



Public comments on the Proposed Rule for the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

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Overview

The Biden Cancer Initiative agrees with the comments of the SMART community that the current proposed rule:

“reflects clear thought, responsiveness to the community, attention to detail, and tremendous skill in expressing critical desiderata for a robust health IT ecosystem.

However, we note with concern that the proposed rule allows for a period of 24 months for the rules to take effect. Given the nearly two decades that have passed since the creation of the Office of the National Coordinator for Health Information Technology, we believe this time frame is too generous to the status quo, which was intentionally designed to serve interests other than those of patients.

We propose that based on the proposed rule and the progress in developing the FHIR standard for EHI's and the adoption of the API standards, that **providers should be required to provide all patients their complete medical record as it is created from the first visit through all subsequent visits.**

Comment

The Biden Cancer Initiative is dedicated to bringing a sense of urgency to building the cancer research and care system that all of us deserve (and that most people assume we have) – a system that can better prevent, detect, diagnose and treat cancer and provide the social, emotional and financial support necessary for cancer patients to survive cancer and get back to living their lives. Accordingly, we are interested in this proposed rule because it has the potential to greatly improve patient care, expand research opportunities and respect the rights of patients to have and use as they see fit their own medical records. This is especially true in cancer where the lack of complete information and the difficulty in obtaining one's own medical records can have dire consequences for care.

On March 19, 2018, Vice President Joe Biden, co-founder and at that time, Co-Chairman of the Board of the Biden Cancer Initiative, published an article supporting the spirit of the CMS announcement to put patients in charge of their health data and to improve data interoperability. Vice President Biden put forth the following principles guiding the work of the Biden Cancer Initiative:

- Patients should not be made to jump through hoops to access and share their own data, the data should automatically be shared with patients (like monthly bank statements), and seamlessly move with patients and be in the hands of their care team in real-time.
- There should be a uniform and straightforward way for patients to authorize doctors and hospitals to share their data with entities they designate, including contributing it to research with a single click.
- Patients and physicians shouldn't have to search for clinical trials (which inevitably leads to disparities in access depending on where a patient is treated). Patients should be alerted that they potentially qualify for a trial based on the data already contained in their records.
- Data agreements and repositories are creating more siloes and preventing faster research progress, therefore we must build technological bridges across existing data sets and design all future repositories to be open to all qualified researchers and to interact with one another in order to move discovery forward.
- We must continue to invest in developing the proper health care data security infrastructure to maintain the integrity of the system and the trust of patients and providers.

Based on these principles, we agree with the comments of the SMART community that the current proposed rule:

“reflects clear thought, responsiveness to the community, attention to detail, and tremendous skill in expressing critical desiderata for a robust health IT ecosystem. The product of these efforts, the Proposed Rule, is extraordinarily impressive to us. The Rule addresses and reinforces virtually all of the major underpinnings which are currently feasible and needed to produce an interoperable apps-based ecosystem.

We state clearly and emphatically that the Rule should be largely left intact in its spirit and in most of its details.”

We defer to technical groups such as SMART on the technology needed for the API's and the incorporation of the FHIR standards into the EHRs. We are focused on the patient side of the equation. Specifically, we are concerned with the nature of the interaction between patients and the providers and payers with whom they interact.

In his article in 2018, Mr. Biden on behalf of the Biden Cancer Initiative made the following recommendations which we feel are appropriate to highlight here.

1. Health care providers should be required to provide patients with their full medical record in electronic form within 24 hours of a request, and those providers who do not comply should be held accountable by the U.S. Department of Health and Human Services for data-blocking as outlined in the 21st Century Cures Act.

2. The Center for Medicare and Medicaid Innovation (CMMI) should invest in a patient data system that brings data from disparate formats and care providers into a uniform patient data portal—this portal should be dynamic and allow for all providers for an individual patient to input and validate data in one place, to reduce confusion and duplication and eliminate unnecessary procedures. In other words, it is great that people will be able to get their data, but they need a safe place to store it, and CMMI should “close the loop” of the good work they started. This goes beyond a digital download of a patient’s record and creates a new way for patients and their physicians to communicate and make decisions. The technology exists to do this, and those receiving benefit through federal programs should have access to the best in practice—not only could it improve outcomes, but it would reduce reimbursement costs for CMS.

3. HHS should focus on expanding their agreements with the electronic health record vendors—Allscripts, athenahealth, Cerner, drchrono, Epic, and McKesson—who participate in Sync for Science. Additional

pilot groups should be launched, starting with cancer, to allow patients to opt in to contributing their medical records for research. After all, the law is clear that patients own their records and have the right to direct their transfer to trusted people of their choice.

4. The National Cancer Institute (NCI) should partner with their network of designated NCI-comprehensive cancer hospitals and patient groups, to launch a new cancer data trust—wherein data contributors and data users would agree to set of criteria and act as the “trustees” of the contained EHR, diagnostic, genomic, and outcomes data. This would allow not just piecemeal sharing of incongruent data sets but would require real agreement to share comprehensive patient data that could make a difference for research.

We are encouraged by ONC’s work in the support of the 21st Century Cures Act requirement to make Electronic Health Information accessible to patients and their designees, including researchers. Specifically, the following:

ONC proposes to promote policies that would ensure a patient’s EHI is accessible to that patient and the patient’s designees, in a manner that facilitates communication with the patient’s healthcare providers and other individuals, including researchers, consistent with such patient’s consent through the following proposals: United States Core Data for Interoperability (USCDI) standard; “EHI export” criterion; “standardized API for patient and population services” criterion, “data segmentation for privacy (DS4P)” criteria, “consent management for APIs” criterion; API Condition of Certification; and information blocking requirements, which include providing patients access to their EHI at no cost to them.

•Patient access to their EHI would be improved through the adoption of the following proposed 2015 Edition standard and certification criteria: USCDI standard; standardized APIs for patient and population services; and EHI export.

However, we note with concern that the proposed rule allows for a period of 24 months for the rules to take effect. Given the nearly two decades that have passed since the creation of the Office of the National Coordinator for Health Information Technology, we believe this time frame is too generous to the status quo, which was intentionally designed to serve interests other than those of patients.

We propose that based on the proposed rule and the progress in developing the FHIR standard for EHI’s and the adoption of the API standards, that **providers should be required to provide all patients their complete medical record as it is created from the first visit through all subsequent visits.** Given the requirement for exportable digital records and given the fact that every provider already knows how to send bills to every patient on a monthly basis, there is no technical barrier to providers providing patients their medical records – as defined in the proposed rule -- as the default position without waiting for a request. Patients could designate third parties to receive their records if they wish or providers could move the records to a cloud-based storage site available to the patients to retrieve without any special effort as is already the rule.

The Biden Cancer Initiative is actively recruiting cancer centers to commit to such a position on the theory that it should not take 24 months and further detailed regulations for providers to do the right thing now.

We urge the adoption of the position that providing patients their medical records in a digital format should be the default obligation of providers, NOW. There is no need to, nor is it practical, to require patients to decipher how to ask for their medical records given the complexity of provider networks and the confusion among provider employees as to who owns and has rights to the medical record. Medical records are the patients’ property and should be provided to them as a matter of course similar to how banks and investment institutions are required to send statements and records of transactions as a matter of course without being asked.

The Biden Cancer Initiative appreciates the chance to comment on the proposed rules and urges the adoption of the principles and goals set out here, especially the requirement that providing patients their medical records should be the default obligation of providers, without putting a burden on patients to figure out how to request their records from diverse and often non-responsive institutions.