January 25, 2018

Submitted electronically via email to: CompetitionRFI@hhs.gov

Office of the Assistant Secretary for Planning and Evaluation
Department of Health and Human Services
Hubert H. Humphrey Building Room 415F
200 Independence Avenue SW
Washington, DC 20201

RE: Request for Information: Promoting Healthcare Choice and Competition Across the United States

To Whom It May Concern:

The Pew Charitable Trusts is pleased to respond to the Department of Health and Human Services' (HHS) request for information (RFI) regarding promoting healthcare choice and competition across the United States. Pew is a non-profit research and policy organization with a number of initiatives focused on improving the quality and safety of patient care, facilitating the development of new medical products and reducing costs.

Achieving the goals outlined in the President's Executive Order 13813, "Promoting Healthcare Choice and Competition Across the United States" requires that individuals and their clinicians have access to the information they need to make informed healthcare decisions. The advancement of a free and open healthcare market that operates efficiently and preserves access and options for patients relies on individuals and providers receiving better information. Access to necessary data requires two overarching changes to how information is gathered and used: enhanced interoperability among electronic health record (EHR) systems through improved patient matching and use of standards; and specific data on the type of medical implants used in procedures to better evaluate the quality and safety of devices.

Interoperability
The Executive Order and the HHS RFI's focus on the need for patients and clinicians to obtain key information requires that individuals' complete and accurate health data be sent to the healthcare providers that they choose to see. For example, some patients may seek care from a specialist who is not affiliated with their primary care physician or the hospital in which they typically obtain medical treatments. Several key barriers inhibit the ability for patients to have their data—including laboratory results, radiology images, and medical history—sent among clinicians, including: an inability to link individuals with their records (referred to as patient matching); and challenges exchanging medical information due to the standards used.

Improvements to patient matching are essential to interoperability
Patient matching is the ability to link a patient to his or her health records that may be held at multiple locations. Researchers have found match rates as low as 50 percent when matching across healthcare facilities.[1] As a result of this challenge in correctly linking an individual with his or her records, patients and healthcare providers may lack critical data to inform care decisions. Improving patient matching is a necessary step in creating a healthcare system that provides high-quality care at affordable prices for the American people, in accordance with the stated goals of the RFI.

Pew is conducting research to better understand challenges with patient matching and evaluate solutions to this interoperability problem. For example, we are assessing whether the use of more detailed standards for demographic data—such as name and date of birth—could help enhance match rates, or whether individuals can be involved in matching their records—such as by using a smartphone application.

Improving patient match rates is critical as we consider a system that allows patients to access care anywhere they wish to receive it, and has the potential to improve outcomes and lower healthcare costs. We urge you to consider how to address patient matching and collaborate with the private sector and research organizations to ensure that data transmitted can be matched to the right patients.

Effective use of standards critical to interoperability
In addition to patient matching, the use of standards for clinical data elements—such as vital signs, medications or laboratory test results—can affect interoperability. This can occur when one health IT system documents and shares information in a certain way, but receives that data from another system in a different manner or form. The data might be sent without key information—such as a drug's route or frequency of administration—or the receiving system may not know how to process or code that data, which could result in it being lost or rendered unusable.[2]

Achieving the vision of a free and open market requires that healthcare organizations be able to receive and process information critical to care. Addressing challenges associated with standards can foster more accurate and robust data sharing so that the information is both available and usable, which could lead to improved outcomes, lower healthcare costs, and foster innovation.

Pew is identifying solutions to address challenges with data standards—including those that could be advanced by government or the private sector—to support the exchange of information.

There are critical steps that the federal government could take to advance the use of standards to support high-quality care. Several HHS initiatives currently underway could help make progress on data standards, including the fulfillment of provisions from the 21st Century Cures Act (Cures).

The Office of the National Coordinator for Health Information Technology (ONC), as required by Cures, will develop regulations for patients and clinicians to receive greater access to information through a tool that allows two systems or software applications to communicate with each other, known as an application programing interface (API), and make documentation and terms of use open and available to the public. These APIs must allow access, exchange, and use of "all data elements in a patient's electronic health record to the extent permissible under applicable privacy laws" without "special effort." This API functionality could not only allow patients easier access to more information from their health record, but also facilitate many other uses, including fostering interoperability among facilities and development of new clinical decision tools for care providers.

