2019 Interoperability and Patient Access, Cures Act Proposals

The Latest Health IT Policies from CMS and ONC

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Proposed rules emphasize interoperability, patient access

June 3rd deadline to submit public comments to CMS and ONC

On Monday, February 11, 2019 the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health IT (ONC) released complementary proposed rules that promote greater interoperability for the healthcare industry and patient access to their health information, and implement key provisions of the 21st Century Cures Act.

The CMS proposed1 rule mostly concerns improved access to clinical, encounter, claims, and other types of data that can be shared among patients, plans, and federal agencies. There are some additional policies proposed on how CMS can discourage information blocking, capture more electronic addresses for providers, and require hospitals to electronically send admission, discharge, and transfer notifications.

The ONC proposed rule2 primarily impacts health IT developers, as it includes major changes to the certification program that will require updates to their technology, with releases expected to be made available to end users two years after the final rule is issued. The proposed rule also clarifies how the healthcare industry can prevent information blocking among health care providers, health IT developers, exchanges, and health information networks.

Together, these proposals reflect a significant step by both agencies to “crack down” on siloes of patient data and any practices that prohibit access to and exchange of health information in the healthcare industry. We anticipate when these rules are finalized in later 2019, they will provide a floor from which CMS and ONC will build on to continue to encourage greater interoperability.

Overview of CMS and ONC Proposed Rules, February 2019

<table>
<thead>
<tr>
<th>CMS interoperability and patient access proposal</th>
<th>ONC 21st Century Cures Act implementation proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improve access to beneficiary data</td>
<td>Implement key provisions of 21st Century Cures Act</td>
</tr>
<tr>
<td>Mandate certain CMS health plans enable APIs</td>
<td>Clarify when information blocking applies and does not</td>
</tr>
<tr>
<td>Increase electronic data exchange, digital delivery</td>
<td>Update the ONC certification program and criteria</td>
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CMS “doubles down” on access to data through APIs

Proposal expands data sharing beyond Medicare fee-for-service

The CMS “Interoperability and Patient Access” proposed rule aims to improve access to beneficiary data, and encourage greater interoperability in the healthcare industry. The most significant proposals affect Medicaid and CHIP fee-for-service programs and enrollees in Medicare Advantage organizations, Medicaid and CHIP managed care entities, and QHP issuers in the FFES. CMS proposes enhanced care coordination and health information exchange requirements, and that these stakeholders publish open application programming interfaces (APIs) so that a variety of data can be accessed by patients, plans, and federal agencies beginning in 2020 (see below). This proposal follows and expands on the CMS MyHealthEData initiative, and reflects much of the same requirements for providers in their Promoting Interoperability (PI) Programs—where APIs must be enabled to provide patients with access to their health information using an application of their choice.

Summary of information proposed for API access

<table>
<thead>
<tr>
<th>Provide information to patients</th>
<th>Send information to another plan</th>
<th>Accept information from another plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjudicated claims (including cost)</td>
<td>Send the USCDI (Version 1) Data Set^4 any time during an enrollee’s enrollment and up to 5 years later</td>
<td>Accept the USCDI (Version 1) Data Set from another plan that covered the enrollee within the previous 5 years</td>
</tr>
<tr>
<td>Encounters with capitated providers</td>
<td></td>
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<tr>
<td>Provider remittances</td>
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<tr>
<td>Enrollee cost-sharing</td>
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<tr>
<td>Clinical data, including laboratory results (where available)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provider directories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formularies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How to get covered benefits in the plan</td>
<td></td>
<td></td>
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<tr>
<td>Facilitate decision making about plan choice, providers, and benefits</td>
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</tbody>
</table>

Additionally, the proposal includes some specific implications for providers as well, although they are less far-reaching than those proposed for the stakeholders above:

1. CMS proposes to publicly list the clinicians, eligible hospitals (EHs), or critical access hospitals (CAHs) that attest in the PI programs to not preventing information blocking.
2. Providers would also be publicly listed if they do not have electronic addresses listed in the National Plan and Provider Enumeration System.
3. Medicare-participating EHs/CAHs and psychiatric hospitals would be required to send electronic admission, discharge, and transfer notifications in order to meet Conditions of Participation.

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1) CHIP = Children’s Health Insurance Program.
2) QHP = Qualified Health Plans.
3) FFES = Federally-Facilitated Exchanges.
4) United States Core Data for Interoperability (USCDI) uses data classes supported by commonly used standards, including Health Level Seven (HL7), Consolidated Clinical Data Architecture (C-CDA) Version 2.1, and Fast Healthcare Interoperability Resources (FHIR).
5) The metadata, or extra information about data, that can help answer questions such as when and who created the data.

Sources: CMS, ONC, Advisory Board Research and Analysis.
ONC proposes significant certification program changes

Health IT developers should assess potential impact

The ONC proposed rule implements key provisions of the “21st Century Cures” Act, updates the ONC health IT certification program, and clarifies how the healthcare industry can prevent information blocking. The 21st Century Act was passed in 2017 to encourage greater levels of interoperability; access, exchange, and use of electronic health information (EHI); and prevention of information blocking. While the rule contains significant implications for all healthcare providers, the majority of the proposal relates to developers of certified EHR technology (CEHRT).

