U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

December 9, 2018

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled, "Implementing the 21st Century Cures Act: An Update from ONC."

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Tuesday, December 11, 2018, at 10:15 a.m. in 2322 Rayburn House Office Building. The hearing is entitled, "Implementing the 21st Century Cures Act: An Update from the Office of the National Coordinator."

II. WITNESS

- Donald Rucker, M.D., National Coordinator for Health Information Technology, U.S. Department of Health and Human Services.

III. BACKGROUND

The *21st Century Cures Act* (Cures) was signed into law on December 13, 2016.[1] Enactment of Cures was the culmination of a bipartisan, multi-year effort by Congress to modernize the cycle of discovery, development, and delivery of innovative medical products.

On November 30, 2017, the Subcommittee on Health held its first Cures implementation hearing, focusing on research and development. Since that time, additional Cures oversight hearings have focused on the law's mental health initiatives[2] and provisions being implemented by the Food and Drug Administration (FDA),[3] and the National Institutes of Health (NIH).[4] This hearing will complete the oversight of Cures implementation for the 115th Congress by focusing on the Office of the National Coordinator for Health Information Technology (ONC). Members will have the opportunity to learn more about health information technology (HIT) and the work ONC has done in implementing Cures.

A. The Health Information Technology for Economic and Clinical Health Act (HITECH ACT)

The Health Information Technology for Economic and Clinical Health Act, or HITECH Act, passed in 2009 as part of the American Recovery and Reinvestment Act of 2009.[5] The

[1] 21st Century Cures Act, Pub. L. No. 114-255.
[2] https://energycommerce.house.gov/hearings/21st-century-cures-implementation-examining-mental-health-initiatives/
[3] https://energycommerce.house.gov/hearings/implementing-21st-century-cures-act-update-fda-nih/
[4] https://energycommerce.house.gov/hearings/21st-century-cures-implementation-updates-from-fda-and-nih/
[5] American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5.

HITECH Act encourages the adoption and use of electronic health records (EHRs) by giving providers monetary incentives for demonstrating meaningful use of EHRs, and, after 2015, penalties for not using certified EHR technology. The HITECH Act created three separate categories of providers—physicians, acute care hospitals, and critical access hospitals—each with different payment and penalty schemes. These Medicare providers could receive payments to adopt EHR technologies between 2011 and 2014. Physicians who did not adopt qualifying technology by the end of 2014 and hospitals that did not adopt qualifying technology by the end of FY 2014 face the following penalties:

Physicians **Payment Reduction**	*Acute care hospitals* **Market Basket (MB) Update reduction**	*Critical access hospitals (CAHs)* **Reimbursement Rate Reduction**
Payment reduction: 2015: 1% 2016: 2% 2017 and later: 3%	FY 2015: • 25% for failure to report required RHQDAPU quality data • Remaining three-quarters by 33% o FY 2016: 67% o FY 2017 and later: 100%	FY 2015: 100.66% FY 2016: 100.33% FY 2017 and later: 100%

The HITECH Act also expanded Health Insurance Portability and Accountability Act (HIPAA) protections for these technologies, increasing the requirements for responses to breaches of patients' health information and corresponding penalties and enforcement mechanisms.

The ONC also was established in the HITECH Act to manage and coordinate nationwide efforts to improve and implement HIT. A HIT Policy Committee was formed to provide recommendations to ONC on policy ideas to advance our national HIT infrastructure. Similarly, a HIT Standards Committee was formed to recommend implementation standards and certification criteria.

B. HIT Provisions of 21st Century Cures Act

As the HITECH Act was implemented, many providers, developers, innovators and additional public and private stakeholders raised significant concerns about the lack of interoperability and functionality of these systems that was hampering implementation, innovation, and patient care. Through Cures, Congress sought to both build on the HITECH Act as well address some of the issues that arose in implementation, notably, addressing functionality, implementing policies to ease interoperability, and outlawing information blocking.

Section 4001. Assisting Doctors and Hospitals in Improving Quality of Care for Patients

Section 4001 of Cures reduced the documentation burden on health care providers while maintaining quality by allowing physicians to delegate electronic medical record documentation to non-physicians, provided this flexibility is consistent with state law and that certain criteria are met. The section also encourages certification of HIT for specialty providers and sites of service and certification criteria for HIT used by pediatric health care providers. In Fall 2017, ONC submitted a proposed rule to the Office of Management and Budget (OMB) (RIN: 0955-AA01) that contained conditions and maintenance of certification for HIT developers and the voluntary certification of HIT products for pediatricians.

