

Scott A. Sinder
202 429 6289
ssinder@steptoe.com



1330 Connecticut Avenue, NW
Washington, DC 20036-1795
202 429 3000 main
www.steptoe.com

April 1, 2019

TO: The Council

FROM: Scott Sinder
Kate Jensen

RE: CMS & ONC Proposals to Facilitate Patient Access to Health Data and Interoperability of Health Data Systems

The Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC)¹ have released related proposed rules to improve individuals' access to their complete health data and facilitate interoperability and timely information flow between healthcare providers and payers.² While large portions of the proposals are highly technical, the underlying policies and objectives appear to be aligned with feedback we have received from the CEBE Board and other Council members.

The CMS proposal applies to the following entities (hereinafter "regulated entities"):

- Issuers of qualified health plans (QHPs) certified by federally-facilitated exchanges (FfEs);
- Medicare Advantage (MA) organizations;
- Medicaid managed care plans;

¹ ONC is responsible for implementing various provisions and policies in the 21st Century Cures Act, including: advancing interoperability; supporting access, exchange, and use of electronic health information; and addressing occurrences of information blocking in the healthcare system.

² CMS Proposed Rule, 84 Fed. Reg. 7610 (Mar. 4, 2019); ONC Proposed Rule, 84 Fed. Reg. 7424 (Mar. 4, 2019).

- CHIP managed care entities;
- Medicaid state agencies; and
- CHIP agencies that operate fee-for-service systems.

Generally, CMS and ONC recognize that lack of standardization (i.e., healthcare data systems “not speaking the same language”) inhibits the exchange of healthcare data along the care continuum. Their goal with these proposals is to improve: care coordination; ability to analyze health outcomes, trends and costs; management of benefits and health for populations; and ability to track quality and results.

We anticipate filing comments (due May 3) on the Council’s behalf and would appreciate hearing from interested members by April 24.

Background & Proposals’ Purpose

In late 2017, President Trump issued an executive order calling for federal action to improve Americans’ access to, and the quality of, health data in order to make individuals smarter consumers of healthcare. In response, CMS and the White House’s Office of American Innovation launched a MyHealthEData multi-part initiative, of which these proposals are a piece.

Through various studies and requests for public input, CMS has identified certain barriers to healthcare information access and flow, including:

- Lack of unique patient identifiers (UPI);
- Lack of standardization (i.e., currently, systems/interface technology are not speaking the same language to allow for quick data access and/or transfer);
- Information blocking (i.e., providers and health IT vendors limiting or preventing information exchange to competitors in an effort to retain patients/business);
- Lack of adoption and use of certified health IT among post-acute care (PAC) providers (e.g., nursing homes, long-term care providers, skilled nursing facilities, etc.); and
- HIPAA Privacy concerns.

The current proposals, as described below, aim to address some of these challenges.³

³ Some of these challenges are not tackled directly by these proposals, but CMS is working on other measures to address them. For instance, with respect to lack of UPIs, CMS is working on developing accurate patient matching techniques in lieu of UPIs via public-private partnerships, and is generally requesting information on how to advance patient matching strategies.

(Continued...)

Overview of Proposals

The ONC proposal is mostly technical in nature and would, for instance:

- Update certification requirements for health IT developers under the ONC Health IT Certification Program (Program), including new privacy and security attestations and requirements;
- Make patients' information more electronically accessible by adopting standards and certification criteria for Application Programming Interfaces (APIs); and
- Clarify what provider activities do and do not constitute "information blocking" (enumerating limited exceptions for activities that promote patient safety, security, and privacy; and activities related to maintenance and performance of health IT) and prohibit health IT developers under the Program from engaging in information blocking.

The CMS proposal would deploy the technical standards from the ONC proposal in the marketplace via several data access and sharing requirements. To address challenges related to lack of standardization, CMS proposes the following:

- To require that certain information be made accessible to patients "by common technologies and without special effort" via open APIs (i.e., APIs for which technical and other information required for a third-party application to connect to them is publicly available);⁴ and
- To require covered entities to implement open APIs consistent with technical, content and vocabulary standards proposed by ONC (where applicable law does not require a different

Regarding HIPAA privacy concerns, CMS is developing resources for providers to understand how HIPAA and interoperability can work together. CMS does not intend to expand patients' rights of access under HIPAA with this proposal or to "contravene existing requirements related to disclosure of PHI" under any existing legal standards, but rather, is creating a new mechanism through which to share information as directed by the individual.

