



To: CHIME Members
From: Public Policy Staff
Date: December 11, 2018
Subject: Recap of the House Energy and Commerce Health Subcommittee Hearing, "[Implementing the 21st Century Cures Act: An Update from the Office of the National Coordinator](#)"

Key Takeaways:

- Timing of the "Information Blocking" rule release is uncertain, but expected to be soon
- Committee members are disappointed in the lack of progress on interoperability to date
- Significant interest exists across the Committee in the privacy and security capabilities of open application programming interfaces (APIs)

Witness: [Dr. Don Rucker](#), National Coordinator for Health Information Technology, Department of Health and Human Services (HHS)

Committee Attendance: Subcommittee Chairman Michael Burgess (TX), *Subcommittee Ranking Member Gene Green (TX), Diana DeGette (CO), Marsha Blackburn (TN), Brett Guthrie (KY), Doris Matsui (CA), Bob Latta (OH), Morgan Griffith (VA), Larry Bucshon (IN), Anna Eshoo (CA), Bill Long (MO), Eliot Engel (NY), Gus Bilirakis (FL), Susan Brooks (IN), Markwayne Mullin (OK), Buddy Carter (GA), Richard Hudson (NC), Joe Kennedy (MA), Tony Cardenas (CA), Fred Upton (MI), Cathy Castor (FL)*

Summary:

On December 11, 2018, the House Committee on Energy and Commerce Subcommittee on Health held a hearing entitled, "[Implementing the 21st Century Cures Act: An Update from the Office of the National Coordinator](#)."

Subcommittee Chairman Michael Burgess (R-TX) opened the hearing citing that EHRs, improving access to patient data and open APIs will bring healthcare into the 21st Century. He highlighted key health IT provisions of the 21st Century Cures Act to be: provider burden reduction, common principles for networks (Trusted Exchange Framework and Common Agreement [TEFCA]), health IT advisory committee (HITAC) and patient access to data. He reminded the Committee that the law prohibits information blocking and expressed his disappointment that two years after passage the rules are not yet released.

Ranking Member Gene Green (D-TX) commented on the high electronic health record (EHR) adoption levels in hospitals and physician practices but said there is a long way to go to ensure EHRs are as useful as possible. He expressed his support that ONC is undergoing a rigorous comment process for TEFCA and said that patient education on who their data can and should be share with is needed.

Congresswoman Diana DeGette (D-CO) reminded the Committee that the 21st Century Cures Act was signed into law nearly two years ago. She expressed interest in learning what has been working and what can be done to improve the health IT ecosystem and interoperability.

Congresswoman Marsha Blackburn (R-TN) mentioned the presence of healthcare entities in Tennessee. She highlighted the Center for Medical Interoperability and the SOFTWARE Act provisions of the 21st Century Cures Act.

Dr. Rucker summarized his written comments citing ONC's work on quality, safety and efficacy of health IT and the need to increase the value of EHRs. He expressed his desire for patients to have their medical records and to be able to shop for care on their cell phones. He discussed ONC's work with CMS on the [draft strategy to reduce provider burden](#) stemming from health IT. He acknowledged industry security and privacy concerns stemming from APIs but said security incidents in healthcare often result from password issues or lack of patched systems. He discussed payer data needs. He also discussed the limited interoperability progress for mental health and behavioral health providers and said local health information exchanges (HIEs) are best positioned to help these providers. He closed by saying ONC has made great progress implementing the 21st Century Cures Act.

Congresswoman Blackburn asked about mobile health (mhealth) apps and how they may include sensitive information. She asked how Health Insurance Portability and Accountability Act (HIPAA) and privacy should evolve to accommodate the proliferation of mhealth apps.

Dr. Rucker said that there are mhealth apps that do touch sensitive information and many that don't. He said he doesn't think there needs to be any changes made to HIPAA to accommodate the app economy, and that technology and enriched consent will address any issues.

Ranking Member Green asked what has been done to reduce clinician burden. He also asked what research went into the forthcoming information blocking rule.

