

General Questions (reviewed 07-July-2020, recommended for submission 09-July-2020)

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1. Is there a requirement for one API endpoint for all data or may a payer support multiple endpoints (e.g. one for EOB and another for USCDI data) to meet the requirements of the final rule?
 - a) Is there need for a payer to provide access to covered information for more than one covered product (e.g. CHIP, MA, Medicaid, QHP) through the same API endpoint? Does answer/guidance change depending on organizational/legal/entity structure providing products within a single payer (e.g., different organizations for CHIP, MA, Medicaid, QHP)?
 - b) Are there any data blocking implications if multiple patient access API endpoints are implemented as described in preceding questions?

Response: The final rule does not define the number of endpoints payers must have. A payer may support one or more endpoints to implement the final rule requirements.

The final rule also does not specify how each payer must approach making covered information for covered products available through their API or (APIs).

Generally speaking, as long as the enrollees covered by this policy are able to obtain their data in the manner required, how the API endpoints are operationalized is not a factor. For details about the HHS information blocking policy, please refer to the ONC 21st Century Cures Act final rule (see <https://www.healthit.gov/curesrule/overview/about-oncs-cures-act-final-rule>), and for specific questions about how those provisions apply and to whom, please send inquiries to: <https://www.healthit.gov/form/healthit-feedback-form>.

2. If outsourced benefit managers process claims or maintain clinical data under delegation, may they provide the Patient Access API endpoint(s) for those specific services?
 - a) Which organization holds responsibility for Patient Access API mandate compliance, the payer of record or the delegated benefit manager?

Response: The impacted payer is responsible for ensuring that the enrollee, upon request, receives the required data, regardless of who processes the claims or maintains the clinical data under delegation. It is up to each payer to ensure that data processed by a contractor on the payer's behalf are available, as required, under this policy.

3. The rule suggests that FHIR patient data access scope should not be recognized as part of the implementation of the Patient Access API and that the only mode is ‘all data’ available (e.g., read/*). Is this interpretation correct?

Response: Per the final rule, if a patient requests their data be made available to a third-party app via the Patient Access API, the patient is authorizing the payer to share all available data as specified in the final policy. This means all claims/encounter data and clinical data in the form of the USCDI that the payer maintains with a date of service on or after January 1, 2016, as well as formulary data. A payer is not required to provide the patient the opportunity to choose specific types or segments of this available data be shared or not shared.

4. Does the concept of data that payers “maintain” require that the payer has current information available for a USCDI element (e.g., smoking status) or is the payer required to make any USCDI element available even if the data is known not to be current or to be incomplete?

Response: A payer is only required to make available the data that they maintain in their system as part of the current enrollee’s record with a date of service on or after January 1, 2016. A payer is not required to verify the current status of the USCDI data elements maintained. Per the final rule, payers are not prohibited from indicating additional information about the USCDI data, such as perceived or known status (e.g. currency or completeness) of a USCDI data element.

5. Is there any requirement in the final rule that would impact a payer’s standard data retention policy?

Response: Impacted payers must make the specified data they maintain with a date of service on or after January 1, 2016 available through the Patient Access API for current enrollees. As such, this policy requires impacted payers to maintain data they have from January 1, 2016 forward for all current enrollees.

6. As part of telephonic case management, payers may verbally acquire from the member information such as vital signs that are not obtained by clinical observation.
 - a) Is this type of information considered to be USCDI elements and therefore covered by the final rule requirement to make these data available (e.g., is member-reported data included under the rule)?
 - i. As part of the Patient Access API requirement?
 - ii. As part of Payer to Payer exchange requirement?

Response: Though the payer did not obtain the information through direct observation, the payer is required to include the information in the Patient Access API or Payer-to-Payer data exchange if the payer maintains the data. Again, the final rule defines “maintain” to mean the payer has access to the data, control over the data, and authority to make the data available through the API (85 FR 25538). As such, if the data meet the above definition of maintain, the data are part of the enrollee’s record, and within the timeframe, then the data need to be included.

Formulary (reviewed 07-July-2020, recommended for submission 09-July-2020)

- 1) Does the rule require that a Formulary API includes an indicator of the status of covered drugs, tiering information, and utilization management requirements?
 - a) If prior authorization is required, is a single indicator (e.g., Y/N) sufficient?

Response: The final rule requires that impacted payers, specifically MA-PD plans, Medicaid and CHIP FFS programs, Medicare managed care plans, and CHIP managed care entities make formularies or preferred drug lists available via the Patient Access API. MA organizations that offer MA-PD plans are specifically required to make available formulary data that includes covered Part D drugs, and any tiered formulary structure or utilization management procedure which pertains to those drugs (42 CFR 422.119(b)(2)(ii)). Medicaid and CHIP FFS programs, Medicare managed care plans, and CHIP managed care entities are required to make information about covered outpatient drugs and updates to such information, including, where applicable, preferred drug list information through the Patient Access API (see requirements under 42 CFR 431.60(b)(4), 438.242(b)(5), 457.730(b)(4), and 42 CFR 457.1233(d)(2)).

We suggest leveraging the PDex Formulary IG to meet these requirements.

- a) If prior authorization is required, a single indicator of Y/N is sufficient.