines investments in the nation's health IT infrastructure but also frustrates efforts to use technology to improve care. The Cures Act directed ONC to identify activities that would not be treated as information blocking and the proposed rule outlines seven exceptions. At the same time, the Cures Act authorizes the HHS Office of the Inspector General to investigate information blocking allegations against healthcare providers, developers of certified health IT, health information exchanges, and health information networks.

ONC's proposed rule makes it clear that data should move seamlessly in a private and secure manner without special effort on the part of the end-user. In addition, we have heard the concerns from stakeholders about security of APIs and secondary uses of health data. When it comes to security, this proposed rule requires the same API standards used by other industries which have to protect valuable assets such as banking and brokerage.

Secondary use of data creates privacy challenges that extend beyond the healthcare industry. Today, deeply sensitive health facts can be inferred from online searches, credit card purchases, and social media postings.

For example, location services can show which clinical a patient visited. While ONC's proposed rule empowers patients to take control of their data and their health, we are actively engaged with the Office of Civil Rights to inform patients about both their HIPAA rights and potential risks. Our proposed rule also recognizes the importance of price data. Today, payment data is retrospective and largely disconnected from clinical data. However, without price data, it is difficult for patients to either assess value or shop for care. Recent advances and standards may allow improved integration between clinical financial data streams.

As defined in the Cures Act, ONC recently issued an updated draft of the Trusted Exchange Framework and Common Agreement, known as TEFCA, for public comment. TEFCA is designed to provide a single on-ramp to nationwide connectivity for health information exchanges and to include all providers. It includes a common set of principles that will facilitate trust and sharing between health information exchanges.

Today, much of American healthcare remains complex and opaque. Congress's Cures Act and advances in computing allow us to revisit many assumptions about what medical care can be. ONC's proposed rule and TEFCA service major steps to make care more accessible, transparent, and affordable. We believe these policies place the Nation on the path to achieving the long-term benefits of interoperability.

Mr. Chairman, Ranking Member, Members of the Committee, thank you for the opportunity to testify.

[The prepared statement of Dr. Rucker follows:]

PREPARED STATEMENT OF DON RUCKER

Chairman Alexander, Ranking Member Murray, distinguished Members of the Committee, thank you for the opportunity to testify in support of the Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology's (ONC) efforts to implement provisions of title IV of the 21st Century Cures Act (Cures Act). I want to thank Congress and this Committee for your shared commitment to stimulate a modern and connected health care system. The bipartisan Cures Act accelerates our efforts to ensure that patients' records follow them when and where they need them.

The Cures Act directs the HHS Secretary to adopt standards and policies that advance the seamless and secure flow of electronic health information (EHI) across the health system. On March 4, 2019, ONC issued a proposed rule to implement key provisions in title IV of the Cures Act. This proposed rule aims to drive the electronic access, exchange, and use of health information. It seeks to inject competition into the health care delivery system by addressing both technical barriers and business practices that impede the secure and appropriate sharing of data. A central purpose of the proposed rule is to facilitate patient access to their EHI on their smartphone, growing a nascent patient- and provider-facing app economy.

I would like to begin by discussing the current health care and health information technology (health IT environments. In an extraordinary shift from a decade ago, most hospitals and providers now use electronic health records (EHR).[1] However,

[1] Office of the National Coordinator for Health Information Technology (2018). Report to Congress: Annual Update on the Adoption of a Nationwide System for Electronic Use and Exchange of Health Information [online] Washington, DC. Available at: *https://www.healthit.gov/sites/default/files/page/2018—12/2018—HITECH—report—to—Congress.pdf* [Accessed 25 Apr. 2019.

information captured in these systems often remains inaccessible to patients and to their providers across different settings.

Fragmented care can lead to hospital readmissions, medical errors, and poor health outcomes, especially among patients with multiple chronic conditions who rely on coordinated care to help manage their health.[2], [3], [4] Today, only half of hospitals report having the necessary information electronically available from outside providers or sources at the point of care. Notably, hospitals with advanced interoperability capabilities are significantly more likely to have information available from outside sources compared with hospitals lacking those capabilities.[5] A health system where information flows appropriately and securely to patients and their providers can improve care coordination, reduce adverse events, and lower costs. ONC designed this proposed rule to help stimulate a more connected health system that leverages health information to better serve patients.

To develop this proposed rule, ONC coordinated extensively with relevant Federal agencies. We also met with more than 150 external stakeholders from across the health system to improve our understanding of the on-the-ground needs and barriers related to the flow of EHI. While the proposed rule covers many provisions within title IV of the Cures Act, today, I am going to highlight how the proposed rule addresses the Conditions of Certification and Information Blocking provisions.

The conditions and maintenance of certification proposals include requirements for health IT developers under the ONC Health IT Certification Program and cover a range of business practices and behaviors that impede the access, exchange, and use of EHI. The first condition I will highlight focuses on the Cures Act requirement for health IT developers to publish application programming interfaces (APIs) that allow health information to be securely accessed, exchanged, and used "without special effort." Requiring health IT developers to publish an API is not enough. Without common standards, third-party app developers need to learn and use different requirements and data base structures for each health IT system. This hampers competition by binding patients and app developers to particular clinicians or products.

The proposed rule includes a suite of proposals that focus on certified health IT developers making available secure, standards-based APIs that facilitate patients' use of their smartphones (or other mobile devices) for accessing EHI at no cost. It also supports clinicians' ability to partner with third-party software developers offering unique and competitive services that support patient care. Specifically, ONC proposes to adopt a new standards-based API certification criterion that would require that a health IT product support "read" access to health information for both a single patient and for a group of patients. The proposed rule addresses the Cures Act phrase "without special effort" through a number of proposals that promote standardized, transparent, and pro-competitive market practices. Once finalized, health care providers would have two years from the final rule's publication date to offer patients' access to their EHI through secure, standards-based APIs.

While developing the proposed rule, stakeholders shared two overarching security concerns. The first concern has to do with the overall security of APIs. The second concern touches upon the secondary use of data. When it comes to security, it is important to note that the health IT developers and health care providers using certified health IT would deploy APIs with the same security measures used by other industries, such as banking (through the OAuth 2 standard). In fact, health care providers already offer the same security measures to protect patient portals. Third-party health care apps who wish to connect to a health IT developer's certified API would need to establish secure connections, prompt patients to authenticate themselves to their health care provider, and obtain a patient's approval on the scope of data that the app may access.

How data is secured and used once in third-party apps illustrates a pressing issue that is currently part of a national discussion a discussion that extends beyond health care and into data privacy, stewardship, and regulatory interventions. How APIs secure their connections and follow patients' individual preferences in health

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[2] Moore, Carlton et al. "Medical Errors Related To Discontinuity of Care From An Inpatient To An Outpatient Setting." *Journal Of General Internal Medicine*, vol 18, no. 8, 2003, pp. 646–651. *Springer Nature*, doi:10.1046/j.1525–1497.2003.20722.x. Accessed 25 Apr 2019.

[3] Tsai TC., Orav EJ., & Jha AK. "Care Fragmentation in the Postdischarge Period: Surgical Readmissions, Distance of Travel, and Postoperative Mortality." *JAMA Surg*. 2015 Jan;150(1):59–64. Accessed 25 Apr 2019.

[4] Robert Wood Johnson Foundation (U.S.) *The Revolving Door: A Report on U.S. Hospital Readmissions.* The Dartmouth Institute for Health Policy and Clinical Practice, 2013.

[5] Pylypchuk Y., Johnson C., Henry J. & Ciricean D. (November 2018). "Variation in Interoperability among U.S. Non-Federal Acute Care Hospitals in 2017." ONC Data Brief, no.42. Office of the National Coordinator for Health Information Technology: Washington DC.

care is no exception. Many third-party apps are not required to implement the privacy protections and patient rights of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules, but they may be subject to the Federal Trade Commission (FTC) jurisdiction, including the Health Breach Notification Rule.

The HHS Office for Civil Rights (OCR) has regulatory authority to ensure the privacy and security of data applies only to HIPAA covered entities (e.g., many health care providers, health plans) and their business associates (e.g., EHR developers). In April 2019, OCR released new frequently asked questions (FAQs) about the HIPAA right of access related to patient-designated apps and APIs. The FAQs clarify that once protected health information has been shared to a third-party app, as directed by the individual, the HIPAA-covered entity (or its business associate that fulfills the access request on behalf of the covered entity) will not be liable under HIPAA for subsequent use or disclosure of that particular electronic protected health information. This is provided that, with respect to the app, the app developer is not itself a business associate of a covered entity, directly or through another business associate.

Across all business sectors, individuals often have little say with respect to the secondary use and disclosure of their personal data. However, the misuse of health information can have lifelong consequences for the patient. Individuals should balance their selection and use of a health app with the potential risk of having negative implications. These risks are similar to when they enter sensitive health data into an online search, contribute their DNA to learn about their ancestral heritage, share their credit card information when making an online purchase, or consent to location services on their phones. It is important to note that deeply sensitive health facts about patients can be inferred from consumer data "exhaust" such as accelerometers, location services, and a wide variety of app and social media usage patterns.

Individuals should have the ability to decide whether the potential benefit of an app to manage their health care information and medical conditions outweighs potential risks. This should be the patient's choice. Interestingly, some entities advocating to protect the patient from inappropriate secondary uses and disclosures of the patient's data have business models at risk from patients accessing their EHI. ONC's proposed rule empowers individuals to electronically access and share their EHI, enabling an individual's HIPAA right of access, and affording the patient agency over their own health information that is often absent in health care.

Today's fragmented health system forces individuals or caregivers to navigate a byzantine system to manage their care. Emerging technologies and the use of mobile apps will provide individuals with access to their own EHI that can follow them across providers and health plans, and advance an app marketplace that addresses unique patient needs.[6] For instance, an app may empower patients with multiple chronic conditions to consolidate and share their care journey with each clinician they visit, potentially preventing adverse and life-threatening events due to missing clinical information. A robust health app ecosystem can also lead to the development of disease-specific apps that allow patients to choose whether to share their health information with researchers working on clinical trials to test a drug or treatment's efficacy like those in the National Institutes of Health's *All of Us* Research Program. Apps could also help address barriers related to access by presenting complex information in easy to understand ways.

