IMPLEMENTING THE 21ST CENTURY CURES ACT: AN UPDATE FROM THE OFFICE OF THE NATIONAL COORDINATOR

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES

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C O N T E N T S

WITNESS

SUBMITTED MATERIAL

IMPLEMENTING THE 21ST CENTURY CURES ACT: AN UPDATE FROM THE OFFICE OF THE NATIONAL COORDINATOR

TUESDAY, DECEMBER 11, 2018

House of Representatives,
Subcommittee on Health,
Committee on Energy and Commerce,
Washington, DC.

The subcommittee met, pursuant to call, at 10:15 a.m., in room 2322, Rayburn House Office Building, Hon. Michael Burgess (chairman of the subcommittee) presiding.

Members present: Representatives Burgess, Guthrie, Upton, Blackburn, Latta, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Carter, Green, Engel, Matsui, Castor, Kennedy, Cárdenas, Eshoo, and DeGette.

Staff present: Adam Buckalew, Professional Staff Member, Health; Daniel Butler, Legislative Clerk, Health; Adam Fromm, Director of Outreach and Coalitions; Caleb Graff, Professional Staff Member, Health; Ed Kim, Policy Coordinator, Health; J.P. Paluskiewicz, Professional Staff Member, Health; Brannon Rains, Staff Assistant; Austin Stonebraker, Press Assistant; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Samantha Satchell, Minority Senior Policy Analyst; and C.J. Young, Minority Press Secretary.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. Burgess. The subcommittee on Health will come to order, and I will recognize myself 5 minutes for the purpose of an opening statement, and I want to thank everyone for joining us for this important and long-awaited hearing in 2018.

In 2018 we have held two Cures implementation hearings, including focusing on biomedical research and innovation at the National Institute of Health and the Food and Drug Administration and the hearing on the mental health title. Today's hearing completes the 21st Century Cures trifecta covering the last remaining title, Health Information Technology.

Our society, our economy have become increasingly driven by technology, and healthcare, of course, is no exception. Electronic health records, patient data, the move to open application programming interfaces, and other developments have brought healthcare into the 21st century. Law lagged behind such advances which led to various pieces of legislation to address the aforementioned issues including the HITECH Act in 2009 and 21st Century Cures Act in 2016.

Cures built on top of the foundation laid by the HITECH Act which passed in 2009 and encouraged adoption and the use of electronic health records through payment incentives and penalties. For the record, I opposed that. This law also established the Office of National Coordinator for Health Information Technology in statute. Previously it had been via executive order, but the HITECH Act established that in statute, signifying the importance of health IT in the future of healthcare data and delivery.

Some argue that HITECH was well intentioned. Stakeholders have reported concerns during implementation related to the interoperability and functionality of this technology. While we have seen widespread adoption of electronic health records, there does continue to be significant fragmentation of the healthcare system, making it difficult to ensure continuity of evidence-based care for patients. The 21st Century Cures Act has set us on a path toward achieving this nationwide interoperable healthcare information system, and the idea is to put the needs of patients and providers first.

The first health IT provision in Cures was aimed at assisting doctors and hospitals in improving the quality of care for patients. One goal of this provision was to reduce the burden on physicians regarding electronic health records. As the Office of National Coordinator moves forward, it is of utmost importance that it take into account the impact of policies on both patients and physicians.

Section 4003 of the Cures act expedites interoperability and security among electronic health records through a voluntary model framework and a common agreement among vendors. The Office of National Coordinator released a draft of this trusted exchange framework and common agreement in January of this year. Today, the National Coordinator for Health Information Technology, Dr. Don Rucker, will explain the common principles that will guide health information networks, recognize coordinating entities and others through the exchange of data.

The Office of National Coordinator also has sunset the old Policy and Standards committees, to which I say good riddance because they were quick to chase any issue to spark their attention. Instead, a new Interoperability Committee has been set up with clear guidance from Congress to focus on interoperability, security, and privacy.

Another theme throughout the health IT title of 21st Century Cures was patient access to data. While electronic health records are critically important to physicians, it turns out they are equally important to patients, and it is important that patients have access. Cures required the Department of Health and Human Services in coordination with the Office of Civil Rights to educate providers about lawful patient health information sharing. The Get It, Check It, Use It program shows patients how to access, update, and use their health information appropriately.

The reason this hearing was delayed was, there is a rule required by Cures that will cover several items, most notably the rule regarding information blocking as yet to be released. I believe it is currently awaiting approval by the Office of Management and the Budget, so Dr. Rucker will be unable to address the pending rule.

It is important to note that the Cures legislation defined and prohibited information blocking while, in fact, levying civil money penalties on those who engage in information blocking. The Office of National Coordinator rule will define what does not constitute information blocking, therefore outlining what is permissible.

I am extremely disappointed that, 2 years after the passage of Cures, we still do not have the regulations necessary to implement these provisions. It is hard to explain to people that Congress provided the tools necessary for doctors and patients to better coordinate their care through the sharing of patient data, but nothing has changed.

I will submit the balance of my statement for the record and recognize Mr. Green of Texas for his opening statement, please.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Good morning, everyone, and thank you for joining us for this important and long-awaited hearing. In 2018, we have held two Cures implementation hearings, including one focusing on biomedical research and innovation at the National Institutes of Health and Food and Drug Administration, and one on the mental health title. Today's hearing completes the 21st Century Cures trifecta and covers the last remaining title, health information technology.

As our society and our economy become increasingly driven by technology, healthcare is no exception. Electronic health records, patient data, the move to open application programming interfaces (APIs), and other developments have brought healthcare into the 21st Century. Law lagged behind such advances, which led to various pieces of legislation to address the aforementioned issues, including the HITECH Act in 2009 and 21st Century Cures in 2016.

Cures built on top of a foundation laid by the HITECH Act, which passed in 2009 and encouraged adoption and use of electronic health records through payment incentives and eventually penalties. This law also established the Office of the National Coordinator for Health Information Technology in statute, signaling the importance of health IT in the future of healthcare data and delivery. While HITECH was well intended, stakeholders reported concerns during implementation, mainly related to interoperability and functionality of the technology.

While we have seen widespread adoption of electronic health records, our Nation continues to maintain a fragmented healthcare system, making it difficult to ensure continuity of evidence-based care for patients. The 21st Century Cures Act has set us on the path towards achieving a nationwide interoperable health information system that puts the needs of patients and providers first.

The first health IT provision in Cures was aimed at assisting doctors and hospitals in improving the quality of care for patients. One goal of this provision was to reduce the burden on physicians regarding electronic health records. As the Office of the National Coordinator moves forward, it is of the utmost importance that it take into account the impact of policies on both patients and physicians. I was pleased to see that ONC released a draft report on physician burden reduction in November that includes recommendations to address the issue.

Section 4003 of Cures expedites interoperability and security among electronic health records through a voluntary model framework and common agreement among vendors. ONC released a draft of this "Trusted Exchange Framework and Common Agreement," known as the TEFCA, in January of 2018. Today, the National Coordinator for Health Information Technology, Dr. Don Rucker, will explain the common principles that will guide Health Information Networks, Recognized Coordinating Entities, and others through the exchange of data.

The Office of the National Coordinator has also sunset the old Policy and Standards committees, which I found were well-intentioned but too quick to chase any issue that sparked attention, and stood up the new Interoperability Committee that has clear guidance from Congress to focus on interoperability, security, and privacy.

Another theme throughout the health IT title of 21st Century Cures was patient access to data. While electronic health records are critically important to physicians, it is equally important that patients have access to their own data. Cures required the Department of Health and Human Services, in coordination with the Office of Civil Rights, to educate providers about lawful patient health information sharing. The "Get It. Check It. Use It." Program shows patients how to access, update, and use their health information appropriately.

The reason we delayed holding this hearing is that the rule required by Cures that will cover several items, most notably, information blocking has yet to be released. It is currently awaiting approval by the Office of Management and Budget. While Dr. Rucker will be unable to address the pending rule, it is important to note that the Cures legislation defined and prohibited information blocking, while levying civil monetary penalties for those who engage in information blocking.

The ONC rule will define what does not constitute information blocking; therefore outlining what is permissible activity. I am extremely disappointed that 2 years after the passage of Cures we still do not have the regulations necessary to implement these provisions. It is hard to explain to people that Congress provided the tools necessary for doctors and patients to better coordinate their care through the sharing of patient data, and nothing has changed.

While I am disappointed that we still do not have the proposed rule, I am glad that we have proceeded with this hearing. Health information technology opens the door to many possibilities, but we will continue to face challenges moving forward as Congress works with the Office of the National Coordinator to navigate the landscape and having an ongoing dialogue like this is very important. I would like to thank our witness, Dr. Rucker, for testifying this morning, and I look forward to the exciting updates you have to provide us.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, and I would like to thank you for calling this hearing and the continuation of the oversight over the Cures Act, which along with the Affordable Care Act and Cures, is probably the two major pieces of legislation in my 26 years in Washington. And I would like to thank Dr. Rucker for testifying today on the Office of National Coordinator's work to implement the 21st Century Cures Act.

In little over a decade, the Office of the National Coordinator has helped to drive the rapid adoption of electronic health records, EHR, in doctors' offices and hospitals across the country. Today, nearly all hospitals and three-quarters of the office-based physicians use some form of certified EHR technology. This uptake has allowed for improved communication in patient care, but we still have a long way to go in ensuring neuro that EHRs are as useful as possible to providers as well as easily accessible and understandable to consumers.

The Cures Act aimed to build on the progress of the HITECH Act of 2009, but by focusing on improving interoperability, patient access to their health records, and reducing provider burden. For example, the Cures Act tasked ONC with—tasked with providing examples of what does not constitute information blocking. This information is a critical part of the law's implementation and will inform the Office of the Inspector General's enforcement regarding information blocking. I look forward to this proposed rules release.

The Cures Act also called for the development of Trusted Exchange Framework and Common Agreement, TEFCA. This framework outlines the minimum terms and conditions providers should meet in order to securely and appropriately exchange information with each other. Setting clear parameters around exchanging information is necessary for widespread interoperability. I am pleased to hear that ONC is undergoing a rigorous public comment process before finalizing this provision.

In addition to improving interoperability, we need to increase consumer education so folks understand that they have a right under HIPAA to obtain access to their records and to decide who their records should be shared with. I am glad that ONC has partnered with the Office of Civil Rights to release new information for consumers on HIPAA's patient right to access. Increased interoperability and better HITECH in general has the potential to improve every American's healthcare experience, so I hope that ONC will continue its implementation of the law in a timely manner.

And I would like to yield the balance of my time to Congresswoman DeGette.

[The prepared statement of Mr. Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN

Good morning, I'd like to thank Dr. Rucker for testifying today on the Office of the National Coordinator's work to implement the 21st Century Cures Act.

In a little over a decade the Office of the National Coordinator (ONC) has helped to drive the rapid adoption of electronic health records (EHRs) in doctor's offices and hospitals across America. Today nearly all hospitals and three quarters of office-based physicians use some form of certified EHR technology. This uptake has allowed for improved communication and patient care.

But we still have a long way to go in ensuring that EHRs are as useful as possible to providers as well as easily accessible and understandable to consumers. The Cures Act aimed to build on the progress of the HITECH Act of 2009 by focusing on improving interoperability and patient access to their health records and reducing provider burden.

For example, the Cures Act tasked ONC with providing examples of what does not constitute information blocking. This information is a critical piece of the law's implementation and will inform the Office of the Inspector General's enforcement regarding information blocking. I look forward to this proposed rule release.

The Cures Act also called for the development of a Trusted Exchange Framework and Common Agreement (TEFCA). This framework outlines the minimum terms and conditions providers should meet in order to securely and appropriately exchange information with each other. Setting clear parameters around exchanging information is necessary for widespread interoperability. I'm pleased to hear ONC is undergoing a rigorous public comment process before finalizing this provision.

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Increased interoperability and better health IT in general has the potential to improve every American's healthcare experience, so I hope that ONC will continue its implementation of the law in a timely manner. Thank you.

Ms. DEGETTE. Thank you. Thank you so much to the ranking member for yielding. And I want to take a moment of personal privilege to thank Mr. Green for all of his years of service on this committee and the Congress. Mr. Green has been a stalwart leader on healthcare policy, not just on Cures, not just on the ACA, but on the many, many pieces of legislation, and Mr. Green, I am going to tell you something: You are going to be missed by every single member of this subcommittee.

The 21st Century Cures Act, as we heard, was signed into law 2 years ago this week, and it really was a remarkable bipartisan achievement for the committee. I want to thank you, Mr. Chairman, for holding this hearing of oversight, and I hope we will continue to have the same level of robust oversight to make sure all of the many provisions are implemented.

We took extraordinary steps in that bill in accelerating the approval of breakthrough therapies and lowering the cost of bringing these drugs to market through strengthening the PRECISION MEDICINE initiative. We also increased the health system's ability to interact through health IT interoperability measures, and we made a $4.8 billion investment in the NIH intended to jump-start research into new treatments for diseases like cancer and Alzheimer's. We also modernized the clinical trial process, increased the government's ability to recruit top scientists, and broke down agency and interagency research silos to accelerate and advance coordination among the sciences.

I know that Mr. Upton and I and every single member of this subcommittee are very impressed with the progress that this bill has achieved, but we know there is much more to be done, and that is why, Dr. Rucker, I am glad that you are with us here today to sort of complete this trifecta of hearings on health IT. I would like to hear from you about what is working and what we can do to improve.

And again, Mr. Chairman, I thank you for working with us and especially Mr. Green for all his years of service, and I yield back.

Mr. BURGESS. The Chair thanks the gentlelady. The gentleman yields back.

Mr. GREEN. I yield back, Mr. Chairman.

Mr. BURGESS. I am not seeing the chairman of the full committee here, be prepared to yield to the gentlelady from Tennessee, the Senator-designate from that State, because I know this is an important issue in Nashville, in your part of the world.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you so much, Mr. Chairman, and thank you for the good work that you have done in leading this committee over the past couple of years. We appreciate that, and we are thrilled with 21st Century Cures being signed into law.

