

**Testimony before the
United States Senate
Committee on Health, Education, Labor & Pensions
March 26, 2019
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Chairman Alexander, Ranking Member Murray, members of the committee, thank you for holding this hearing and for the opportunity to present testimony.

My name is Ben Moscovitch; I serve as the Project Director of Health Information Technology at The Pew Charitable Trusts (Pew), a nonprofit, nonpartisan research and policy organization. Our health information technology project focuses on improving the safety of electronic health record (EHR) systems, and enhancing the exchange of information so that health care providers and patients have the data they need to make informed decisions.

EHRs have revolutionized how clinicians deliver care by equipping them with better tools to document patients' health status, safely prescribe medications, and otherwise order health care interventions. And, these tools have the potential to make it easier for patients and clinicians to have more complete and robust data to coordinate care across health care settings.

Seeking to build on the improvements spurred on by the digitization of paper records, Congress recognized that gaps remain in realizing the full potential of EHRs to give patients their data, make clinical care more efficient, and enhance patient safety. The 21st Century Cures Act (Cures), passed in 2016, marked an important step toward remedying these deficiencies by addressing barriers to both the effective exchange of health data, known as interoperability, and the usability of these systems.

Congress, through Cures, set a positive vision for the future of EHRs—a vision where patient data are securely accessible to patients and clinicians wherever and whenever they need them. Access to health data would help advance the coordination of care for patients who see multiple

physicians. This coordination would help patients live longer and better lives, and reduce costs associated with duplicate laboratory and other services. And, this vision would have EHRs serve as a critical, helpful tool that clinicians can seamlessly use to administer higher quality care. In this vision, EHRs are indispensable, yet almost invisible to patients because the systems are easily and efficiently used, and only interject in care to offer essential support services to help clinicians provide safer, higher quality care.

Earlier this month, the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare & Medicaid Services (CMS) issued proposed rules to begin implementing that vision captured in Cures. The regulations aim to ease the exchange of health data when patients want to access their information or have it transmitted to their health care providers, and otherwise focus on barriers to the use of these systems to improve patient care.

My testimony will focus on three key aspects of the proposed rules from ONC and CMS published earlier this month that address Congress' desire to improve the interoperability of health data and effective use of EHRs. Specifically, I will discuss:

- provisions enabling easier extraction and use of health data from EHRs via application programming interfaces (APIs), which enable different technologies to communicate;
- needed enhancements to better match patient records across the different health care providers where individuals seek care; and
- necessary improvements to the usability of EHR systems to address design and implementation factors that can both introduce burdens on clinicians and contribute to medical errors.

Enhanced Interoperability via Application Programming Interfaces

For patients to obtain their records or health care providers to exchange information, they first need the ability to effectively extract data from EHRs. To address that challenge, Congress required ONC to develop new criteria for EHRs to make “all data elements” available via APIs, which are software tools that allow systems to request and deliver information to other systems. APIs are the foundation to the modern internet; they allow travel websites to aggregate fares from

different airlines, personal financial applications to pull data from an individual's accounts, and countless other everyday uses.¹

Currently, EHRs often do not support the robust use of APIs for data exchange, or if they do, those APIs can be implemented in proprietary ways that inhibit the use of the data by clinicians and patients. The Cures provision on APIs—colloquially referred to as “open APIs”—would let other technologies more readily access data within the system in a secure manner. The term “open” does not suggest that health data can be freely accessed by any user. Instead, “open” refers to the fact that these APIs would be easier to use, such as that the business and technical documentation would be publicly available.

By including this provision in Cures, Congress recognized that APIs reflect the future of data exchange in health care. They can enable patients to access their health records, hospitals to better exchange data with other organizations, and health care facilities to build and implement new decision support tools on top of their EHRs.

In the recently proposed regulations, ONC implements this API provision, making several critical decisions on the standards to use for data and what information EHRs must be able to release.

ONC Advances Standard, Secure APIs

For third-party technologies—like smartphone applications that patients use to download their records or clinical decision support tools that sync with EHRs—to utilize APIs to access data, the developers of these tools must know how to request and access the information. When EHRs use different standards for APIs, each third-party technology must change its systems to reflect every variation.

Recognizing this challenge, ONC sought to minimize the variability across systems by requiring the use of standards for APIs. Achieving standardization across APIs necessitates consistency both for how information can be accessed and how the data elements are represented. ONC accomplishes that goal by requiring use of the Fast Healthcare Interoperability Resources (FHIR)

standard, which technology developers are increasingly adopting, for how to exchange information.