We have seen promising signs of this occurring in the private sector. Last year, Apple introduced their Health Records on the iPhone using the same modern computing standards included in our proposed rule. A little over a year later, over 200 health institutions use the Health app to offer their patients access to their health records. Many other entrepreneurs are developing novel health apps as well, and our proposed rule is designed to lower the barriers to their entry into the health app industry. Later, I will discuss how we can envision this same approach taking shape when it comes to price transparency and providing patients with the ability to shop for care based on the price and quality of care.

In addition to addressing the flow of EHI, this proposed rule seeks to enhance the safety of health IT. In 1999, when most clinicians were still using paper records, the former Institute of Medicine (now the National Academy of Medicine) published a seminal report, to *Err is Human*, where they estimated that between 44,000 to

[6] Mandl, Kenneth D., Mandel Joshua C., & Kohane Isaac S. "Driving Innovation in Health Systems through an Apps-Based Information Economy." *Cell Systems*. 2015 Jul;1(1):8–13. Accessed 25 Apr 2019.

98,000 people die in hospitals each year due to preventable medical errors.[7] There is ample evidence that well-designed health IT systems can make care safer.[8] However, due to the innate complexity of medicine and radical changes to established clinical workflows, health IT has introduced new safety issues and also exacerbated others.

One resounding complaint we heard from the patient safety community is that health IT developers use gag clauses to inhibit the flow of essential information that could improve safety across systems. A 2012 National Academy of Medicine report found that such clauses discourage users from sharing information about patient safety risks, significantly limiting the ability of users to understand how health IT products impact patient safety. The report stressed the need for health IT developers to enable the exchange of information regarding user experiences, including the sharing of screenshots.[9] As part of ONC's patient safety efforts that are paramount to its mission, programs, and policies, this proposed rule would prevent certified health IT developers from prohibiting or restricting communications regarding usability, interoperability, security, user experiences, business practices, and technology use. We also included provisions to respect health IT developers' intellectual property in the software.

The promise of standards-based API technology can only be successful if current business practices that enable information blocking to occur are dismantled. For that reason, I thank Congress for establishing consequences for information blocking in the Cures Act. The information blocking provisions were enacted in response to concerns that some individuals and entities engage in practices that unreasonably limit the availability and use of EHI for authorized and permitted purposes. These practices undermine public and private sector investments in the Nation's health IT infrastructure. They also frustrate efforts to use modern technologies to improve health care quality and efficiency, accelerate research and innovation, and provide greater value and choice to health care consumers.

The information blocking provisions apply to health care providers, developers of certified health IT, health information exchanges, and health information networks. Under the Cures Act, the HHS Office of the Inspector General (OIG) has authority to investigate information blocking claims against these entities. Health care providers can be subject to disincentives determined by the HHS Secretary if the OIG finds that the provider has knowingly and unreasonably engaged in information blocking. Developers of certified health IT, health information exchanges, and health information networks can be subject to civil monetary penalties determined by OIG of up to $1 million per violation.

The proposed rule establishes seven exceptions that identify certain reasonable and necessary activities that do not constitute information blocking. To develop the proposed exceptions, we were guided by three overarching policy considerations. First, the exceptions would be limited to certain activities that clearly advance the aims of the information blocking provision. Second, each exception is intended to address a significant risk that regulated actors (i.e., health care providers, health IT developers of certified health IT, health information networks, and health information exchanges) would not engage in certain reasonable and necessary activities because of potential uncertainty regarding whether those activities would be considered information blocking. Third, each exception would be tailored, through appropriate conditions, so that it is limited to those reasonable and necessary activities that it is designed to exempt. These exceptions also would be subject to strict conditions to ensure that they do not extend protections to practices that should be considered information blocking.

An action would not be treated as information blocking if it satisfies one or more of these seven exceptions. The first three exceptions extend to certain activities that are reasonable and necessary to prevent harm to patients and others; promote the privacy of EHI; and promote the security of EHI. We believe that without these exceptions, it would erode trust and undermine efforts to provide access and facilitate the exchange and use of EHI for important purposes.

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[7] Institute of Medicine. 2000. *To Err Is Human: Building a Safer Health System*. Washington, DC: The National Academies Press. *https://doi.org/10.17226/9728*.

[8] Office of the National Coordinator for Health Information Technology. "Effects of Meaningful Use Functionalities On Health Care Quality, Safety, And Efficiency." *Dashboard.Healthit.Gov*, 2014, *https://dashboard.healthit.gov/quickstats/pages/FIG-Health-IT-Literature-Review-Infographic.php*.

[9] Institute of Medicine (U. S.). *Health IT and Patient Safety: Building Safer Systems For Better Care (Health Information Technology And Patient Safety)*. National Academies Press, 2012.

The next three exceptions promote competition and innovation. First, we propose to permit the recovery of certain types of reasonable costs incurred to provide technology and services that enable access to EHI and facilitate the exchange and use of that information. For example, this exception enables the recovery of costs reasonably incurred to develop technologies and provide services that enhance interoperability, while not protecting rent-seeking, opportunistic fees, and exclusionary practices that interfere with access, exchange, and use of EHI. Second, the proposed rule would permit an entity to decline infeasible requests to exchange EHI but would still require the actor to find a reasonable alternative for providing the EHI. Third, we propose an exception that would permit the licensing of interoperability elements on reasonable and non-discriminatory terms. Contractual and intellectual property rights are frequently used to extract rents for access to EHI or to prevent competition from developers of interoperable technologies and services. Such practices frustrate interoperability and stifle competition and innovation. In many scenarios, however, it is generally appropriate to license intellectual property on reasonable and non-discriminatory terms to support access, exchange, and use of EHI. This exception would further the goals of the information blocking provision by allowing for the protection of the value of their innovations and earn returns on the investments made to develop, maintain, and update those innovations.

For health IT to perform properly and efficiently, it must be maintained, and in some instances improved. This may require that health IT be taken offline temporarily. The final exception would allow EHI to be temporarily unavailable during health IT implementation upgrades, repairs, and other changes.

ONC's proposed rule primarily focuses on clinical data. However, advances in computer science and the maturity of data standards are accelerating the convergence of medical data with billing and price data. As such, the rule proposes to include such information as part of a patient's EHI that should be available for access, exchange, and use. The idiosyncratic and complex nature of pricing within the health care system has decreased efficiency and negatively impacted patients, clinicians, health systems, plans, plan sponsors, and other stakeholders.

In our current health system, there is an asymmetry of information for patients. They have few ways if any to anticipate or plan for costs, lower or compare costs, and, importantly, measure their quality of care or coverage relative to the price they pay. Transparency in the price and cost of health care could help address some of those concerns by empowering patients with information they need to make informed decisions. Further, the wide availability of price information for health care services could engender competition and accountability based on the quality and value of those services in health care. Increased consumer demand, aligned incentives, more accessible and digestible information, and the evolution of price transparency tools are critical components to move from a delivery system that rewards volume of services to one that recognizes and rewards the value of health care services.

Unfortunately, the complex and decentralized nature of how payment information for health care services is currently created, structured, and stored presents many challenges to achieving price transparency. This entire information chain is geared to retrospective payments rather than prices. The public has little idea what the CPT billing codes mean, or how they might be combined if at all to determine a prospective price. As noted in my discussion of APIs, we can see a future where, for example, platforms use raw data to provide consumers with digestible price information through their preferred medium such as an online tool or smartphone app. As such, the proposed rule seeks public input on both how we can scope and capture price information as part of EHI as well as what steps HHS can take, using all its available resources, to provide price transparency.

I also want to note that, as part of ONC's implementation of congressional direction articulated through the Cures Act, we recently issued an updated draft of the Trusted Exchange Framework and Common Agreement (TEFCA) for public comment, which includes a common set of principles that facilitate trust between health information networks. The TEFCA is designed to provide a single "on-ramp" to nationwide connectivity and advance a landscape where information securely follows the patient where and when it is needed. We also issued a funding opportunity announcement for the selection of a private sector non-profit organization that will serve as the Recognized Coordinating Entity responsible for developing, updating, implementing, and maintaining the Common Agreement with ONC. This Common Agreement will create the baseline technical and legal requirements for networks to share EHI across the Nation. Nationwide interoperability is not a simple undertaking, and something as expansive as a final TEFCA requires thoughtful consider-

ation of the issues and challenges. ONC's intention with releasing the draft for a second round of public comment is to ensure we get it right.

I also wanted to note that a significant unmet need in the health care system is for patients with behavioral health conditions. These patients may transition between emergency rooms, primary care, mental and behavioral health specialists, shelters, group homes, and various treatment centers. When these patients present at a new setting, a provider may know where they transferred from, but lack the necessary insight about their care journey. ONC previously funded various programs to accelerate health information exchange at the state, regional, and local level. These community information exchanges have demonstrated reductions in care utilization, such as through reduced duplicate testing and imaging for patients. 1A[10], [11] Community information exchanges are positioned to connect patients with clinical services and social supports. ONC remains committed to advancing community information exchange to support care coordination and improve health, especially for patients with behavioral health conditions.

In addition, the provisions in our proposed rule to support the use of secure APIs and to support the access, exchange, and use of electronic health information can also offer promising strategies to combat opioid use disorder (OUD). Data such as opioid prescription drug data, prior OUD diagnosis and treatment data, and community health information is essential for providers to be able to prevent and treat OUD. This data continues to be siloed across systems. This makes access to this information and to related decision making tools burdensome for providers. We look forward to continuing to advance the adoption of common industry standards that could help to address opioid use disorder prevention and treatment while addressing the patients' need for privacy.

In summary, much of today's American health care delivery system remains complex and opaque to providers and patients. Congress's 21st Century Cures Act and advances in modern computing allow us to revisit many of the assumptions about what delivery of medical care could and should be. ONC's proposed rule and advancements on the Trusted Exchange Framework and Common Agreement serve as major steps to make health care more transparent, accountable, and patient and provider accessible. We believe these policies firmly place the Nation on the path to achieving the long-term benefits of interoperability of electronic health information connecting for the U.S. health system.

