Testimony before the Committee on Health, Education, Labor and Pensions

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Statement of

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Chairman Alexander, Ranking Member Murray, and distinguished Committee members, thank you for the opportunity to appear today. My name is Dr. Jon White, and I am the Deputy National Coordinator for Health Information Technology. On behalf of Dr. Rucker, the National Coordinator, I appreciate your invitation to discuss our progress with the implementation of 21st Century Cures Act (Cures Act).

The Office of the National Coordinator for Health Information Technology (ONC) was established by Executive Order in 2004. Today our mission is to improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most. In 2009, ONC was statutorily established by the Health Information Technology for Economic and Clinical Health (HITECH) Act as part of the American Recovery and Reinvestment Act, or "stimulus bill." The HITECH Act provided important resources and infrastructure needed to stimulate rapid nationwide adoption and use of electronic health record (EHR) systems. In the eight years since the HITECH Act was enacted, we have seen dramatic progress in the use and adoption of health IT. Today, 97 percent of hospitals and three-quarters of office-based physicians use health information technology (health IT)[1] that has been certified under the ONC Health IT Certification Program (Certification Program). ONC initiatives like the Regional Extension Centers, the Certification Program, and terminology standardization, as well as the Centers for Medicare & Medicaid Services (CMS) Medicare and Medicaid EHR Incentive Programs under the HITECH Act, and the Quality Payment Program (QPP) under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), have accelerated health IT adoption across many care settings. As ONC stated to this Committee in 2015, the Nation is on the path to a digital healthcare information system. We thank the Committee for its leadership in the enactment of the bipartisan Cures Act and look forward to implementing the Act's health IT provisions.

My career has been dedicated to improving health and healthcare quality through the use and sharing of electronic health information. In my 15 years as a family physician, I have worked in a variety of settings with multiple health IT systems. At ONC, I advance key National Coordinator and Administration priorities, and provide executive direction and leadership for all

[1] Office of the National Coordinator for Health Information Technology (December 2016). 2016 Report to Congress on Health IT Adoption. https://www.healthit.gov/sites/default/files/2016_report_to_congress_on_healthit_progress.pdf. Accessed October 2017

ONC programs and policies. Before my service at ONC, I was Director of Health IT at the Agency for Healthcare Research and Quality (AHRQ) where we established hundreds of health IT projects in 48 states. These included research, demonstration, and implementation projects on a variety of applications such as telemedicine and e-prescribing. I have worked with Federal partners, including CMS and the Department of Veterans Affairs, and state and local government, as well as key clinician, patient, and policy stakeholders to advance health IT progress.

Despite gains in health IT adoption, important work remains. ONC's highest priorities – improving interoperability, reducing clinician burden, and addressing information blocking – are central to recasting our healthcare system. In recent years, ONC has focused on advancing data liquidity among clinicians, patients, and their caregivers; addressing information blocking; and advancing developers' move to interoperable systems that are easy to use for clinicians. In 2015, ONC outlined a 10-year plan to achieve nationwide interoperability, "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap." That year we also released the Federal Health IT Strategic Plan 2015-2020, developed in partnership with over 35 Federal entities that use and support the use of electronic health information and designed to support and align important changes across the Federal health landscape. In April 2015, we submitted a report to Congress, "Report on Information Blocking,"[2] which was the first time the government issued a formal report on the problem of information blocking. Information blocking is the act of providers and EHR vendors knowingly and unreasonably engaging in business practices that interfere with electronic health information exchange (HIE). Since we submitted the Report, additional studies and experience have confirmed that information blocking persists and is a serious impediment to interoperability.[3] Recognizing these concerns, Congress included provisions in the Cures Act that provide a robust response to the information blocking problem. We are working closely with our Federal partners to implement these provisions.

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[2] ONC, Report to Congress on Health Information Blocking (Apr. 2015), https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf [hereinafter "Congressional Report"]

[3] See, e.g., Julia Adler-Milstein and Eric Pfeifer, Information Blocking: Is It Occurring And What Policy Strategies Can Address It?, 95 Milbank Quarterly 117, 124–25 (Mar. 2017), available at http://onlinelibrary.wiley.com/doi/10.1111/1468-0009.12247/full; Martin Gaynor, Farzad Mostashari, and Paul B. Ginsberg , Making Health Care Markets Work: Competition Policy for Health Care, 16–17 (Apr. 2017), available at http://heinz.cmu.edu/news/news-detail/index.aspx?nid=3930; Diego A. Martinez et al., A Strategic Gaming Model For Health Information Exchange Markets, Health Care Mgmt. Science (Sept. 2016).