In the proposed updates to the ONC certification program, criteria are slated to be removed, replaced, or revised/newly added in order to support evolving health IT standards and bolster interoperability (see below). For example, health IT developers would need to re-configure their systems and deploy updates for end users to collect data according to the USCDI standard. This update would replace the existing Common Clinical Data Set (CCDS) standard. Another significant change for ONC is to formally adopt the API standard, the Fast Healthcare Interoperability Resources (FHIR)—in previous rulemaking they had not adopted one. ONC also intends to update their conditions of certification, and one significant requirement is that health IT developers remove “gag” clauses from their agreements. Additionally, ONC proposed a voluntary certification pathway for pediatric care—which was required as part of the Act.

For end-users of CEHRT, ONC has signaled that these changes to certified health IT systems will require updates and upgrades likely starting in late 2020 and throughout the 2021 calendar year.

**Proposed ONC CEHRT Changes**

<table>
<thead>
<tr>
<th>Remove</th>
<th>Replace</th>
<th>Revise/New</th>
</tr>
</thead>
<tbody>
<tr>
<td>• (a)(6) Problem list</td>
<td>• (b)(10) EHI Export replaces (b)(6) Data Export</td>
<td>• (c)(3) CQMs² Report</td>
</tr>
<tr>
<td>• (a)(7) Medication list</td>
<td>• (b)(11) Electronic Prescribing replaces (b)(3) Electronic Prescribing</td>
<td>• (d)(12) Encrypt authentication credentials</td>
</tr>
<tr>
<td>• (a)(8) Medication allergy list</td>
<td>• (b)(12) DS4P¹ Send replaces (b)(7) DS4P Send</td>
<td>• (d)(13) Multi-factor authentication</td>
</tr>
<tr>
<td>• (a)(11) Smoking status</td>
<td>• (b)(13) DS4P Receive replaces (b)(8) DS4P Receive</td>
<td>• (g)(11) Consent management for APIs</td>
</tr>
<tr>
<td>• (a)(10) Drug formulary and preferred drug list checks</td>
<td>• (c)(3) CQMs² Report</td>
<td></td>
</tr>
<tr>
<td>• (a)(13) patient-specific education resource</td>
<td>• (b)(10) EHI Export replaces (b)(6) Data Export</td>
<td></td>
</tr>
<tr>
<td>• (b)(4) CCDS create</td>
<td>• (b)(11) Electronic Prescribing replaces (b)(3) Electronic Prescribing</td>
<td></td>
</tr>
<tr>
<td>• (b)(5) CCDS receive</td>
<td>• (b)(12) DS4P¹ Send replaces (b)(7) DS4P Send</td>
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<tr>
<td>• (e)(2) Secure messaging</td>
<td>• (b)(13) DS4P Receive replaces (b)(8) DS4P Receive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• (g)(10) Standardized API for patient and population services replaces (g)(8) Application Access - Data category request</td>
<td></td>
</tr>
</tbody>
</table>

¹) DS4P = Data Segmentation for Privacy.
²) CQMs = Clinical Quality Measures.

Health IT developers have **24 months** from the final rule effective date to re-certify their product(s) and release updated software to end users.

Sources: ONC; Advisory Board Research and Analysis.
Long-awaited clarifications on information blocking
ONC defines exceptions, seeks comment on provider disincentives

A central provision of the 21st Century Cures Act is prevention of information blocking, defined as actions that “inhibit the appropriate exchange, access, and use of EHI.” After the 21st Century Cures Act was passed, CMS has exercised its authority to require that health care providers attest that they do not practice information blocking as part of their PI program data submission each year (for an overview and guidance on this topic see our ready-to-present slides). ONC’s proposed rule further defines information blocking and specifies activities that would not constitute information blocking—seen as exceptions to the definition (see below).

ONC defines information blocking “actors:” health care providers, health IT developers, health information exchanges, and health information networks. An example of information blocking is if health IT developer A’s users cannot receive incoming secure, electronic messages from health IT developer B’s users. ONC explains that their health IT certification program will prohibit developers from taking any action that constitutes information blocking. Not only could a health IT developer incur a fine for information blocking, but they could also risk a full ban from ever seeking certification for their product(s) in the future.

Together, ONC and the Office of the Inspector General (OIG) have authority to enforce prevention of information blocking policies. When it is determined that a health IT developer, exchange, or network has engaged in information blocking, the penalty is $1 million per offense. ONC also seeks comment on what penalties may be an appropriate disincentive for healthcare providers.

Seven Proposed Exceptions to Information Blocking

1. **Prevent harm**
   Situations where disclosure is reasonably likely to endanger the life or physical safety of the patient or another person

2. **Promote the privacy of EHI**
   When an actor has been unable to obtain reasonable assurances to an individual’s identity

3. **Promote the security of EHI**
   When an actor implements measures in direct response to a known security incident or threat

4. **Recover costs reasonably incurred**
   The costs are reasonably incurred to provide the relevant interoperability elements to enable access, exchange, or use of EHI

5. **Respond to requests that are infeasible**
   Requests may be declined when an actor lacks the requisite technological capabilities, legal rights, or other means necessary to facilitate the access

6. **License interoperability elements on reasonable and non-discriminatory terms**
   Actors can protect and exercise their IP rights in a reasonable and non-discriminatory manner that does not impede the flow of EHI

7. **Maintain and Improve Health IT Performance**
   Actors can make IT unavailable in order to implement upgrades, repairs, and other changes

Source: ONC; Advisory Board Research and Analysis.

1) IP = Intellectual Property.

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