We will continue to keep Congress informed of milestones as they occur. Mr. Chairman, Ranking Member, and Members of the Committee, thank you for the opportunity to testify. I look forward to responding to any questions you may have.

[SUMMARY STATEMENT OF DON RUCKER]

The 21st Century Cures Act directs the HHS Secretary to adopt standards and policies that advance the seamless and secure flow of electronic health information (EHI) across the health system. On March 4, 2019, ONC issued a proposed rule to implement key provisions in Title IV of the Cures Act. This proposed rule aims to drive the electronic access, exchange, and use of health information. It seeks to inject competition into the health care delivery system by addressing both technical barriers and business practices that impede the secure and appropriate sharing of data.

A central purpose of the proposed rule is to facilitate patient access to their EHI on their smartphone, growing a burgeoning patient- and provider-facing app economy. The proposed rule includes proposals that focus on certified health IT developers making available secure, standards-based APIs that facilitate patients' use of their smartphones (or other mobile devices) for accessing EHI at no cost.

The promise of standards-based API technology can only be successful if current business practices that enable information blocking are dismantled. The Cures Act's information blocking provisions were enacted in response to concerns that some individuals and entities engage in practices that unreasonably limit the availability and use of EHI for authorized and permitted purposes. These practices undermine

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[10] Ayer, Turgay et al. "The Impact of Health Information Exchanges on Emergency Department Length Of Stay." *Production and Operations Management*, vol 28, no. 3, 2018, pp. 740–758. *Wiley*, doi:10.1111/poms.12953. Accessed 25 Apr 2019.

[11] Lammers, Eric J. et al. "Does Health Information Exchange Reduce Redundant Imaging? Evidence from Emergency Departments." *Medical Care*, vol 52, no. 3, 2014, pp. 227–234. *Ovid Technologies (Wolters Kluwer Health)*, doi:10.1097/mlr.0000000000000067. Accessed 25 Apr 2019.

public and private sector investments in the Nation's health IT infrastructure. The proposed rule establishes seven exceptions that identify certain reasonable and necessary activities that do not constitute information blocking.

ONC's proposed rule primarily focuses on clinical data. However, advances in computer science and maturing data standards are accelerating the convergence of medical data with billing and price data. As such, the rule proposes to include such information as part of a patient's EHI that should be available for access, exchange, and use.

ONC also recently issued an updated draft of the Trusted Exchange Framework and Common Agreement (TEFCA) for public comment, which includes a common set of principles that facilitate trust between health information networks. The TEFCA is designed to provide a single "on-ramp" to nationwide connectivity and advance a landscape where information securely follows the patient. We also issued a funding opportunity announcement for the selection of a Recognized Coordinating Entity responsible for developing, updating, implementing, and maintaining the Common Agreement with ONC.

In summary, much of today's American health care delivery system remains complex and opaque to providers and patients. The Cures Act and advances in modern computing allow us to revisit many of the assumptions about what delivery of medical care could and should be. ONC's proposed rule and advancements on the TEFCA serve as major steps to make health care more transparent, accountable, and accessible for both patients and providers. We believe these policies firmly place the Nation on the path to achieving the long-term benefits of interoperability of electronic health information connecting for the U.S. health system.

The CHAIRMAN. Thank you Dr. Rucker, Dr. Goodrich, welcome.

STATEMENT OF KATE GOODRICH, M.D., DIRECTOR AND CENTER FOR MEDICARE AND MEDICAID SERVICES CHIEF MEDICAL OFFICER, CENTER FOR CLINICAL STANDARDS AND QUALITY, CENTER FOR MEDICARE AND MEDICAID SERVICES, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. GOODRICH. Thank you. Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the invitation to testify today on behalf of the Centers for Medicare and Medicaid Services. I appreciate this opportunity to discuss our efforts to foster innovation that promotes patient access to and use of their health information.

At CMS we are committed to advancing interoperability and improving access to health information for patients in the healthcare system. As a practicing physician, I know how important it is to be fully informed of a patient's medical history before making a diagnosis, or proposing a treatment plan, or prescribing a medication. And as a patient, I value my right to access my own health information and to use it to better manage my care. A core policy principle underlying our proposals is that every American should be able, without special effort or advanced technical skills, to see, obtain, and use all electronically available information that is relevant to their health, care, and choices of plans, providers, and specific treatment options.

While many consumers today can often access their own health information through patient portals and proprietary applications made available by various providers and health plans, they typically must go through distinct processes, separate processes, to obtain access to each system and often need to manually aggregate information that is delivered in various non-standardized formats. CMS believes that when a patient receives care from a new pro-

vider, a complete record of their health information should be readily available to that provider regardless of where their care may have been previously provided or by whom. Similarly, when an enrollee changes health plans or ages into Medicare, the enrollee should be able to have their claim's history and encounter data follow them so that information is not lost.

Last year, the administration launched the My Healthy Data Initiative, a Government wide initiative spearheaded by the White House Office of American Innovation with participation from CMS and other Federal agencies. A key goal of this initiative is to empower patients by giving them the ability to move from health plan to health plan and from provider to provider while having both their clinical and administrative information follow them. In support of My Healthy Data, CMS launched Blue Button 2.0, our first developer-friendly, standards-based application programming interface that allows Medicare fee-for-service beneficiaries to access and share their healthcare claims data with applications and services that help them manage their health, as well as with their doctors and their caregivers. Through Blue Button 2.0, the nearly 40 million beneficiaries enrolled in traditional Medicare now have the ability to access their claims data using third-party applications.

On March 4th, inspired by the vision set out by Congress in the 21st Century Cures Act, CMS issued a proposed rule that would, for the first time, require health plans doing business in Medicare Advantage, Medicaid, and through the Federal exchanges to follow our lead and share health claims data and other important information electronically with their patients. We announced our proposal concurrently with the office of the National Coordinator who's proposed rule updates standards for certified electronic health records.

As we move forward through the rulemaking process, our agencies will continue to collaborate to make sure our policies work together in order to drive interoperability and improve care coordination for patients. Our efforts are designed to help patients access their health data through common technologies and without special effort. And while patients had a right to access their health care data and use it in any way they deem fit, we also feel a responsibility to protect the privacy and security of this sensitive information. That is why our proposed rule includes a requirement for plans to educate patients about the risks that they should consider when sharing their health data with third-party application developers. We also expect developers to maintain strong privacy and security standards as they develop applications for patients.

Across the agency, CMS relies heavily on stakeholder feedback to help us improve our programs. We extended a public comment period on our interoperability proposed rule by 30 days, and we encourage plans, providers, Members of Congress, and other interested parties to provide us comments for us to consider as we move forward through the decision making process. The deadline is June 3d, and we look forward to hearing ideas about how we can improve upon our proposals and implementation strategies.

Thank you again for the invitation to be here and I look forward to answering your questions.

[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 Centers for Medicare & Medicaid Services' (CMS's) efforts to foster innovation that promotes patient access to and use of their health information. We are committed to advancing interoperability and improving access to health information for patients in the U.S. health care system. As evidenced by our ongoing work, as well as our proposed rule now out for public comment, CMS is taking an active approach to move the health care market toward interoperability and the secure and timely exchange of health information by proposing policies for the Medicare and Medicaid programs, the Children's Health Insurance Program (CHIP), and issuers of health plans sold on the Federal Exchange.

Last year, the administration launched the MyHealthEData Initiative, which aims to break down the barriers that prevent patients from gaining electronic access to their health information from the device or application of their choice, empowering patients and taking a critical step toward interoperability and patient data exchange. As part of this initiative, we are taking a patient-centered approach to health information access and moving to a system in which empowered patients have immediate access to their health information electronically. Patients will have the ability to securely share their health information, creating a single record that will follow them as they move throughout the health care system, giving them the data they need to make the best decisions for themselves and their families.

Medicare Blue Button 2.0

In support of this goal, and in support of the MyHealthEData initiative, last year, the CMS announced the launch of Blue Button 2.0, our first secure, standards-based Application Program Interface (API) that allows Medicare beneficiaries to access and share their health care claims data with applications and services that help them manage their health, in addition to sharing this information with their doctors and caregivers. API technology allows software from different developers to connect with one another and exchange electronic health information in electronic formats that can be more easily compiled and shared.

Through Blue Button 2.0, Medicare beneficiaries can select third party applications to connect to their data to compile and use their electronic health information. There are now 20 Blue Button apps available, which are posted on Medicare.gov, and developers are currently working on many more. Among other uses, these applications can help beneficiaries find plans, organize and share medical information and claims, or make appointments. We are also excited about the promises of research that can be enabled through beneficiaries choosing to share their data to help in the development of the next generation of cures and innovative treatments.

Ensuring the privacy and security of beneficiary data has been a priority for CMS since the beginning of this effort. We have taken a number of steps to protect beneficiary data, including regular systems security testing. Blue Button applications use existing CMS standards for beneficiary authorization, and they must use clear and plain language to alert beneficiaries to the sensitivity of the data they are sharing. Additionally, CMS offers a user-friendly dashboard on MyMedicare that allows beneficiaries to turn off data access for any application at any time.

Interoperability and Patient Access Proposed Rule

Continuing to build on the MyHealthEData initiative, on March 4, 2019, CMS issued a proposed rule 1A[1] on Interoperability and Patient Access that is intended to move the health care market toward interoperability. This proposed rule was inspired by, and demonstrates our commitment to, the vision set out in the 21st Century Cures Act and Executive Order 13813 to improve access to and the quality of information that Americans need to make informed healthcare decisions, including data about health care prices and outcomes while attempting to minimize the burden associated with these changes to plans, health care providers and payers.

The proposed rule would enable patients to access their health information electronically by requiring the payers subject to this proposed rule to share health claims and other information electronically with their enrollees by 2020, much like CMS is already doing for Medicare beneficiaries through Blue Button 2.0. This empowers patients to take charge of and better manage their health care.

