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IMPLEMENTING THE 21ST CENTURY CURES ACT: AN UPDATE FROM ONC

TUESDAY, DECEMBER 11, 2018

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:15 a.m., in Room 2322, Rayburn House Office Building, Hon. Michael Burgess, M.D. [chairman of the subcommittee] presiding.

Present: Representatives Burgess, Guthrie, Upton, Blackburn, Latta, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Carter, Green, Engel, Matsui, Castor, Lujan, Kennedy, Cardenas, 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; James Paluskiewicz, Professional Staff, Health; Brammon 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.

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.

It is on? I am just not speaking into it. In 2018 -- is it on now? Yeah.

Ms. DeGette. It is just that I am so far away.

Mr. Burgess. Come on up here. There is space on the top dais.

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 committee to which I say good riddance because they were quick to chase any issue to spark their attention. Instead, new interoperability -- 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 of 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 after -- 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:]

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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 Coordinators 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:]

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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.

[The prepared statement of Ms. DeGette follows:]

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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.

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.

[The prepared statement of Mrs. Blackburn follows:]

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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, U.S. 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:]

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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. Yeah. 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 consultations. 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 is 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 block chain technology, just trying to figure that out. So if you look at hardware and software, regulatory reform, and completely new technologies like block chain, 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 is 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. Okay. 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. Yeah. 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. Okay. 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 is many, many layers to some of these API's that even if people give some consent, they really don't understand.

Dr. Rucker. Yeah. 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. Okay.

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 data is definitely --

Ms. Matsui. Right.

Dr. Rucker. -- a 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 is 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 is other cost drivers. I think security is a large part of what's driving that. I think there is 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. Yeah. 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.  5 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.  Yeah.  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 is 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, multi-layered 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. Okay. 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 okay. 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. 5 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. Yeah. 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 is 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 yield back? The gentleman yields back.

The Chair thanks the gentleman. The Chair recognizes the gentlelady from California, Ms. Eshoo. 5 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. -- 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 is A students, and there is 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. Okay. 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 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 low-hanging 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. Yeah. 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. Okay. 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. Okay. 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 John 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.

RPTR MOLNAR

EDTR HUMKE

[11:40 a.m.]

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 -- 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. Yeah.

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 -- there is a 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. Yeah.

Mr. Mullin. So they had to get HIPAA permission --

Dr. Rucker. Yeah.

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. -- 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. Okay, 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. Yeah. 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 -- 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. Okay. 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. Yeah, 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. Yeah. 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 Health Care Information Management Executives, and the American Society for Clinical Oncology.

[The information follows:]

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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 will -- we actually have done some very good work this 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 12:00 p.m., the subcommittee was adjourned.]