August 21, 2023

The Honorable Micky Tripathi, PhD MPP
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, 7th Floor
Washington, D.C. 20201

Re: The United States Core Data for Interoperability (USCDI) Draft Version 5

Dear National Coordinator Tripathi,

The CARIN Alliance developed the Common Payer Consumer Data Set (CPCDS), an agreed upon set of data fields to exchange with consumers (similar to ONC 2015 Edition Common Clinical Data Set), and the CARIN IG for Blue Button, a FHIR-based implementation guide for health plans and consumer facing applications to use to implement the API to answer the challenge for health plans to 'meet or exceed' the CMS Blue Button 2.0 capabilities. The STU 1.0.0 version of the IG was published in November 2020 and the STU 2.0.0 version was published in November 2022.

The CARIN Alliance previously submitted new Data Class and Element recommendations for USCDI versions 2, 3, and 4 suggesting the inclusion of core administrative data found in the CPCDS and CARIN IG for Blue Button that did not exist in USCDI, but are necessary to further the ONC's mission of "a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange." Many of the submitted Data Element recommendations have been included within the **Health Insurance Information** and **Patient Demographics/Information** Data Classes in USCDI v3 or v4, however the **Explanation of Benefits (EOB)** Data Class and Data Elements associated with the CARIN IG for Blue Button were not included as part of USCDI v3 or v4 and were instead added to the ONC USCDI Comment level and are currently in the new Level 0 category.

Adding these missing Data Classes and Elements is critical to the implementation of the CARIN IG for Blue Button, which has been adopted by CMS Blue Button for all Medicare FFS beneficiaries[1] and by more than 90 percent of all CMS payers across the country (https://www.cmscompliancetracker.com/).

As we suggested in September 2021, April 2022, September 2022, and June 2023, these Data Elements are required to meet the *CMS Advancing Interoperability and Improving Prior Authorization Processes Rule*.[2] Additionally, to meet the *Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule* January 1, 2026 requirement,[3] the next version of the CARIN Blue Button IG will include a new set of non-financial EOB Data Elements. **The proposed rule requires "impacted payers build and maintain a Provider Access API to share patient data with in-network providers with whom the patient has a treatment relationship" including "patient claims and encounter data (excluding cost**

[1] https://bluebutton.cms.gov/developers/
[2] https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and
[3] https://www.federalregister.gov/documents/2022/12/13/2022-26479/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability

information).”[4] Furthermore, we anticipate, based on the Provider Access API requirements and conversations with providers, that when providers receive EOB information from a Payer they will be able to query other providers in the patient’s care team for the patients records (e.g., using the EOB information for record location services or RLS). Finally, we are in active dialogue with NCQA to include the HEDIS quality measures data as additional data elements within CPCDS (CARIN IG for Blue Button data model). This data would be immensely valuable to providers systems around the country.

In the final rule, CMS stated that “we believe patients should have the ability to move from payer to payer, provider to provider, and have both their clinical and administrative information travel with them throughout their journey. When a patient receives care from a new provider, a record of their health information should be readily available to that care provider, regardless of where or by whom care was previously provided. When a patient is discharged from a hospital to a post-acute care (PAC) setting there should be no question as to how, when, or where their data will be exchanged. Likewise, when an enrollee changes payers or ages into Medicare, the enrollee should be able to have their claims history and encounter data follow so that information is not lost.”[5] If it is CMS’ intent that “claims history and encounter data follow” the Medicare enrollee, then EOBs should be included in USCDI as EOBs give the enrollee information about how an insurance claim from a medical provider was paid on their behalf and what they might be responsible for paying.

CMS explained the importance of financial data in a response to a comment in the final rule stating that, “with access to price information, patients who would have cost sharing that is tied to such prices can be more informed consumers of their health care. Even patients who have no direct financial responsibility tied to these prices can benefit from knowing the information in the event their insurance coverage changes in the future or so they can appreciate the relationship between the services they receive and their cost to the health care system. It is important for patients to understand as much as they can about their care. For instance, understanding the costs of past services can help them plan for future services. As a result, this information has great value to patients even if it does not directly impact their ability to specifically influence what they pay for their care, or tell them exactly how much their next service will cost out of pocket.”[6]

A quick review of comments submitted to the final rule illustrates that many in the health care community agree that EOBs should be included in USCDI. Several examples are quoted below:

DirectTrust commented: “For example, after a claim is processed, CMS could require that plans push the patient’s explanation of benefits (EOB) automatically to the third party application of their choice via Direct message, without waiting for a patient to request it (similar to how many patients receive EOB information via paper today, or through their plan-tethered patient portals). This would improve convenience and usability for patients.”[7]