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[1] Available at: *https://www.Federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and*

The rule also facilitates data exchange for health care providers and suppliers, including doctors and hospitals, to have access to health information about their patients, regardless of where the patient may have previously received care. Our proposals aim to connect providers through data exchange and provider directories while preventing them from engaging in the act of information blocking, or inappropriately restricting the flow of information to other health care providers and payers. These proposals support interoperable practices that may reduce the burden on health care providers.

CMS announced the rule concurrently with another proposed rule, issued by the Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC). ONC's proposed rule updates the standards for certified EHR by identifying certain activities that ONC has determined are reasonable and necessary and making those activities exceptions to the original statutory definition of information blocking. Inspired by the 21st Century Cures Act, and in collaboration with ONC, the proposals in the CMS Interoperability and Patient Access proposed rule drive interoperability to promote competition and improve patient care.

Patient Access Through Application Programming Interfaces (APIs)

A core policy principle underlying our proposals is that every American should be able, without special effort or advanced technical skills, to see, obtain, and use all electronically available information that is relevant to their health, care, and choices—of plans, providers, and specific treatment options. While many consumers today can often access their own health information through patient portals and proprietary applications made available by various providers and health plans, they typically must go through separate processes to obtain access to each system, and often need to manually aggregate information that is delivered in various, non-standardized formats.

We are proposing to require that certain kinds of plans—Medicare Advantage plans, Medicaid fee-for-service and managed care plans, CHIP fee-for-service and managed care plans, and Qualified Health Plans on the Federal Exchange—maintain secure APIs that enrollees can use to access certain categories of their health data. This proposal would enable enrollees to use the application of their choice to access and use their own electronic health information. We hope that other payers might voluntarily offer this type of data accessibility so that even more patients across the American health care system can be empowered through easy access to their electronic health data.

Health Information Exchange and Care Coordination Across Payers

As patients move throughout the healthcare system, in particular from health plan to health plan, they should be able to maintain access to their health information. Our proposed rule would require health plans to support patients in coordinating their own care through plan-to-plan health information exchange, electronic exchange of data as patients move between plans.

This proposed policy also leverages interoperability to facilitate care coordination among plans to reduce unnecessary care, as well as ensure that health care providers are able to spend their time providing care rather than performing unnecessary administrative tasks. For instance, effective information exchange between plans could improve care coordination by reducing the need for health care providers to write unneeded letters of medical necessity; by reducing instances of inappropriate step therapy; and by reducing repeated utilization reviews, risk screenings or assessments.

Care Coordination Through Trusted Exchange Networks

We propose that Medicare Advantage organizations, Medicaid managed care plans, CHIP managed care entities, and issuers on the Federal Exchange be able to participate in a trusted exchange network, which would allow them to join any health information network they choose and be able to participate in nationwide exchange of data. Trusted exchange networks allow for broader interoperability beyond one health system or point-to-point connection by facilitating secure exchange of electronic health information without special effort on the part of the user.

API Access to Published Provider Directory Data

We believe access to provider directories and network information is critical for helping patients get the care they need. Health plan provider directories help pa-

tients find in-network providers and allow healthcare professionals to locate other providers for purposes of referrals, transitions of care, and care coordination. To ensure that patients and providers have easy access to provider directory information, we propose to require Medicare Advantage organizations, state Medicaid and CHIP programs, Medicaid managed care plans, and CHIP managed care entities to make standardized information about their provider networks available to enrollees and prospective enrollees through API technology, much like the Qualified Health Plans on the Federal Exchange.

Provider Digital Contact Information

Provider contact information is critical to interoperability, care coordination and patient care. Last summer, to implement the requirements in the 21st Century Cures Act that required the Secretary to create a provider digital contact information index, CMS updated our online National Plan and Provider Enumeration System (NPPES) that maintains the National Provider Identifier (NPI) records for providers to collect this information and to allow providers to include one or more pieces of digital contact information that can be used to facilitate secure sharing of health information. Digital contact information, or electronic addresses for providers, allow them to exchange data faster and more efficiently while improving interoperability. Ultimately, we believe this technology could eliminate the need for fax machines in the clinical setting, but to make this technology effective, we need providers to make the most of it. To promote increased use of this provider digital contact information index, CMS is proposing to publicly report the names and National Provider Identifiers of those providers who have not added digital contact information to their entries in the NPPES system beginning in the second half of 2020.

Public Reporting of Information Blocking

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) included a requirement that eligible clinicians and hospitals demonstrate that they have not knowingly and willfully taken action to limit or restrict the compatibility or interoperability of certified EHR technology.[2] CMS implemented these policies through attestation requirements in our Promoting Interoperability Programs.[3] We believe it would benefit the public, which includes patients and caregivers, to know if individual clinicians, hospitals, and critical access hospitals have submitted a "no" response to any of the three attestation statements regarding the prevention of information blocking. In our proposed rule, we propose including an indicator on the *Physician Compare* website for eligible clinicians participating in the Quality Payment Program, and to post information on a CMS website available to the public for eligible hospitals and critical access hospitals participating in the Medicare Promoting Interoperability Program, who submitted a "no" response to any of the three attestation statements regarding the prevention of information blocking.

Revisions to the Conditions of Participation for Hospitals and Critical Access Hospitals

We have helped to facilitate data sharing and notification capabilities through our policies on provider directory information, and we further promote this by proposing to require that hospitals send electronic patient event notifications to other providers treating a patient when the patient is admitted, discharged or transferred from the hospital. Clinical event notifications are widely recognized as an effective tool for improving care coordination across settings, especially for patients at admission, discharge, and transfer.

We are proposing to revise the conditions of participation for hospitals and critical access hospitals to require that these entities send patient event notifications to other care providers or facilities that have an established care relationship with

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[2] Section 106(b)(2)(A) of MACRA amended section 1848(o)(2)(A)(ii) of the Act to require that an eligible professional must demonstrate that he or she has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology, as part of being a meaningful EHR user. Section 106(b)(2)(B) of MACRA made corresponding amendments to section 1886(n)(3)(A)(ii) of the Act for eligible hospitals and, by extension, under section 1814(l)(3) of the Act for CAHs. Sections 106(b)(2)(A) and (B) of MACRA provide that the manner of this demonstration is to be through a process specified by the Secretary, such as the use of an attestation.

[3] To review our discussion of these requirements, see the CY 2017 Quality Payment Program final rule (81 FR 77028 through 77035).

their patient. While deploying these notifications is low-cost and easy to achieve with any electronic health record system, many hospitals have not developed capabilities to send these notifications to other providers and facilities to whom they transition patients. We propose to limit this requirement to only those Medicare-and Medicaid-participating hospitals and CAHs that possess EHR systems with the technical capacity to generate information for electronic patient event notifications. This limitation will avoid burdening hospitals wishing to participate in the Medicare and Medicaid programs while still supporting efficient transitions of patient care whenever feasible.

Request for Information: Advancing Interoperability Across the Care Continuum

Transitions across care settings have been characterized as common, complicated, costly, and potentially hazardous for individuals with complex health needs. Yet despite the need for functionality to support better care coordination, discharge planning, and timely transfer of essential health information, interoperability by certain health care providers such as long-term and post-acute care, behavioral health, and home- and community-based services continues to lag behind acute care providers. We are soliciting comment on several potential strategies for advancing interoperability across care settings to inform future rulemaking activity in this area. We are seeking solutions to more broadly incentivize the adoption of interoperable health IT systems and use of interoperable data across settings, such as long-term and post-acute care, behavioral health, and settings that serve individuals receiving home- and community-based services or who are dually eligible for Medicare and Medicaid.

Advancing Interoperability in Innovative Models

We believe that the Center for Medicare and Medicaid Innovation ("Innovation Center") models offer a unique opportunity to engage with healthcare providers in innovative ways and test new concepts and are an important lever to advance interoperability. CMS plans to promote interoperability across the healthcare spectrum through model testing that focuses on using emerging standards, models leveraging non-traditional data, and technology-enabled patient engagement platforms. The Innovation Center is seeking public comment on promoting interoperability among model participants and other healthcare providers as part of the design and testing of innovative payment and service delivery models.

Request for Information: Policies To Improve Patient Matching

Finally, because patient identification is so critical to patient safety and information exchange, CMS is investigating ways to facilitate private sector work on a practical and scalable patient matching strategy. Together, CMS and ONC are requesting feedback on how we can leverage our respective authorities to improve patient identification, and thus patient safety, to encourage better coordination of care across different healthcare settings while advancing interoperability. We are also seeking comment on how we may leverage our program authority to provide support to those working to improve patient matching.

Promoting Interoperability

Last year CMS announced an overhaul of the Medicare and Medicaid Electronic Health Record Incentive Programs (often known as the "meaningful use programs") for hospitals after the Bipartisan Budget Act of 2018 increased our flexibility in implementing these programs.[4] We renamed these programs the "Promoting Interoperability Programs" to promote interoperability, help to maintain a focus on patients and reduce burden. With these changes, hospitals and critical access hospitals are subject to a new performance-based scoring methodology with fewer measures beginning in 2019, which moves away from the threshold-based methodology that was in place.[5] For clinicians, we changed the Merit-Based Incentive Payment System "Advancing Care Information" category to the "Promoting Interoperability" category by generally aligning with the revised requirements for hospitals by moving

[4] Bipartisan Budget Act of 2018 (Pub. L. 115–123), Section 50413, Reducing the Volume of Future EHR-Related Significant Hardship Requests, and section 51003, Technical Amendments to Public Law 114–10.

[5] 83 FR 41150.

clinicians to a single, smaller set of objectives and measures.[6] We think these changes provide a less burdensome structure, allowing eligible hospitals, critical access hospitals, and clinicians to put their focus back on patients while still moving forward toward interoperability.

Moving Forward

CMS is committed to creating a patient-centered health care system in which empowered patients have immediate access to their health information so they can better engage in and make decisions about their care. From our work with Blue Button 2.0 to the policies in the proposed rule, we want every stakeholder focused on the need for seamless data sharing so patients and providers can make decisions with complete, accurate sets of information and deliver the best health outcomes. Ultimately, we all need to work together to drive the seamless flow of information across the health care system. We are working toward a healthcare future when patients are able to obtain and share their health data securely and privately, with just a few clicks, and can ensure their care team is comprehensively informed of their specific care needs.