Dr. Rucker highlighted ONC's work with CMS on the draft strategy to relieve administrative burdens. He pointed to CMS' simplified Promoting Interoperability Program regulations and highlighted the recent changes to clinician documentation. In response to the information blocking question, Dr. Rucker cited the complexity of accounting for all of the health information generated for patient care, the need to understand the patchwork of state laws and the rights of patients to access their information and the charge structure for obtaining their data.

Congressman Brett Guthrie (R-KY) said he is working with Congresswoman Matsui on blockchain policies. He asked about the future of healthcare and how sensitive information is being protected. He also asked about how ONC is working with the payer community to work toward a quality-focused health system.

Dr. Rucker responded saying that technology is available to help with authentication and authorization. He said they don't want to put out specific directives or rules concerning security so as to not make healthcare a target. He also discussed challenges with payers obtaining clinical data and suggested current work with HL7 FHIR will help with getting data for patient populations.

Congresswoman Doris Matsui (D-CA) called attention to the importance of telehealth. She asked about what ONC is doing to help healthcare providers concerning cybersecurity as more data sharing is encouraged. She also asked what ONC is doing to help patients understand that when sharing data with other apps via APIs that their data is no longer covered by HIPAA.

Dr. Rucker said the biggest challenge is complexity, ONC tries to be mindful of the complexity. He said there is a lot of protection with open APIs and existing standards to authenticate. In response to the question about patient data not covered by HIPAA, he said they are pushing people to access their data

through their portal so that will help with user authentication. He said ONC is working with Substance Abuse and Mental Health Services Administration (SAMSHA) on mental health issues.

Congressman Bob Latta (R-OH) cited the [Energy and Commerce Cybersecurity Strategy Report](#) released last week and asked how HHS is making sure systems get patched and vulnerabilities get addressed. He asked if ONC puts information out in the event of a breach.

Dr. Rucker said that awareness is growing in the sector and pointed to the security risk assessment that is mandatory under the Promoting Interoperability Program. He said that providers are moving to cloud-based solutions for security reasons. He said ONC does not directly put information out for providers during an incident; HHS has a strategic operations center. He also said HHS is working with global partners.

Congresswoman Diana DeGette (D-CO) said that a concern when working on the Cures legislation was how to improve interoperability and the advances from the bill wouldn't be useful unless interoperability is addressed. She echoed concerns about interoperability not being further along. She asked what the biggest impediments are to interoperability and how Congress can help move it forward. She also asked when the final rule is expected.

Dr. Rucker cited the complexity of the human body and the volume of data generated contributes to the challenges. He said APIs are a powerful component; they serve as an end point for patients to connect to and cited Apple as an example of leveraging APIs. He said Cures was comprehensive and further Congressional action isn't necessary. He reminded the Committee that the information blocking rule is in clearance at OMB and was optimistic it would be released soon.

Congressman Morgan Griffith (R-VA) voiced his disappointment that the rules are not yet public.

Congressman Larry Bucshon (R-IN) said he hopes APIs will help reduce burden as he remains concerned about clinician burnout, sharing his personal experience as a physician. He asked if APIs would help make EHRs more usable in a clinical setting. He voiced concerns about code consolidation and referenced CMS' Patients Over Paperwork Initiative. He also expressed concerns about cybersecurity and discussed the need for broader education on proper password management.

Dr. Rucker said ONC is working with CMS to simplify documentation and is working on a clinical quality language. He also referenced the security risk assessment in Promoting Interoperability as well as efforts with the Office for Civil Rights on patient access to their medical records.

Congresswoman Anna Eshoo (D-CA) reminded the Committee that she is responsible for the legislation that established ONC in statute, which also addressed EHR interoperability, and voiced her displeasure that we still have interoperability issues. She said it is unfortunate that Dr. Rucker is testifying in a state of limbo because the rules aren't out. She said she has seen the Apple health app. Cures was important because it requires health systems to make data available. She asked how they are addressing the need for additional privacy and security caused by API adoption. She asked Dr. Rucker to grade interoperability. She also asked what was missing from Cures.

Dr. Rucker said that the upcoming Cures rule at OMB will address API security; it will be part of the CEHRT rule. APIs will use the industry standard for security. The rule will help make progress to adopt provider APIs. He gave a "C-" for an interoperability grade. He said Cures was thoughtful and well put together and further action isn't necessary.

