

**Testimony before House Committee on Energy & Commerce
Subcommittee on Health**

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Statement of

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Chairman Burgess, Ranking Member Green, and distinguished Members of the Subcommittee, thank you for the opportunity to testify in support of the Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology (ONC) efforts to implement provisions of Title IV of the 21st Century Cures Act (Cures Act).

Since ONC's creation in 2004 through Executive Order (EO) 13335 and codification in 2009 through the Health Information Technology for Economic and Clinical Health (HITECH) Act, ONC has focused on promoting technical standards to improve the quality, safety, and efficiency of health care including through health IT certification. Programs and policies required by HITECH and implemented by ONC and the Centers for Medicare & Medicaid Services (CMS) helped drive most physicians and hospitals to adopt health IT systems.¹ As of 2015, 96 percent of non-federal acute care hospitals and 78 percent of office-based physicians adopted certified health IT. While progress has been made, additional work is necessary to help advance the availability of electronic health information to patients and their providers. Barriers to the appropriate and secure movement of electronic health information include technical limitations and business incentives. The Cures Act takes a great step toward addressing those barriers.

The Cures Act directs the HHS Secretary to adopt standards and policies that advance health IT to enable and stimulate the trusted exchange of electronic health information. The Cures Act, thus, materially advances our mission to enable patients' records to follow them when and where they need it. A health system where information flows appropriately and securely to patients and their clinicians will help coordinate care and reduce costs by making care faster and less duplicative.

The Cures Act also gave the Secretary the authority to address clinician burden stemming from the use of EHRs and health IT, and the Secretary delegated that authority to ONC. Due to multiple overlapping factors, including poor usability of health IT systems, as well as government, institutional, and payer administrative and regulatory requirements, clinicians often spend much time on documentation and reporting, which contribute to clinician burnout. In November, ONC and CMS released a strategy for reducing regulatory and administrative burdens using input from public listening sessions attended by over 1,000 stakeholders. To develop this strategy, we convened four HHS workgroups comprised of policy and clinical specialists to focus on common sources of burden, including clinical documentation, health IT usability and user experience, EHR reporting programs, and other government requirements.

CMS recently finalized bold changes to the Medicare Physician Fee Schedule that address provider burnout and provide clinicians immediate relief from excessive paperwork tied to outdated billing practices by changing the documentation and coding requirements for physician services known as "evaluation and management" visits. CMS also overhauled the Merit-based Incentive Payment System Promoting Interoperability

¹ ONC's 2016 Annual Report on Adoption of Health IT and Related Efforts to Facilitate the Electronic Use and Exchange of Health Information. Accessed at:
https://www.healthit.gov/sites/default/files/2016_report_to_congress_on_healthit_progress.pdf

performance category in order to support greater electronic health record interoperability and patient access while aligning with the Medicare Promoting Interoperability Program requirements for hospitals. These changes will reduce regulatory and administrative burdens in line with the Cures Act § 4001(a) burden reduction goal and help allow providers to spend more time with their patients and less time performing data entry tasks for billing purposes.

This important work will continue as we receive comments from our stakeholders on HHS's draft strategy for reducing clinician burden, and will continue to be an HHS and ONC priority moving forward.

I would like to highlight some of the progress ONC has made implementing other provisions included in the Cures Act. In January, ONC established a new federal advisory committee pursuant to Cures Act § 4003(e) called the Health IT Advisory Committee (HITAC) that provides recommendations to the National Coordinator. The full HITAC—its taskforces and Annual Report workgroup—have met more than 33 times and have provided recommendations related to the three priority target areas identified by the Cures Act: achieving interoperability, the promotion and protection of privacy and security of health information, and facilitating secure access by individuals and their caregivers to their electronic health information. Input from the HITAC contributed to the draft of the Trusted Exchange Framework, the US Core Data for Interoperability (USCDI), the development of priority standards use cases, and the Congressionally-mandated HITAC annual report under development.

ONC also started implementation of the EHR Reporting Program. Section § 4002(c) of the Cures Act requires ONC to provide publicly available, comparative information on certified health IT products. In August 2018, ONC issued a request for information for the public to share their views on the components of the EHR Reporting Program and to provide feedback that will inform the development of reporting criteria and processes as required by the Cures Act. We received 77 public comment submissions from health IT developers and provider organizations representing all major segments of the provider community, payers and health plans covering millions of beneficiaries, and consumer and quality improvement organizations representing patients and consumers.