[SUMMARY STATEMENT OF KATE GOODRICH]

At the Centers for Medicare & Medicaid Services (CMS), we are committed to advancing interoperability and improving access to health information for patients in the U.S. health care system. As evidenced by our ongoing work, as well as our proposed rule now out for public comment, CMS is taking an active approach to move the health care market toward interoperability and the secure and timely exchange of health information by proposing policies for the Medicare and Medicaid programs, the Children's Health Insurance Program (CHIP), and issuers of health plans sold on the Federal Exchange.

Last year, the administration launched the MyHealthEData Initiative, which aims to break down the barriers that prevent patients from gaining electronic access to their health information from the device or application of their choice, empowering patients and taking a critical step toward interoperability and patient data exchange.

In support of this goal, and in support of the MyHealthEData Initiative, last year, the CMS announced the launch of Blue Button 2.0, our first secure, standards-based Application Program Interface (API) that allows Medicare beneficiaries to access and share their health care claims data with applications and services that help them manage their health, in addition to sharing this information with their doctors and caregivers.

Continuing to build on the MyHealthEData Initiative, on March 4, 2019, CMS issued a proposed rule on Interoperability and Patient Access that is intended to move the health care market toward interoperability. The proposed rule would enable patients to access their health information electronically by requiring the payers subject to this proposed rule to share health claims and other information electronically with their enrollees by 2020, much like CMS is already doing for Medicare beneficiaries through Blue Button 2.0.

A core policy principle underlying our proposals is that every American should be able, without special effort or advanced technical skills, to see, obtain, and use all electronically available information that is relevant to their health, care, and choices—of plans, providers, and specific treatment options. While many consumers today can often access their own health information through patient portals and proprietary applications made available by various providers and health plans, they typically must go through separate processes to obtain access to each system, and often need to manually aggregate information that is delivered in various, non-standardized formats.

From our work with Blue Button 2.0 to the policies in the proposed rule, we want every stakeholder focused on the need for seamless data sharing so patients and providers can make decisions with complete, accurate sets of information and deliver the best health outcomes. Ultimately, we all need to work together to drive the seamless flow of information across the healthcare system. We are working toward a health care future when patients are able to obtain and share their health data securely and privately, with just a few clicks, and can ensure their care team is comprehensively informed of their specific care needs.

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[6] 83 FR 59785.

The CHAIRMAN. Thank you, Dr. Goodrich. We will now go to five minute round of questions.

During the 21st Century Cures, when we had six bipartisan hearings on electronic health care records, we formed a working group of interested Senators and I am going to discuss it with Senator Murray. We might do that again, and keep, for those Senators who are interested in this, every 90 days or so as Dr. Rucker and Dr. Goodrich come up, spend an hour with us, give us an update on whether they are running into unexpected things. We know you are going to run into unexpected things. We want to create an environment in which you can succeed. So that would be what we may ask you to do.

I mentioned earlier that my music teacher, and I will just repeat that, who said play it a little slower than you can play it and you will make fewer mistakes, and hopefully we will learn lessons from Meaningful Use 3. I do not mind saying it was Vanderbilt University who was pretty far ahead in electronic records and they said Meaningful Use 1 was very helpful, 2 was Okay, 3 was terrifying, and I think it would have been better if we had taken time and work with doctors and hospitals and others and incorporated them into the process. But that is a lesson to learn.

It is true as Dr. Goodrich said and Dr. Rucker said, if you go to many hospitals or doctor's offices today, you can obtain your own personal medical information very rapidly and in an easy way. Our goal is to make it as easy to get your medical information, your own medical information, than it is to make an Airline reservation, and in some cases, that is already the case at an institution. But if you want to go from one institution to another, as Dr. Goodrich said, basically you crawl down to the basement of some hospital, find your information, put it in a wheelbarrow, and take it over to the next place. So that is what we are talking about with interoperability.

Let me take an example of what I mean by making sure we do not go too fast. We deliberately left it up to you, with your expertise, to make a judgment about how to do this practically, and you have said that you want to have most of this data in two years after this rule is final. The rule will be final toward the end of this year. So that leaves two years.

Why not have a more phased approach for that? For example, starting with the U.S. Core Data for Interoperability and do that well within those first two years, and then take a second step. You had a common clinical data set that was set in 2015, and many people still have not been able to comply with that.

Now you are having to update the data set and you are not only asking for that information, but you are asking for all of the other information within a two-year period of time. In other words, why not phase in starting with the U.S. Core Data for Interoperability, Dr. Goodrich?

Dr. GOODRICH. Certainly. So, we did propose in our proposed rule that plans make available an API to be able to make data accessible to third-party application developers as designated by a patient, January 1st of 2020. We also, and most of these data are administrative claims data, encounter data that already exist, but we do reference also the USCDI.

The CHAIRMAN. But wait a minute, is it not true though that you get to do this kind of thing in 2015? You have set some standards and most providers and doctors haven't yet mastered that, is that correct?

Dr. GOODRICH. Are you referencing the 2015 edition of certified technology?

The CHAIRMAN. Of the Common Clinical Data set. That has been out there for four years——

Dr. GOODRICH. Correct.

The CHAIRMAN. Has everybody mastered that in that four year period of time? Or would that be for Dr. Rucker?

Dr. GOODRICH. I might defer to Dr. Rucker to answer that as well. I think we do require that clinicians and hospitals that participate in our programs use the edition of certified technology that contains that Core Data set. We have seen fairly good adoption, but I will if Dr. Rucker wants to add anything.

The CHAIRMAN. Well, what does fairly good mean, Dr. Rucker? Have they all—is that in really good shape? Because they have had four years to do it and what you are proposing to do, would be an even greater gathering of information than that.

Dr. RUCKER. Right. So, the Common Clinical Data set includes things like problem lists, medications, allergies. The difference between the U.S. Core Data for Interoperability and the Common Data set is we are adding in clinical notes and some, what is called metadata, so people know who did the note.

The CHAIRMAN. But I am running out of time. I guess my question is, if you could not get it—if four years wouldn't do it for what you tried to do in 2015, why do you think you can do it in two years all of this other data collection? Why not start with a more modest start like the U.S. Core Data for Interoperability?

Dr. RUCKER. Well, that is actually what we are doing. So, what we have, all the core technical provisions and the testing are really about the Core Data for Interoperability because that is the part that is computable. That is the part, once the final rule and then two years after, that is where the testing is and that is an increment over the 2015 rule, which for the first time is being required in 2019. We have evidence that the vast majority of providers both physicians and hospitals have access to that software today.

The CHAIRMAN. Okay. Thank you.

Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman. Dr. Rucker, as you know prohibiting information blocking was one of the Committee's top health IT priorities in the 21st Century Cures Act. We want to make sure the Department of Health and Human Services takes the time to implement the Cures the right way but if health or care organizations or technology vendors are hoarding data in order to gain a competitive advantage for themselves, there are real consequences for the health and safety of patients if the Department takes too long to implement these policies. What are the risks of delaying the prohibition on information blocking?

Dr. RUCKER. Well, I think the risks are, as you have outlined them, I think the main risk fundamentally is, to the extent that this is delayed or prevented, the American public is not in charge of their healthcare and they are paying more for their care, they

are not getting as good a care as they could get, and fundamentally they are not in control of their care.

With the information blocking rule to make that to follow the intent of Congress we have, in our proposed rule, have seven specific exceptions based on literally over a hundred stakeholder meetings were this almost invariably came up as a topic for discussion to narrow the scope and make that enforceable for the Office of the Inspector General and to provide clarity for the public. We think that they are very common sense types of things. The one area where there has to be sort of a definition, if you will, is on allowable costs.

We have heard vendors are charging over $1 million to a start up to, just get that data that obviously stops innovation in its tracks. So, we have language allowing reasonable recovery of costs and profit but that it is not used as a strategy to prevent competitors from entering potentially reserved spaces.

Senator MURRAY. Okay, thank you. Dr. Goodrich, as I talked about in my opening statement, Congress aimed to prevent information blocking in all its forms in the bill. We asked HHS to decide what the appropriate consequence for providers and hospitals that block flow of information should be. In the CMS rule, your agency proposes creating a public list of the physicians and hospitals that respond yes when they are asked if they participate in this behavior. What was the thought process behind a public list as the proposed mechanism of enforcement?

Dr. GOODRICH. Certainly. And I will first say that the Department is still considering other ways to address that particular provision of the 21st Century Cures Act. What this does in our proposed rule is it builds upon what we finalized through actually the MACRA legislation related to requiring that providers attest that they did not willfully or knowingly block the flow of information. That is part of the MIPS program as well as what hospitals have to do for the Promoting Interoperability program.

What we are doing in the Proposed Interoperability rule is merely saying, for people who do not attest that they did not block information flow essentially, that we would make that list of hospitals or clinicians public, but we are still considering other mechanisms.

Senator MURRAY. Okay. What if a provider says they don't information block, but they are found guilty of that conduct?

Dr. GOODRICH. Anytime that we have any concern about information blocking that we discover through any of our usual mechanisms, that is something that we would certainly refer to the OIG to look into as well.

Senator MURRAY. Okay. And open APIs which allow for data exchange between products developed by different companies. They are an essential feature for an interoperable healthcare system and allow patients actually to get more control over their own healthcare data. Last year, CMS allowed beneficiaries and traditional Medicare to access their healthcare claims and information through an API, and I was glad to see in your proposed rule CMS is expanding that initiative to beneficiaries and programs like Medicare Advantage, Medicaid Managed Care, CHIP, marketplace plans. Talk to us why that is so important.

Dr. GOODRICH. Yes. We have—again a core principle that it is critical for patients to have access to their data. They currently do have access to their data through individual patient portals or their various doctors' offices or proprietary applications their providers may have. And what our proposed rule does is it intends to lower the burden on patients by requiring that plans who do business with CMS aggregate that information and make it a bit available through an API. We have seen a lot of interest in this technology and Medicare beneficiaries wanting to access their data through our Blue Button 2.0, and we really hope that health plans would take our lead and build upon that while maintaining the highest standards of privacy and security.