Congressman Bill Long (R-MO) asked what the main driver of healthcare costs is. He asked if there are health IT usability problems.

Dr. Rucker said documentation is a major burden because of the fee for service model, a reverse stimulus. He also cited prior authorization as an issue, as well as, quality reporting and prescription drug monitoring programs (PDMPs) as burdens, saying PDMPs should be integrated into the record. On usability, he said the EHR Association is working on standardizing things. He also said ONC is working with CMS to make quality measurement more real.

Congressman Eliot Engel (D-NY) referenced the [GAO report](#) on patient access to medical records, citing concerns about patients incurring high references when requesting their medical records. Patients also don't know they can challenge providers to get access to their data. He asked what patient education is occurring.

Dr. Rucker said that by law patients are entitled to electronic access to their data, they shouldn't be charged for it. APIs will help patients get their records on their smart phones. He said that with more APIs will come more patient awareness.

Congressman Gus Bilirakis (R-FL) called attention to the more than \$35 billion made available for health IT, designed to help providers and the implementation was far from perfect. He reminded the Committee that behavioral health providers were not eligible for incentives. He asked what ONC is doing to enable physical therapists and other providers to satisfy EHR requirements.

Dr. Rucker cited the SUPPORT Act and the potential for the Center for Medicare and Medicaid Innovation (CMMI) to pursue demonstration projects for EHR incentives for behavioral health providers. He said that regional HIEs can help to share data among all providers. He said Admission, Discharge and Transfer (ADT) must be simplified, but many providers don't have the software today. In areas where technology isn't certified, he said standards are necessary and ONC is doing lots of standards work and cited the Interoperability Standards Advisory.

Congresswoman Susan Brooks (R-IN) asked if there are any regulatory changes needed to accelerate or incentivize smart phone-based apps. She asked how we can get the average citizen to begin using mhealth apps. She asked if there should be additional approval processes for mhealth apps. She cited a medical error study and asked if apps will help reduce deaths.

Dr. Rucker said we are in a good position and was confident the Cures language will do a lot. Modern technology will be helpful to move healthcare into the modern economy stacks, especially leveraging FHIR. He said we need to address ease of use and that needs to be balanced with privacy and security. He said there should not be any additional regulation, by ONC or FDA. He said the Office of American Innovation has been heavily involved in efforts to advance mhealth apps. He said technology will make things simple and will make healthcare more transparent and will reduce errors.

Congressman Markwayne Mullin (R-OK) raised [H.R. 6082](#), which would help providers get the information they need as doctors need more information about patients. He asked if the misalignment of Part 2 with HIPAA hinders providers getting information about HIPAA. He asked if it would be helpful to providers if Part 2 was aligned with HIPAA.

Dr. Rucker initially deferred to SAMHSA on Part 2. He said HIPAA does a great job with privacy and doesn't warrant updates. After a series of follow-up questions, he concluded that aligning Part 2 with HIPAA would be helpful.

Congressman Buddy Carter (R-GA) asked when we should expect the information blocking rule and what is in the rule. He inquired about healthcare provider documentation and efforts to relieve administrative burdens. He also asked about the EHR Reporting Program.

Dr. Rucker said that he defers to OMB on the rule. He has read the rule multiple times and believes that it will help. He said ONC has worked with CMS on simplifying documentation. On the EHR Reporting Program, he said that ONC has contracted it out and is putting the construct together and beyond budget, hasn't encountered other hurdles.

Subcommittee Chairman Michael Burgess (R-TX) closed out the hearing citing a study about why doctors dislike computers.

Dr. Rucker said CMS and ONC share goal of reducing administrative burdens. He said EHRs were built as billing systems. He said the Meaningful Use program tried to be the steward of what is a complete health record. He said not we need to focus on interfaces and burden. He also discussed prior authorization and hopes that APIs will simplify transactions and become bidirectional.

Useful Links:

- [Hearing Background Memorandum](#)
- [Hearing Recording](#)
- [CHIME Statement for the Hearing Record](#)
- [CHIME TEFCA Response](#)
- [CHIME EHR Reporting Program Response](#)
- [21st Century Cures Health IT Provisions Summary Chart](#)
- [21 Century Cures Health IT Provisions Implementation Timeline](#)