And as the chairman said, middle Tennessee, which is home for me, is home to over 400 healthcare companies. And while many people rightfully think of Nashville as Music City U.S.A.—and, indeed, it is—it is also the center of much of the healthcare management and healthcare delivery in this Nation.

And you see these 400 healthcare companies that are located there, working not only in hospital management but in insurance products, home health, hospice, you name it, every single sector of the healthcare industry. You also have some non-profits that are working on how you deliver better patient care. One of those is the Center for Medical Interoperability which is located right in Nashville and is looking at that intersection of healthcare technology, healthcare informatics, predictive diagnoses. And we were so pleased with the Software Act provisions which Mr. Green and I authored being included in 21st Century Cures and then the follow on implementation of this through the FDA and the implementation that you at ONC are overseeing.

So we are watching that very closely because we know of the impact that that has on care coordination, that it has on post acute care, that it has on managing and following chronic conditions, and that it also has on home health. And we know that this impact is going to be felt, so we thank you, Dr. Rucker, for being here to give us an update.

Mr. Chairman, I thank you for the leadership that you have provided, and at this time I would yield to any other member of the subcommittee seeking time.

No one seeking time?

I yield back, Mr. Chairman. Thank you.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields back. Not seeing the ranking member of the full committee here, is there anyone on the minority side who wishes to claim the time?

If not, that will conclude Member opening statements.

The Chair would like to remind Members that, pursuant to committee rules, all Members' opening statements will be made part of the record.

We certainly want to thank our witness for being here today, taking time to testify before the subcommittee. Our witness will have the opportunity to give an opening statement followed by questions from Members, and today we are going to hear from Dr. Donald Rucker, the National Coordinator for Health Information Technology for the United States Department of Health and Human Services.

Dr. Rucker, we appreciate you being here with us. It has been a long time coming, and you are now recognized for 5 minutes to summarize your opening statement, please.

STATEMENT OF DONALD RUCKER, M.D., NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. RUCKER. Chairman Burgess, Ranking Member Green, distinguished members of the subcommittee, thank you for the opportunity to testify.

Since its start in 2004, ONC has worked to improve the quality, safety, and efficiency of healthcare. While hospitals and physicians have made great progress adopting electronic medical records, additional work is needed to increase the value of these records.

Clinicians often spend hours a day at the computer. The Cures Act asks HHS to address clinician burden related to electronic records. In November, ONC and CMS released a draft strategy to reduce administrative burdens. We have worked with CMS to address burnout, changing documentation requirements, and simplifying reporting.

The Cures Act directs the secretary to adopt policies to increase the trusted exchange of electronic health information. ONC has developed a proposed rule to support this exchange of clinical data. As requested, the rule will implement the Cures Act prohibition of information blocking by defining allowable exceptions. We want patients to get their medical records on their smartphones. We want consumers to get—to shop for care on their smartphones.

To do this, the Cures Act calls for EHR developers to publish application programming interfaces, APIs, that permit secure access without special effort. We expect an app marketplace will evolve with products for both illness and health. Recently Apple introduced their health record app using the RESTful JSON and fire technical interface standards. Now over 100 health systems provide patients their data here. ONC has been instrumental in advancing the healthcare part of these standards.

Some of our stakeholders have shared security concerns with the requirement to publish APIs. We take cybersecurity threats seriously. It is important to note that in general, APIs are not usually where security vulnerabilities

reside. The OAuth standard used to authorize exchange through open APIs, and these are secure open APIs, provides robust security. Security breaches often reflect password issues or servers with unpatched operating systems.

Secretary Azar has identified value-based care as a priority. The ability to analyze health outcomes for an entire group of patients rather than just one individual patient is essential to identifying providers with the best value. Today payers and employers have little information on provider performance. Often, payers are forced to negotiate contracts with hospital systems based on network consolidation rather than value. ONC is working with the HL7 standards group and ensures to build APIs that truly measure care. ONC is also working to increase connectivity among health information networks.

There are about 100 regional national networks which exchange health information. While these organizations have made significant progress, connectivity across networks has been limited due to variations in technical and data use agreements. The Cures Act directs ONC to, quote, "develop or support a trusted exchange framework including a common agreement among health information networks nationally," end quote.

In January ONC released the first draft of the Trusted Exchange Framework. We will release an updated draft for further public comment. The Trust Exchange Framework can also support community information exchange. There is limited interoperability for patients with mental health or addiction illnesses. These patients move between emergency rooms, shelters, group homes, and treatment centers with little awareness of how often and how ineffectively these expensive services are being used. Regional health information exchanges are ideally positioned to link these patients and services.

In summary, ONC has made great progress implementing the provisions of the 21st Century Cures Act. We believe the proposed rule for open, secure APIs with the Trusted Exchange Framework allow patients to get their medical care on their smartphone and to control the care they receive. We will continue to keep Congress informed.

Mr. Chairman, Ranking Member, members of the subcommittee, thank you for the opportunity to testify. I look forward to questions.

[The prepared statement of Dr. Rucker follows:]

Testimony before House Committee on Energy & Commerce Subcommittee on Health

United States House of Representatives

Statement of

Donald Rucker, MD
National Coordinator for Health IT,
Office of the National Coordinator for Health IT
Department of Health and Human Services

December 11, 2018

Chairman Burgess, Ranking Member Green, and distinguished Members of the Subcommittee, 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 (ONC) efforts to implement provisions of Title IV of the 21st Century Cures Act (Cures Act).

Since ONC's creation in 2004 through Executive Order (EO) 13335 and codification in 2009 through the Health Information Technology for Economic and Clinical Health (HITECH) Act, ONC has focused on promoting technical standards to improve the quality, safety, and efficiency of health care including through health IT certification. Programs and policies required by HITECH and implemented by ONC and the Centers for Medicare & Medicaid Services (CMS) helped drive most physicians and hospitals to adopt health IT systems.[1] As of 2015, 96 percent of non-federal acute care hospitals and 78 percent of office-based physicians adopted certified health IT. While progress has been made, additional work is necessary to help advance the availability of electronic health information to patients and their providers. Barriers to the appropriate and secure movement of electronic health information include technical limitations and business incentives. The Cures Act takes a great step toward addressing those barriers.

The Cures Act directs the HHS Secretary to adopt standards and policies that advance health IT to enable and stimulate the trusted exchange of electronic health information. The Cures Act, thus, materially advances our mission to enable patients' records to follow them when and where they need it. A health system where information flows appropriately and securely to patients and their clinicians will help coordinate care and reduce costs by making care faster and less duplicative.

The Cures Act also gave the Secretary the authority to address clinician burden stemming from the use of EHRs and health IT, and the Secretary delegated that authority to ONC. Due to multiple overlapping factors, including poor usability of health IT systems, as well as government, institutional, and payer administrative and regulatory requirements, clinicians often spend much time on documentation and reporting, which contribute to clinician burnout. In November, ONC and CMS released a strategy for reducing regulatory and administrative burdens using input from public listening sessions attended by over 1,000 stakeholders. To develop this strategy, we convened four HHS workgroups comprised of policy and clinical specialists to focus on common sources of burden, including clinical documentation, health IT usability and user experience, EHR reporting programs, and other government requirements.

CMS recently finalized bold changes to the Medicare Physician Fee Schedule that address provider burnout and provide clinicians immediate relief from excessive paperwork tied to outdated billing practices by changing the documentation and coding requirements for physician services known as "evaluation and management" visits. CMS also overhauled the Merit-based Incentive Payment System Promoting Interoperability

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[1] ONC's 2016 Annual Report on Adoption of Health IT and Related Efforts to Facilitate the Electronic Use and Exchange of Health Information. Accessed at: https://www.healthit.gov/sites/default/files/2016_report_to_congress_on_healthit_progress.pdf

performance category in order to support greater electronic health record interoperability and patient access while aligning with the Medicare Promoting Interoperability Program requirements for hospitals. These changes will reduce regulatory and administrative burdens in line with the Cures Act § 4001(a) burden reduction goal and help allow providers to spend more time with their patients and less time performing data entry tasks for billing purposes.

This important work will continue as we receive comments from our stakeholders on HHS's draft strategy for reducing clinician burden, and will continue to be an HHS and ONC priority moving forward.

I would like to highlight some of the progress ONC has made implementing other provisions included in the Cures Act. In January, ONC established a new federal advisory committee pursuant to Cures Act § 4003(e) called the Health IT Advisory Committee (HITAC) that provides recommendations to the National Coordinator. The full HITAC—its taskforces and Annual Report workgroup—have met more than 33 times and have provided recommendations related to the three priority target areas identified by the Cures Act: achieving interoperability, the promotion and protection of privacy and security of health information, and facilitating secure access by individuals and their caregivers to their electronic health information. Input from the HITAC contributed to the draft of the Trusted Exchange Framework, the US Core Data for Interoperability (USCDI), the development of priority standards use cases, and the Congressionally-mandated HITAC annual report under development.

ONC also started implementation of the EHR Reporting Program. Section § 4002(c) of the Cures Act requires ONC to provide publicly available, comparative information on certified health IT products. In August 2018, ONC issued a request for information for the public to share their views on the components of the EHR Reporting Program and to provide feedback that will inform the development of reporting criteria and processes as required by the Cures Act. We received 77 public comment submissions from health IT developers and provider organizations representing all major segments of the provider community, payers and health plans covering millions of beneficiaries, and consumer and quality improvement organizations representing patients and consumers.

ONC also has developed a proposed rule to support the access, exchange, and use of electronic health information. The proposed rule would implement provisions of the Cures Act, including conditions and maintenance of certification requirements for health IT developers under the ONC Health IT Certification Program (Section § 4002) and reasonable and necessary activities that do not constitute information blocking (Section § 4004). This rule will be the culmination of significant stakeholder outreach, including public listening sessions and more than 150 meetings with key health IT stakeholders. We look forward to receiving and addressing any comments that may be submitted, before issuing a final rule.

ONC is focusing on accelerating individuals' ability to access and control their health information with ease, in a user-friendly way, using apps on their smartphones or other devices. This ability would allow consumers to shop for and coordinate their own care if they choose. Today, many patients have trouble accessing their electronic health information in a timely manner. Sometimes, health systems provide patients with their electronic health information in unreadable formats or on dated technology, such as CDs. Patients should have better options to securely access their information, and those options should align with modern technology. The Cures Act builds on ONC's 2015 Edition health IT certification criteria by calling for health IT developers to publish application programming interfaces (APIs) that permit the secure access, exchange, and use of health information without "special effort." APIs are technology that allow one software program to access the services provided by another software program. Standardized, transparent, and pro-competitive APIs will facilitate an individual's ability to use a third-party app of their choice to securely access and share their electronic health information.

Emerging technologies and the use of mobile apps will not only provide individuals with access to their electronic health information, but an app marketplace will evolve with tailored products to address unique patient needs, such as helping patients manage multiple chronic conditions. A robust health app ecosystem can lead to disease-specific apps and allow patients to share their health information with researchers working on clinical trials to test a drug or treatment's efficacy, or monitoring outcomes like those in the National Institutes of Health's *All of Us* Research Program. Apps can also help address barriers related to patient literacy and comprehension 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 app using the same modern computing standards, and in a short time, over 100 health systems began using that app to provide patients their data. Many smaller vendors are developing health apps as well.

Part of the health care API evolution is incorporating current protocols from leading standards development organizations such as the newer Health Level Seven (HL7®) FHIR® (Fast Healthcare Interoperability Resources) standard, which is a web developer-friendly way of representing electronic health information. These specifications will expand information sharing for electronic health records and other health IT solutions based on modern computing standards (e.g., RESTful and JavaScript Object Notation (JSON)). Some of our stakeholders have shared security concerns with the requirement to publish their APIs. We take cybersecurity threats and issues related to information security seriously. However, it is important to realize that APIs are not usually where these security vulnerabilities reside. The OAuth standard used to authorize information exchange through "open APIs" provides robust security. Security breaches typically come from the large installed footprint of IT systems and most often reflect password issues or network deficiencies such as servers running dated operating systems. We encourage health IT developers and users to use modern software and industrywide security best practices.

To promote standards and address the interoperability goals of the Cures Act, ONC published the 2018 Reference Edition Interoperability Standards Advisory and launched the USCDI, which specifies a common set of health care record data classes required for health data interoperable exchange. The modifications to the 2018 Reference Edition address important health information (such as pregnancy status, care plans, patient identification, public health reporting, and provider-to-provider communication) and contain endorsements of 151 health information standards covering over 60 interoperability needs, including, but not limited to clinical, public health, and research purposes.

These efforts around standards and interoperability are foundational for having a modern and connected health system that lowers health care costs. Secretary Azar has identified value-based transformation as one of HHS's top four priorities, as the U.S. health care system is not delivering outcomes commensurate with its cost. Central to a value-based health system is the ability to analyze data and track health outcomes for an entire group of patients. Looking at an entire group of patients is essential to having a learning health system, advancing many research priorities and use cases, and modernizing public health reporting. It is also essential for payers trying to identify the providers with the best outcomes or highest quality of care for their members. Today, payers and employers who purchase care have little information on health outcomes. Payers cannot effectively represent their members if they are unaware of which providers offer the highest quality care at the lowest cost. Often times, providers and payers negotiate contracts based on provider reputation or market presence rather than on quality care. Providers should compete on the entire scope of the quality and value of care they provide, not on the exclusivity of their networks. In conjunction with HL7, ONC is collaborating with payers on developing standards for providers to send to payers health information on the patients covered by their health plans.

ONC is also working to increase connectivity among health information networks. Currently, there are more than 100 regional networks[2] and multiple national level organizations that support health information exchange. While these organizations have made significant progress to expand interoperability, connectivity across networks has been limited due to variations and gaps in technical specifications, and in the participation and data use agreements that govern the secure exchange of health information. In Section § 4003 of the Cures Act, Congress directed ONC to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally."

