

Final Rule Questions for CMS – 06-23-2020 V1.0

- 1) The definition of provenance in USCDI requires both the date/time at which the information was created as well as the organization associated with the individual that “used” the data. Payers frequently will not have knowledge of the actual date/time of creation of the specific organization that created the data (they know the organization from which it was received).

May the payer provide a non US Core profile on the provenance resource (as specified by the Da Vinci PDex IG) to indicate that the payer is the transmitter and optionally, a second provenance resource to indicate the source of the information and method of receipt (e.g. received from xxxx organization on xxxxx via a CCDA)?

If not, should the payer

- a. make a US Core provenance resource available and use a data absent reason for unknown data, or
- b. exclude the provenance resource?

Response: Appreciating the additional value the PDex IG provides for payers, and the compatibility of the PDex IG with the US Core IG, we are adding PDex as “suggested” option available to payers to meet the requirements of the rule. This information is being added to the CMS website: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>.

- 2) Please clarify the Payers obligation to make data (e.g. claims, encounter, clinical) available via the member access API in the following situations:

- a. Payer uses separate legal entities to provide different covered plans (e.g. Medicare Advantage and Medicaid HMO). Is the payer required to make the data from all plans available to the current enrollee in one of the plans via the member API? If yes, are multiple APIs acceptable? *Response: If the patient is a current enrollee in the Medicare Advantage plan, the payer is required to make all data they maintain for that patient as part of their enrollee record within the Medicare Advantage plan. Critical here is the definition of “maintain”. 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). If the data meet this definition of maintain per the payer’s assessment and are part of an enrollee’s record, the data would need to be made available via the Patient Access API upon the patient’s request. If these maintained data are not currently in a FHIR format, these data would need to be converted to a FHIR format and shared via the Patient Access API. How a payer chooses to implement the API (one or many), is completely up to the payer.*
- b. If the current enrollee in a covered plan (e.g. Medicare Advantage) was previously enrolled in the same or another covered plan (e.g. QHP in Federal Marketplace) is the payer required to make the data available from all covered plans via the member API?

Response: As noted above, this goes back to how the payer “maintains” the data for the enrollee in their current plan.

- c.** Is the payer required to make data available from a non-covered plan (e.g. commercial coverage and not a qualified QHP) when the member is enrolled in a current covered plan (e.g. Medicare Advantage)? *Response: No, this is not required. Again, this goes back to how the payer “maintains” the data.*
- d.** If a member leaves the payer for five years and then returns as an enrollee in a covered plan (e.g. Medicare Advantage) is the payer required to make data available to the member via the member API going back to 1/1/2016? *Response: All payers need to make data they maintain for their current enrollees with a data of service on or after 1/1/2016 available. If an enrollee is with a plan from 1/1/2016 through 1/1/2021, leaves, and returns 1/1/2026 it would depend on how the payer maintains the data from 1/1/2016 through 1/1/2021. If these data are maintained and part of the enrollee’s record upon their return in 2026, then, yes. If the payer essentially considers the enrollee a new member in 1/1/2026 and has not maintained the previous years’ data as part of the enrollee’s current record, it would not be part of the enrollee’s record and would not be available via the Patient Access API. We note that all existing and applicable data retention requirements are assumed to be taken into account here by the payer, as appropriate.*
- e.** Must enrollee authorize access to all prior coverages to the third-party app or can they restrict the data to only the current covered plan. *Response: Starting in July 2021 when compliance with the Patient Access API is officially enforced, all specified data the payer maintains for the enrollee with a date of service on or after 1/1/2016 must be made available. If the payer maintains data other than data from the current covered plan as part of the enrollee’s record, then it would be included in what is available. Again, this goes back to how the data are maintained.*
- f.** If the payer is not required to make the data from a prior enrollment (regardless of plan type) available in the member API, is the payer required to make the data available via the Payer to Payer requirement as of 1/1/2022. *Response: As with the Patient Access API, the Payer-to-Payer data exchange is based on the USCDI data the payer maintains as part of the enrollee’s record. That said, if a payer receives data from a current enrollee’s former payer via a FHIR-based API under this Payer-to-Payer data exchange provision and then the enrollee asks their data be made available via the Patient Access API, the previous payer’s data should be included.*

3) With respect to information received via a claim or encounter:

- a. Is there any prohibition against including relevant data classes (e.g. procedure, diagnoses, medications) from a claim or encounter as part of the data the payer makes available to satisfy the requirement for clinical data where the minimum expectation is USCDI and the exchange standard is based on FHIR R4 US Core profiles? **Response:** *There is no prohibition.*
- b. Is there a requirement to include such information to meet the final rule requirement for, at a minimum, clinical data represented in USCDI (e.g. Procedures, Medications)?
 - i. In the member access API?
 - ii. As part of Payer-Payer exchange at enrollee request?

Response: *In both cases, if the payer maintains data elements defined as part of the USCDI version 1, these data must be shared via the appropriate API or data exchange provision.*

- 4) Is data in PDF format considered electronic data for the purposes of meeting the requirements for enrollee access to clinical data via the member API? Same question for Payer – Payer exchange? **Response:** *As noted above, if the required data elements are maintained by the payer but are not currently in a FHIR format, these data would need to be converted to a FHIR format and shared via the Patient Access API. The Payer-to-Payer data exchange does not require the use of a FHIR format starting in 2022, though we strongly encourage exchange via a FHIR API as these data will be prepared to share via this format for the Patient Access API requirements. Under the current Payer-to-Payer provision, this could be an exchange of PDF records.*
- 5) Is data in image format (clinical images, scanned documents, etc.) considered electronic data for the purposes of meeting the requirements for enrollee access to clinical data via the API? Same question for Payer – Payer exchange? **Response:** *The USCDI version 1 defines the clinical data classes and data elements that need to be included in the Patient Access API and via the Payer-to-Payer Data Exchange. Clinical images are not included in the USCDI version 1. Scanned documents should be evaluated the same way as PDF documents, as discussed in the previous question.*