Section 4002. Transparent Reporting on Usability, Security, and Functionality

Section 4002 established a grant program to create a reporting system to engage stakeholders and gather information about EHR usability, interoperability, and security to help providers better choose EHR products. To develop appropriate criteria, ONC has sought input from the public and stakeholders through a Request for Information (RFI).[6] These criteria are intended to help both end-users and the purchasers of EHR systems, while ensuring such criteria are not overly burdensome on developers. The RFI was released in August 2018 and the deadline to submit comments was October 17, 2018. Once public comments are aggregated by an independent contractor, the contractor will draft criteria proposals that ONC will provide to the Health Information Technology Advisory Committee (HITAC) for feedback. This feedback will be incorporated into the EHR reporting program.

Section 4003. Interoperability

Section 40003 expedites interoperability among EHRs by developing and supporting a voluntary model framework and common agreement for the secure exchange of health information to help foster bridging between networks. To achieve this, a digital health care provider directory is created to facilitate exchange and requiring the U.S. Department of Health and Human Services (HHS) to defer to HIT standards developed in the private sector. Additionally, the existing HIT Policy and Standards Advisory Committees were combined and repurposed to create a more streamlined HITAC to address issues related to interoperability, privacy, and security. The new HITAC engaged stakeholders to identify priorities for standards adoption. The HITAC held its first meeting in January 2018 and has continued meeting roughly every month.

On January 5, 2018, ONC released a draft of the "Trusted Exchange Framework and Common Agreement" (TEFCA).[7] The goal of the TEFCA is to encourage interoperability and connectivity across the more than 100 regional health information exchanges (HIEs) and multiple nationwide organizations. While some of these networks have begun connecting to one another, there are variations in individual agreements that make it difficult to create a uniform set of standards that govern connectivity between these exchanges.

[6] https://www.healthit.gov/topic/certification-health-it/ehr-reporting-program
[7] https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf

The draft TEFCA has two parts – Part A and Part B. Part A provides common principles that Health Information Networks (HINs) should follow to gain the trust of participants and patients. Part B articulates specific terms and conditions that a single private-sector organization, referred to as a Recognized Coordinating Entity (RCE), will incorporate into one common agreement. The RCE will be selected through a competitive process that began in Spring 2018.

The draft TEFCA also made it an objective to ensure the HIT developers have open and accessible application programming interfaces (APIs) to facilitate high quality data exchange across HINs. This policy sought to allow smaller, private sector developers to make significant contributions to the speed and ease with which patients can access their own health data. Authors of the law aimed to spur competition and inspire growth in the HIT industry so it would look more like the burgeoning tech industry, where apps allow for the quick creation of different business models that help the consumer and patient.

Section 4004. Information Blocking

Section 4004 defines and prohibits the practice of information blocking, which is enforceable by the Office of Inspector General (HHS OIG). ONC also is tasked with defining what does not constitute information blocking and outlining reasonable safe harbors where information may not be transmitted, but would not be considered information blocking. There can be no enforcement of the ban on information blocking until the definition and the safe harbors have been established through regulation. The HHS OIG is authorized to investigate claims of information blocking and assign civil penalties for practices found to be interfering with the lawful sharing between EHRs. ONC is also permitted to share their investigations into information blocking with the Federal Trade Commission (FTC).

In Fall 2017, ONC submitted a proposed rule to OMB (RIN: 0955-AA01) that defines which activities do not constitute information blocking.

Section 4005. Leveraging Electronic Health Records to Improve Patient Care

Section 4005 encourages the exchange of health information between clinical registries and EHR systems. Developers of health information technology are included in Patient Safety Organizations definition to improve the safety of HIT products for patients.

Section 4006. Empowering Patients and Improving Patient Access to their Electronic Health Information

Section 4006 supports the certification and development of patient-centered EHRs so that patients have better access to their secure and up-to-date health information. It encourages the use of (HIEs) to promote patient access by requiring HHS, in coordination with OCR, to educate providers on allowable sharing of patient health information and clarify misunderstandings that may impede lawful sharing. In 2017, OCR created the “Get It. Check It. Use It.” program as an online resource for patients to access, update, and use their health information.

Section 4007. GAO Study on Patient Matching

Section 4007 requires the Government Accountability Office (GAO) to conduct a study on methods for securely matching patient records to the correct patient and submit the report to appropriate congressional committees in December 2018.

Section 4008. GAO Study on Patient Access to Health Information

Section 4008 requires the GAO to carry out a review of patient access to health information, including barriers to access, complications health care providers experience when providing access, and methods patients may use for requesting their personal health information. This study was published in May of 2018.[8]

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact James "J.P." Paluskiewicz or Jay Gulshen of the Committee staff at (202) 225-2927.

[8] https://www.gao.gov/assets/700/691737.pdf