While Cures requires health IT developers to make "all data elements" in the EHR available, it does not provide details on what information specifically should be included as part of defining that term. As ONC develops regulations to implement this provision, the agency should define "all data elements" for availability via APIs to encompass information beyond what is currently in the Common Clinical Data Set (CCDS). Although the CCDS contains information on medications, allergies and some other data that EHRs must exchange, it lacks some medically relevant information that patients and clinicians need. Establishing APIs for patients and clinicians to extract data from EHRs will better ensure that individuals can take their medically relevant information to specialists and other medical professionals, and provide clinicians with better tools to make informed medical decisions.

Cures also directs ONC to develop a framework to support the exchange of data among health information networks, which help healthcare providers share data about patients. This type of interoperability is often referred to as network-to-network exchange. Effective exchange of information across networks, as envisioned in Cures, could benefit from advances in both patient matching and data standards. The development of this Trusted Exchange Framework and Common Agreement, so long as it sufficiently addresses matching and standards, can ensure that patients are better able to receive their data and have their information sent to providers of their choosing. We urge you to prioritize these important issues as the Cures rulemaking process continues.

Better data on device performance can save lives, reduce costs
In addition to interoperability, better access to information on the quality and safety of medical devices can equip patients and clinicians with the data they need to make informed care decisions, which could lead to improved outcomes and increased efficiency in our healthcare system.

To provide better data on medical devices, Congress required the Food and Drug Administration (FDA) to develop a unique device identifier (UDI) system, which provides each medical device with a code corresponding to its brand and model number. Once added to real-world data sources—such as EHRs and insurance claims forms—UDIs can provide patients and clinicians additional information on the medical devices they use. While ONC has advanced the addition of UDIs to EHRs, the incorporation of device identifiers—particularly implants, such as cardiac stents and artificial joints—to claims data still requires support from HHS.

Adding UDIs to patients' health records cannot provide the same benefits as claims. Claims, unlike other data sources, contain data for nearly every encounter with the healthcare system for a specific individual. For example, claims information collected over many years may contain data showing that a patient received a specific prescription drug, had surgery and visited the emergency department. EHRs store information in varying ways and cannot easily exchange information because of a lack of interoperability. As a result, researchers face many challenges in combining EHR data across providers to understand quality and value. Claims, on the other hand, are already standardized for providers and payers, resulting in easier aggregation of information across the healthcare system. Adding UDI to claims would allow researchers to use claims to evaluate devices in the same way they already evaluate drugs and procedures—thus equipping patients and clinicians with more data to make informed medical decisions.

Incorporating UDIs in claims can also generate savings. The HHS Office of the Inspector General (OIG) has found that the failures of just seven cardiac implants cost Medicare $1.5 billion to treat affected patients, and an additional $140 million directly to beneficiaries in out-of-pocket costs. OIG recommended the addition of device identifiers to claims to detect these problems sooner, saving lives and money.

The policy also has support from the Medicare Payment Advisory Commission and other groups from across the healthcare system—including health plans, large hospital systems, clinical societies that represent physicians who implant these products, patient groups, and many other organizations. Adding device identifiers to claims has also generated bipartisan support in Congress.

The private committee responsible for maintaining the standard claims transaction used by Medicare, Medicaid and private health plans has recommended the addition of device identifiers to claims, and we urge HHS to help further advance this commonsense policy by supporting efforts to finalize that recommendation.

Conclusion

As HHS works to promote competition and increase efficiency in our healthcare system without compromising patient outcomes or access to care, we urge you to consider the importance of interoperability and robust data on device performance in reaching those goals. A free and open healthcare market that operates efficiently and preserves access is only achievable if information is accessible to patients and providers. By prioritizing these topics, HHS can ensure that patients and healthcare providers have the information they need to coordinate care and make informed decisions.

Thank you for considering our comments on this important issue. Should you have any questions or need additional information, please contact me at 202.540.6333 or bmoscovitch@pewtrusts.org.

Sincerely,

Ben Moscovitch
Manager, Health Information Technology
The Pew Charitable Trusts

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[1] Genevieve Morris et al., "Patient Identification and Matching Final Report," Feb. 7, 2014, https://www.healthit.gov/sites/default/files/patient_identification_matching_final_report.pdf.
[2] The Pew Charitable Trusts "Patient Matching Errors Risk Safety Issues, Raise Health Care Costs" Fact Sheet. June 2017 , http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/11/electronic-health-records-patient-matching-and-data-standardization-remain-top-challenges.