The Trusted Exchange Framework and the Common Agreement seek to expand health information exchange nationwide and ensure that patients, providers across the care continuum, community and social services, and other stakeholders such as payers can access real-time health information. In January 2018, ONC released the first draft of the Trusted Exchange Framework for public comment. Informed by stakeholders, public listening sessions, and an initial public comment period, the draft Trusted Exchange Framework outlined the minimum set of principles, terms, and conditions to support the development of a full Common Agreement that would enable health information

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[2] Julia Adler-Milstein, Sunny C. Lin, and Ashish K. Jha. The Number Of Health Information Exchange Efforts Is Declining, Leaving The Viability Of Broad Clinical Data Exchange Uncertain. Health Affairs Vol. 35 No. 7: July 2016. https://doi.org/10.1377/hlthaff.2015.1439

exchange among disparate networks. ONC received more than 200 comments on the draft, and plans to release an updated draft for public comment in the coming months.

ONC will also select a Recognized Coordinating Entity, through a Cooperative Agreement, to develop, update, implement, and maintain the Common Agreement subject to ONC approval. The Cures Act's focus on trusted exchange is an important step for advancing an interoperable health system. Together, the Trusted Exchange Framework and Common Agreement will provide the governance necessary to scale a functioning system of connected health information networks that can grow over time to meet the demands of consumers, health care providers, health plans, and other stakeholders.

In addition to expanding nationwide exchange across disparate networks, the Trusted Exchange Framework and Common Agreement should also support community exchange efforts. Through the HITECH Act, ONC's previous grant programs accelerated health information exchange at the state, regional, and local level. A significant unmet interoperability need is for patients with behavioral health conditions, including those with substance use disorders and mental illness, who transition between emergency rooms, shelters, group homes, and various treatment centers. Health information networks, as intrinsically local resources, are positioned to more effectively connect patients with the clinical services and social supports they need. These services might include treatment for substance use disorders and mental illness, ongoing support of medication use, and broader social service needs. Currently, individuals with these conditions tend to be high utilizers of health care, social services, and criminal justice resources and improvements in their health outcomes could be achieved with better coordinated care.

Before concluding, I want to note that ONC has made strategic investments in innovative efforts through grants and pilots that have considerable impacts. ONC funded the initial development of the Patient Unified Lookup System for Emergencies, also known as PULSE, which allows emergency volunteers to access critical health information, such as medications, allergies, and major illnesses during disasters. California's PULSE has been used during the recent devastating wildfires to help victims receive their necessary prescriptions without going to an overwhelmed emergency room. ONC also funded research at Boston Children's Hospital Computational Health Informatics Program and the Harvard Medical School Department for Biomedical Informatics that led to the development of SMART Health IT - an open, standards based technology platform that enables innovators to create apps that seamlessly and securely run across the health care system. ONC and the National Institutes of Health initiated the Sync for Science pilot, which allows individuals to access their health information and send it to researchers in support of the goals of the Precision Medicine Initiative. These small investments addressed significant gaps in the health system.

In summary, ONC has made great progress towards implementing key provisions of the 21st Century Cures Act. These actions will maximize the potential of health IT and result in improved care and reduced cost. Due to development timelines and the size and complexity of the U.S. health system, it is important to note that nationwide interoperability will take time to achieve. We believe the policies forthcoming in ONC's proposed rule on interoperability, information blocking, and the ONC Health IT Certification, along with the Trusted Exchange Framework and the Common Agreement firmly place us on the path to achieving the long-term benefits of interoperability 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 Subcommittee. Thank you for the opportunity to testify before the Committee today. I look forward to responding to any questions you may have.

Mr. BURGESS. Well, thank you, Dr. Rucker, for your testimony, and we will move to the question portion of the hearing. And I would like to yield my time first to the gentlelady from Tennessee again for her questions.

Mrs. BLACKBURN. Thank you, Mr. Chairman, and I do thank you and your team for the work that you all are doing. And you know, in this town where they say there is no bipartisanship, I think that we would all say 21st Century Cures and working together, getting that across the finish line so President Obama could sign it, was one of the stellar accomplishments of our work here.

You touched on privacy, and that is what I want to discuss with you because so many of the mHealth apps contain the most sensitive of information about us. And every day, as I am out working in my community or going to the grocery store or going to church, or you know, even a basketball game with my grandsons, somebody who is working in health technology will tell me about something that they are working on that is going to improve patient care in some way, shape, or form.

But we have had the Browser Act which would require individuals to opt in, to share their sensitive information, and then they would have the option of opting out for non-sensitive information. So as you look at the utilization of the mHealth apps and the plethora of these that are now in the marketplace on both the non-sensitive and the sensitive information, talk to me a little bit about how you see HIPAA evolving, how you see privacy policy evolving as it affects our healthcare data.

Dr. RUCKER. All right. So——

Mrs. BLACKBURN. I know it is a lot to unpack in that.

Dr. RUCKER. Yes, yes, yes. Obviously, I think first and foremost, we have to protect privacy, right, so we have to think about, you know, what the software approaches are that protect privacy, and there are folks who do a very good job at that. If you look at, for example, the banking industry, the brokerage firm, there are some people who really have nailed the privacy stack.

Right now, if you look at the mHealth world right now, I think there is actually a fairly stark divide between the apps that have access to clinical information and then the apps that don't, right. So you know, classically, the FitBit type of app. I think part of—in my understanding of Cures, part of it is to actually allow some merger of these things so that patients clinical information can ensure their broader health choices and not have this divide.

As soon as we get to clinical information, we have to work with HIPAA. HIPAA, I think, is a very powerful, very straightforward rule that I think sets a very nice bound on privacy. There is absolutely nothing in ONC's activities that requires changing HIPAA, and so we follow HIPAA. We think it is actually a very solid rule to protect privacy. So there is a combination of technology on the security side.

Clearly, the tools to really fully inform patients and to really get rich consent, I think some of this is honestly still a work in progress. I mean, we can look at specific things, but I don't think we have fully solved the full communication of how patients share information. That may be broadly true, you know, throughout the app economy. We believe what we are doing in the world will empower patients with fairly precise ability to control their information.

Mrs. BLACKBURN. Thank you. I yield back.

Mr. BURGESS. The gentlelady yields back. The Chair thanks the gentlelady.

The Chair now recognizes the gentleman from Texas. Mr. Green, 5 minutes for your questions, please.

Mr. GREEN. Thank you, Mr. Chairman.

Again, Dr. Rucker, thank you for being here. In the 21st Century Cures, we made a number of changes from the HITECH Act to address clinician burden and encourage communication between providers. What progress has been made to date with these changes to the 21st Century Cures Act?

Dr. RUCKER. Yes. There are a number of things, Congressman, that have happened already. So one of the provisions in 4001 is to actually start by identifying what those burdens are. So we have released recently a draft report out for public comment on a 70-page report listing what we think the main burdens are on physicians and other providers.

These burdens come in a couple different areas, you know. I think the top level, documentation, some of the things around quality reporting, some of the things around just overall usability which, in and of itself, is a very complicated issue. Things like prior authorization come into that. In terms of what has been done, pleased to say working—and this report was done jointly with CMS.

So working with CMS, we have had the first reconsideration of documentation requirements since the 1995 CPT things, trying to reduce reentry of data on, you know, parts of the history that aren't changing, so reducing reentry of data and flattening some of the economic incentives in the CPT coding system to do all of the boilerplate text that infiltrates all of the notes in America when you actually—and I have been a clinician for 30 years. I actually have to find out something about a patient and wade through this template, generate a text. There is more to be done there, but I think literally, the first effort at fixing this since 1995.

CMS, and we have been part of that, has also simplified a number of the requirements around what was formerly meaningful use, clearing up things there and focusing on promoting interoperability to have a much more constrained set of reporting requirements. So those are some of the things that we have done directly out of the Cures Act.

Mr. GREEN. Information blocking is a topic ONC's been examining since even before we passed the Cures Act. In fact, in April of 2015, ONC released a report on information blocking in the healthcare sector. In this report, ONC describes information blocking as when persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information. That definition alone without additional context creates a great deal of uncertainty about the specific practices that are considered information blocking.

That is why Congress asked the ONC to draft a proposed rule providing more detail on what may or may not constitute information blocking. Unfortunately, this rule has still not been released, and I know your ability to discuss the content of the rule is limited. But Dr. Rucker, can you share with us some of the research and analysis that went into the development of the rule.

Dr. RUCKER. Yes. So what information to share is obviously one of the most complicated issues when you think about the vast amount of clinical information that floats in the care of a sick patient. In the care of, you know, all patients, there is just—we are looking at things like images. We are looking at lab tests. We are looking at notes. We are looking at consults. I mean, that is just scratching the surface, you know. Dozens and dozens and dozens of types of information, you know.

Now we are looking at some of the prescription—you know, opiate descriptions, so lots and lots of information. It is a large world in terms of who potentially has information, who could share it.

So our analysis has been focused, A, to understand the breadth of that from a legal—right, from a rule-making perspective to make sure we get try to the first time as opposed to sort of putting to stuff out that is a little bit—you know, that needs a lot more further work.

The areas that I think you can anticipate, you know, that have come up in this research are things like, first of all, just being in harmony with existing State laws, right. There are a lot of privacy laws, and so we have to think about that. We have to think about security issues. We were just asked a question about privacy and security. We have to think about cases where patients have deep mental illness where there may be some information issues.

Frankly, we have to think about what can be charged, you know. We, you know, have heard where either the information is blocked simply by charges to share that information that appear not to be related to any observable software development cost.

So those, Congressman, are the types of considerations that we have to consider in putting out the exceptions that we are asked to put out the exceptions as you have pointed out.

Mr. GREEN. Thank you, Mr. Chairman. I have some other questions I will submit. I know I ran out of time.

Mr. BURGESS. The gentlemen yields back. The Chair thanks the gentleman.

The Chair recognizes the gentleman from Kentucky, vice chairman of the subcommittee, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you very much, and I do want to echo, I am going to miss Mr. Green. He has been a good person to work with as vice chairman of this committee, and I am going to miss you and the chairmanship for, I guess, a lot of reasons, but you have done a great, great job, Mr. Chairman. We really appreciate your work as well.

I have similar concerns that my friend, the future Senator from—the next Senator from Tennessee, I guess I should say now, she is not future, she is the next—about privacy. One of the things that I am working with my friend, Ms. Matsui from California, we have worked to reintroduce a bill related to developing Federal policy on blockchain technology, just trying to figure that out. So if you look at hardware and software, regulatory reform, and completely new technologies like blockchain, just so much is changing is what I am getting at. Where do you see the future of healthcare information going, and what can we do to best protect Americans' most sensitive information?

Dr. RUCKER. I think when you look at the protection of information, I think there are actually three areas to unpack here from, if you will, a somewhat technical point of view.

One is the authentication, so when you log on, are you actually the person you say you are as opposed to somebody in—you know, some rogue agent. So that is authentication.

The second is authorization, right. Now that you have logged on, are you allowed to actually get this information from the point of view of the provider.

And third is from the point of the view of the patient consent, right, and so these all actually have—especially authentication, have some very, very interesting technologies out there.

I believe that the advance in technology is going to make some of these things materially easier in healthcare. Let me give you an example. It turns out today that pretty much you can authenticate anybody from their ownership of their cell phone, right. And even if some rogue agent gets your cell phone account number and tries to switch it out, there is so much information in just how you have configured your apps, where you use the cell phone, how you use it, how you, you know, swipe on it, that there are a number of companies out there that can authenticate to a very high degree. I am told a lot of the financial services industry uses that, so I think the broader technologies on security are getting much better.

One of the things that we are very focused on at ONC is making sure for the critical security privacy things that we don't cook up healthcare-specific things that, you know, will then make healthcare more vulnerable because they are more outdated, they haven't kept up with the most modern technology. So as you hear us talk over time, we are very conscious to try to have the best security tools that are out there and not inadvertently do any type of policies that prevent that from happening. Hopefully that gives you a bit of a flavor of how we unpack that.

Mr.GUTHRIE. Thanks. Thank you. And also, in your testimony you mentioned that payers and providers who negotiate contracts based on quality, and I couldn't agree more. Can you please explain ONC's role in collaborating with payers and providers on developing standards? The question is how do you determine the quality? That is where we——

Dr. RUCKER. Yes. And so this was a bit of a surprise to me which, from just my clinical experience as an ER doc, right now when you talk with a lot of the large payers, they actually have—they get the claims data very rapidly, right, so that is all electronic and pretty much instantaneous. It is actually very hard for them to get clinical data.

So typically, if they want to get clinical data, they can either in the network contracts negotiate that there are, you know, queries, so database downloads, very narrowly defined, predefined, or they can go out and download the entire record at a cost, I am told by some of the largest payers in the U.S. of between $4 and $6 per chart, right.

So at $4 to $6 per chart, you can't actually be downloading everybody's, you know, record. That is prohibitive from a cost point of view.

In working with some of the research folks we have worked with and the payers, pretty much simultaneously, it turns out that the new FHIR standards that we are implementing, that the whole healthcare ecosystem is very excited about and is implementing can be extended to get a population of patients, get that data.

This is critical for things like the learning health system. It is critical if we are going to have payers figure out what they are getting from providers. So it is really having the ability to use all the big data things we are talking about from a computational point of view is what that is about. We work very tightly with them. We have a whole standards group that works on that. Steve Posnick who is it right here leads all of that work, I am pleased to say.

Mr. GUTHRIE. OK. Thank you. I appreciate your answers, and my time's expired, and I yield back.

Mr. BURGESS. The gentleman yields back. The Chair thanks the gentleman. The Chair recognizes the gentlelady from California, Ms. Matsui, for 5 minutes of questions, please.

