Chairman Michael C. Burgess, M.D. E&C Health Subcommittee Implementing the 21st Century Cures Act: An Update from ONC December 11, 2018

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

As our society and our economy become increasingly driven by technology, health care is no exception. Electronic health records, patient data, the move to open application programming interfaces (APIs), and other developments have brought health care into the 21st Century. Law lagged behind such advances, which led to various pieces

of legislation to address the aforementioned issues, including the HITECH Act in 2009 and 21st Century Cures in 2016.

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

While we have seen widespread adoption of electronic health records, our nation continues to maintain a fragmented health care system, making it difficult to ensure continuity of evidence-based care for patients. The 21st Century Cures Act has set us on the path towards

achieving a nationwide interoperable health information system that puts the needs of patients and providers first.

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

Section 4003 of Cures expedites interoperability and security among electronic health records through a voluntary model framework and common agreement among vendors. ONC released a draft of this "Trusted Exchange Framework and Common Agreement," known as the TEFCA, in January of 2018. Today, the National Coordinator for Health Page 3 of 6

Information Technology, Dr. Don Rucker, will explain the common principles that will guide Health Information Networks, Recognized Coordinating Entities, and others through the exchange of data.

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

Another theme throughout the health IT title of 21st Century

Cures was patient access to data. While electronic health records are

critically important to physicians, it is equally important that patients

have access to their own data. Cures required the Department of

Health and Human Services, in coordination with the Office of Civil

Rights, to educate providers about lawful patient health information

sharing. The "Get It. Check It. Use It." Program shows patients how to

access, update, and use their health information appropriately.

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

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

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