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[4] https://www.cms.gov/newsroom/fact-sheets/advancing-interoperability-and-improving-prior-authorization-processes-proposed-rule-cms-0057-p-fact

[5] https://www.federalregister.gov/d/2020-05050/p-78

[6] https://www.federalregister.gov/d/2020-05050/p-304

[7] https://www.regulations.gov/comment/CMS-2019-0039-1506

Alliance of Community Health Plans commented: "CMS is proposing that plans be ready to receive and disclose USCDI information, including clinical data and financial data, but the USCDI does not yet include financial data – information that is typical in an Explanation of Benefits." [8]

Apple commented: "Furthermore, because the USCDI does not include financial data, we recommend adding coverage and explanation of benefit data to the USCDI and strict adherence to the CARIN Alliance Implementation Guide by payers. This would subsequently require additional guidance to clarify the situations where a subset of the USCDI would be expected to be made available vs the complete set (e.g., that plans should only be required to make data available to the extent the data is electronically stored or managed in a database under the plan's control)." [9]

Microsoft commented: "We recommend that ONC and CMS work together to expand the US Core Data for Interoperability over time, to include the key financial data, including health coverage and explanation of benefit information, in addition to clinical data. This will provide a single, consistent source of truth to understand the set of data that have been well standardized."[10]

Humana commented: "If CMS is seeking to provide beneficiaries with additional transparency into the costs of covered items and services, the financial information available via the Explanation of Benefit (EOB) FHIR service will prove much more valuable to consumers."[11]

BCBSA commented: "As noted earlier, BCBSA supports patient access to their clinical healthcare data from providers, as well as access to usable claims information from payers. In particular, data points provided to consumers today through their explanations of benefits (EOBs) such as amounts providers charge, amounts insurers pay, amounts patients are responsible to pay, and information on where patients are with respect to meeting their deductible and out-of-pocket limits – are of interest to consumers."[12]

Furthermore, adding the Data Elements associated with the CARIN IG for Blue Button to the USCDI will provide everyone in the health care ecosystem the much-needed direction to include financial and administrative data in their technology roadmaps to support multi-sector interoperability. Moreover, these Data Elements are already made available by electronic health record vendors including Epic (see https://fhir.epic.com/Specifications?api=1072 and https://fhir.epic.com/Specifications?api=1073) as early as May 2020 and as part of the CMS data at the point of care pilot (https://dpc.cms.gov/) that was launched in July 2019.

We recommend that USCDI adopt all of the Data Classes and Elements that are required by the CARIN IG for Blue Button, including the Data Elements listed below, which are not currently in USCDI. We believe these Data Classes and Elements demonstrate extensive existing use in systems and exchange between systems and as part of multiple use cases that show significant value to current and potential users.

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[8] https://www.regulations.gov/comment/CMS-2019-0039-1086
[9] https://www.regulations.gov/comment/CMS-2019-0039-1492
[10] https://www.regulations.gov/comment/CMS-2019-0039-1253
[11] https://www.regulations.gov/comment/CMS-2019-0039-1184
[12] https://www.regulations.gov/comment/CMS-2019-0039-1081

The CARIN Alliance proposes the following:

NEW Data Class: Explanation of Benefit (EOB)

Currently, the **Explanation of Benefit** Data Class and Elements are in USCDI v4 Level 0. The CARIN Alliance recommends that the **Explanation of Benefit** Data Class be added to draft USCDI v5 along with key EOB Data Elements (non-financial), and others as selected by ONC. If ONC believes that more community feedback is warranted before EOBs are included in the final draft of USCDI v5, then the CARIN Alliance recommends that ONC move the **Explanation of Benefit** Data Class and Elements to Level 2. There are four criteria that must be met for inclusion of Data Elements within USCDI Level 2, and we believe these criteria *are* currently met by the EOB Data Class and corresponding Data Elements. Below we list the four criteria and how they are met.

The first key criteria is the representation of the Data Element within "a terminology standard or SDO-balloted technical specification or implementation guide."

- The Data Elements found in the Explanation of Benefit Data Class are found in CPCDS, which is included in the HL7 balloted CARIN Blue Button IG.

The second key criteria for inclusion within USCDI is that the "data element is captured, stored, or accessed in multiple production EHRs or other HIT modules from more than one developer."