Ms. MATSUI. Thank you, Mr. Chairman, and thank you, Dr. Rucker, for being here. This is a hearing that I have been looking forward to. Several of us are working on the telehealth working group, and we really believe that this attention has to be paid on particularly in telehealth because we know not only is information sharing important but also the security aspects of it, and we also know that we want the patient to be able to access a lot of this information and the providers.

You know, the healthcare providers face an onslaught of cybersecurity threats. I think a June 2017 healthcare cybersecurity task force report went so far to identify healthcare's cybersecurity as a key public health concern that needs immediate and aggressive attention. Now, with that in mind, I am really concerned that as data moves more freely and becomes interoperable which we want, there may be more opportunity for bad actors to compromise this data. While open APIs may be common to a tech space, standards aren't in place for healthcare.

And I am particularly interested in this because healthcare—the information provided in healthcare is very, very personal to an individual, and in particular, as we also talk about mental health too because there is still a stigma attached to some of that information.

So Dr. Rucker, what is ONC doing to enhance the cybersecurity readiness of healthcare providers as we encourage more data to be shared across the healthcare ecosystem?

Dr. RUCKER. Yes. So, I think there are a couple of things. I think, first of all, as a background, we are very mindful. The biggest cybersecurity risk generally is just system complexity, right. When you just look at it, it is the built footprint. It is the number of passwords. That is the biggest risk. So we are, A, just mindful. Are we, you know, increasing system complexity, you know, in quirky kind of ways.

The open API, honestly, in some ways is a bit misnamed. It should really be a very secure API. It is like—you know, it is the difference between a door that is open and a door on a bank vault, but there is a lot of protection on that. We are really talking more the door on the bank vault. The term, the O of 2 standard. So there is a very tight sort of three-way standard that authenticates patients to make sure that it is them and that they are getting the data and that it is being transmitted securely. So those are the policies that we encourage in our rulemaking. You will see those high technology standards to actually provide all of that security on access and transport.

So that is—I mean, that is the technical answer. I think the broader answer is we just have to be very mindful of this. The mental health issues are huge, all of these issues, and of course, it is forever, right, when something gets out. It doesn't—there is no way to retract it, right.

Ms. MATSUI. Right.

Dr. RUCKER. It is literally forever. I think there will be over time an evolution of how patients think about their data. There is clearly an education task on what apps patients would allow to access their data that I think is out there. So there are a bunch of components. Again, there may be some interesting new technologies to allow that.

Ms. MATSUI. OK. Then what is ONC doing to ensure that consumers understand their rights? Specifically, when a person's data is transferred from a health system to an app of their choosing using an API that the data is no longer protected by HIPAA. I know HIPAA came up before, but——

Dr. RUCKER. Yes.

Ms. MATSUI. It is really sort of the standard that we have, and we have had discussion before, particularly in the mental health arena.

Dr. RUCKER. Uh-huh.

Ms. MATSUI. And it becomes a little bit more complicated because individuals themselves may not be able themselves to understand what this really means. So I am curious because there are many, many layers to some of these API's that even if people give some consent, they really don't understand.

Dr. RUCKER. Yes. Well, this is evolving, but in the initial go-around, we are trying to make it a very conscious process where patients actually have to get authenticated by going back to the portal, right. The challenge here, the first challenge is how do you authenticate. So we are making it a very conscious process. This is not one of these things where you just sort of click, you know. We have all clicked through consents, right.

Ms. MATSUI. Right.

Dr. RUCKER. There is nobody here who hasn't clicked through who knows how many consents with GPR and all of that, you know. It is every day, right, you know, click through consents. We are making this a very conscious process so people understand. Actually, the authentication—let's say there is an app that they want to use. They have to go back to the provider and authenticate to get that transfer, so it is really a three-way party thing. So we think it is a very conscious thing as a start, so nobody's just accidentally clicking through the way we do on much of the rest of our lives.

Ms. MATSUI. OK.

Dr. RUCKER. I think that is a big part of it to start. And then, you know, we are working with our community on what—you know, what that information is. We have done various things with the Office of Civil Rights, with SAMHSA in terms of mental health to sort of propagate an understanding on that.

Ms. MATSUI. So you are basically saying it is a work in progress as of this moment right now.

Dr. RUCKER. Part—I would say the long-term public use of their datas is definitely——

Ms. MATSUI. Right.

Dr. RUCKER [continuing]. To be determined. We are putting it out. The rules we are putting out are to allow it securely, but, you know, how that—you know, what the public take on that is, you know, it is——

Ms. MATSUI. Right. Well, I see I have gone way over, so thank you very much. I yield back.

Dr. RUCKER. Thank you.

Mr. BURGESS. The gentlelady yields back. The Chair thanks the gentlelady.

Before I recognize the gentleman from Ohio, I do want to point out that it was a visit to the gentleman's district 5 or 6 years ago when I spoke to your medical staff section when many of these problems with interoperability were really brought home to me in a way that had not previously been disclosed, and the intensity of that the exchange that morning is one of the things that I have carried with me over these years which actually has led up to the language in the Cures bill, the previous interoperability bill that I had done.

And now I am pleased to recognize the gentleman from Ohio. Five minutes for questions, please.

Mr. LATTA. Well, thank you very much, Mr. Chairman, and I want to thank you not only for coming out that time, but you have come out to the district twice to speak with folks in the healthcare community. And it is by having that personal touch, you might say, is where you get this what is going on with the professionals out there and the other individuals in the healthcare industry are facing, so I appreciate that.

If I could also take a quick point of personal privilege to thank the Ranking Member, the gentleman from Texas, for all your years here on—service on the committee and also on all the different pieces of legislation that we have worked on together. I just want to thank you very much for your tenure and best wishes in the future. So thank you very much.

Mr. BURGESS. The gentleman yields.

Mr. GREEN. I appreciate the working relationship. My most fun was when we worked across the aisle, both our leaderships worried about it, so thank you.

Mr. LATTA. But it always turned out.

But thank you very much, Dr. Rucker, for being with us today, and you know, you have been hearing quite a bit of the questioning, especially when we were talking about cybersecurity because, in fact, the majority staff just put this out last week which is our cybersecurity strategy report that came out on December 7. And we have done a lot of work on this committee on cybersecurity, but I would like to go back just—if I could, just because there have been a lot of questions on the cyber side.

You were talking about some of the problems that you looked at with cybersecurity in health is because the subcommittee I chair on digital commerce, we had a hearing that involved a lot of people that had been breached, and it was because the question about something hadn't been patched.

But you talked about something, you just mentioned about somebody having been unpatched but by some providers. How do you look in the future that, you know, you through your group with ONC and HHS can make sure that these things get patched because that is one of the problems we have out there, you know. Can there be a cure real quick, but if this isn't done, isn't followed, then we have a massive breach out there.

So how do you—you know, because it is, you know, you talk about the voluntary, or you could be talking about maybe more of a forced approach, but how you are going to encourage these things to be patched.

Dr. RUCKER. I think, you know, part of it is just I think people have more and more awareness of this. I think—you know, so I think there is that out there. There is actually a—you know, we have specific provisions on the Medicare side and payments with promoting interoperability that folks have to do a security assessment.

So we are actually asking providers or requiring—you know, asking is, I think, a nominal term when there are Federal incentives and disincentives involved. But we are actually in that program asking providers to do a security analysis, just to sort of a self-awareness to be aware of these things.

I think there is an evolution that more and more of those things are moving into the cloud and to distributed computing where you don't have to maintain all of that on your own—you know, on your own just IT shops.

So I think security is a large part. I mean, there are other cost drivers. I think security is a large part of what's driving that. I think there are also increasing encryption technologies so that, if you do actually get at some of this information, that it is less damaging.

So I think there is a conjunction of trends that are coming together, but there is clearly—and the vendors, of course, do a huge amount of work here, right, in putting this out for their customers. So it is that combination of things. It is not perfect by, you know, any means.

Mr. LATTA. Well, do you see the ONC, then—just to follow up real quick on that. Do you see that the ONC would be—if there is some kind of a breach out there or there is something out there that can be patched that you would be putting information out there to say that look, you have got to really get out there to make sure that this is being taken care of because, you know, this is an imminent threat with all these records out there.

Because again, a lot of folks out there are very, very concerned, of course, that what happens to those records once—you know, as the practitioners are putting it in the computer, all of a sudden it is out there then.

Dr. RUCKER. Yes. Actually, a lot of that happens at the level of HHS, right. So, HHS has a cybersecurity process, a strategic operations center that is geared to do that. We are starting to work with a number of countries globally with their governments, their healthcare, you know, ministries and the folks there on information technology to think about how we get even more global rapid notification of these threats.

So those are some of the things out there. But right now that is largely the initial response, right, because these things sometimes have to be, you know, pretty much instantaneous. It is coming through the cybersecurity work at HHS and the command center there just because of the scope. ONC has—you know, obviously we are not—we don't have a big operational footprint as a small staff agency to do that, so we rely on that broader set of HHS tools.

Mr. LATTA. Thank you. Mr. Chairman, my time has expired, and I yield back.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back.

The Chair now recognizes the gentlelady from Colorado, Ms. DeGette. Five minutes for questions, please.

Ms. DEGETTE. Thank you, Mr. Chairman.

Dr. Rucker, when Mr. Upton and I worked on the 21st Century Cures Act along with this whole committee, one of our concerns was really improving interoperability of health data systems because all these wonderful advances that we achieve won't be very useful unless we do that. And we also felt at the time that one of the least fleshed-out areas of the bill, shall I say, was the interoperability and some of the health data. And we had hoped that we would be able to, frankly, be farther along now than we are in these areas.

So I kind of want—I know you've been answering a lot of really specific questions that Members have, but I would like it if you can take it back out a little bit and talk for a moment about what the biggest impediments in general to greater interoperability are at the moment and maybe talk a little bit as we move into the 116th Congress about what Congress could do, if anything, to help ONC further the goals set out by Cures because again, I think that my colleagues on both sides of the aisle will agree. Even though the leadership is changing, we still have a strong commitment to implementing this fully.

Dr. RUCKER. Yes. So, obviously, I wish I could tell you that the rule had been passed through clearance and so we could talk about the exact specifics of that rather than talking about it with a certain amount of generality, but there are some fairly specific things I can talk about that are part of—they are part of interoperability.

Why there is not interoperability is a very complex, multilayered thing, and it, frankly, starts with the raw complexity of human biology, right. Unlike a financial transaction where there is, you know, a dollar sum and a destination and maybe a few other pieces of data to describe that, the human biology, just think about the thousands of lab tests, all the different modalities of imaging, all the different narrative. It is immensely complicated, and most of that is not standardized. It is not really structured data, so there is an innate complexity there.

Then you get into the business things. Then you get into just the technology. It is worth noting, and I am dating myself here, but the first couple years I was involved in building the first Windows EMR, right. So, you know, advice to anybody, don't build a software product with Windows 2.1. It will crash during your demo for sure.

But even, you know, years later, with Windows 95 was the first time there was even a TCP/IP internet stack that you could even communicate. Before that—and you all are too young, but for anybody who's, you know, listening, on the internet, we had to do those, like, RS232 ports and serial wires, right. You know, there was no Bluetooth. There was no WiFi. So I am intimately familiar with that.

I look at these things, I think, in a good and ready framework to take it to the top level.

In Cures there are two powerful components. One is the API which means how do you connect to individual providers' records, right. So what is that end point where you connect to the record.

The other is the Trust Exchange Framework. What is the sharing network? Some cases make a lot more sense connecting to the record. Other cases make a lot more sense sharing. There may be hybrid approaches. So, for example, Apple has a hybrid approach. So what Apple does is they have single point connections, and they—well, let me be clear. They broker, actually, a connection between the patient and the provider providing security. Apple does not get that data.

Ms. DEGETTE. So I hate to interrupt you, Dr. Rucker, because what you just described right here in 4 minutes of my 5 minutes of time is exactly what Mr. Upton and I identified, why it was impossible for us to be much more robust.

What can Congress do going forward to not just identify the problem that you so much better than I can articulate it, but what can we do? Are there legislative barriers to trying to overcome these burdens and to move forward?

Dr. RUCKER. I feel pretty confident that what has already been passed, when we have the rollout will be, I think, very effective increasing interoperability.

Ms. DEGETTE. All right. OK. Great. Thank you. I love hearing that.

One last thing. When can we expect the regulation to be released?

Dr. RUCKER. I do not have a specific date for you.

Ms. DEGETTE. Well, that is OK. Like, a timeframe is good.

Dr. RUCKER. So it is currently in clearance with OMB, so I think that tells you that all of the text has been written. All of that has been done. All of the analysis that I think Congressman Green was asking about.

Ms. DEGETTE. So soon, you think?

Dr. RUCKER. I am optimistic that it will be soon, but these are folks that are not under my control, so I don't honestly——

Ms. DEGETTE. Thank you.

Thank you, Mr. Chairman.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields generally. The Chair now recognizes the gentlemen from Virginia, Mr. Griffith. Five minutes for questions, please.

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

First, I would be very remiss if I didn't say thank you to Mr. Green for all of the work that he has done. He has been willing to discuss ideas. We worked together on a couple things, and some of them were big. Our pharmacy—compounding pharmacy bill was a big deal, and I appreciate all that and appreciate your help on that. Likewise, I look forward to finding out what those rules are when they come out as Ms. DeGette was just asking you.

And Mr. Chairman, I think this is an important hearing, but a lot of the questions have already been asked. Some will additionally be asked, and I will be looking forward listening to the answers to those. At this time, however I would yield my time to Dr. Bucshon.

Mr. BUCSHON. Thank you very much for yielding. ONC's recently released draft Clinician Burden Report acknowledges how information overload and electronic health records is contributing to physician burnout. I was a physician before I was in Congress. How does the ONC plan to address these challenges faced by clinicians? Would open application program interfaces help address some of the challenges by making electronic health records easier to use in a clinical setting?