We have also kept pace with the specific needs of the health IT community and the clinicians and patients they serve. In support of industry innovation and requests, we updated our Certification Program to support greater transparency around developer product capabilities and even the types of costs users can incur. We have considered industry developments around technology in our work and included application programming interface (API) capabilities as part of the 2015 Edition Health IT Certification Criteria. Published APIs, or doorways to the data, are a critical component of our connected future. Mobile applications use APIs to connect us with the life tasks we complete each day—from seamlessly banking online, to ordering dinner and rides on our smartphones. APIs, when securely linked with health IT, hold the same promise for patients and clinicians with regards to their ability to readily access health information without special effort.

ONC works closely with the health IT community in a number of ways and looks forward to expanding these types of engagements. For example, we have partnered with the innovation community through various prize competitions under the America COMPETES Act[4] to better understand patient matching, patient privacy, API security, and how information can flow to the patient[5]. We also approved two alternative testing methods administered by stakeholders in the private sector[6,7].

Today, under the National Coordinator's leadership, ONC is deeply engaged in supporting the implementation of the Cures Act, specifically the provisions in Title IV. Looking ahead, ONC is committed to the critical role we play to advance health IT usability and interoperability that supports coordinated care and reduces clinician burden. We continue to engage with our Federal partners, including CMS, and with external stakeholders to better understand and find ways to address the regulatory and administrative burdens identified by stakeholders related to the use of EHRs. I would like to express particular gratitude for my colleagues at CMS who have taken several concrete steps to address clinician burden in their programs head-on. As outlined in section 4001(a) of the Cures Act, ONC will establish a goal, develop a strategy, and provide recommendations with respect to the reduction of regulatory or

[4] America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act
[5] https://oncprojectracking.healthit.gov/wiki/display/TechLabI/ONC+Challenges+and+Winners
[6] https://www.healthit.gov/buzz-blog/healthit-certification/step-diversify-certification-programs-testing-portfolio/
[7] https://www.healthit.gov/buzz-blog/interoperability/onc-health-certification-program-approves-himssimmunization-integration-program-iip-testing-method/

administrative burdens, such as documentation requirements, relating to the use of electronic health records. With CMS, we have established four working groups which address (1) EHR Reporting; (2) Documentation, Administrative, and Reimbursement Models; (3) Health IT and User-Centered Design; and (4) Non-Federal Payers (State/Private) and other Government Requirements, and are engaging with relevant stakeholders in each area.

We also have other efforts underway to reduce the regulatory burden on health IT developers. ONC now allows health IT developers to self-attest to certain functionality-oriented certification criteria to which most had previously been tested in the past in order to focus more on interoperability testing. Additionally, we allow ONC-Authorized Certification Bodies to use discretion in their randomized surveillance of certified health IT in the field, thus reducing the potential of unnecessary productivity impacts on clinicians. These two steps preserve the integrity of the Certification Program while at the same time improving its efficiency and overall impact on the industry.

We have met with stakeholders representing medical specialties, including pediatrics and long-term care, to better understand how health IT can best help them meet the needs of their patients, as outlined in section 4001(b) of the Cures Act. We are working to implement the conditions of certification and maintenance in section 4002. We are also working with AHRQ regarding the treatment of health IT developers as providers with respect to patient safety organizations, as outlined in section 4005(c), and with the HHS Office for Civil Rights (OCR) to identify effective means to, for example, promote convenient patient access to health information, as outlined in section 4006. We are also working to implement the information blocking provisions in Title IV, in close coordination with all of our Federal partners, including the HHS Office of the Inspector General (OIG), CMS, OCR, and the Federal Trade Commission (FTC).

