10/1/20 HITOC-sponsored Federal Interoperability Final Rules Webinar Q & A

This document captures the questions raised at the 10/1/20 HITOC-sponsored Federal Interoperability Final Rules Webinar and provides responses based on OHA's current understanding of the rules. Given their complexity, additional clarification may be provided in the future. Please visit the ONC and CMS final rules websites for updates and resources. These questions and answers will be compiled with other questions submitted by Oregon stakeholders and posted as FAQs on the Office of Health IT's federal interoperability final rules webpage.

Webinar materials:

- Slides
- Handout
- Webinar recording

Oregon Health Authority's Office of Health IT's Interoperability final rules webpage:
https://www.oregon.gov/oha/HPA/OHIT-HITOC/Pages/Federal-Rules.aspx

Webinar agenda

- Webinar Introduction
- Final Rules Overview
- ONC 21st Century Cures Act Final Rule
- CMS Interoperability and Patient Access Final Rule

Webinar Questions & Answers

ONC Cures Act Final Rule: Policy 1 Updates to EHR Certification Criteria

1. **If an app developer spills data we provide them, are we responsible for breaches?**
   A provider that makes health information available to patients at their request, in the method that they are requesting, is not responsible for a breach if that information is further disclosed after that lawful disclosure. App developers may not be subject to HIPAA privacy rules, so information disclosed by an app developer may not be a HIPPA violation or qualify as a breach. The question to keep in mind is whether patients know their app developer may not be covered by HIPAA privacy protections, and that app developers can use that information in any way allowable under Federal Trade Commission rules, not HIPAA rules. While not the responsibility of the disclosing provider, patients should be made aware that their app developer is not prohibited from using the health information they obtain, for instance, for targeted marketing.

ONC Cures Act Final Rule: Policy 2 Exceptions to Information Blocking

2. **Is there a delay in the information blocking penalty, do we know when that is?**
   Yes and no. On 10/29/20 ONC published an extension to the compliance date until April 5, 2021. OIG has proposed that it would not enforce information blocking further until 60 days after publication of its final rule on enforcement and penalties for information blocking. Information blocking will not be enforced before April 5, 2021, we don't know when it will be enforced because OIG has not put out its final rule yet.

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3. **Are CCOs considered HINs w/regard to information blocking?**
ONC created a functional definition of HINs. However, whether a CCO is an HIN is not a question ONC can or will answer. ONC instead has said that the answer is not about the characteristics of an organization, it is instead about the functions they undertake. The definition of a HIN is about control and facilitation of exchange policies and infrastructure, and about exchange between more than two unaffiliated organizations for treatment, payment or healthcare operations purposes. CCOs should look at that definition and the functions they control or facilitate in exchanging information and determine whether it applies to them. ONC is unlikely to rule on whether CCOs are HINs. In the CCO contract we have noted that CCOs need to determine that for themselves.

4. **Do the rules include eReferral exchange?**
eReferrals are not part of the USCDI at this time so, no, eReferrals fall outside of the requirements for the data that must be shared for patient access in both the CMS and the ONC rules, and outside of the data that must be shared to avoid information blocking. Note however that consultation notes must be shared.

5. **Does information need to be made available for immediate release to not be considered information blocking? For example, a 3-day delay on labs?**
The answer really depends upon the reason that the information is not immediately available. The Privacy Exception might provide reasons for delays to get patient consent. The Security or Health IT Performance exceptions might provide reasons for delays due for IT infrastructure reasons. ONC has stated that timely access to data must be required, but has not established a set timeframe for what "timely" access means because there is so much variability regarding what "timely" will mean given the broad scope of health IT involved. ONC instead emphasizes that whether access is considered timely will be determined based on the specific facts and circumstances.

   The CMS final rule requires payers to provide patients with access to clinical data with 24 hours of receipt.

6. **Are Community Information Exchanges (CIEs), such as Aunt Bertha and Unite Us, included in these rules?**
To extent that the community information exchange performs actions that meet the definition of a Health Information Network (HIN), answer is probably yes. At a high level, the definition of HIN includes exchanging information for treatment, payment, or healthcare operation purposes among more than two unaffiliated organizations. If the CIE is only exchanging health or community services information for other reasons such as to meet housing needs, food support needs, etc., it may not be a HIN because the exchange is not for treatment purposes. You can't say yes or no whether any CIE does or does not meet definition of a HIN, as the definition is functional, not based on organization characteristics.

7. **Is there anything that limits the fees EHR vendors can charge providers to exchange data? And if not, if an EHR vendor charges a rate that is much higher than others can that be determined to be information blocking?**
Yes, unreasonable fees associated with interoperability might constitute information blocking. Organizations are allowed to charge fees, or to license their software for purposes of exchanging information. The Fees and Licensing exceptions list limitations on what those fees may be. They may not be excessive and they must be traceable to actual effort required to provide that service.

8. **What state specific laws are on your radar as relates to information blocking rules?**
Disclosures required by CMS (and ONC) rules are subject to state restrictions, such as regulation on the disclosure of BH information, HIV status, minors, etc.

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CMS Interoperability and Patient Access Rule: Requirements 1 & 2

9. **Is the state under the same requirement as the CCOs?**
   The requirement to provide patient access and provider directory APIs extends to Medicaid and CHIP fee-for-service programs (as well as to other CMS-regulated payers).