And let me just be brief about my own experience Spears. I support EMRs. We put one in our medical practice in 2005. I wouldn't want to go back to paper charts. It is a major advance, but we have challenges as we have heard here today.

One of the big ones I am concerned about is the physician burden, and so if you were to address how that the ONC plans to address the physician challenges, I would appreciate that.

Dr. RUCKER. Yes. To get to the very specific part, we do believe that having better, more robust application programming interfaces will make it easier to get data on patients, so when you get a referral patient for your practice or send somebody to another provider that that will be materially easier. We have made a lot of progress there, but the progress has been patchy.

In terms of the burden, there are a number of areas that we are working on. I mentioned documentation which is, I think, one of the biggest areas. We are doing a number of things on usability, working with the vendors there on that. We are actively engaged in ongoing discussions with CMS on are there other things we can simplify in the CMS stack which, as you know, includes quality measures of a vast type of varieties.

CMS is working on clinical quality language to try to make that whole process less burdensome. An area that we are working on internally and with CMS and outside stakeholders is on prior authorization which is another big thing that has been extremely problematic for everybody. And the thought there is can we use interchange standards so this is not having your office waiting on the phone with a payer, you know, for—who knows, for some cryptic, ill-defined set of information that you don't know ahead of time to decide whether something is authorized. This is bad for patients. It is bad for providers.

So those are some of the areas. We are happy to get into much more detail.

Mr. BUCSHON. Sure.

Dr. RUCKER. You know, in these 5-minute slots——

Mr. BUCSHON. Yes. It is a complicated problem.

Dr. RUCKER. We can't even again to go into nuance.

Mr. BUCSHON. Can I express one concern about code consolidation, you know, and simplification as it has been promoted. The physician community, as you probably know, has concerns about code consolidation even though going from one to three codes, for example, something like that as the billing—different billing levels. There is a specific concern that very complicated patients that currently bill level 5 now would be a level 3 but that the reimbursement wouldn't be consistent with a level 5. So we would have physicians specifically that see very complicated patients are very concerned about, and I know you are aware of that situation.

I have personally voiced that concern to Administrator Verma. I think they understand that, but it is very laudable what they are doing. They, as you know, have a Patients before Paperwork program that goes through a lot of these things.

So you know, the challenges that we have today are obviously security and, really, and interoperability. The only way I see that you totally secure a patient's medical record is you never put it on a computer, but we are not obviously going to do that. Are you talking about educating, you know, broader educating people to utilize the computers including staff and physicians on proper password management? I mean, basic fundamentals, right? And if you look at cybersecurity, the first thing is—the first step is the user and their password stuff.

So what are you all doing to try to— you know, there are obviously big things we can do on cybersecurity. What are you doing to fundamentally educate people that access the system on how they protect their information?

Dr. RUCKER. Right. So, you know, to mention briefly, obviously we have that as part of the promoting interoperability program with Medicare just so that, you know, folks at least have one exposure to doing that. We have done work with the Office of Civil Rights on educating patients on that.

Mr. BUCSHON. So my time has expired. I am fine with a written response to that.

Dr. RUCKER. We would be happy to provide you with a written response.

Mr. BUCSHON. Send that to the committee.

Dr. RUCKER. We would be happy to provide you with a written response on that.

Mr. BUCSHON. Thank you. I yield back.

Mr. BURGESS. Does the gentleman from Virginia from yield back? The gentleman yields back.

The Chair thanks the gentleman. The Chair recognizes the gentlelady from California, Ms. Eshoo. Five minutes for questions, please.

Ms. ESHOO. Thank you, Mr. Chairman, not only for having this hearing today but for your service as chairman of the subcommittee. We all salute you for the work that has been done, and even though Gene Green is not here, I want to acknowledge his work with you. I think that you have been an excellent pair of leaders of the subcommittee, and Gene and I were classmates. We came in the same year, so thank you to both of you.

Dr. Rucker, welcome. I can't help but think that I am listening to someone whose job I created because I did the legislation to establish the Office of National Coordinator of Health Information Technology. That was signed into law as part of the American Recovery and Reinvestment Act, what, 9 years ago, in 2009.

Now, the legislation also addressed, as you know, electronic health record interoperability, and I think that you have heard from just about every Member that has questioned, made comments, that we are still having issues with it. We don't have a seamless system of interoperability in our country. It seems to—you have talked about many things that you would like to look at or that you are looking at, but it seems to me that you are testifying today in a state of limbo because the rules have not been written, so it is—I think—it is a little awkward, I think, but nonetheless, we can still ask you whatever questions we want, right?

I would like to—you mentioned in your testimony, in your written testimony Apple's, health records app. Now, I have seen the app, obviously, firsthand. I think it is a very exciting concept, and I think it is important for patients to be able to access their health data, but that requires health systems to make their data available. And it also, going back to an issue that is been raised by just about every single Member, it introduces the need for additional privacy and data security.

So I just want to ask you a direct question. How are you as the director going to address this?

Dr. RUCKER. So——

Ms. ESHOO. Not how you think you might or what some several ideas are. Do you have a specific——

Dr. RUCKER. Yes.

Ms. ESHOO [continuing]. Answer to a specific question? Thank you.

Dr. RUCKER. Yes. So the upcoming Cures will specifically address the security requirements for what you are referring to which is the application programming interface that providers need to provide. That will be—it is going to be part of the certification process for electronic health records that API exists, and we are designing it in a way to use industry standard API technology to maximize security. So those are very specific things with very specific technology.

We have—to the earlier part, just by—I have probably had 150 stakeholder meetings and been out on the speaking circuit. So we have actually already made a fair amount of progress in getting people to understand the concept of open APIs. Some of the large vendors have opened up their APIs in response to the Cures Act.

We are seeing a lot more network sharing which I believe, when you look at the temporal sequence of events, is based on the upcoming Cures Act rulemaking. So even as we speak, the Cures Act has had a significant impact on what——

Ms. ESHOO. If you were going to grade interoperability when it comes to electronic health records in our country, what grade would you give it?

Dr. RUCKER. It is highly patchy which is the problem. There are A students, and there are F students.

Ms. ESHOO. Patchy is not——

Dr. RUCKER. Right. So I guess maybe it averages out to a C minus, but it's an average. It's an average.

Ms. ESHOO. And when was the last time you had any communication from OMB? Are they the ones that are—who is writing the rule?

Dr. RUCKER. ONC is writing the rule.

Ms. ESHOO. ONC?

Dr. RUCKER. ONC is writing the rule.

Ms. ESHOO. I see.

Is there anything that you think is missing from the legislation that you need relative to implementation?

Dr. RUCKER. I have to be honest. I was surprised at how thorough it was when I actually read it and took the position, and I obviously hadn't read it in great detail before. I was amazed at how thoughtful it was and how well put together it was.

And, you know, I was extremely pleased coming into the National Coordinator, and I want to thank, frankly, my predecessors because I know there was a lot of technical work and a lot of technical support with my predecessors under the Obama administration working with Congress to support Congress in the bipartisan way in putting that together.

So I think I was pleased, and I think we have accomplished something in a you know, bipartisanship trajectory.

Ms. ESHOO. Thank you. Merry Christmas.

Dr. RUCKER. Thank you.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields back. The Chair recognizes the gentleman from Missouri, Mr. Billy Long. Five minutes for your questions, please.

Mr. LONG. Thank you, Mr. Chairman, and there is Gene Green back. I just want to echo what everyone has said about my buddy Gene. We are going to miss you and Helen, and thank you for all your years of service to Congress, to the committee, to the folks in Texas. You are going to be a big loss for us.

Dr. Rucker, when Obamacare first went into effect, I happened to have an appointment with my doctor shortly after that. And I went in, and I thought I was going to have to give him—prescribe him blood pressure medication for the amount of paperwork that he—he said you sit there, you sit there, and I have to enter all this in the computer. I have to—you know, and he was so upset about the burdensome paperwork. Shortly thereafter, he decided to take early retirement. He just said I am out of here. He wasn't at retirement age, but he just had all the fun he could stand.

And when I talk to physicians, they mention how overly burdensome their paperwork requirements are and how too much of their time is spent on data entry instead of seeing patients. He calculated he lost 1 day a week of seeing patients because of the amount of paperwork he had to do. So instead of seeing patients 5 days a week, in essence, he was seeing them 4 days a week.

In November, ONC and CMS released a draft strategy on reducing regulatory administrative burdens. What do you think the main driver of this burden is, and what would——

Dr. RUCKER. In working with CMS on that report, I think in deciphering out just some of the times, you know, the time component, a lot of people have told us it is over a day a week. It is over 20 percent. You know, when you go to 3 or 4 hours a day, I think 20 percent would be on the low side.

I think, to me, the biggest area to start with is documentation. So because we are gating fee-for-service through the CPT billing codes, they have sort of—they have a bit of what, you know, in a Pavlovian psychology thing could call an reverse of stimulus. If you want to get paid more, you have to deal with more of this burden. I think that has caused huge dissatisfaction.

I have worked with thousands of doctors, you know, in the ER. It is sort after communal pit. You hear what everybody says. I know in talking with thousands of people, they hate this. It is very hard for us to teach this to the residents. They look at us, like, are you out of your mind? Literally. So that is a big issue.

Prior authorization. We hear that is a little bit more specific to the types of practices. It is a big issue. We have heard quality, some of the quality measure reporting, very expensive and time consuming, and frankly, we are getting an early signal, and we are doing a lot of work at ONC to try to make sure that the prescription drug monitoring programs don't become an additional burden, you know. They are required pretty much in every State, and often that means you have to get out of your computer, logon to another computer, get out again, document it. That is a lot of time on a go-around, right, about a because you know how long it takes to logon to a computer even if you can memorized all niece passwords.

So we are, you know, doing some work to sort out, and I know a number of people are working on integrating PDNP into the record so that we are not adding additional burden inadvertently as we try to solve the opiate crisis.

Mr. LONG. So are there health IT system usability problems?

Dr. RUCKER. Yes.

Mr. LONG. What are some of the key recommendations from the strategy, and how can we reduce the overall burdens on clinicians?

Dr. RUCKER. So key recommendations from the strategy. We discussed documentation. We discussed prior auth. Those are things on usability. The Electronic Health Records Association, the vendor association, is working on standardizing some things, even small things like what is the order of results? Is it the most recent result first? Is it the first result first? Even some simple things like that.

The APIs in terms of getting the programming interfaces to get data from other providers is going to be a big thing. The quality group at CMS with whom we work with quite intensively have a number of programs they are working on to make quality measures more responsive, more real, and simpler. We have worked a lot with CMS in just the rules around, you know, what used to be the Electronic Health Records Incentive Program, what is now promoting interoperability.

Seema Verma has been very aggressive in pushing everybody she can get her hands on, and that includes me, in terms of making things easier and working with CMS to do that, so a number of things are in progress.

Mr. LONG. So you are working with stakeholders in developing these strategies——

Dr. RUCKER. We have had meetings with about 150 stakeholders, and many of the meetings have been on burden.

Mr. LONG. OK. Mr. Chairman, I don't have any time to yield back, but if I did, I would.

Mr. BURGESS. The Chair appreciates your willingness.

The Chair now recognizes the gentleman from New York, Mr. Engel. Five minutes for questions, please.

Mr. ENGEL. Thank you, Mr. Chairman, and I too want to express my chagrin at Gene Green not going to be here any more, but I know he is going to be doing some great things and with some time, spare time, with his wife and—with Helen, and I just want to tell everybody how much we are going—we always sat next to each other. We are going to miss you.

Mr. GREEN. I haven't got him to talk like a Texan during all of that.

Mr. ENGEL. I would attempt to do it, but I would just laugh—make a fool of myself.

Thank you, Dr. Rucker, for being here today.

As you know, in May, the GAO issued a report on the challenges patients and providers face when it comes to access to medical records. And I am particularly concerned about this finding in the GAO's report, and I quote it.

Patients' challenges include incurring what they believe to be high fees when requesting medical records, for example, when facing severe medical issues that have generated a high number of medical records. Additionally, not all patients are aware that they have a right to challenge providers who deny them access to their Medicare—medical records.

So, Dr. Rucker, let me ask you. Is ONC doing anything to help mitigate the costs that patients face as a result of this?

Dr. RUCKER. Yes. By law, the electronic access to records is something that should not be charged for. As the open application, the application programming interfaces under Cures are designed, and our rulemaking will implement that patients can direct their smartphones at the providers' end point,you know, the URL, if you will, and download their records and do it in a way that is convenient to patients. They can aggregate records from other providers. We believe there will be apps to do that.

Apple already has one. There are smaller companies that have these apps out there now. We believe this line of business will grow. It will add value in all kinds of ways, but I think the key practically is charts, you know, the printouts of these charts.

Now, if you get a, quote, printout from one of these electronically generated charts, it is hundreds of pages of stuff that is impossible to read for a physician, let alone a patient. When you are on the inbound side of this in referrals, it basically jams up the laser printer fax machine.

At Ohio State where I work, I am told by some of their staff they would get 90 calls a day where inbound faxes were so large that they jammed up the nursing units' fax server which are, you know, the laser printers on the unit. Smartphones are powerful computers and I think are exactly what we need to get patients their records and to do it in a way that patients can control their care and, frankly, shop for their care.

Mr. ENGEL. Well, doctors who can't read it know how the rest of us feel when we try to read doctors' signatures or doctors' notes.

What about patient education? Is anything being done to ensure that patients know that they have a right to access their medical records?

Dr. RUCKER. We have worked with the Office of Civil Rights on an ongoing basis, I think over a number of years, to describe for patients how to get their information. Now, some of this is consumer marketing. We don't have a budget for consumer marketing, but to the extent that we are able, we are encouraging that, and we believe that with the open APIs, there is going to be a lot more public awareness of the availability of this because right now, that is—you know, these simple things aren't available, so it is hard for people to learn about them because what they learn about is so complex.

Mr. ENGEL. Thank you very much.

Thank you, Mr. Chairman.