We agree with Congress that health IT must be more interoperable, that it should be easier to use for everyone, and that information must flow seamlessly — that is, without unreasonable impediment — while still respecting individual privacy rights and applying strong security protections to the information. Transaction costs to move health information within Federal programs alone are considerable. For example, in FY'2016 the Social Security Administration Office of Disability Determination received medical records from healthcare

organizations costing about $180 million and consultative exams costing about $391 million for a total cost of about $571 million.

Frictionless access to and use of medical data will increasingly improve the ability of patients to shop for care. As authorized by the Cures Act, we are working to support a competitive marketplace by improving the ease with which clinicians, patients, and their caregivers can securely send and receive medical information. These pro-competitive steps include combatting information blocking and will allow new business models and software applications to flourish.

It should be noted that increased interoperability is also important to the payers who purchase most of our medical care and who often have difficulty accessing data they need for reimbursement decisions. Computationally open APIs provide the data liquidity that artificial intelligence and machine learning are dependent upon to realize their full potential in healthcare (that can be used consistent with the privacy and security requirements of the Health Insurance Portability and Accountability Act of 1996 regulations).

There are many potential avenues for us to work to advance interoperability. To provide focus and clarity for ONC stakeholders, we are concentrating on three framing questions. The first is about the patient: can patients access their medical data in a secure, straight-forward, and consumer-friendly way? The second is about institutional accountability: can payers efficiently assess the quality and value of the care purchased, and can clinicians efficiently and effectively provide care for entire populations? The third guiding question is how to operationally define an open API without special effort.

Most patient data is held by clinicians and EHR vendors, so what do open APIs at the clinician and at the vendor level look like? The Cures Act requires that the use of these APIs be "without special effort," so we are looking at advancements in the health IT community to help understand the full opportunities presented by APIs. ONC is leading efforts to bring these modern data standards to healthcare working with the Health Level Seven® standards organization and key developers of Fast Healthcare Interoperability Resources (also known as FHIR®) interface technology.

APIs provide one avenue to interoperability, especially for patients and payers. Regional and commercially initiated interoperability networks provide another route to interoperability. To date, these have focused exclusively on facilitating communications between certain groups

of clinicians for the purpose of treatment (though often behavioral health and substance use treatment information is not exchanged) but not payment or healthcare operations purposes. ONC has initiated efforts to implement the "trusted exchange" frameworks and common agreement provisions outlined in section 4003(b) of the Cures Act. We held two public listening sessions with stakeholders across the health IT spectrum and completed one round of public comment to gain insight from stakeholders on the policies and practices the Trusted Exchange Framework and Common Agreement (TEFCA) should address. The TEFCA will be an integral component of nationwide network-to-network exchange of health data and a critical part of our charge to support nationwide interoperability. ONC will hold one more listening session before we release draft materials for public comment.

As in the past, ONC is committed to serving as a coordinator and convener of most participants in the health IT field. As part of our implementation of the Cures Act, ONC has worked closely with the HHS Secretary's office to wind down the previous two health IT federal advisory committees and to stand up the new Health IT Advisory Committee called out in the Cures Act, as outlined in section 4003(e). To select new committee members, we have worked closely with members of Congress and the Government Accountability Office. The new charter has been finalized and we anticipate meetings will commence this winter.

We are excited about our work underway to advance Congress's goals in the Cures Act, however it is important for me to share with you what ONC has not been able to advance at this time. Due to competing priorities, at this time ONC is unable to move forward with implementation of Section 4002(c), which calls for a transparent process to develop reporting criteria as part of an "EHR Reporting Program" for certified health IT.

ONC recognizes the importance of working with our Federal partners, members of Congress – this Committee included – and external stakeholders such as patients, clinicians, health IT developers, and payers. ONC has a primary role in implementing the health IT provisions in the Cures Act. We are excited to work with Congress and our stakeholders to make health information more accessible, decrease documentation burden, and support EHR usability while simultaneously accelerating innovation and competitive healthcare markets.

Health IT holds great promise to increase more effective and efficient care. Importantly, we believe that computational ownership, or access to and use of, electronic data by patients and payers (not just clinicians) can set a floor for increased market competition. The Cures Act

encourages new approaches and business models for healthcare, and ONC will use the tools provided by Congress through the Cures Act to tackle today's challenges of interoperability, usability, and information blocking. We look forward to working with you to achieve our shared vision. Thank you again for the opportunity to speak before you today and I look forward to your questions.