10. **Will OHA be providing a patient portal?**
    There is no requirement in the CMS rule for a payer to provide a patient portal. The requirement is to provide an access API (a program interface) that the patient can use with the third-party app (e.g., an app on their smart phone) to download their data and provider directory. The requirement to provide patient access and provider directory APIs extends to Medicaid and CHIP fee-for-service programs (as well as to other CMS-regulated payers).

11. **What solutions/vendors will OHA fee-for-service employ to achieve compliance?**
    OHA will make this information available once they have completed the special procurement process.

12. **For the Patient Access API, what is the mechanism of authenticating members?**
    Access to health information through the patient API must use SMART Application Launch Framework Implementation Guide Release 1.0.0, which specifies how OAuth2 and OpenID Connect are used to authenticate a patient and authorize the third-party app's access to health information. EHR portal access for patients has been a requirement for some time, so there is probably a mechanism most providers have put in place to create and manage login IDs and passwords for patients that can support patient access using SMART. Payers may need to develop processes to create and manage patient credentials.

13. **What is the definition of an administrative transaction as used for these items?**
    Plans get health and health-related information through what are sometimes called "administrative transactions" or HIPAA transactions or X12 transactions that have certain data dictionaries associated with them and a certain organization that differs significantly from what the FHIR standard is requiring. Plans will need to translate from the format and terminologies used to currently get that type of information into a new data model defined in FHIR. That process and those mappings may be foreign to their vendors and something they need to plan for.

14. **Are we responsible for data where we are not the source of truth (e.g., medications)? Are we expected to provide health information we have access to?**
    Yes, you must pass on all clinical data that is included in the United Stated Core Data for Interoperability (USCDI) and maintained by the payer. Data provenance, a new requirement under the USCDI, allows you to identify who is responsible for generating that data so that the recipient will know the source and can determine the trustworthiness of the information. Yes, you're required to share all of the information in the USCDI (which includes a medication list) independent of provenance (original data source).

15. **Is translation of information required if a patient doesn't speak English?**
    The CMS final rule does not specify requiring translation.

16. **Does the API rule require reading and writing through FHIR to the EHR or just being able to read and not write from the EHR?**

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Both the patient access rule in certification criteria and the patient access rule in the CMS rule for payers are for read access only. They are for the sole purpose of making claims and clinical data available to the patient. There is no requirement that FHIR be used to send data to the EHR or the payer system.

17. **If a *clinic* has claims in their data warehouse is it incumbent upon them to share the claims, or are those the responsibility of the plans?**
The CMS rule doesn't apply to health systems or providers. What is required for patient access for providers are the USCDI data elements, and only the USCDI data elements. Claims are not included in the USCDI data elements. If providers do have claims in their system, they don't need to provide them, and yes the patient can get claims from their plan instead.

18. **What, if any, work should individual healthcare systems expect as a result of the new payer requirement under the CMS Interoperability and patient access final rule?**
Nothing associated with patient access or payer to payer exchange in the CMS rule applies to healthcare systems.

CMS Interoperability and Patient Access Rule: Requirement 3

19. **For payer-to-payer exchange are there any candidate API standards recommended by OHA or CMS that are likely to be adopted nationally; that is, is there a coordination effort in progress?**
Not from within the CMS final rule, but when CMS talks about payer to payer exchange they reference the Da Vinci project guidance on how FHIR could be used for this purpose. Therefore, the implementation guides could be considered. But there is no direction from CMS at this time on what standard is required or on a process for payers to adopt a particular standard. Payers planning for the implementation of the payer to payer exchange API might want to consider the work of the Da Vinci project.

20. **Does OHA intend to play a role in establishing/proposing a technical standard for payer-to-payer data exchange applicable to CCOs?**
OHA will not have a mandate, but OHA encourages payers to collaborate on a standard. CMS has strongly encouraged applicable payers to consider using a FHIR-based API, since the data they need to make available for this exchange are also data that will be made available via the patient access API and there are therefore synergies.

21. **How does the plan provide USCDI data when it is not collected?**
The CMS rule only requires a plan to exchange USCDI data elements that are maintained by the payer. It does not require the payer to obtain additional USCDI data elements not maintained by it from the providers rendering care.

22. **How do payers exchange USCDI data when they don't manage it and it's in the patient's EHR?**
The CMS rule requires payers to exchange claims data and clinical data maintained by it, if the clinical data is in the USCDI. If a payer doesn't maintain that data already, it is not required to obtain that data from the providers and provide it to patients. Payers are only required to provide access to clinical data that is already maintained by it and that they obtained through existing processes.

23. **Do these rules apply to data held by the state?**
Certification and information blocking provisions apply to a state only under certain circumstances. First, information blocking applies to the state if the state meets the criteria of a health information network

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(HIN) as defined in the ONC final rule. Second, CMS-regulated entities, including state Medicaid and CHIP programs, must provide patient access to their claims and clinical information based on the CMS final rule provisions.

CMS Interop Policy 4, 5, 6, 7

24. **Since CCOs as payers cannot apply for an NPI with NPPES, do the last three CMS requirements apply to CCOs?**
    The requirement for listing your digital contact information is a provider requirement, not a payer requirement, even though it appears in the CMS rule. The last 3 areas in the CMS rule, the attestation that you're not information blocking, the requirement to list digital contact info in NPPES, and the ADT event notification requirement are provider requirements and not payer (or CCO) requirements.

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