However, FHIR permits the depiction of data elements in different ways and considers the inclusion of some data as optional, which could inhibit interoperability. To reduce this variability, ONC proposes to require the use of an implementation guide developed by the Argonaut Project—a collaboration among technology developers and health care providers—that provides constraints on how to implement FHIR.

This combination of the FHIR standard and the Argonaut Project implementation guidelines will reduce the barriers to API use, so that patients and clinicians are better able to access data contained in EHRs. As ONC finalizes the rule, Congress should ensure that the agency maintains its commitment to standardized APIs—both through the use of FHIR and refined implementation guidelines.

ONC Expands Data Elements Made Available

To fully take advantage of APIs as a tool to improve interoperability and patient access to electronic health data, Congress required that they provide access to “all data elements” within an EHR system. In ONC’s proposed rule, the agency provides guidance on what information constitutes “all data elements” that systems would be required to make available.

In prior regulations, ONC has required EHRs to have APIs that make certain information—referred to as the Common Clinical Data Set (CCDS)—available for patient access, such as through a smartphone application. The CCDS contains some critical information, including medications, laboratory tests ordered, and problem lists, but lacks other data, such as physicians’ notes. ONC has proposed expanding and adjusting the CCDS to meet the statutory requirement of making “all data elements” available. This expanded data set would be renamed the U.S. Core Data for Interoperability (USCDI), and would include additional key information. ONC’s proposed additions include:

- *Different types of clinical notes.* These clinical notes include free text entered by clinicians and other data about laboratory and imaging observations, treatment plans, and other aspects of care. In clinical notes, clinicians describe the nuances of care and patients' medical conditions. The addition of notes to the USCDI can give patients and other clinicians critical information that may not be captured effectively in structured fields or medical codes.
- *Provenance.* Provenance indicates the author, the author's organization, and a time stamp for data elements in the EHR. The inclusion of provenance would allow patients and clinicians to understand the origin of the data, such as whether a medication was entered by a primary care physician or at a hospital. The time stamp will allow applications to chart or sort information, such as by listing patients' medications starting with the most recent. The addition of provenance to the USCDI would provide much needed context for the data.
- *Patients' addresses and phone numbers.* The availability of addresses and phone numbers will better enable systems to link patient records across systems, and is described in more depth below.
- *Pediatric vital signs.* The inclusion of pediatric vital signs would enable more precise care for children by allowing different applications to model the growth of a patient according to biologic reference ranges, and prescribe the proper dosing of drugs based on weight and age.

ONC has also requested comments on whether to expand the “medication allergies” list to also encompass reactions for other substances, such as food. By expanding this capability, clinical decision support tools could, for example, alert clinicians when patients are allergic to substances from which medications are made, such as eggs or pigs, and could improve patient safety.

Electronic Health Information Export Could be Enhanced

ONC's implementation of the API provision from Cures supports API-based access to some—but not all—data contained in EHRs. In parallel, the ONC proposed rule also includes provisions that would facilitate the extraction of a broader group of data—referred to as electronic health information (EHI)—from health information technology systems. The EHI provision in the proposed rule would require EHR systems to support the export of all their patient data, and

potentially information from other databases connected to it. The EHI export function must support the export of an individual patient's data as well as information on all patients in the system to allow health care providers to switch EHR systems if they so choose.

Unlike the API provisions in the proposed rule, ONC does not propose to require that technologies make this information available via any specific standards or format. Indeed, no such standard exists to describe all possible data elements across all EHRs. Instead, ONC indicates that the information should be extracted and remain computable wherever possible. Eventually, ONC states, it expects that health technologies would increasingly enable the extraction of EHI via APIs.

As noted above, Cures required ONC to issue new criteria for EHRs to make “all data elements” available via APIs. However, ONC has proposed API requirements that would only expose a subset of data—the USCDI—via APIs. To address the gap between what Congress required in Cures and ONC's current proposal for APIs, Congress should encourage ONC to expeditiously make all EHI available via APIs wherever possible.² However, unlike the USCDI data, much of EHI data may not have widely adopted standards or be easily exchanged via FHIR. Therefore, ONC should require EHR vendors to support an API-based export capability for all data elements (i.e., information beyond the USCDI), even without requiring any particular standard for EHI that is not part of the USCDI. Eventually, as standards are more widely adopted for different data elements that are made available via the EHI provision, ONC should expand the USCDI to encompass more of this information.