ONC also has developed a proposed rule to support the access, exchange, and use of electronic health information. The proposed rule would implement provisions of the Cures Act, including conditions and maintenance of certification requirements for health IT developers under the ONC Health IT Certification Program (Section § 4002) and reasonable and necessary activities that do not constitute information blocking (Section § 4004). This rule will be the culmination of significant stakeholder outreach, including public listening sessions and more than 150 meetings with key health IT stakeholders. We look forward to receiving and addressing any comments that may be submitted, before issuing a final rule.

ONC is focusing on accelerating individuals' ability to access and control their health information with ease, in a user-friendly way, using apps on their smartphones or other

devices. This ability would allow consumers to shop for and coordinate their own care if they choose. Today, many patients have trouble accessing their electronic health information in a timely manner. Sometimes, health systems provide patients with their electronic health information in unreadable formats or on dated technology, such as CDs. Patients should have better options to securely access their information, and those options should align with modern technology. The Cures Act builds on ONC's 2015 Edition health IT certification criteria by calling for health IT developers to publish application programming interfaces (APIs) that permit the secure access, exchange, and use of health information without "special effort." APIs are technology that allow one software program to access the services provided by another software program. Standardized, transparent, and pro-competitive APIs will facilitate an individual's ability to use a third-party app of their choice to securely access and share their electronic health information.

Emerging technologies and the use of mobile apps will not only provide individuals with access to their electronic health information, but an app marketplace will evolve with tailored products to address unique patient needs, such as helping patients manage multiple chronic conditions. A robust health app ecosystem can lead to disease-specific apps and allow patients to share their health information with researchers working on clinical trials to test a drug or treatment's efficacy, or monitoring outcomes like those in the National Institutes of Health's *All of Us* Research Program. Apps can also help address barriers related to patient literacy and comprehension by presenting complex information in easy to understand ways. We have seen promising signs of this occurring in the private sector. Last year, Apple introduced their Health Records app using the same modern computing standards, and in a short time, over 100 health systems began using that app to provide patients their data. Many smaller vendors are developing health apps as well.

Part of the health care API evolution is incorporating current protocols from leading standards development organizations such as the newer Health Level Seven (HL7®) FHIR® (Fast Healthcare Interoperability Resources) standard, which is a web developer-friendly way of representing electronic health information. These specifications will expand information sharing for electronic health records and other health IT solutions based on modern computing standards (e.g., RESTful and JavaScript Object Notation (JSON)). Some of our stakeholders have shared security concerns with the requirement to publish their APIs. We take cybersecurity threats and issues related to information security seriously. However, it is important to realize that APIs are not usually where these security vulnerabilities reside. The OAuth standard used to authorize information exchange through "open APIs" provides robust security. Security breaches typically come from the large installed footprint of IT systems and most often reflect password issues or network deficiencies such as servers running dated operating systems. We encourage health IT developers and users to use modern software and industrywide security best practices.

To promote standards and address the interoperability goals of the Cures Act, ONC published the 2018 Reference Edition Interoperability Standards Advisory and launched the USCDI, which specifies a common set of health care record data classes required for

health data interoperable exchange. The modifications to the 2018 Reference Edition address important health information (such as pregnancy status, care plans, patient identification, public health reporting, and provider-to-provider communication) and contain endorsements of 151 health information standards covering over 60 interoperability needs, including, but not limited to clinical, public health, and research purposes.

These efforts around standards and interoperability are foundational for having a modern and connected health system that lowers health care costs. Secretary Azar has identified value-based transformation as one of HHS's top four priorities, as the U.S. health care system is not delivering outcomes commensurate with its cost. Central to a value-based health system is the ability to analyze data and track health outcomes for an entire group of patients. Looking at an entire group of patients is essential to having a learning health system, advancing many research priorities and use cases, and modernizing public health reporting. It is also essential for payers trying to identify the providers with the best outcomes or highest quality of care for their members. Today, payers and employers who purchase care have little information on health outcomes. Payers cannot effectively represent their members if they are unaware of which providers offer the highest quality care at the lowest cost. Often times, providers and payers negotiate contracts based on provider reputation or market presence rather than on quality care. Providers should compete on the entire scope of the quality and value of care they provide, not on the exclusivity of their networks. In conjunction with HL7, ONC is collaborating with payers on developing standards for providers to send to payers health information on the patients covered by their health plans.