Senator MURRAY. Okay. Thank you very much.

The CHAIRMAN. Thank you, Senator Murray.

Senator Braun.

Senator BRAUN. Thank you, Chairman Alexander. I think it is interesting that we are here talking about stuff like this, and that I think back to the 38 years I have had a logistics and distribution business. I remember taking handwritten orders back in the early 80's and remember being on a RadioShack information system in the late 80's. I remember going on the Great Plains in the 90's, and all I can tell you is that most industries would not be having hearings because there is transparency, and there is competition, and there is embracing of technology. Hated to hear that within the medical sector, it is the only place where we see neutral to may be negative annual gains in productivity or the use of technology.

I think it begs the question, what is wrong with the industry itself? And as a conservative, a Main Street entrepreneur, I lay the burden not here in the Senate, on the shoulders of the industry itself. I mean when you are cloaking and making things so difficult to get simple things like interoperability and when you are dealing with talking about blocking information, that is so far out of the mainstream of all other industries and I want the industry to hear what I have been preaching all along get with it or you are going to be changed radically with all kinds of approaches that are out there based upon frustration.

We have got a dysfunctional industry that is not consumer driven. The consumer needs to be responsible. There is no other industry sector where the people that buy stuff are not engaged in it. It is due to the paternalistic evolution of healthcare. It has got the change. And we have got an industry that is full of smart individuals and big corporations that have figured out how to take advantage of it. That is why we are talking about some of the stuff, nudging through Committee hearings and possibly legislation. It is frustrating to me because it evolves naturally everywhere else.

My question is, do you think there is any chance that among consumers of healthcare, through some of the efforts I see to make it more consumer-driven—I have done it in my own business and all I can tell you is when you embrace it, you cut costs and you got to change your behavior because you are doing things you are not used to but like we evolved from taking handwritten orders and having the most high-tech system in the logistics and distribution business, and that is why we do well, we embraced it. And an industry that obviously is dragging its feet, does not see the hand-

writing on the wall, do you think there is any chance that the consumers that use it, the industry that provide it, will get to where they need to be without our nudging legislation and Committee hearings? And I would like each to comment on that kind of broad topic a little bit.

Dr. GOODRICH. Thank you. I would say that at CMS, we feel as a core principle for everything that we do at CMS, that consumers need to be in driver's seat. And I would say that many of our policies, including what we have proposed through this interoperability rule, are intended to do exactly that, whether it be through fostering transparency, nudging providers because our jurisdiction is of course over providers, to ensure that data flows to the patient and it is shared with the patient in a usable format, and of course through our interoperability efforts. And that is what we have been doing very closely in partnership with ONC. So, I think we absolutely believe that a consumer-driven system is necessary.

Dr. RUCKER. The rule I think, the proposed rule absolutely puts healthcare I think into a competitive place. It has not been literally in 50 years. Modern technology, these RESTful Json, those computer science terms, those APIs have transformed business after business after business. Logistics would be a perfect example of that. We think that they are going to transform healthcare by bringing other parties and new parties into the game who are not incumbents, who are not part of the current sort of system of consolidated delivery system and raise provider guilds. It has opened up markets throughout the world in other industries. We are quite optimistic that this will do it in healthcare.

Senator BRAUN. Thank you. And I would encourage the industry, publicly, to get with it because I think if I am not happy about the speed we are moving, and I respect the Chairman's advice to make sure we do not move too quickly. But it is a sad state of affairs that where we are at now and the industry needs to get with it because they is so much they know they could do to make it better. Thank you.

The CHAIRMAN. Thank you, Senator Braun.

Senator Kaine.

Senator KAINE. Thank you to the witnesses. Important topic. My staff members suggested that I read an Atul Gawande's New Yorker piece from November on "Why Doctors Hate Their Computers," and what a great article. It is hard to really summarize it because there is a lot of nuances to it but two observations from the article were that the increasing use of EHRs and computers generally may be increasing job dissatisfaction among physicians, but it is also giving patients all kinds of access to the notes of their meetings and tests results and ability to schedule appointments that they did not have before. I am just curious as to your reaction to that piece and whether in proposing this rule you are trying to, figure out a way to make the advance of EHR continue to be a great thing for patients but also let more of a value add and a pleasurable value add for physicians.

Dr. GOODRICH. Certainly, yes. This is a topic that I personally care deeply about as a practicing physician. I have been around long enough to have practiced when I had, handwritten notes and then transitioning into a variety of different EMR systems over

time. And I would say there is no question that the implementation of EMRs in many ways has actually been a positive improvement. Now nurses do not have to read my chicken scratch to take an order off. The computerized provider order entry has, I think really made some significant gains in improving patients' safety but there are real concerns that still remain that were highlighted in Dr. Gawande's article. We have done a number of things at CMS to try to address that related to what was passed in 21st Century Cures but also related to, for example, reducing the burden of documentation, which is a big pain point for clinicians.

In our physician fee schedule rule last year, we sort of overhauled the requirements related to documentation and we intend to further build those out through rule-making this year. That will make using EMRs easier. That is so much an EMR specific issue, but it is manifested through the EMR. So, there are things like that we are continuing to explore. The patient access issue to data though is critical. I take care of my mother's Medicare beneficiary and her having access to her information has been transformative.

Senator KAINE. Dr. Rucker, do you want to add anything to that?

Dr. RUCKER. Yes. I think the article makes a number of good points. I think the challenge is we have bundled all kinds of payment and policy things into the EMR. It is a lot easier for somebody to put that, oh, let the EMR sort it out so the EMR becomes a little bit of a waste basket for various things. Jointly with CMS under Cures, a physician-provider burden report was required. We have a draft out of that, and we have identified, in addition to the documentation that Kate mentioned another area, is prior authorization, a vast time sink for people, and so we are doing early work to try to figure out how to make that actually electronic. Right again, this is logistics, if you will, in healthcare as a lot of transaction cause opacity and delay.

I think there are things—I went into this business to actually automate things. It is a source of personal embarrassment that after thirty odd years in the field that computers generate more work for me when I practice than anything else. I would not have guessed it if you had asked me in 1988, when I graduated from Computer Science school after residency, what was going to happen, but we have a lot of incentives that are maybe not in the right place.

Senator KAINE. Let me move to a particular area. Health IT has a great potential to improve treatment pain management, especially help us deal with addiction issues. Everybody on this Committee has been very focused on opioid and other addictions. But IT can help us prevent prescription shopping, reduce inappropriate prescriptions, and facilitating interdisciplinary care. And the ONC proposed rule discusses these important issues and acknowledges the importance of patient privacy. Talk a little bit about the promise that increased standardization might offer to us as we are grappling continually with addiction issues, especially with respect to opioids.

Dr. RUCKER. Yes. I mean, the various state PDMPs which are now pretty much universal throughout the United States, have been very helpful. As an ER doc believe me, I have had every story of shopping for opioids in 30 years pitched at me, I think. So, I

mean I have lived this for decades and decades, the challenges of these group of patients. So, the PDMPs, I think, are good for what they do.

I think each state has a different approach to this. This makes it very complicated on a National basis to do this. It makes integration into workflows. You just talked about burden in the Atul Gawande article, and obviously having every state have different implementation is a type of impediment that I think we want to think about as we move forward and really harness the true power of this.

Also, we want to look at some of the surround, such as health information exchanges, that can help these patients, in a more positive way rather than—it is one thing to say, do not give somebody opioids but when you look at mental health and behavioral health, we also have great opportunities in computerization to help the patients. So, we want to look at both sides of them.

Senator KAINE. Great. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Kaine.

Dr. Cassidy.

Senator CASSIDY. Thank you all for being here. I often take the position as a physician but today I will take the position of the patient. Are apps going to be covered entities?

Dr. RUCKER. Apps will not be covered entities unless they are part of a covered entity or business associate. Unless they are currently part. So, for example, if a provider——

Senator CASSIDY. I get that. I just have a limited time. Can they resell the data?

Dr. RUCKER. That, at the moment, is a contractual thing to be negotiated between the patient and the app——

Senator CASSIDY. No that is not, again I——

Dr. RUCKER. Subject to Federal Trade Commission——

Senator CASSIDY. I do not mean to be rude, we have just got limited time—he is going to wrap on me. And so, if I read down it says, will you agree, after ten-page legalese. I mean I realize that I have just given permission to an app to combine my data with location data and, or to resale it to Facebook—God knows what happens then. So is there any protection for the patient from, because she is not going to, he is not going to do that. I do not do it until finally now I do it. And now I do not sign up for stuff. What do we do to protect that patient from legalese dulling their mind to the fact that they just gave away their family history?

Dr. RUCKER. I think you raise a very real and major issue here. And this is true of every app and everything on our smartphone, right. I mean the data about us is constant. Every browser you use uniquely identifies you on the entire planet as we speak today. Under the rule, the OUF–2 provides security. That is the authentication. So, the patient has to make a very conscious decision to download the data to the app. That offers an opportunity certainly for providers to give those warnings. Once it is under the HIPAA right of access, then the broader legal protections, we have a model consent notice that we suggest using, but I think it is still an open area.

Senator CASSIDY. Perhaps something for us to consider, what would we require of the app in order to protect the patient. Next,

we are docs. You take a family history. It is not just doctor and Mr. Braun whom I am taking history on, but I actually end up knowing whether his mama had diabetes. You see where I am going with that. Whether the brother had—I don't know anything about him by the way. I could go into all sorts of terrible things.

[Laughter.]

Senator CASSIDY. When I give my permission for that medical record to be downloaded, I am not sure patients understand how much I have just gotten, even before talking about genetic data, about somebody's family history. Do we have protections on that, number one, and number two, can I say I want you to download everything but not my medical—but not my family history?

Dr. RUCKER. That is a major problem. I have seen all of the DNA sites, all the DNA testing sites. That is extremely specific and extremely broad. The privacy issue you ranged right now, there is some data segmentation for privacy opportunities. We are optimistic that the market will provide clarity here the same way that consumer branding helps with things like banking, right. We do not just put our money anywhere, we go to brands. We hope that a consumer economy will drive this with trusted brands but at the moment the prohibitions against secondary use of data are exactly as you describe.