Mr. GUTHRIE. Thank you. The gentleman yields back. The Chair now recognizes Mr. Bilirakis for 5 minutes for questions.

Mr. BILIRAKIS. Thank you so much.

Dr. Rucker, HITECH made available over $35 billion to modernize HIT infrastructure centered on the meaningful use of certified EHRs. These incentive funds were designed to assist eligible providers to purchase, implement, and maintain her systems as well as meet criteria to advance reporting on quality indicators. While the implementation of the HITECH was far from perfect, it was the launching pad for the implementation of her ecosystem we have here today. Yet certain provider types such as behavioral health providers were not eligible for this incentive funding to build out electronic health platforms.

Meanwhile, today as a result of the opioid crisis and increasing suicide rates in the U.S., we are increasingly aware of the importance that behavioral health plays in whole personal—person care, healthcare. Given that behavioral health was carved out of HITECH and serves as a critical linkage to integrated care, what, if any, plans exist to cross this bridge?

Dr. RUCKER. Well, I think first—there is, first of all, a start with the Center for Medicare and Medicaid innovation in the support act, the recent opioid act to, you know, look specifically at the question of behavioral health records.

I think one of the big opportunities we have is to use these regional health information exchanges to share even the simplest of data on patients with behavioral health and substance use issues. The data I am talking about because as an ER doc, you see these people. They float in and out of the system. They float from group homes, shelters, all kinds of situations.

In some parts of the country, health information is simple ADT. ADT is admit, discharge, transfer. So all it says is where was this person? Where are they located? That simple information often helps to coordinate some of this care, so there may be a very lowhanging fruit here that is worth looking at, and we are looking at how to expand that to get at the behavioral health issues.

Part of the challenge is a lot of these folks, as you pointed out, don't have software, per se, right. So, but to the extent they do have software and any ability, this is sort of the simplest common denominator that we think—we have some anecdotal experience that's going to be very powerful for helping these folks. I have taken care a lot of these folks over many, many, many years, so I am pretty excited about trying to do something in this role.

Mr. BILIRAKIS. Thank you. All right. Next question. What is ONC doing to enable physical therapy and other non-physician her vendors to satisfy certified her technology requirements?

Dr. RUCKER. Yes. So for the broader healthcare ecosystem, the biggest thing we do, you know, in areas where we are not, per se, certifying, you know, for the non-certified part of that world is a lot of work on standards, right. So people can share information, have lower costs of getting information, providing information, entering information. We do a lot of standards work. We actually summarize it with an interoperability standards advisory which is a constantly updated database of the best standards in healthcare. We have used resources to encourage some of these standards.

We do a lot of work with a number of the standards organizations, most specifically HL7, and we have also supported some of the deeper technical things needed to advance standards to make, you know, the communication across the healthcare board more efficient.

Mr. BILIRAKIS. OK. I guess I have a couple more. You know what? Let me just go ahead and submit them for the record, Mr. Chairman, in the interest of time. Thank you.

Mr. BURGESS. The chairman yields back. The Chair thanks the gentleman.

The Chair recognizes the gentlelady from Indiana. Mrs. Brooks, 5 minutes for your questions, please.

Mrs. BROOKS. Thank you, Mr. Chairman. Thank you, Dr. Rucker, for being here.

I also want to add my thanks to Ranking Member Green. As fellow Texans, you two gentlemen have led this subcommittee so admirably. We have gotten so much done, and we are really going to miss you.

With that, Dr. Rucker, I want to elaborate a bit more on the use of smartphone-based apps and obviously your desire to continue to advance that. Are there any additional regulatory changes that would be helpful in further accelerating or incentivizing health record applications?

Dr. RUCKER. I think we are in a very good position with the Cures Act language on that. I think when the rule comes out, and you know, there is obviously public comment and that whole annealing process on the rule. I believe we are going to be in a very good position to have accomplished that, so I am very confident.

Predicting the future, obviously, you know, hard to impossible, but I feel very confident that the language that Congress has put in that and that will—implementing will do a lot there. I think modern technology is very helpful. Having the API stack that the rest of the smartphone economy uses in starting to move healthcare into that is going to be very powerful, and you know, so that allows healthcare to write off the development of all of the rest of the app economy, right.

Historically, part of the challenge of interoperability is we have done it all ourselves with one-off healthcare protocols. You know, if you go to any other computer person and you show them, those guys are like, what, right? I mean, there is just befuddlement. We are trying to move healthcare, you know, with the Fast Healthcare Interoperability resources, the so-called FHIR, into the modern economy stack. We are mindful of the work that is been done, the sharing that is going on. We want to, you know, support and acknowledge that, but over time, and certainly for the smartphone part of it, we believe that is the way to go.

Mrs. BROOKS. So I am hopeful that the new rule that is coming out will address maybe barriers to the app development, but how about with respect to utilization? How about with respect to getting average citizens to begin using it? What comments do you have about what we could do to either incentivise or to encourage its use?

Dr. RUCKER. To me, the absolute as somebody who has built computer software, the only thing that counts is how easy is it to use? How many clicks, how much reading, how much thinking do you have to do? Ease of use is everything in consumer apps. Everything we do in our rulemaking is geared to encouraging ease of use.

Now, as all the other questions have pointed out, you have to balance that against security and privacy, so there is an inherent tension there, but with what we think is an appropriate balance, that is our focus.

Mrs. BROOKS. But these types of apps that are being developed and that are in development and with the rulemaking, they are approved by your organization, correct?

Dr. RUCKER. No.

Mrs. BROOKS. OK. Should there be some additional approval process on the app development necessary to, you know——

Dr. RUCKER. Right. So, these apps are not approved by us or by the FDA, you know, in the current go-around. I think we want to be very, very careful that we don't have further burden on innovation. This is a fast-moving part of the economy. I know working with the White House, we are trying to get investment in this, highlight the investment opportunities.

The Office of American Innovation has been heavily involved in that outreach, so I think we are trying to encourage people to enter the space. I think regulating it, a priority. I don't believe is going to be a public—I don't think that is going to get a public value because I think it is actually very hard to regulate the privacy and security breaches that are coming because a lot of that is the law of unintended consequence.

Mrs. BROOKS. I recently saw a study that Johns Hopkins did concluding that more than 250,000 people in the U.S. die every year due to medical errors, and then also, we obviously know about all of these duplicative tests that can often happen. Do you believe that that access to mobile health records will actually help reduce this number?

Dr. RUCKER. I think it will because I think it allows further clarification, I think better APIs. Part—by no means the only reason for medical errors, but clearly a part of it is just the complexity of what we have out there, any technology that makes it simpler.

Patients are probably the best check on what is going on for their care, right? They are presumably the most interested in it, so having them be able to say "No, I am not on that med," or you know, "Why did you put this diagnosis down?" I think that transparency is essential.

I think the Cures Act provides a vast amount of transparency to patients in healthcare, so I think that is very powerful. The more eyes you have on a problem, I think the better it can be.

Mrs. BROOKS. Thank you. I yield back.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields back.

The Chair recognizes the gentleman from Oklahoma, 5 minutes for your questions, please.

Mr. MULLIN. Thank you, Mr. Chairman, and I also want to thank my colleague from Texas, Mr. Green.

Mr. GREEN. Tough for an Okie to do that.

Mr. MULLIN. It is. It is. But football season is over, and we won, so that matters.

Mr. GREEN. Somehow I thought that might come up.

Mr. MULLIN. Anyway, Mr. Green and I, we have worked together probably more than any other person on the other side of the aisle, and he is going to be missed. He is one of the rarer ones around here that sees it from a perspective, not from a party perspective but from his perspective, so I really enjoy working with him.

Mr. MULLIN. You know what, let's talk—we have talked a lot about privacy, and I have a bill out right now, H.R. 6082, which has to do with redlining part 2, and helps with, in my opinion, the provider getting the information they need.

My colleague from Indiana just brought up that there is obviously a need for doctors to get more adequate information about the patient. Do you feel right now with 42 CFR, part 2, with them being realigned outside of HIPAA, do you think that hinders the provider from getting the adequate information on the individual?

Dr. RUCKER. Well, as you know, it is very controversial. We have had a number of people lobby, you know, come to us on both sides of that coin. I am going to defer to my colleagues at SAMHSA and the deputy secretary. I know the deputy secretary's reading a regulatory sprint for coordinated care, looking specifically at those—the issues around 42 CFR, part 2. So I am going to—because they are the primary agency, I think we are going to defer to them on that.

Mr. MULLIN. Well, I read in your agency's draft clinician burden report published last month that the healthcare providers struggle to navigate health IT privacy regulation governed by 42 CFR, part 2. Is that correct?

Dr. RUCKER. Yes.

Mr. MULLIN. So what exactly do they struggle with, then?

Dr. RUCKER. Well, we have heard as the struggles are around knowing—I think one of the big struggles—there are some others, but one of the big one is knowing who is actually covered, so that the technical language is that providers who provide a specialized class of substance abuse treatment are covered.

But if you are part of a larger entity, right, so if you are a big, you know, delivery system who is covered, right, is that psychiatry, is it just that practice, those boundaries are very hard to navigate for folks, you know, that boundary and that description generates and so people default to just saying, it might all be covered. You know, nobody wants to risk it and so——

Mr. MULLIN. So does part 2 strengthen the patient's care or worsen it, then?

Dr. RUCKER. I think that, you know, again, I am going to defer to SAMHSA. They, I think, will have some data on that. I want to be——

Mr. MULLIN. Well, we already know that there has been accidental deaths because of part 2 not aligned with HIPAA. We are talking about the patient, and we also talked about privacy too.

Dr. RUCKER. Yes.

Mr. MULLIN. But through HIPAA, individuals with heart disease or HIV, do you think they are adequately covered through privacy, through HIPAA?

Dr. RUCKER. I think HIPAA does a great job with privacy.

Mr. MULLIN. So, in your opinion, then, is it right that we separate individuals with mental illness or disorders, or abuse disorders, separate from anybody else's care?

Dr. RUCKER. Well, I think there is an overall goal to get those things integrated, to have, you know, what sort of folks call wholistic care, you know. The specifics I am going to defer to the, you know, specific agency that handles that, but I think there is an overall desire to have integrated care. I think that is just good patient care. All of these things blend together.

Mr. MULLIN. One last question, then. How difficult is it for a provider to access part 2, and what risk comes along with that?

Dr. RUCKER. Well, I think the—the difficulty is not in the access. It is in—it is—you know, the difficulty is the availability.

Mr. MULLIN. Well, they can't just access it. They got to get the patient's—they got to get the patient's permissions, right?

Dr. RUCKER. Yes. Yes.

Mr. MULLIN. So they had to get HIPAA permission——

Dr. RUCKER. Yes.

Mr. MULLIN. So they have to go one step further, and they have to ask for that, right?

Dr. RUCKER. Yes. That is my understanding.

Mr. MULLIN. So if the provider has no reason to ask, doesn't that create a problem right there?

Dr. RUCKER. Potentially, it does.

Mr. MULLIN. Now, what if the patient shows up in the emergency room is unconscious. How many providers automatically access part 2?

Dr. RUCKER. I do not know the answer to that. I can see if there is information on that. I do not have information on that. As a practical matter in the emergency department, if they are unconscious, we try to treat them immediately——

Mr. MULLIN. Well, I know, but——

Dr. RUCKER [continuing]. And part of that will be giving the Narcan. Part of that will be an assumption from any patient far more—we will assume, in many cases that there is an opioid and a standard part of that treatment is to administer Narcan, or some, you know, some version of that on the possibility that that might be the cause. I mean, we administer things like glucose on the thought that maybe the person's hypoglycemic as well.

Mr. MULLIN. So do you think it would improve the patient's care if we could align part 2 and HIPAA?

Dr. RUCKER. I think alignment there, I think that would be helpful.

Mr. MULLIN. Thank you.

I yield back. Thank you, Mr. Chairman.

Mr. BURGESS. The gentleman yields back. The answer to the gentleman's question is yes.

Mr. MULLIN. Both sides of the aisle.

Mr. BURGESS. Chair recognizes the gentleman from Georgia, Mr. Carter, for 5 minutes for questioning.

Mr. CARTER. Thank you. And thank you for being here.

I just want to begin by adding my voice to those who have already talked about the proposed rule on information blocking and just that, you know, it is obviously very critical, we all understand that, but I just wanted to see if you could give me an update. I understand it is out of your hands right now and it is with OMB, is exactly where they are at with it. Do you have any idea when we could look forward to seeing that?

Dr. RUCKER. I wish I could give you specifics. I think they are looking at it. I think we would, you know, we would have to defer to them to—to things. I believe we are close on that. I am not aware of any, you know, insurmountable difficulties or challenges. But I think there is a large checks and balances process here that, you know, is part of—is part of the way things work, our democracy. And I just—as somebody who is in, you know, in a staff agency, I just have to be mindful of that, you know.

Believe me, I share your frustration. I share your frustration. I wish I could tell you exactly what is in it, tell you it was all done, but I,—you know, unfortunately, I can't.

Mr. CARTER. Do you have idea what is in it? I mean, have you——

Dr. RUCKER. I have read it multiple times. I have a very precise idea of what is in it. We have had vast number of discussions with Liz Anthony, who heads our rule-making group. Intimately familiar with the details. Many of the details are quite challenging to put together and, you know, to reflect on the complexity of the American healthcare system. So, yes, I am very familiar with what is in it.

Mr. CARTER. But I am hoping you are optimistic that it is going to help.

Dr. RUCKER. I am extremely optimistic.

Mr. CARTER. OK, good, I am glad to hear that.

I wanted to ask about health provider documentation and the documentation burden. We are all aware of that. In fact, you mentioned in your testimony the ability to address clinical burden, and how burnout especially, has been impacting healthcare professionals. Can you describe some of the efforts that have been made to—to relieve some of the administrative burden?