ONC is also working to increase connectivity among health information networks. Currently, there are more than 100 regional networks² and multiple national level organizations that support health information exchange. While these organizations have made significant progress to expand interoperability, connectivity across networks has been limited due to variations and gaps in technical specifications, and in the participation and data use agreements that govern the secure exchange of health information. In Section § 4003 of the Cures Act, Congress directed ONC to “develop or support a trusted exchange framework, including a common agreement among health information networks nationally.”

The Trusted Exchange Framework and the Common Agreement seek to expand health information exchange nationwide and ensure that patients, providers across the care continuum, community and social services, and other stakeholders such as payers can access real-time health information. In January 2018, ONC released the first draft of the Trusted Exchange Framework for public comment. Informed by stakeholders, public listening sessions, and an initial public comment period, the draft Trusted Exchange Framework outlined the minimum set of principles, terms, and conditions to support the development of a full Common Agreement that would enable health information

² Julia Adler-Milstein, Sunny C. Lin, and Ashish K. Jha. The Number Of Health Information Exchange Efforts Is Declining, Leaving The Viability Of Broad Clinical Data Exchange Uncertain. *Health Affairs* Vol. 35 No. 7: July 2016. <https://doi.org/10.1377/hlthaff.2015.1439>

exchange among disparate networks. ONC received more than 200 comments on the draft, and plans to release an updated draft for public comment in the coming months.

ONC will also select a Recognized Coordinating Entity, through a Cooperative Agreement, to develop, update, implement, and maintain the Common Agreement subject to ONC approval. The Cures Act's focus on trusted exchange is an important step for advancing an interoperable health system. Together, the Trusted Exchange Framework and Common Agreement will provide the governance necessary to scale a functioning system of connected health information networks that can grow over time to meet the demands of consumers, health care providers, health plans, and other stakeholders.

In addition to expanding nationwide exchange across disparate networks, the Trusted Exchange Framework and Common Agreement should also support community exchange efforts. Through the HITECH Act, ONC's previous grant programs accelerated health information exchange at the state, regional, and local level. A significant unmet interoperability need is for patients with behavioral health conditions, including those with substance use disorders and mental illness, who transition between emergency rooms, shelters, group homes, and various treatment centers. Health information networks, as intrinsically local resources, are positioned to more effectively connect patients with the clinical services and social supports they need. These services might include treatment for substance use disorders and mental illness, ongoing support of medication use, and broader social service needs. Currently, individuals with these conditions tend to be high utilizers of health care, social services, and criminal justice resources and improvements in their health outcomes could be achieved with better coordinated care.

Before concluding, I want to note that ONC has made strategic investments in innovative efforts through grants and pilots that have considerable impacts. ONC funded the initial development of the Patient Unified Lookup System for Emergencies, also known as PULSE, which allows emergency volunteers to access critical health information, such as medications, allergies, and major illnesses during disasters. California's PULSE has been used during the recent devastating wildfires to help victims receive their necessary prescriptions without going to an overwhelmed emergency room. ONC also funded research at Boston Children's Hospital Computational Health Informatics Program and the Harvard Medical School Department for Biomedical Informatics that led to the development of SMART Health IT - an open, standards based technology platform that enables innovators to create apps that seamlessly and securely run across the health care system. ONC and the National Institutes of Health initiated the Sync for Science pilot, which allows individuals to access their health information and send it to researchers in support of the goals of the Precision Medicine Initiative. These small investments addressed significant gaps in the health system.

In summary, ONC has made great progress towards implementing key provisions of the 21st Century Cures Act. These actions will maximize the potential of health IT and result in improved care and reduced cost. Due to development timelines and the size and complexity of the U.S. health system, it is important to note that nationwide

interoperability will take time to achieve. We believe the policies forthcoming in ONC's proposed rule on interoperability, information blocking, and the ONC Health IT Certification, along with the Trusted Exchange Framework and the Common Agreement firmly place us on the path to achieving the long-term benefits of interoperability for the U.S health system.

We will continue to keep Congress informed of milestones as they occur. Mr. Chairman, Ranking Member, and Members of the Subcommittee. Thank you for the opportunity to testify before the Committee today. I look forward to responding to any questions you may have.