⁴ "By common technologies and without special effort" means ability to access data through use of common consumer technologies like smart phones, computers, tablets, etc., with third-party software and payer portals able to connect to the API and provide enrollees access to their data. HHS envisions this as a simple, electronic way for individuals to access and transfer their own personal health information (PHI) in accordance with their HIPAA right to access.

content standard); and relatedly, to prohibit regulated entities from implementing API technology using alternative or outdated technical standards.⁵

To help ensure individuals have easy electronic access to their complete health data, the *minimum* information to be provided/made accessible through these open APIs includes:

- Adjudicated claims, including cost, for both approved and denied claims as soon as the plan has made an initial payment decision (regardless of appeal timeframe or status);
- Encounters with capitated providers;
- Provider remittances;
- Enrollee cost-sharing;
- Clinical data covered by the U.S. Core Data for Interoperability (USCDI) standard, including:
 - assessment and plan of treatment;
 - care team members;
 - clinical notes;
 - patient goals;
 - health concerns and problems;
 - immunizations;
 - laboratory tests and results;
 - medications (including allergies);
 - patient demographics;
 - procedures;
 - smoking status;
 - unique device identifier(s) for implantable device(s); and
 - vital signs;
- Provider directories;⁶
- Drug benefit data; and

⁵ The full open API proposal addresses, *inter alia*: technical standards, content and vocabulary standards, data required to be available, timeframes for data availability, documentation requirements (i.e., business and technical documentation necessary to interact with the API must be freely and publicly available), routine testing and monitoring of APIs, compliance with privacy and security requirements (i.e., authorization and authentication practices sufficient to comply with HIPAA's privacy and security requirements), circumstances in which there may be denial or discontinuation of access to the API by regulated entities, and exceptions specific to certain programs or sub-programs.

⁶ Because QHP issuers already must provide machine-readable provider directories, CMS is not proposing to add a duplicative requirement for them here.

- Formularies (including information about preferred drug lists and covered outpatient drugs, and pharmacy directories).

To promote timely disclosure of data, the proposal would generally require regulated entities to provide claims and encounter data via the open API within one business day of adjudication, the encounter, or claim processing, as applicable (for issuers of QHPs, they must provide encounter data within one business day of receiving the information). CMS suggests in the preamble to its proposal that regulated entities could consider contracting with network providers to ensure timely transfer of data necessary to comply with these timeframe requirements.

To facilitate improved data sharing by and between plans, HHS also proposes:

- To require plans, if asked by a beneficiary, to transmit – via the open APIs discussed above or some other mechanism such as a regional health information exchange⁷ – his/her information to a new plan or other entity designated by the beneficiary during enrollment in the plan and for up to 5 years after the beneficiary has disenrolled with the plan;⁸
- That plans must exchange, at a minimum, the data elements in the USCDI standard (described above) upon an enrollee’s request; and
- To require covered entities, by January 1, 2020, to participate in a trusted health information exchange network⁹ meeting criteria for interoperability.

Finally, CMS proposes the following additional measures to address certain other marketplace challenges:

- To deter information blocking, CMS proposes to publicly post information about health care providers that attest negatively to any of the prevention of information blocking attestations currently required by law; and

⁷ HHS is not proposing to dictate the means of information exchanges between plans at this time, but expects that regulated entities naturally will migrate over time to open APIs and other interoperable systems in response to policy proposals like these.

⁸ Ultimately, under HHS’s proposal, all covered plans, upon the enrollee’s request would: (1) accept the data set from another plan that covered the enrollee within the last 5 years; (2) send the data set at any time during enrollment and for 5 years thereafter to another plan that currently covers the enrollee; and (3) send the data set during enrollment and for 5 years after to a recipient identified by the enrollee.

⁹ Trusted exchange networks provide “rules of the road” and “scale” for interoperability and, according to HHS, could help expand interoperability beyond point-to-point data sharing.

- To increase the number of providers supplying current and valid digital contact information to the National Plan and Provider Enumeration System (NPPES), CMS would publicly identify those who have not submitted digital contact information and require each payer/issuer to make provider directory information publicly available via an API.

CMS proposes to make the requirements and measures applicable on the following dates:

- For QHP issuers, for plan years beginning on or after January 1, 2020;
- For MA organizations, Jan. 1, 2020; and
- For Medicaid and CHIP agencies/entities, July 1, 2020.

In addition to the specific proposals outlined above, HHS generally plans to continue testing ways to promote interoperability across all providers (e.g., physician practice groups, hospitals, long-term care, behavioral health, home care providers, etc.) in the health care system through models tested by the CMS Innovation Center.

Requests for Information on Potential Future Rulemaking Activities

The CMS proposal also contains requests for information to help inform future rulemakings in this area. For instance, CMS anticipates that providers and plans eventually will want to share and request data on overlapping patient populations (i.e., data “in bulk” shared between multiple entities) that is more comprehensive than the USCDI standard (e.g., information on urgent care/emergency department visits, discharge notices, records of tests done at specialists’ offices, complete list of clinicians caring for a patient, etc.). CMS is therefore seeking feedback on issues related to such an expanded data sharing regime:

- Potential requirements for patient notice and consent;
- Applicable legal and regulatory requirements;
- Whether transfers could be cumulative over time and between various providers; and
- General benefits, potential unintended consequences, and administrative burdens of more robust data sharing of this nature.