Senator CASSIDY. Yes, that is I think we need to consider that, because this is going to be a mess. And some people get a loan charge right? So not everybody will have the kind of ability to sort out.

Dr. RUCKER. The one caveat I would put for you on that is, right now you can infer health data from many non-health records, right. You can infer from location of a clinic. You can infer it from your credit card statements. You can infer very specific health data from a lot of things. So, I think as Congress thinks about secondary use of data, it really should be a fairly broad consideration of that.

Senator CASSIDY. Let me flip back to being a physician or being an EHR vendor. If somebody requests—I got 10 data elements including the family history and maybe including HIV status. And I want to share all of this, but I do not want to share my HIV status or my family history. I think that is going to—I am assuming that is going to cost me, the provider, to figure out how to send some but not all. Am I going to be busted if I send too much or am I going to be busted if say, do see where I am going with that? How is that going to be handled and what would be the penalties if my EHR does not allow me to do it, but I am a doc and I have been requested to not give the family history?

Dr. RUCKER. That is a significant challenge with data segmentation for privacy. It is a brittle technology from a computer science point of view. We have in our information blocking provisions, provisions around what can actually be computed, so there is a protection in there for the physicians with those clauses.

Senator CASSIDY. The physician would not be busted for either not giving enough or giving too little if the EHR is inadequate? Does the EHR get busted?

Dr. RUCKER. Well, I think it is a joint challenge for both the physician and for the EHR, and we believe in the information blocking provisions that are up for public comment now, that we have provi-

sions there to help that. But as it is a deeply complicated technical issue because of the way it impacts the architecture of every data base field.

Senator CASSIDY. I thank the Chairman and the Ranking Member, and I look forward to those further hearings. And we will have some more QFRs, questions for the record.

Thank you.

The CHAIRMAN. Thank you, Senator Cassidy. I think a good subject for an early working group discussion would be, what are the rules and who is in charge when a patient gives his or her information to third party.

Senator Baldwin.

Senator BALDWIN. Thank you, and I want to thank the Chairman and Ranking Member for our continuing work on implementation of the 21st Century Cures Act. I want to thank both Dr. Rucker and Dr. Goodrich for your hard work to advance this law with the recent proposed rules. The proposed rule from ONC seeks to improve electronic health record quality by allowing providers or patient safety organizations to share screenshots for usability or safety reviews. I believe that certainly basic transparency is essential to improving data exchange on the quality and safety of patient care. However, these screens do demonstrate how information is organized within an electronic health record system, which could open up opportunities for bad actors.

We have to figure out a way to guarantee that the effort to improve safety and usability also protects information that could be used to reverse engineer the system, reverse-engineer the software or create malware frankly that could cause harm. So, Dr. Rucker how do we strike that balance of permitting, if necessary, screen sharing for legitimate purposes while also protecting the IP, the Innovation, and the cyber security in this arena?

Dr. RUCKER. In the 21st Century Cures Act, there is a list of very specific allowed uses of those screenshots that I think goes back to a history of complaints about "gag" clauses. So, in our proposed rule we enumerate through the specific list that is in 21st Century Cures and do not allow sort of other broader uses and actually call out the requirement to respect intellectual property. So, if you are not using it for those specific purposes, those are copyrighted, trade-mark owned screens by the software developers.

You have to have a very specific purpose in mind to do that, and broad reengineering of product as it has happened, as would not be allowed under those provisions. The cyber security we hope to have taken care of in large with some of the APIs by using industry-standard, cyber security thing so that we are not coming up with healthcare specific one-offs but actually using the broad industry thing that would be used by any industry protecting valuable information.

Senator BALDWIN. I may have some follow-up on that. I want to second move to an area explored by our Chairman in his questioning relating to moving from the 2015 U.S. Core Data for Interoperability to what appears to be a larger collection of information EHI, electronic health information. The Chairman was asking about where various health systems are with regard to the 2015

U.S. Court Data for Interoperability and then the impact of adding additional information.

My question for you Dr. Rucker is how do you reconcile the ongoing industry work that is being done on this U.S. Core Data set with these new requirements to comply with more expansive standard for exporting EHI and if you could give a little bit more descriptive information on what is a part of the expanded EHI versus what was a part of the Core. And then, as you work to finalize a rule that requires compliance with these additional standards, how do you make sure that it is manageable for interoperability?

Dr. RUCKER. Yes. So, the U.S. Core Data for Interoperability again, the change from the prior common clinical data set is in getting the notes to patients and identifying better who actually generated the note, which believe it or not is sometimes very hard to know who put the note into the chart as this gets to the Gawande type of issue. There is a provision in Cures for all data download and that provision was placed because I believe Congress heard complaints that when folks switch from one EHR to another, their data is locked into the old EHR and can't get to the new one.

There are no current extant standards to allow that data to be transmitted in any, I believe, really fundamentally usable format as structured data, so the rules says other than just giving the dictionary name of the term, it is just a simple download without structure. It can be done idiosyncratically to every system because there is no broader way of doing that.

That data, I think, will be very challenging to put into a new system. I am guessing the folks who might be able to use that are people who are using machine learning and natural language processing to get at that data but that is a simple right and does not have an enforceable data structure unlike the U.S. Core Data for Interoperability. That is a very nuanced technical issue but hopefully I have explained it. And it is a complicated history.

The CHAIRMAN. Well that clears that up.

[Laughter.]

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman. Dr. Rucker, Dr. Goodrich thank you for being here. In 2016 my question to a panel like this was how the hell you going to do this. I think what you have heard is different variations of that going around the room, difference is we are in 2019 and this is a discussion that we started in 2013 about how do we get systems to talk to other systems. 2015, there was a rule and one of you said today, in 2019 the rule is being required.

Here is my problem, over the 2013 to 2019 timeframe, Dr. Rucker, you know better than I do that technology innovation has exploded. It runs at an unbelievable pace, and here we are trying to set standards and set architecture of software, what technology can offer us whether it is a doctor's office, a hospitals, a provider that 12 months from now is going to be obsolete because that is how fast technology is changing. A good provider is going to constantly upgrade their technology to match the capabilities, not all, and there becomes the horror stories. That is not even getting into with Dr. Cassidy is talking about which is data control.

Here is my question as it relates to apps. Are the apps that you are talking about, are they holistic apps or do they target on one disease, I have got diabetes, I have got an app to help me manage my diabetes. Two, is there a holistic app, one that manages my health care based upon all the data that goes into it? And Dr. Goodrich, a third piece of that would be has CMS looked through, my understanding then and now is Meaningful Use, can you create an incentive for somebody to utilize this. Have we looked at an incentive for that third-party entity to create a platform that can manage an individual's health care?

I think one of the problems that I keep running up against is, I think the answer to the question I was asking, if Government can get the hell out of the way, we will find a solution to this. I think that gets to what Senator Braun said. I think the private sector, the private sector sees a problem and funds a solution to do it. Their business model makes some change based upon technology.

Our problem is that we can't get rules through when the technology that we are applying it to is in existence, and by the time we get a rule through, technology has changed, it may or may not apply. So, I know I have thrown a lot at you. I will get both of you to comment on it.

Dr. RUCKER. Yes. So, I think—so, I have been in the computer science business for 30 years and I have seen these things. I think for the first time we have API technology that is pretty technically stable and broadly doable. That was not the case in prior versions. Again, a long history there. So, this is what is fueling the app economy broadly. Right now, to your point, medical data is not accessible to most health apps, to several hundred thousand apps out there who have not, believe it or not, no access to medical data.

The entire point of what we are doing jointly is to allow these apps in the market economy to incorporate the patient's medical data into that. Some of them will incorporate a holistic view. There are companies, Apple most notably largely, there are small startups, my PatientLink, Humetrix, that are taking a broad view. There are going to be other companies that are going to be very disease-specific and focus on potentially life-threatening or lethal diseases.

In an app economy, we see both of those happening and that is the way we are designing it. We also have a number of provisions to try to have standards evolve. All of the standards we use actually are from the private sector so ONC is not generating any standards whatsoever in this and we actually maintain and curate the current private sector standards on an ongoing basis. And we work a lot and we actually, some of our budget, we actually used to fund key parts of the standards organization to do this and to have the broadest public input into the development of these standards.

Dr. GOODRICH. Just quickly, I would absolutely agree with Don that the timing is really right for this because of where the state of play is with the standards, and I think it is a good time to sort of take advantage of that and move the field forward. You asked about the types of applications. I can tell you through our Blue Button 2.0 experience, we now have 1,800 developers who are working in our sandbox which has synthetic data to develop apps

and we have twenty that are actually out in production that Medicare beneficiaries are currently using. And they kind of run the gamut, so everything from essentially a personal health record and app that can function as a personal health record for a Medicare beneficiary, to apps that help beneficiaries find health plans or get them connected to research studies, and as well as disease-specific apps.

It really does run the gamut and we have 7,000 Medicare beneficiaries using these right now and have gotten very, very positive feedback.

Senator BURR. Well, let me—if the Chairman will give me 30 more seconds to editorialize. Let me thank you for the work that you have done. I am probably no less convinced that we are going to get to the finish line today than I was in 2016, though the tools that we have are much better. I saw providers, insurers when they wanted to have a different outcome on diabetes, they took the responsibility, internally with their patients, their covered lives, to drastically change what they provided to them.

It seems to me that is the most appropriate first place to go is to create an incentive for the providers, those individuals that are covered in lives, to do a holistic approach to not just diabetes or a particular disease but to manage their health care. And it is to their financial benefit to do that and they are the ones that can certify the benefits to the patients' overall health condition.

I want to ask you to clarify what you said but Dr. Rucker I just wrote down a comment that you said, we have a lot of incentives that are in the wrong places. Now, if I understood it the way you said, for God's sakes, will you guys share with us where it takes a legislative remedy to move the incentives to the appropriate place? It is no longer good enough to have them but have them in the wrong place where they cannot be fully utilized. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Burr.

Senator Rosen.

