January 10, 2018

Don Rucker, M.D.
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Floor 7
Washington, DC 20201

Dear National Coordinator Rucker,

As the Office of the National Coordinator for Health Information Technology (ONC) implements bipartisan provisions in the 21st Century Cures Act (Cures) that facilitate the exchange of health information, we urge you to support expansion of the data available for clinicians and patients to access in application programming interfaces (APIs) beyond the Common Clinical Data Set (CCDS), which contains key information on patients' health history—such as medications and allergies—but still omits essential data relevant to individuals' care.

Over the past decade, the rapid adoption of electronic health record (EHR) systems has revolutionized the healthcare industry, but the promise of better care, improved outcomes, and lower costs has not yet been fully realized. Challenges with interoperability—the ability to exchange information electronically—hinders clinicians and patients from obtaining medically relevant, actionable, and usable data to inform treatment decisions. As part of ONC's most recent regulations that set baseline standards and criteria for health information technology (IT), EHR developers are required to provide patients with access to data through a tool that allows two systems or software applications to communicate with each other, known as an API, and make documentation and terms of use open and available to the public. However, the regulation only required EHRs to grant patient-facing APIs access to the CCDS that often lacks key data necessary for patient-care decisions, such as family health history and diagnostic image reports.

21st Century Cures Act
Cures expands upon the current state by requiring ONC to include, as a condition of product certification, that health IT developers provide APIs that 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 expansion of 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 in the CCDS, as it may not contain all the medically relevant information that patients and clinicians need. ONC has recognized the limitations of the CCDS in its recently released draft Trusted Exchange Framework and Common Agreement, which defines a set of information for exchange termed the U.S. Core Data for Interoperability (USCDI). As envisioned by ONC, the USCDI goes beyond the CCDS and will grow over time to incorporate more data elements that should be exchanged electronically.

Additionally, while some data elements contained in EHRs may not be structured in a standard way, the agency should not limit access to that information solely due to the lack of standardization. For example, some free text notes may be essential to transmit, or some critical data elements may be coded in standards that are not widely adopted. Non-standardized data are useful for clinicians and patients even when displayed as text or in a PDF and should be accessible through APIs. When conducting rulemaking on how to implement the API provision, ONC should consider the following data elements—among others—that may be appropriate to require access via APIs when considering how to define "all data elements":

Standards exist and are fairly widely adopted
- *Radiology*: Medical imaging provides important information about the body—such as the location of a tumor or skeletal abnormalities—that clinicians need to properly diagnose their patients and would be especially important during referrals or transitions of care. ONC's Interoperability Standards Advisory (ISA) lists the Logical Observation Identifiers Names and Codes (LOINC)—which is typically used to document laboratory findings—as the standard for recording when radiology procedures are ordered and states that the standard has medium adoption. The API could include these codes to indicate that radiology tests have been ordered or returned. The image itself, for which the Digital Imaging and Communications in Medicine standard exists, could also be considered as part of the API payload if it is available in the EHR.
- *Allergies*: The CCDS only requires a list of medication allergies, but there are other allergens that could be important for a clinician to know when treating patients—including food and environmental substances. In fact, some of these allergens could be relevant to the administration of some medications; for example, some patients have egg allergies that might affect the use of certain vaccines developed using egg-based methods. The ISA lists SNOMED CT as the standard to record these allergies and a medium to medium-high level of adoption.
- *Family Health History*: Some medical conditions can be inherited from relatives and a family history of these illnesses can put patients at higher risk of having certain diseases. This information could be recorded using LOINC and the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), and both code sets see medium adoption.

Standards are mature, but have yet to be widely adopted
- *Social determinants*: Studies have shown that only 10 percent of patient health is due to the care that they receive, while social and environmental factors make up 20 percent.[1]

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[1] Harry J. Heiman and Samantha Artiga, "Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity," The Henry J Kaiser Family Foundation, Nov. 10, 2015, https://www.kff.org/disparities-policy/issue-brief/beyond-health-care-the-role-of-social-determinants-in-promoting-health-and-health-equity/.

Social determinants of health—such as socioeconomic status, employment status, living surroundings, education level and other factors—can influence the care that patients would receive so long as healthcare providers are aware of the information. These data could help clinicians create better care plans for patients, especially those with chronic disease. While codes exist to record social determinants in LOINC, they have yet to be widely adopted.

Standards are not yet fully developed
- *Medical device data*: Many medical devices are used in the inpatient and outpatient settings and provide important information about a patient's current state. This could include glucose monitors that diabetics use to track their blood sugar or infusion pumps that control release of opioids for pain. These data could help inform future treatment or development of care plans. Standardization among many medical devices is uncommon.[2]
- *Patient generated data*: As more and more patients begin generating their own health data using fitness trackers and smartphone applications that can track everything from blood glucose to exercise and diet patterns, these data can provide a wealth of information to help inform care. Widely agreed upon standards for patient generated data have yet to be fully developed because these technologies are still fairly new to the health care industry.
- *Genomic data*: Over the past two decades, the cost of sequencing the human genome has dramatically decreased and companies now offer genetic reports to consumers. The prospect of precision medicine and targeted approaches to treating disease means that genetic information will become increasingly valuable for clinicians to help guide patient care. While there are some standards for naming specific genes or variants,[3] this field is still very new and will undoubtedly see changes in the years to come.

<u>**Other considerations**</u>
ONC should consider several other factors when implementing regulations on APIs. First, increased development and adoption of the Fast Healthcare Interoperability Resources (FHIR) standard—which enables health information technology systems to communicate specific data elements as opposed to only entire collections of information, known as documents—could serve as a technological backbone to the API functionality. ONC should consider whether to identify or facilitate the use of this standard in the regulations to provide health IT developers a clear direction when developing APIs. Additionally, ONC should consider situations where the use of FHIR may not be appropriate or simple. For example, it may be more appropriate to exchange certain information—such as certain free text or unstructured data—through electronic clinical documents using templates already developed for this purpose.

Second, when EHRs contain data in structured and standardized formats, the data should remain in that format. For example, this would prevent the conversion of structured data that can be used by computers for clinical decision support to a PDF, where the use of the information is more challenging. Even in scenarios where standards are not widely adopted, retaining the data in

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[2] Association for the Advancement of Medical Instrumentation, "Medical Device Interoperability," 2012, http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/Summits/2012_Interoperability_Summit_Report.pdf.
[3] HUGO Gene Nomenclature Committee, accessed Jan. 8, 2018, https://www.genenames.org/.

those structured formats will facilitate their use. When data are not standardized but deemed appropriate for inclusion in APIs, the information should still be made available to give clinicians and patients access to the information.

Finally, ONC should consider whether health IT developers should allow access to the full longitudinal patient record available in an EHR or just a subset of time. Falling short of requiring access to longitudinal data could limit clinician and patient access to key information that could hinder their ability to obtain a complete picture of an individual's health and how it changes over time, especially for individuals with chronic diseases. However, challenges could emerge when accessing historical data outside a particular timeframe.

Conclusion
The API provisions in Cures greatly expand the ability for patients and clinicians to obtain critical health information. As ONC develops regulations to implement this provision, the agency should consider incorporating additional data elements beyond just the CCDS—for example the USDCI, even when information is not structured or standardized—for inclusion as part of APIs to foster better sharing and use of data that can improve the quality, safety, and coordination of care.

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
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The Pew Charitable Trusts