- Some EHRs may include the clinical and financial data that is used to submit a claim. Some EHRs support this direct submission through EDI 837 attaching documents as part of a claim. EHRs kick off the prior authorization request, which is a mock claim.
- Another key factor is that the CMS *Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule* would require that EHRs exchange EOBs as part of the Provider Access API. Therefore, if USCDI is intended to be "a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange," EOBs should be included.

The third key criteria for inclusion within USCDI is that the "data element is electronically exchanged between more than two production EHRs or other HIT modules of different developers using available interoperability standards."

- If the HIT modules definition is expanded to a payers adjudication system and excluded from certification then this could be true.

The fourth key criteria for inclusion within USCDI is that the "use cases apply to most care settings or specialties."

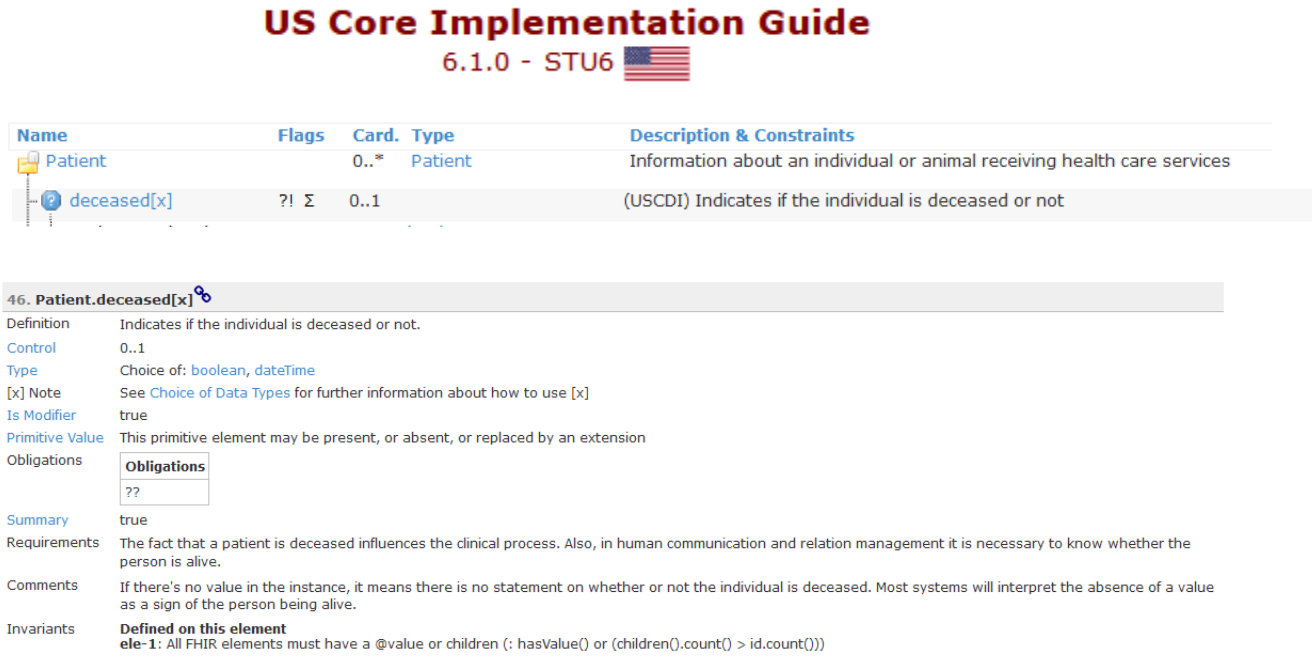
- EOBs absolutely apply to most care settings or specialties and include general information about the health plan, claims, provider charges, allowed charges, charges paid by insurer, what is owed or the balance, and are generated each time there is a claim.

Data Class: Patient Demographics

Data Element: Deceased Flag: Not included in any version of USCDI
USCDI v4 includes Date of Death, defined as the "known or estimated year, month, and day of the patient's death." However, as the Date of Death is not always known, it is important to have a way to indicate that the patient is deceased. The Deceased Flag would accomplish this.

Currently, Patient.deceased in US Core 6.1.0 points to USCDI, however this Data Element does not currently appear in USCDI.

Recommendation: We agree with US Core that "the fact that a patient is deceased influences the clinical process" and that ". . . it is necessary to know whether the person is alive." Therefore, we recommend adding the **Deceased Flag** Data Element to draft USCDI v5.



Source: http://hl7.org/fhir/us/core/StructureDefinition-us-core-patient-definitions.html#Patient.deceased[x]

Data Element: Member Identifier: USCDI v4
USCDI Definition: Sequence of characters used to uniquely refer to an individual with respect to their insurance.