Timeline for Health Care Provider Adoption

Historically, ONC releases regulations for a new edition of certification criteria for EHRs and separately CMS issues rules for health care providers to adopt technologies that meet those requirements.

However, as currently written, ONC's regulations would require technologies certified to the 2015 version of the criteria to upgrade to meet provisions in the new regulations within approximately two years of when they are finalized by the agency. By the end of that two-year period, health care providers that have not upgraded their systems to include functions—such as for APIs and EHI—

required by the new regulations would no longer be using certified products and could fall out of compliance with CMS requirements.

In effect, ONC has created a system that would require several steps to occur in approximately two years: the development of new functions by EHR vendors; the testing and certification of those functions; implementation of changes at health care facilities; customization and configuration of the technology by health care providers; the testing of systems to ensure that they function properly within a facility and do not introduce inadvertent patient safety risks; and the training of staff.

Given all the steps that need to occur during that time period, Congress should ensure that these systems, once implemented, are sufficiently tested—including for safety—by health care providers. Additionally, ONC should work with CMS to ensure that the timeline the agency finalizes in the regulations is not subsequently delayed. This assurance would provide certainty to both EHR developers and health care providers on government’s expectations on when these provisions take effect.

CMS Regulations Advance API Use for Patient Access to Claims

In parallel to ONC’s regulations, the CMS proposed rule also advances the use of standard, FHIR-based APIs for patients to gain access to their information held by health plans. This would allow patients to—for example—download claims data on their phones, giving them a holistic understanding of the services and treatments that they have received from different health care providers. Equipping patients with their claims data builds on previous efforts from CMS to leverage this information, including by providing increased access to the data by researchers working to identify ways to improve care quality and reduce costs.³

Claims are especially useful because, unlike other information sources, they contain data for nearly every encounter an individual has with the health care system. Claims are standardized for providers and payers, resulting in easier aggregation of information across the health care system. As CMS states in this proposed rule, “[w]hereas EHR data is frequently locked in closed, disparate health systems, care and treatment information in the form of claims and encounter data is comprehensively combined in a patient’s claims and billing history.”

CMS' efforts to give patients access to their claims data and provide researchers with this information, while laudable, omits one critical element particularly important for the Medicare population. Currently, claims only indicate that a procedure was performed—for example, a total knee replacement—but not the brand and model of implant used. In parallel, the unique device identifier system developed by the Food and Drug Administration (FDA) provides each medical device with a code corresponding to its brand and model. Adding the device identifier to claims can fill the gap, and provide patients, clinicians, and researchers with additional information on products used to sustain life and support care.⁴

Incorporating device identifiers in claims can also generate significant savings. The Department of Health and Human Services Office of the Inspector General (OIG) found that the failures of just seven types of cardiac implants cost Medicare \$1.5 billion to treat affected patients, and an additional \$140 million directly to beneficiaries in out-of-pocket costs.⁵ These findings led the OIG to support the addition of device identifiers to claims. The White House's fiscal 2020 budget request for FDA also listed strong support for the addition of device identifiers to claims.⁶ For CMS to effectively equip patients with their data—including from claims—and provide researchers with information to evaluate care, the agency should ensure that claims contain critical information on the products used.

Given broad support across the health care industry and CMS' recognition of the importance of access to claims data, Congress should ensure that device identifiers are incorporated into claims.

Ineffective Patient Matching Also Inhibits Widespread Interoperability

To achieve interoperable exchange of medical data, health organizations must also know that they are communicating about the same person. Presently, up to half of the information exchanges made by health care organizations may fail to accurately match records for the same patient. Both ONC and CMS included requests for information (RFIs) on patient matching in their proposed rules.

To accurately match records held at different health care facilities, organizations typically compare patients' names, dates of birth, and other demographic data to determine if records refer to the same individual. Health care facilities use algorithms to conduct these matches, and also employ

staff to manually review records—which is both costly and time consuming. This process, referred to as patient matching, often fails to accurately link records because of typos entered into the system; similarities in names, birth dates or addresses among different patients; changing information, such as when individuals move or get married; and many other reasons.⁷

While some private sector technologies—such as referential matching, wherein third-party data are used to support matches—show promise, market forces have been unable to solve the patient matching problem for decades. In fact, patient matching requires collaboration between unaffiliated organizations, even competitors, that lack incentive to agree to a set of standards or develop systems that seamlessly exchange information.