Senator ROSEN. Thank you. Well as a former software developer and systems analyst, my head is spinning. I have some questions I want to get to but what I want to say is this, is absolutely nothing is more important or is more private or precious than your personal medical data and history. Its accuracy, its privacy and security must be part of any design, and the monetization of your personal data may be not in your best interest.

We have to be careful when we allow apps to design what helps you or helps your family and what might hurt you through the monetization or data brokerage. There are many things the private sector can do that are so fantastic and there are also ways that they can take this most private and precious information and use it against you. So, what you are doing in taking this approach is very important. But what I really wanted to talk about today is a little bit about administrative costs in your implementation timeline. And so, we know that we have to improve our interoperability standards.

Maybe we have to create some—you talk about the data sets to cannot be parsed. There are ways to fix that and that is for a different conversation, but it is really important that providers do

have a complete and accurate background on their patients. And so, we have to be careful though and consider the full picture of the resulting administrative costs and the practicality of the implementation, and what the benefits are, how to mitigate the challenges.

Does the ability for the patients to access records, schedule appointments, and contact their medical providers save time and costs overall for physicians, medical office personnel, and patients? Do you have data supporting how that is helping when they are integrated and how you think they can move to it in a particular way?

Dr. RUCKER. We think that making all of this be with relatively straightforward application programming interfaces actually takes the burden off providers, right. The burden at that point is to provide a secure end-point, right, rather than having ongoing conversations, right. This is self-service, right. It is literally like buying the airline ticket, right. You do not need a gate agent to buy your ticket online, right. So, we think that is very fundamental.

Totally agree with the privacy issues that we have discussed but we do think that the application programming interfaces will allow that to simplify. Most, we have calculated that roughly 80 percent of American providers, their EHR vendors already have these, what are called FHIR healthcare interoperability interfaces up and running. Apple's version, which uses the design standards that ONC has funded over the years with the standards group, I believe has over a thousand, several thousand providers who are on it as we speak.

Senator ROSEN. It seems as if people are moving toward it. It is helping the independent practice and our practices become more integrated, but I do have a concern on the other hand, that we must always be mindful about people who have barriers to accessing their health information be it due to a lack of internet access, technology, a disability, a disease. I talk about my beloved father-in-law, his birthday, his 97th birthday would have been this week, and he was a civil engineer for 50 years. Beautiful handwriting and drew bridges and all these wonderful things, and when he got in his 80's, he had a tremor and he couldn't see, and he could not use a computer.

His brain was fine, but he did not have the skills to do that anymore. So, in your long-term planning, what are you doing to help people who either do not have internet access, a computer, physical barriers, emotional, mental, whatever those are, dementia, etc. and may not have an advocate for them to be on the computer. So, what are you doing to help those folks?

Dr. RUCKER. Well we think that having industry standard APIs will lead to the broader democratization of access here. It is very interesting that in countries like India, smartphones, right, are very—countries with vast limitations in resources, they are actually using a smartphone technology first.

Senator ROSEN. Would that have helped—your Medicare population is an older population.

Dr. RUCKER. Obviously, for some disabilities unfortunately the nature of the illness is that it is just part of the illness, but we think in general the affordability and the markets making access

easier. There are all kinds of assistive devices built into modern smartphones. Are probably going to be better than trying to get on a bus or a cab or ride-sharing service to go to the hospital and try to dig out your patient record, which is the current.

Senator ROSEN. Thank you. I appreciate it. I yield back my time. Thank you.

The CHAIRMAN. Thank you, Senator Rosen.

Senator Romney.

Senator ROMNEY. Thank you, Mr. Chairman and Ranking Member for having this hearing and I appreciate also Dr. Rucker and Dr. Goodrich for your testimony and the work that you are doing. I would like—Senator Burr, I am somewhat skeptical and have been somewhat skeptical but am more optimistic in listening to you today. Skeptical in part because it struck me that when Congress said, interoperability is a good thing, make it so, it would be like saying to the Department of Energy, we got to reduce greenhouse gas emissions, please do so. It is like, well, how do you go about doing that? How big of a task is that?

My background is in the private sector. I have seen settings were two companies will come together, they had different computer systems, and they wanted to make them talk to each other and share data across the systems. It usually takes years for that to happen, and even within two relatively small companies, relative to the Government of the United States, it takes hundreds of millions of dollars. So, the idea of achieving interoperability through Government oversight would be massively expensive, if not impossible, and would take a long period of time.

I am drawn to the comments of the Chairman which is should we do this out of phase basis. Senator Burr suggested perhaps let the private sector deal with this over a longer period of time, but you seem to have optimism that we can make progress here. And I wonder exactly whether that is conceivable for us to achieve standards that will allow systems to talk to each other from one hospital system, for instance, to another provider or whether that is frankly a bridge too far at this stage.

I participated in the healthcare system called Intermountain. It includes physicians in the group. It includes the hospitals and so forth. It is interoperable. It works extremely well, but to get it to communicate with let us say a system in Detroit, would strike me as being a very intensive, long-term process. Are we barking up the wrong tree here? Do we have a shot of actually making this work? Should we make it a more phase process? Is it a pitch too far? I am using a lot of metaphors here. I am just suggesting how distant the goal may be, but I am interested in your thoughts about whether we need to rethink how we approach this goal of interoperability. Whether we should, if you will, begin by restricting our sites a little bit and by looking within current healthcare systems as opposed to trying to reaching across systems across the country and across different types of practices, and whether instead we should move on a more, I guess standard-oriented process as opposed to implementation process.

Interested in both of your comments in that regard.

Dr. RUCKER. Yes, there is plenty of room for skepticism. So, I started my computer science career building an EMR in Windows

2.1, right. So, if anybody remembers what a serial port is. So, the thought of sharing data was totally in the future. The internet did not actually, I think, the first stack didn't come until Windows '95. There are now hundreds of thousands of apps out there, hundreds of thousands, using the RESTful Json and the internet stacked share information. So, we know broadly in the economy, this is absolutely doable. It is done, more times than you can count in, many, many apps today.

The healthcare part is customizing this to healthcare so the fast healthcare interoperability resource, which is ultimately vocabulary exercise, there has been very rapid progress on this FHIR protocol. ONC has supported that. CMS has supported that. That gives, I think, us vast grounds for optimism that we did not have the HL7 version 2 and its various iterations and parts of version 3. So, I think the technology has fundamentally changed and so we are moving. The U.S. Core Data for Interoperability is a very limited set of data and I know it is sometimes portrayed as an expansive set of data but is actually a very limited set of data that we are starting out with.

Dr. GOODRICH. I would agree with everything Don has said, and I will also reiterate that we have seen significant changes over time. I mean, I started practicing medicine in the late 1990's, did not have an EMR, and increasingly, incrementally I have seen the ability to get more and more information from systems outside of my own, not necessarily complete information but I can get information through my regional healthcare exchange, is a great example of that.

I think based upon what Don said related to the standards plus the health information exchanges that we are seeing around the country where you are seeing the opening up of exchange even in distant places. There is reason for optimism. I do think the 21st Century Cures also is sort of a transformative moment to be able to move forward in a way that we just haven't been able to before. So yes, plenty of room for skepticism but also more optimism than probably any of us would have had a couple of years ago.

Senator ROMNEY. Thank you.

The CHAIRMAN. Thank you, Senator Romney.

Senator Murray, do you have any further comments?

Senator MURRAY. I do not at the time. I want to thank both of you. This is extremely complex and obviously we have seen a lot of good things happen as a result of technology for patient health. We have a lot challenges in front of us, whether it is interoperability, blocking information gag clause, and we have to talk about the developing issues that we are facing in the ever-changing world of cyber security, and privacy, and data stewardship. So, I look forward to continuing to work with you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray. One thing that occurs to me, is reassuring to me is to hear again how important the 21st Century Cures Act has become in so many different ways, and I think the Senators on this Committee and staff should take a good deal of pride in that. And this is one area for that. We did find before that sometimes having working groups that would meet maybe every 90 days with an agenda, the staff could let you know what the Senators are interested in, Senators can come if they

wished, and it would give us a way to continue to keep up with you, to give you our suggestions, to decide if we need to make any further legislative adjustments. And really to create an environment in which you can succeed which is what we want to do.

The issues, I hope you will keep in mind from this, are the concern I have and others have balanced by what Senator Murray said about, there is a need, we need to get on with information blocking for the benefit of people but it is more important that we end up where we want to go, not that we try to get there faster than we can go. And so, taking lessons from Meaningful Use 3 and just the general laws of human nature as expressed by Senator Romney there, I think we would be wise to keep our eyes open as we go along. And the other reason for that, of course, is to work with providers, doctors, hospitals, nurse practitioners or others, incorporate them into this so they can buy into it and absorb it and make suggestions about it.

There is concern about the what happens, who makes the rules, and who is in charge when a patient gives information, personal information to a third party. We need to talk more about that. We were careful in the 21st Century Cures Act not to be too prescriptive, wanting to leave with you many decisions about how to go ahead, and I was hopeful that you would not be too prescriptive, figuring that the reason we can make airline flights on our phone is not because the Government figured it out, but because we left room for somebody the private sector to figure it out. And that is beginning to happen. And as you solve problems, continuing to leave room for the private sector to solve them for us, is a part of the art of Government that I hope you continue to use.

Then finally, the physician burden and the burden on providers is something I hope we keep in mind. I mean the whole idea of this is to make it easier and less expensive not more complicated and more expensive. And you have talked about your own 30 years of experience with computers creating work and I think about the effect of that. I was in South Dakota on Friday and talking about how in rural areas, the electronic health records and other requirements make it very difficult for a smaller rural hospital to manage that, so it is easier for them just to sell out to a big outfit, and that encourages consolidation. And then we have the larger question of whether consolidation of doctors and hospitals, all working for some big outfit, increases competition and increases costs, or simplifies things and lowers costs.

Keeping in mind ways to actually reduce the burden on physicians, especially, is an important part of this. The hearing record will remain open for 10 days. Members may submit additional information for the record within that time if they would like.

The CHAIRMAN. Thank you for being here. It has been a very useful hearing. Thank you for your work on behalf of the country, and the Committee will stand adjourned.

[Whereupon, at 11:28 a.m., the hearing was adjourned.]

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