The definition of the **Member Identifier** Data Element is a little vague and could be more explicit. As an example, in CPCDS we define Member ID as follows: "Identifier for a member assigned by the Payer. If members receive ID cards, that is the identifier that should be provided."

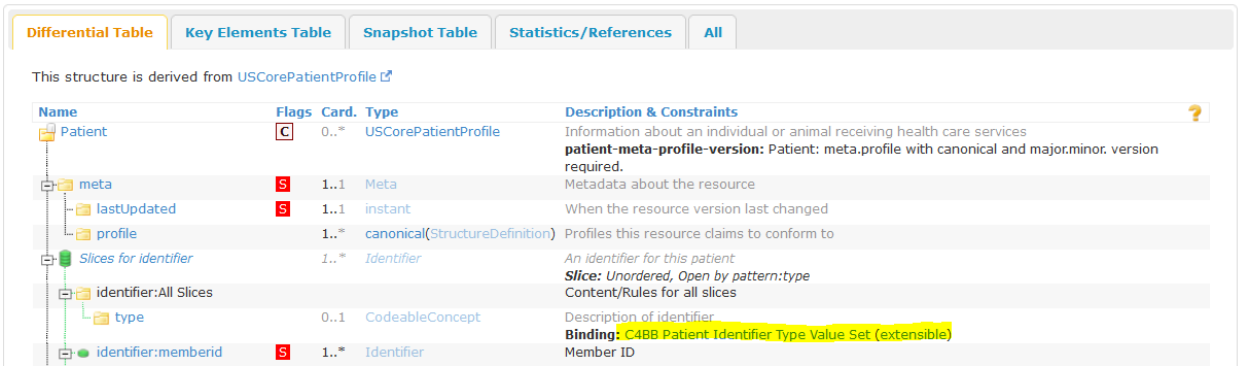
Recommendation: We recommend updating the definition of **Member Identifier** in draft USCDI v5 to be more explicit on the definition of the Member Identifier Data Element.

Data Element: Patient Identifier Type: Level 2
USCDI Definition: Identifies the type of identifier payers and providers assign to patients.

Recommendation: We recommend **Patient Identifier Type** be included in draft USCDI v5 as there is currently no Data Element that captures this information in any version of USCDI. This

Data Element references the HL7-defined V2 code system of concepts specifying type of identifier, which includes a number of identifier codes including a Patient's Medicare number, which is a key Data Element in the CARIN Blue Button IG.

CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®)
2.0.0 - STU 2 US



Source: http://hl7.org/fhir/us/carin-bb/StructureDefinition-C4BB-Patient.html

8.50.1.1 Logical Definition (CLD)

This value set includes codes based on the following rules:

- Include these codes as defined in `http://hl7.org/fhir/us/carin-bb/CodeSystem/C4BBIdentifierType`

Code	Display	Definition
um	Unique Member ID	Indicates that the patient identifier is a unique member identifier assigned by a payer across all lines of business
pat	Patient Account Number	Patient Account Number

- Include these codes as defined in `http://terminology.hl7.org/CodeSystem/v2-0203`

Code	Display	Definition
MB	Member Number	An identifier for the insured of an insurance policy (this insured always has a subscriber), usually assigned by the insurance carrier.
MR	Medical record number	An identifier that is unique to a patient within a set of medical records, not necessarily unique within an application.

Source: http://hl7.org/fhir/us/carin-bb/ValueSet-C4BBPatientIdentifierType.html

HL7 Terminology
1.0.0 - Publication

Code	Display	Definition	V2 Table Status	V2 Concept Comment	V2 Concept Comment As Published	HL7 Concept Usage Notes
MC	Patient's Medicare number	Patient's Medicare number	A	Class: Insurance	Class: Insurance	

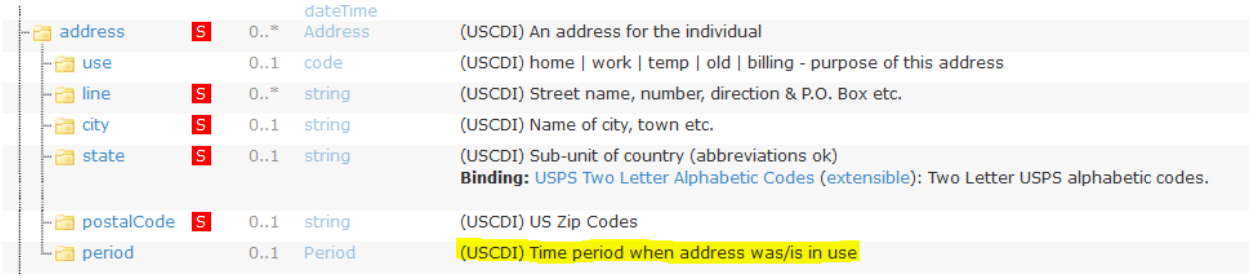
Source: https://terminology.hl7.org/4.0.0/CodeSystem-v2-0203.html

Data Element: Patient Address use Period: Level 1
Definition: This is the address start and end date. The time period is important in determining the current address versus address at diagnosis.