Recognizing that effective patient matching is necessary to achieve interoperability, a provision in Cures championed by several members of this committee required the Government Accountability Office (GAO) to evaluate steps that ONC and the private sector have taken to address this challenge.⁸ The GAO report highlights a solution that many organizations—including a contractor to ONC—have proposed: consistent use of standards for demographic data.⁹

In parallel, Pew conducted two years of research—including interviews with health care providers, focus groups with patients, and contracted studies—to examine different ways to address matching challenges. The Pew research—summarized in a report released in October 2018—examined four main opportunities: the standardization of data; the use of unique identifiers or biometrics (such as facial recognition or fingerprint scans); a smartphone-based, patient-led solution; and referential matching.

ONC Should Advance Standardization to Improve Match Rates

While no single solution will completely solve the patient matching problem, our research identified concrete steps ONC can take to make meaningful progress to address this challenge.

First, ONC should require the use of standards for certain demographic data elements. In Pew-funded research published earlier this month, researchers at Indiana University studied whether the standardization of different data elements improves patient matching rates.¹⁰ Indiana

University researchers attempted to match records in four databases, standardized the data in those databases, and then retried matching the records to determine whether that standardization yielded better results.

The research revealed that the standardization of address to the standard employed by the U.S. Postal Service (USPS), which details the preferred abbreviations for street suffixes and states, for example, would improve match rates by approximately three percent. One technology developer indicated that this would help their system match an additional tens of thousands of records per day. Separately, standardizing last name—while showing limited utility on its own—would further improve match rates if done in addition to address standardization.

ONC already proposes in the new recent regulations to embed address in the USCDI, but further improvements in match rates could be realized if the agency simply updates this provision to require use of the USPS standard when matching records. Software that automatically converts addresses to the USPS standard after they are input into the system is available in the commercial market; it is the reason many websites, for example, automatically make format changes to your address at the time you place an online order. Use of this standard would not necessarily require workflow changes at the point of patient registration, and would meaningfully help better link records using the general processes that providers already employ.

Second, the use of additional data elements could also improve match rates. For example, research published in 2017 showed that email addresses are already being captured in more than half of patient records.¹¹ However, email address is not typically used for matching despite its widespread availability. ONC could improve match rates by identifying and including in the USCDI readily available data elements—potentially email address, mother’s maiden name, or insurance policy identification number—that health information technologies should use for matching.

Given the effect of low match rates on patient safety and health care spending, as well as the failure of the market to address this challenge, Congress should work with ONC to ensure that the agency is requiring use of better standards for address and enabling the utilization of additional data elements for matching.

ONC Should Leverage Key Cures Provisions to Improve Usability and Safety

Along with barriers to the interoperable exchange of data among health care providers and to patients, Congress also recognized in Cures that subpar EHR usability hampers the ability of these systems to meet their full potential in delivering more efficient and safer care.

Usability refers to the layout and design of systems, and how their customization, configuration, and implementation affects their use by clinicians. Usability-related safety problems can emerge due to confusing interfaces, the need to develop workarounds to complete tasks, an overabundance of unnecessary alerts, and many other issues given the central role that EHRs increasingly have in helping clinicians order procedures, review health information, and obtain decision support.

Poor usability has two major consequences. First, ineffective usability can contribute to clinician burden and burnout, which can make them more susceptible to making errors.¹² Second, poor usability can contribute directly to patient harm through errors that occur when clinicians interact with the EHR. Pew collaborated with MedStar Health's National Center for Human Factors in Healthcare to examine the contribution of EHR usability to medication safety events in three health care organizations that treat pediatric patients. The research, published in *Health Affairs* last year, revealed that EHR usability contributed to 3,243 of 9,000 safety events examined.¹³ Of those usability-related events, more than 80 percent involved an inappropriate drug dose, and 609 of the usability-related events reached patients. In one case, a transplant patient missed days-worth of medication that would help prevent organ rejection. In another case, the blood transfusion for a newborn in critical condition was delayed due to the inability to create a record. These findings, including other research conducted by MedStar Health, found a clear link between the usability of EHRs and patient safety.¹⁴

ONC has an opportunity to improve system usability and patient safety under the existing authority provided to the agency by Congress as part of Cures. Congress has required that ONC create voluntary certification criteria for EHRs used in the care of children and develop a new EHR reporting program that could be used to identify and address usability issues. Patient safety could be greatly improved if ONC makes it a priority during their implementation of these provisions.