Dr. RUCKER. Yes. So in the—in the burden report, that we have jointly done with CMS, there are a couple of areas that we are working on. We have discussed simplification of documentation. So one of the specific things, for example, is, you already have a past medical history that hasn't changed, or a family medical history that hasn't changed. You do not need to re-enter it again, would be a very specific thing.

If you have, for example, a resident or a medical student who spends a lot of energy getting a history, you do not have to redocument all of that so that you then have to read it and wade through that much more text on it, some very specific things.

We talked about the prior authorization and work on the technology that might make that a lot simpler. And the promoting interoperability, there is—working with CMS, we have simplified a lot of the provisions around that, tried to sync up between outpatients and inpatients, so these aren't two diametrically opposed things that read differently. If you cross the threshold of the hospital door, I mean, quality and interoperability shouldn't change because you walked one foot into the door—you know, through the door.

Mr. CARTER. What kind of feedback have you gotten? Has it been positive?

Dr. RUCKER. I think we have gotten positive feedback on a number of things on the documentation as Congressman Bucshon mentioned. There were concerns and maybe not a full understanding of how complexity would be paid for, right? You know, how the sickest patients, how the economics of payment for that would work out. There are a number of provisions in there on that.

And I think folks also didn't frankly calculate the amount of money spent on billing to, you know, work these codes through the process. I mean, the—the health—the overhead practices, I think, are spending between 5 and 10 percent, maybe more, of their revenue on billing through these complex coding systems. Much of that is a dead loss to the economy and to the American public.

Mr. CARTER. Absolutely. I am glad you recognize that because that is one of the most frequent concerns that is voiced to me is just how much—how much it is taking, financially, for them to adhere to this. So I am glad to hear you say that.

I am running out of time here, so—but I did want to ask you very quickly about the her reporting program. And I know an RFI was issued for that and released, but there were budgetary concerns. Has that been handled? Are you——

Dr. RUCKER. Well, working within the budget we have, we have contracted out with somebody to start the process of putting, you know, the, you know, that construct together and sorting out what information can be asked to do her reporting, you know, with a goal of giving providers more information on their electronic health record, potential purchases.

Mr. CARTER. Any other hurdles, any other barriers that you have run into in order to implement this?

Dr. RUCKER. I think we are early enough on, that, you know, we probably haven't hit the hurdles. The budget is such that we will—

you know, it is not going to be a comprehensive server, the entire United States, just within the constraints of the budget. But I am confident we are going to get some valuable information that will help folks.

Mr. CARTER. Good. OK. Well, thank you very much.

And thank you for your indulgence, Mr. Chairman. I yield back.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back. I will now yield myself the balance of the time for questions.

Just testing you. I will miss you, too.

Mr. GREEN. Not as much as they will, though.

Mr. BURGESS. How can I miss you if you won't go away?

Dr. Rucker, in preparation for that—and I do thank you for being here—in preparation for this hearing, we had a long time to kind of consider because we have waited for this rule and we kind of ran out of years, so we had to get the hearing in ahead of the rule.

But in preparing for this reading in the Annals of Internal Medicine from November 12, 2018, an article by Atul Gawande, "Why Doctors Hate Their Computers." Let me first stress that I rarely agree with Dr. Gawande on everything. But he does write a paragraph here that I just really thought summed up what our hearing is about today.

He says: Something's gone terribly wrong. Doctors are among the most technology-avid people in society. Computerization has simplified tasks in many industries. Yet somehow we have reached a point where people in the medical profession actively, viscerally, volubly, hate their computers, end quote. True statement, yes or no?

Dr. RUCKER. Yes.

Mr. BURGESS. Yes, it is. And, you know, we hear that—I heard that when I was in Mr. Latta's district, heard it from both doctors and people in the hospital, the medical staff section, about your office and the Center for Medicare and Medicaid Services talks about sharing the goals of reducing physician burden. So can you give us an idea how you are working with CMS along those lines, to reduce physician burden?

Dr. RUCKER. Yes. I mean, I think the root of that problem—and I agree with what was in that article—is that these EMRs have really, first and foremost, grown up as billing systems, right? There has been no automation.

Mr. BURGESS. Bingo.

Dr. RUCKER. Right.

Mr. BURGESS. What he called the tyranny of the ancillaries.

Dr. RUCKER. Yes. So I mean, it is striking to me as somebody who went into this field. I start—the computer science degree coming straight out of residency. I wanted to automate stuff so I didn't have to do scut, which is that, you know, slang word for nonvalue add work that seems to be the bane of residency training. That was my goal.

I mean, I worked in an era when the entire hospital's microbiology results were randomly reported out nonalphabetized. You had to read through every single culture result in the entire hospital to find out if your patient had a urine culture done. So that was the world.

As we have discussed, what we are doing with CMS is trying to be systematic about addressing these things. And so you have seen a couple things. I mean, one I want to highlight is the—the meaningful use program, I think, trying to be a steward of the 30—$35 billion, you know, wanted to have a lot of controls on, is this a full and complete electronic health record. I think we have done that. And now we are really focusing not on that, but on just sort of the interfaces and the burden. I think there is still work to be done in documentation. Some of that is related to fee for service. Some of that, in alternate payment mechanisms, would go away.

I think there is a lot of work to be done in prior authorization, that—so I think there are a number of areas.

Mr. BURGESS. May I ask you a question about that? You did bring up prior authorization and one of the banes of my existence when I practiced was dialing 1–800–California to get permission to do something that I knew was clinically indicated. So it seems like that should just follow then from the data in the electronic record. So if—if an asthma drug is indicated, or a surgical procedure, or an imaging procedure, it should just follow then from the data that is already there, correct?

Dr. RUCKER. Yes. The hope is that these APIs will, in fact, be efficient enough in exposing that information, that these transactions can be greatly simplified, the delivery of the information can be bigged bidirectional so that that whole loop of being on the phone is minimized or goes away, and that may even be a paradigm——

Mr. BURGESS. I prefer it goes away. And only then interacting with the doctor if there is some question as to whether the documentation is complete enough or fulfills all of the requirements.

Dr. RUCKER. Yes.

Mr. BURGESS. That seems like that would be a laudable goal.

I have got other questions, and like others I will submit them for the record. I do appreciate your time. I understand we do have a hard stop. So I will yield back the balance of my time.

And seeing no others Members wishing to ask questions, I do want to thank Dr. Rucker for making time to be here today. Again it has been a long time coming. We have wanted you here on several occasions, but we got you now.

So I would like to submit documents from the following for the record: College of Healthcare Information Management Executives and the American Society for Clinical Oncology.

[The information appears at the conclusion of the hearing.]

Mr. BURGESS. Pursuant to committee rules, I remind Members they have 10 business days to submit additional questions for the record, and I ask the witness to submit his response within 10 days of receipt of the questions.

And then I will just add my voice to the others on the committee, it has been a privilege working with you, Mr. Green.

Mr. GREEN. Most of the time.

Mr. BURGESS. Most of the time. We actually have done some very good work these past 2 years, and it has been a very active session of Congress on the Health Subcommittee. I am not going anywhere, so no one will have to miss me, but we will miss you and wish you success in your future endeavors.

With that, Dr. Rucker, again, thank you, and the subcommittee is adjourned.

[Whereupon, at 11:59 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

With this hearing, this subcommittee will cap off a complete review of the major provisions contained within the bipartisan 21st Century Cures Act of 2016. So far, we have heard from the National Institutes of Health, the Food and Drug Administration, and the Substance Abuse and Mental Health Services Administration. Today, we will hear from the Office of the National Coordinator for Health Information Technology.

In so many parts of our lives technology has allowed us to move data seamlessly and better connect to ease burdens. However, with the transition in the health sector to electronic medical records we have not seen the same results. We hear of limitations in technology functionality, provider burden in documentation, a lack of a robust market to tackle add on technologies, and the lack of the ability to easily share information.

The fundamental value proposition of Electronic Health Record systems is the continuity of evidence-based care, however, patient health data continue to be fragmented and difficult to access for healthcare providers and patients themselves.

The functionality of EHR systems lags behind the technological capabilities presently available, and until we close that gap I do not see how we can truly recognize the potential of clinical registries, payment reform, or health information exchanges.

For these reasons, the 21st Century Cures legislation realized that bedside coordinated care is going to matter the most in delivering new technologies and therapies to patients. Today, we will get an update on the law's implementation.

I know ONC has been able to implement some parts of the law, such as the new Interoperability Committee and the recent draft report on physician burden.

However, some of the pillars of the law remain unimplemented because the needed regulations have not been released. While this update is important despite the lack of regulations, I sincerely hope to see tangible progress soon because every day we wait is another day patients and providers are not able to benefit from some of the most important provisions of the law.

It is my hope that Dr. Rucker you can walk the committee through what you believe the 21st Century Cures Interoperability title can accomplish and how we can unleash the technology revolution that we have enjoyed in so many other sectors of our economy into the healthcare space. There is so much innovation waiting to be unleashed and so many ideas that will lower costs and increase quality. We just need to knock down the artificial walls that stubbornly prevent us from seeing the return on innovation that I think we all know awaits us.

I look forward to your testimony.

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Good morning, I want to thank Dr. Rucker for joining us today to discuss the Office of the National Coordinator's (ONCs) progress in implementing the 21st Century Cures Act.

Since the passage of the HITECH Act of 2009, we've seen an impressive increase in the adoption of electronic health records (EHRs). Today about 96 percent of hospitals and three quarters of office-based physicians use health information technology (HIT) that has been certified by ONC. That represents about a ninefold increase in hospitals with basic EHR technology since 2008, prior to the HITECH Act.

While this is impressive progress, there are still some hospitals and physician offices, particularly small or rural providers, who are still operating with volumes of paper files and outdated fax machines. This is simply unacceptable with all of the technology available today, and we must continue to find ways to incentivize and help these providers to adopt EHRs.

While we've made significant progress in upgrading the way patient data is managed, more work is needed in order to make EHRs more useful and accessible to patients and providers. Interoperability, or the ability to securely exchange electronic health information, remains a challenge today, but the Cures Act has helped put us on the path toward addressing it.

I'm pleased to see that ONC has made substantial progress in implementing Cures Act provisions by releasing a draft Trusted Exchange Framework and Common Agreement (TEFCA) and partnering with the Office for Civil Rights to create new resources to help people better understand their right to access their health records. Clear rules of the road for exchange and informed consumers are necessary for ensuring secure and appropriate transfers of patient data.

I'm also encouraged to hear that ONC plans to release an updated draft of TEFCA for public comment. Given the progress the private sector has made in this area, it's important that we glean any lessons that they learned from their efforts. We should ensure that ONC's work compliments those efforts as much as possible.

The Cures Act also provided the Office of the Inspector General (OIG) with the tools necessary to investigate and penalize those who are information blocking. However, before the OIG can begin their work ONC must first identify cases that do not constitute information blocking. I had hoped that a proposed rule on information blocking and certification requirements would have been released by now. However, I'm encouraged by ONC's statements that the rule is in the final stages of development. I look forward to the release of this important proposed rule.

Finally, I want to take a moment to thank my friend and colleague Congressman Gene Green for his many years of service on the Energy and Commerce Committee and particularly for his leadership of the Health Subcommittee these past 4 years. During his tenure as ranking member, Congressman Green has helped lead this committee to major legislative achievements like the Cures Act and has been a tireless advocate for the Affordable Care Act. Gene is a thoughtful legislator and a good friend. He always sought consensus, often found it, and never stopped trying no matter how hard it could be. I'm incredibly thankful for his leadership, and he will be dearly missed on the committee next year. I wish him nothing but the best as he retires from the House and this committee.

CHiME
College of Healthcare
Information Management Executives

Statement of the College of Healthcare Information Management Executives

House Committee on Energy and Commerce
Subcommittee on Health

Hearing on "Implementing the 21st Century Cures Act: An Update from the
Office of the National Coordinator"

2322 Rayburn

December 11, 2018

The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to submit a statement for the record for the December 11, 2018, hearing entitled, "Implementing the 21st Century Cures Act: An Update from the Office of the National Coordinator." We appreciate the Committee's leadership and continued oversight of the landmark 21st Century Cures Act.

CHIME represents more than 2,800 chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs) and other senior healthcare IT leaders at hospitals, clinics and other health organizations nationwide. CHIME members are responsible for the selection and implementation of clinical and business systems that are facilitating healthcare transformation through technology.

Technology adoption and robust data sharing are vital to enhancing the quality of care and efficiency of the nation's healthcare system. Our members have extensive experience implementing technology that must interoperate with dozens of independent systems, ranging from diagnostic imaging and biomedical devices to financial and remote access systems. The passage and ongoing implementation of the 21st Century Cures Act presents policymakers and the industry with the opportunity to leverage the potential of health information technology to improve patient outcomes and accelerate access to lifesaving treatments.

Since enactment of the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), the healthcare industry has made a significant shift in the way technology is used to treat and engage with patients. The myriad of provisions included in the 21st Century Cures Act such as reducing administrative burdens resulting from health IT, the Trusted Exchange Framework and Common Agreement, the EHR Reporting Program, the Health IT Advisory Committee (HITAC), the definition of what does not constitute information blocking and reports on patient access and patient matching will prove to have significant impacts on the health IT and healthcare delivery ecosystem in the future.

Administrative Burden
Policies ensure providers have access to technology necessary to facilitate their success in new payment models and drive care improvements for patients while ensuring the Administration pursues reasonable policies that will reduce provider burden, facilitate greater care coordination, and direct the maximum amount of attention on the care delivered to patients. A focus on improved outcomes (rather than process measures), facilitated by interoperability, will position providers for success in new payment programs while enabling the delivery of better care to patients.

Technical innovation must flourish but it is also important to keep in mind the importance of fostering the connection between patients and their clinicians. HHS must be mindful of keeping patients and caregivers connected to their providers so technology can be used to deliver better care, not detract from patient care. For instance, the Promoting Interoperability program has unwittingly incentivized clinicians to spend less time with their patients and more time in front of their computer screens. If innovations cause the distance between clinicians and their patients to grow, technology may be perceived as a barrier rather than a solution.