Current Address and Previous Address are included in USCDI v4. However, there is no time period associated with either address. This is an important Data Element in the CPCDS and the CDC has also recommended including the time period associated with an address. As an example of why time period is important, CDC explained that "capturing a time period of when a

patient lived at an address aids public health reporting when assessing time of exposure within specific residences."

Time period is also included in US Core v 6.0.1 and points to USCDI, however time period does not currently appear in USCDI. http://hl7.org/fhir/us/core/StructureDefinition-us-core-patient.html



			dateTime	
address	S	0..*	Address	(USCDI) An address for the individual
use		0..1	code	(USCDI) home | work | temp | old | billing - purpose of this address
line	S	0..*	string	(USCDI) Street name, number, direction & P.O. Box etc.
city	S	0..1	string	(USCDI) Name of city, town etc.
state	S	0..1	string	(USCDI) Sub-unit of country (abbreviations ok) **Binding:** USPS Two Letter Alphabetic Codes (extensible): Two Letter USPS alphabetic codes.
postalCode	S	0..1	string	(USCDI) US Zip Codes
period		0..1	Period	(USCDI) Time period when address was/is in use

Recommendation: We recommend adding **Patient Address use Period** **(currently at Level 1)** to USCDI v5 as there is currently no Data Element that captures this information. In addition, we recommend removing the Data Class Address Begin / End Dates from Level 0 (submitted by the CARIN Alliance) as it is sufficiently covered by **Patient Address use Period.**

Data Class: Health Insurance Information

Data Element: Coverage Type: USCDI v3 and v4
Definition:

- USCDI v3 - Category of health care payers. (e.g., Medicare, TRICARE, Commercial Managed Care - PPO).
- USCDI v4 - Category of health care payers, insurance products, or benefits. Examples include but are not limited to Medicaid, commercial, HMO, Medicare Part D, and dental.

Recommendation:
The definition of **Coverage Type** changed between USCDI v3 and v4, however US Core v6 points to USCDI v3, therefore we will use that version in our recommendation. In USCDI v3, this Data Element captures the "category of health care payers. (e.g., Medicare, TRICARE, Commercial Managed Care - PPO)." This Data Element in US Core v6 points to SOP (example, value set OID: 2.16.840.1.114222.4.11.3591) https://vsac.nlm.nih.gov/valueset/expansions?pr=ecqm, which includes a mixture of different types of concepts. We recommend splitting this resource to have separate resources for plans and products.

Data Element: Coverage Period: Level 2
Definition: The time frame in which the policy is in force.

Recommendation: We recommend adding **Coverage Period** to draft USCDI v5 as knowing the time frame in which the policy is in force (start and end date) is a critical data element to ensure appropriate care is delivered and paid for by the health care insurer.

Data Element: Group Name: Level 2
Definition: Name of the Employer Account.

Recommendation: We recommend adding **Group Name** to draft USCDI v5 as knowing the name of the Employer Account is a critical data element to ensure appropriate care is delivered and paid for by the health care insurer.

Data Element: Plan Identifier: Level 2
Definition: Business concept used by a health plan to describe its benefit offerings.

Recommendation: We recommend adding **Plan Identifier** to draft USCDI v5 as this business concept is used by health plans to describe its benefit offerings and is a critical data element to ensure appropriate care is delivered and paid for by the health care insurer.

Data Element: Plan Name: Level 2
Definition: Name of the health plan benefit offering assigned to the Plan Identifier.

Recommendation: We recommend adding **Plan Name** to draft USCDI v5 as this is the name of the health plan benefit offering assigned to the Plan Identifier and is a critical data element to ensure appropriate care is delivered and paid for by the health care insurer.

Again, we appreciate your consideration of our comments. Please do not hesitate in contacting me if you have any further questions.

RR Ryan Howells

Ryan Howells
Leavitt Partners
On behalf of the CARIN Alliance