Pediatric EHR Certification Program Should Include Patient Safety

The health care needs of children and adults differ substantially; for example, pediatric patients often receive medication dosage amounts based on their weight. Given differences such as this, Congress included provisions in Cures for ONC to develop and adopt new voluntary criteria for EHRs used in the care of children.

In the proposed rule, ONC identified 10 clinical priorities for pediatrics, including weight-based dosing, use of biometric norms for growth charts, as well as age- and weight-specific dose range checking. The 10 clinical priorities selected by ONC rightly recognize many of the key clinical priorities for pediatric patients, including factors that research has shown contribute to patient safety problems. However, ONC should build on the provisions in its regulations to further improve the usability and safety of EHRs. Specifically, ONC could take concrete steps to tailor the certification program to pediatric care and improve patient safety:

- *Involve pediatric end users.* ONC currently requires EHR developers to involve at least 10 end users of the system in testing the system for certification. However, research suggests that some health information technology developers do not use appropriate end users to test their systems.¹⁵ ONC should clarify that any EHR developer seeking certification for pediatric functionalities should test the system using pediatric-focused clinicians, such as pediatricians and pediatric nurses. ONC could indicate, for example, that at least five of the 10 end-users participating in testing have pediatric expertise to obtain this certification.
- *Use pediatric-focused scenarios.* EHR developers currently use different testing scenarios—which mimic real clinic events and workflows—to demonstrate the functionality of their systems. To obtain certification for pediatric functionality, ONC should clarify that some of the testing scenarios must focus on situations involving children as patients.
- *Utilize mock pediatric data.* EHR developers use data on mock patients to demonstrate that their technologies meet ONC's certification program. ONC supplies some test data for those assessments. For a pediatric-focused certification, ONC should supply test data for mock pediatric patients and clarify that the test data used must involve mock data of children.

As ONC revises its approach to the voluntary certification program for EHRs used in the care of children, Congress should work with the agency to prioritize patient safety and system usability by ensuring that these common-sense approaches are incorporated.

Usability Criteria in EHR Reporting Program Should Include Safety

Through Cures, Congress also requires ONC to develop a reporting program to examine several different functions of EHRs, including system interoperability, security, usability and user-centered design. Findings obtained via this EHR Reporting Program, as envisioned by Congress, would be publicly available on ONC's website.

Late last year, ONC began implementing this provision. The agency selected a contractor to administer the program, and issued an RFI to obtain input on what data to collect on the use and functions of EHRs.¹⁶ While the recent regulations do not implement this provision from Cures, ONC is expected to issue associated rulemaking in the future.

In response to the RFI, organizations representing clinicians, health technology professionals, and hospitals—among others—urged ONC to incorporate safety in the usability aspects of the program, though importantly not as a separate category.¹⁷ Pew provided recommendations to ONC on how to collect some of this information, and is collaborating with MedStar Health to identify additional opportunities for embedding safety into the usability aspects of the EHR Reporting Program.

Congress has provided ONC a prime opportunity to improve the usability—and consequently, safety—of EHRs. As ONC implements this program, this committee should work with ONC to ensure that the usability aspects of the EHR Reporting Program focus on the facets of usability that contribute to unintended patient harm.

Conclusion

The bipartisan passage of Cures launched a new era for improving EHR interoperability and patient safety. As CMS and ONC continue their implementation of Cures and other policies related to health information technology, this committee can play an important role in the coming months

by ensuring that these agencies carry out the goals expressed by Congress. Specifically, this committee can conduct oversight in several key areas:

- Support ONC's efforts to require secure, standard API access to a wide range of health data, including clinical notes;
- Address the gap between Congress' requirements in the 21st Century Cures Act and ONC's current proposal to advance the release of more data—including all EHI—via APIs;
- Advance the addition of device identifiers to claims;
- Encourage ONC to address patient matching through the use of the USPS standard for address and the incorporation of additional demographic data elements in the USCDI;
- Press ONC to focus on addressing the risks to patient safety as part of the voluntary criteria for EHRs used in the care of children; and
- Urge ONC to embed safety in the usability aspects of the EHR Reporting Program.

By taking these steps in the coming months, Congress can provide patients and clinicians with better access to health data, reduce medical errors associated with the use of EHRs, and continue to ensure that the potential of the 21st Century Cures Act is fully realized on behalf of patients and clinicians across the country.

Thank you for holding this hearing today, and for your bipartisan commitment to improving the interoperability, usability and safety of electronic health records. I look forward to answering any questions you may have.

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