On November 20, 2018, the Office of the National Coordinator for Health IT (ONC,) along with the Centers for Medicare and Medicaid Services (CMS,) published the draft "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs" as requested by the 21st Century Cures Act. This strategy articulates the Administration's desire to reduce some of the regulatory and administrative burden that clinicians shoulder resulting from health IT rules and regulations. The inclusion of recommendations pertaining to prescription drug monitoring programs (PDMPs) and electronic prescribing of controlled substances (EPCS) are timely and welcomed as the nation grapples with how to leverage technology solutions to curb the opioid epidemic.

Trusted Exchange Framework and Common Agreement
ONC issued a draft of the Trusted Exchange Framework and Common Agreement (TEFCA) on January 5, 2018, with an additional opportunity to comment expected imminently. In the January draft, it was clear ONC's intent as they crafted the TEFCA was to build from existing work already underway aimed at speeding interoperability. However, the draft agreement would create an entirely new national exchange network and it is not entirely clear how this will impact existing agreements, but it does appear to require a substantial amount of change processes. We recommend that ONC work collaboratively with the National Institute of Technology (NIST) as required under 21st Century Cures Act to pilot test TEFCA.

TEFCA is intended to advance interoperability across the healthcare continuum. Some provider segments, including but not limited to those delivering post-acute care (e.g., skilled nursing facilities, home health agencies) and behavioral health, were not included in prior programs that incentivized transition to electronic health records (EHRs). These segments of the healthcare sector continue to lag acute care providers in EHR utilization and in certified EHR technology (CEHRT) adoption. If we are to speed interoperability, all sectors of the healthcare system where patients receive care must be able to exchange data. Population health management and value-based payment implementation for an aging population and other populations for whom healthcare needs can be more complex, will face continued hurdles until post-acute care and other providers across the healthcare ecosystem reach health IT sophistication levels comparable to those of acute care. More attention to this facet of the interoperability conversation is warranted and requires ONC to elaborate on their vision for including more provider types. Rather than creating more hard mandates, collaborative solutions like pilot projects through the Center for Medicare and Medicaid Innovation (CMMI) have merit.

The intrinsic value of interoperability is undeniable, but providers have concerns about being able to put into practice what was outlined under the draft TEFCA. Therefore, each CIO will find him or herself in the spot of determining whether participation makes sense for his or her organization. The feasibility of revising all data exchange agreements on such a tight timeline, as proposed, is problematic. The complexity and aggressive timeframes could discourage some organizations from participating in TEFCA, at least initially. Also, the critical mass of TEFCA participation necessary for benefit to outweigh burden for most participants has not been discussed nor has ONC shared any projections for TEFCA uptake.

The 21st Century Cures Act indeed directs ONC to define interoperability to mean that information be exchanged without "special effort on the part of the user." The law also calls for enhanced certification requirements to accommodate this. The draft Framework did not address this topic, and it appears that this effort will be left to EHR vendors.

The TEFCA draft clearly stipulates that individual choices about access to and sharing of their data be provided at no cost and be respected. It appears that ONC anticipates that consent management will be managed at the Health Information Network (HIN) level, but few details are provided. The process of verifying consent and the maintenance of individual consent choice records in a nationwide data exchange environment offers considerable challenges. The forthcoming TEFCA draft should address Qualified Health Information Network (QHIN) involvement, Recognized Coordinating Entity (RCE) monitoring, and ONC oversight of data-sharing consent. The frequency with which consent choices must be updated should also be addressed by ONC to balance currency, accuracy, and administrative burden. Boundaries and approaches for handling of the complexity superimposed by varying state privacy laws and regulations deserve full consideration. We recommend ONC clearly address how they anticipate consent to be managed under TEFCA.

Further, the consequences to an organization of not participating are unclear; for example, could choosing not to participate be construed as data blocking? ONC must clarify how they envision the interface between TEFCA participation and data blocking regulations during the comment period on the data blocking rule. Also, we are unclear about what the impact to providers will be if some HIEs in their region join TEFCA while others do not. ONC must clarify this as well.

EHR Reporting Program

ONC and Congress have recognized the need for more transparency for EHR end-users, through the establishment of the EHR Reporting Program. ONC published a Request for Information (RFI) on the reporting program on August 24, 2018, and many stakeholders, including CHIME, suggested that what was proposed in the RFI is too onerous for the providers as purchasers of these systems even if it helps them evaluate products.

Vendors should be developing products which are inherently more usable and interoperable and the burden for ensuring this occurs should fall less on providers and occur prior to these systems even reaching the hands of clinicians. As ONC monitors vendors' interoperability capabilities they should consider establishing benchmarks and leverage existing industry sources to monitor progress.

Information Blocking
Effective April 1, 2016, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) required both clinicians and hospitals to attest they are not "data blockers." Accordingly, in this rule CMS calls on providers to demonstrate that they have not knowingly and willfully taken action (such as disabling functionality) to limit or restrict the compatibility or interoperability of CEHRT. Congress and the Administration are to be commended for their interest in combatting information blocking practices within the healthcare industry. There is no place for data blocking in healthcare and patients have a right to timely and secure access to their health information.

Unlike the current CMS information blocking attestation mandate, forthcoming rulemaking from the ONC and Office of the Inspector General (OIG), must recognize the limitations of current technology, regulatory barriers, and challenges some resource-strapped providers face. In terms of limiting or restricting the compatibility or interoperability of CEHRT, a note of caution must be heeded relative to the legal complexity that can ensue depending on how "not information blocking" is defined. Technology, social, economic and community factors must all be accounted for and meticulously evaluated when determining what constitutes "information blocking." The cost of joining HIEs, interface fees and application programming interface development costs must be factored into the forthcoming rulemaking.

Robust information exchange and nationwide interoperability can flourish only once we can confidently identify a patient across providers, locations and vendors; however, that is not happening today. The importance of a coordinated national approach to linking patients to their healthcare data must be underscored. Ensuring that patients are positively identified and matched to their records is a linchpin to increasing interoperability and improving the quality and safety of patient care, especially in a highly digitized environment. When clear, enforceable standards are in play and patients can be safely and securely matched to their data to facilitate exchange, acts of blatant information blocking will become apparent.

Standards-based Interoperability
Among the charges of the Health IT Advisory Committee (HITAC) created by the 21st Century Cures Act is to focus on standards to facilitate interoperability. While a focus on data standards may seem overly simplistic, a more defined technical infrastructure is needed to catalyze innovations in digital health, now just as much as when the 21st Century Cures Act was enacted. Improved data standards will help ensure the data exchanged is valuable and useful to the receiving party. Our members feel that without this, we are destined to repeat mistakes by hoping the mere exchange of data will indeed result in improved outcomes. Without the ability for disparate systems to recognize and successfully use data, we are simply moving data, and in a very difficult and expensive way. For example, the current attempts by third-party developers to force electronic health record vendors to create one-off, custom Fast Healthcare Interoperability Resources (FHIR) interfaces, rather than implementing standardized FHIR interfaces is only adding to the difficulty and cost of interoperability – not improving it. To cure what ails this, a single set of named standards must be used by all parties.

Through the passage of the 21st Century Cures Act[1] Congress declared their interest in an interoperable health IT infrastructure. We recognize the work underway at ONC to tackle these challenges, nonetheless barriers remain and maintaining the status quo will stifle future progress. It's imperative that ONC continue to leverage relationships with the private sector to capitalize on the progress made to date across the industry. Standards-based interoperability

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[1] The 21st Century Cures Act (HR 34), 114th Congress. https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf

should be a top priority for ONC. Understanding how the lack of ubiquitous interoperability and meaningful data exchange is impeding care delivery and making necessary policy recommendations must be a priority as they promulgate TEFCA, as well as forthcoming rulemaking pertaining to information blocking. The Committee should direct ONC to ensure that the instruction to focus on standards and implementation specifications included in the statute is executed.

Patient Matching Report

Today patients and care providers are missing opportunities to improve people's health and welfare when data about care or health status is not easily available. The concept of a longitudinal healthcare record, which necessitates interoperability, should reflect the patient's experience across episodes of care, payers, geographic locations and stages of life. It should consist of provider-, payer- and patient-generated data, and be accessible to all members of an individual's care team, including the patient, in a single location, as an invaluable resource in care coordination and for public health purposes. Without a standard patient identification solution, the creation of an accurate longitudinal care record is simply not feasible.

Congress acknowledged the lack of a national solution to identifying patient is an interoperability and patient safety issue in the 21st Century Cures Act. Congress called on the Government Accountability Officer (GAO) to review policies and activities at ONC and other relevant stakeholders to ensure appropriate patient matching to protect patient privacy and security and ongoing efforts related to those policies and activities within two years of enactment. Further, Congress requested GAO to examine if ONC could improve patient matching by taking additional steps leveraging their current authorities. The report is forthcoming; however, ONC must continue to evaluate ways to improve patient identification and matching in the absence of a national patient identifier.

Application Programming Interfaces (APIs)

Cybersecurity attacks are highly disruptive and can be crippling to healthcare entities, as illustrated by the WannaCry and Petya ransomware attacks in 2017. The attacks impacted more than a dozen hospitals and countless other entities spanning the globe, reaching a reported 150 countries. Healthcare is deemed a critical infrastructure by the Department of Homeland Security (DHS) and as such, patient safety and patient data should be viewed as a public good; protecting those things should be a national priority.

Concerns remain with privacy and security of patient information with the use of application programming interfaces. Cybersecurity threats and emerging challenges associated with the use of APIs pose real concerns and our members continue to worry about the release of data to third parties at the request of patients without their clear understanding of how their data could be used. Recent consumer data breaches rooted in API weaknesses raise security concerns for protecting healthcare data.

As payment and delivery system reforms propel us towards greater connectivity, new vulnerabilities have arisen. Without proper safeguards, the safe and secure transmission of sensitive data will continue to be a challenge and will hinder efforts to care outcomes. We must ensure the implementation of stringent privacy and security standards.

As the Committee monitors the implementation of the 21st Century Cures Act, we urge Members to ensure that a standards-driven infrastructure anchored by a robust national patient matching strategy remains a priority as outlined in the statute.

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December 11, 2018

The Honorable Michael Burgess, MD
Chairman
Energy and Commerce Committee
Subcommittee on Health
U.S. House of Representatives
Washington, DC 20515

The Honorable Gene Green
Ranking Member
Energy and Commerce Committee
Subcommittee on Health
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Burgess and Ranking Member Green,

On behalf of the American Society of Clinical Oncology (ASCO), thank you for your work on 21st Century Cures, a landmark piece of legislation which will help accelerate the discovery, development, and delivery of promising treatments to cancer patients across the country. ASCO applauds the Energy and Commerce Committee's Subcommittee on Health for examining the implementation of provisions of this important healthcare law in its hearing entitled "Implementing the 21st Century Cures Act: An Update from the Office of the National Coordinator."

ASCO, on behalf of our members and along with other stakeholders in organized medicine, has been monitoring the implementation of legislation stemming from the 21st Century Cures Act and providing input and comments as rules are implemented. As this legislation was being drafted, we submitted statements to the Committees of jurisdiction, and we continue to provide feedback to the relevant agencies as they implement the rules governing HIT use and development.

Despite our many steps forward in this area, our members are still plagued by a lack of interoperability between electronic medical records and other forms of health information technology. These types of technology hold great promise for improving and enhancing patient care, especially in the realm of care coordination and quality improvement. To further enhance healthcare quality, we should move with urgency towards realizing the vision of seamlessly integrated health information, easily and securely accessible to all patients. The Cures Act is instrumental in these efforts, as it addresses some of the technical limitations and business practices that may contribute to the current limitations of true interoperability.

In January, the Office of the National Coordinator of Health Information Technology (ONC) released its "US Core Data for Interoperability" (USCDI), which specifies a common set of health care record data classes required for health data interoperable exchange. We support ONC's work in this area, and note that by necessity, these data classes initially tend to be broad and encompassing of primary care; this leaves open an opportunity for specialty societies and other interested stakeholders to engage in the development of data classes, elements, and terminology needed by smaller groups of specialty physicians.

Under our CancerLinQ (CLQ®) subsidiary, ASCO is currently developing a set of "Minimal Common Oncology Data Elements" (M-CODE); this set of data elements is envisioned by ASCO to form the basis of an initial parsimonious set of necessary data that should populate all electronic health records (EHRs) serving patients with cancer. Adoption of these data elements, which are being developed by experts in the fields of oncology and informatics, would greatly streamline the exchange of basic needed data necessary for oncologists, and we look forward to collaborating with ONC wherever possible to encourage consideration and adoption of these elements when they are finalized.

Our members also continue to report significant burden associated with EHR documentation, "check box" requirements, and various reporting requirements across different payers, including Medicare. We were therefore pleased to note the November release of a draft "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs" for public comment by the US Department of Health and Human Services. This work, led by ONC, in partnership with the Centers for Medicare & Medicaid Services (CMS), was required by Congress under the 21st Century Cures Act, and includes recommendations aimed at reducing the administrative burden related to HIT use on clinicians. Again, we look forward to providing our comments to ONC for consideration.

Finally, we are eagerly anticipating the release of ONC's proposed rule titled, "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program." This proposed rule has been under review at the Office of Management and Budget (OMB) since September 17th of this year, and we would encourage its earliest possible release so that all affected stakeholders may engage with ONC and other agencies as necessary to provide iterative feedback and suggested improvements to this rule, which will have a significant impact on the broader sharing of patient health information.

We commend the Subcommittee for its leadership and bipartisan work on this issue. We look forward to working with the Subcommittee as implementation of 21st Century Cures continues. If you have any questions or would like more information, please contact Amanda Schwartz at Amanda.Schwartz@asco.org.

Sincerely,

[redacted]

Clifford Hudis, MD, FACP, FASCO
Chief Executive Officer, American Society of Clinical Oncology