General Questions (4.2)

August 7, 2020. These responses have been provided by the Health Informatics and Interoperability Group at CMS and are based on the Interoperability and Patient Access final rule (CMS-9115-F) published on May 1, 2020. The responses reflect current information from the final rule and do not constitute new policies nor create new requirements on the public. Please feel free to share this information with other individuals and organizations to whom it may apply.

1. The final rule requires that we share information we 'maintain.' Information obtained via CMS Blue Button includes specific consent and release requirements. Does final rule supersede the Blue Button consent model and are we required to share this information as part of the Patient Access API?

Response: If this question is being asked from the perspective of a payer, this could be a unique situation, as Blue Button generally does not share information with payers. The Medicare Blue Button enables beneficiaries to access their Medicare Parts A, B and D claims and encounter data, and share that electronic information through an API with approved applications, services and research programs they select.

2. We are assuming that the FHIR access scope, given to the apps, is patient/*.read. This is particularly important in terms of how we will support access to data for a minor dependent or for access by a personal representative to the person/people they represent. The implication is that the consent flow will require the user to select the person whose data they are connecting the app to (it could be their own, if a member, a minor dependent or a person that they are a personal representatives for). The alternative (some sort of new user scope for multiple patients) does not look to have any convention that can be adopted, without complicating the work for apps.

Response: In the Interoperability and Patient Access final rule, we reiterated that data sharing is already effectively occurring; the API is a new way to make the data available. We also said that the current regulation does not change existing privacy relationships between minors and parents. In most health plans, the policy holder has access to the claims and other information for other members covered by the policy, unless there is a privacy provision in place. And we referenced the HIPAA Privacy Rule at 45 FR 164.522, which says that individuals have a right to request restrictions on how a covered entity will use and disclose protected health information. The final rule does not change any requirements under federal, state, local, or tribal law. Please see 85 FR 25547 for a more complete discussion of privacy and access as it relates to an enrollment group.

3. State Medicaid’s and others have asked that if they have “outsourced” to other entities certain benefits management and claims processing (e.g., behavioral health, pharmacy, dental), does the API requirement still apply to them (the state agency) or can Medicaid direct the member to the outsourced entity and expect the outsourced entity (e.g., benefit manger) will accept the responsibility for compliance?

Response: If an organization impacted by the Interoperability and Patient Access final rule, including State Medicaid programs, has outsourced certain benefits management and claims
processing, the requirements of the final rule still apply to them. For example, a Medicaid beneficiary should be able to find an app of their choice and authorize that app to retrieve their data via the Patient Access API. The identity of the business associate, outsourced entity, or benefit manager is not relevant. It is the responsibility of the State to ensure if a beneficiary covered by them is able to request the specified data. See 85 FR 25532 for further discussion on this point.

ADT Sharing (Scheduled for 16-July-2020)

1. Please confirm that hospitals covered under the final rule that meet the ADT requirement as defined at 45 CFR 170.205(d)(2) (HL7 2.5.1) may exchange the designated minimum data regarding an admission, discharge or transfer by any electronic method and not just by using HL7 V2 messaging.
2. Please confirm that exchange of ADT using Da Vinci Alerts IG would meet notifications going to approved care team members (e.g., primary care, payer)?

Response: The policy for the Patient Event Notification CoP requirement is limited to those hospitals and CAHs that utilize an electronic medical record system or other electronic administrative system with the capacity to generate information for electronic patient event notifications. The standard is defined 45 CFR 170.205(d)(2). It is correct that this requirement does not require the use of a specific standard to share the electronic notification. We did not propose, and thus did not finalize, a specific format or standard for the patient event notification that a hospital would be required to send under the proposed CoP. Thus, hospitals would be allowed to transmit patient event notifications using other standards, such as the CCDA or via a FHIR-based API (see 85 FR 25596 through 25597).

Question arising out of first responses from CMS:

If data covered by USCDI is in PDF or image format, does making it available via the Document Reference resource meet the requirement for the Patient Access API?

Response: We are continuing to evaluate this question.

Patient Access API, Information Blocking, and Organization Type

1. Is the payer a covered actor with regard to data blocking? If so,
   a. Do the civil monetary penalties apply to the payer?
   b. Which exchanges are considered part of the evaluation of data blocking?
      1. to the enrollee’s authorized third-party application (EOB, USCDI)
      2. payer to payer as directed by the enrollee or past enrollee
      3. other requests for data (e.g., from providers)

Response: Information Blocking is beyond the purview of the CMS Interoperability and Patient Access final rule. For questions related to information blocking, refer to the Office of the
2. If a single payer plays multiple roles in the industry (such as providing a covered insurance product, having providers that deliver care, owning part or all of an HIE, developing covered applications, etc.).
   a. Do the CMS rules only apply to the payer role?

**Response:** The CMS Interoperability and Patient Access final rule requirements apply to the payers indicated in the final rule. The data that these payers must make available depends on how the payer maintains the data.

   b. If other roles fall under the actor descriptions for the ONC rule, do the ONC Final Rule requirements only apply to that specific role?

**Response:** Questions specific to obligations under the ONC 21st Century Cures Act final rule should be directed to the Office of the National Coordinator at For additional assistance on the ONC rule, send questions to the ONC feedback form: [https://www.healthit.gov/form/healthit-feedback-form](https://www.healthit.gov/form/healthit-feedback-form).

   c. Does the answer for the questions above depend on the legal structures of the entities delivering these roles?

3. Can clarification of the definitions of HIE and HIN be provided for compliance and operations?

**Response:** Questions specific to obligations under the ONC 21st Century Cures Act final rule should be directed to the Office of the National Coordinator at For additional assistance on the ONC rule, send questions to the ONC feedback form: [https://www.healthit.gov/form/healthit-feedback-form](https://www.healthit.gov/form/healthit-feedback-form).

4. If a payer chooses not to implement a suggested IG (such as CARIN BB or PDex Plan Net) and subsequently adopts their own proprietary IG, does this constitute data blocking?

**ANSWER:** The CMS Interoperability and Patient Access final rule does not require the use of any specific Implementation Guides. That said, the implementation guides suggested provide information payers can use to meet the requirements of the policies finalized in the rule without having to develop an approach independently, saving time and resources. In addition, the reference implementations made available for this IG allow payers to see the APIs in action and support testing and development. We note that the rule does require payers to make documentation about their API publicly and freely available as not to inhibit a third-party app from accessing the API at an enrollee’s request. Ultimately, we do strongly encourage payers to consider using the suggested IGs.
For questions related to information blocking and impacted organizations, refer to the Office of the National Coordinator’s webpage and InfoGraphic which provides a summary: https://www.healthit.gov/topic/information-blocking.

5. If an application vendor (such as Apple Healthkit) adopts the CARIN IG as the method for patient administrative data intake, as recommended by CMS, does every payer need to accommodate that application vendor’s decision to use the CARIN IG?

Response: The CMS Interoperability and Patient Access final rule requires impacted payers to make certain information available via a FHIR-based API. Third-party vendors can leverage these types of data and offer their apps to patients. A compliant payer API will have the necessary data available in the specified FHIR format, and the payer will have the required API documentation publicly available. This will permit third-party apps to accommodate patient requests to retrieve their data from impacted payers. The final rule does not include requirements for third-party vendors.