Interoperability Standards Workgroup

RECOMMENDATIONS ON DRAFT USCDI VERSION 4

Report to the Health Information Technology Advisory Committee

April 12, 2023

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Background

The Health Information Technology Advisory Committee (HITAC) and its United States Core Data for Interoperability Task Force and subsequent Interoperability Standards Workgroup (IS WG) have provided recommendations to ONC regarding the expansion process and content for new versions of USCDI. With these recommendations in mind, ONC published USCDI version 2 in July 2021, version 3 in July 2022, and made changes to the process including additional prioritization criteria to help ONC choose among several hundred data elements for addition to future versions. These additional criteria focused on data classes and elements that could facilitate behavioral health integration with primary care, address health equity and disparities, respond to the needs of underserved communities, and advance public health data interoperability. ONC applied these new criteria to its evaluation of almost 150 public submissions for new data elements and almost 350 comments and feedback on previously submitted data elements received through the ONC New Data Element and Class (ONDEC) Submission System during the USCDI v4 submission cycle.

On January 13, 2023, ONC published its Draft USCDI Version 4 and the companion Health IT Standards Bulletin 2023-1, and sought public feedback on the data classes and elements included in this version and data elements not included in this version. ONC also requested additional feedback on several specific data elements. As part of this public feedback process, ONC charged the HITAC and the Interoperability Standards Workgroup (IS WG) to make specific recommendations on the final content in the USCDI v4.

ONC CHARGE TO THE INTEROPERABILITY STANDARDS WORKGROUP (IS WG)

Overarching Charge

The IS WG was charged with evaluating Draft USCDI v4 and providing recommendations to the HITAC by April 12, 2023, regarding the final version of USCDI v4 which is expected to be published in July 2023.

Detailed Charge

The workgroup's specific charge was to:

Evaluate Draft USCDI v4 and provide HITAC with recommendations for:

1a - New data classes and elements included in Draft USCDI v4 published in January 2023

1b - Level 2 data classes and elements not included in Draft USCDI v4

ADDITIONAL BACKGROUND INFORMATION

The IS WG includes an engaged group of subject matter experts representing various stakeholder groups, including direct patient care, patient advocacy, health IT development, standards development organizations, and others. The roster included in Appendix A to this document reflects the workgroup's membership at the time these recommendations were finalized.

Within the scope of the above charges, the workgroup addressed several specific questions on which ONC requested input during the public feedback period of January 12 to April 17, 2023. These questions included:

1. Suggestions for improvement in the data classes or elements in Draft USCDI v4, including:
    a. Data class and data element definitions
    b. Examples of code sets used by health IT developers and implementers to communicate data element scope.
2. Should other data elements, classified as Level 2 on the USCDI web pages, be added to USCDI v4 instead, or in addition to those in Draft USCDI v4? If so, why?
3. Are there significant barriers to development, implementation, or use for any of these data elements that warrant a change in definition, or removal from Draft USCDI v4?

In addition to these general questions, ONC also requested specific feedback on several data elements in Draft USCDI v4. To assist in the development of these recommendations, the workgroup invited several outside subject matter experts to give testimony regarding their areas of expertise, interest, and work. These presenters also took questions from workgroup members to inform their decisions. These included:

- Laurie Whitsel and Paul Chase from the American Heart Association and Lloyd McKenzie from Dogwood Health presented on March 1, 2023, and discussed the AHA's USCDI submission for several elements assessing physical activity including strenuous activity and weight bearing exercises. This testimony directly informed the workgroup's recommendations on the Physical Activity data element in the Health Status Assessment data class.
- Scott Robertson from Kaiser Permanente presented information on March 1, 2023, on an HL7 project to advance the interoperability of medication information. It directly informed the workgroup's recommendations on the Medication Instruction and Medication Adherence data elements in Draft USCDI v4.
- On March 8, 2023, Holly Miller, MD, from MedAllies and Terry O'Malley, MD, presented their experience in the LTPAC settings related to advance care planning. Maria Moen from ADVault presented her experience with the HL7 Advance Directive project. These presentations directly informed the workgroup's recommendations on the Goals data elements Treatment Intervention Preference and Care Experience Preference.
- On March 15, 2023, the workgroup heard from two workgroup members and representatives of their respective federal agencies, Michelle Schreiber from CMS, and Abigail Viall from CDC, who discussed several aspects of facility and organization data that informed the workgroup's recommendations on the Facility Information data elements in Draft USCDI v4.
- And finally, on March 22, 2023, the workgroup heard from Brian Bialecki, Dr. Keith Dreyer, and Mike Tilkin from the American College of Radiology who discussed their USCDI submissions to add several data elements related to Diagnostic Imaging to USCDI v4. Of note, these data elements were not included in Draft USCDI v4 but are Level 2 data elements and therefore would be considered by ONC for addition to the final USCDI v4.

Recommendations

INTRODUCTION

The focus of the IS WG work was to make specific recommendations on new data classes and elements included in Draft USCDI v4 and those previously submitted data elements that were mature enough to be designed “Level 2” by ONC but not included in Draft USCDI v4.

WORK GROUP RECOMMENDATIONS

New Data Classes and Elements in Draft USCDI v4

The IS WG supports the addition of all proposed data elements and data classes included in Draft USCDI v4 and based on their review makes the following detailed recommendations on definitions and scope of specific data elements and classes. Data elements with consensus approval without comment are not detailed below. The WG acknowledges that some data elements included in Draft USCDI v4 and the additional data elements recommended below may require additional development in the applicable exchange implementation specifications, such as HL7® FHIR® US Core and HL7 C-CDA® Companion guides. The WG understands that there may be implementation barriers identified by HL7 and the implementation community that could impact inclusion of one or more recommended data elements in USCDI v4.

- **IS-WG-2023_ Recommendation – 01 – Recommend that ONC add Allergies and Intolerances - Substance (Non-Medication) with clarification that this extends the existing elements to cover non-medication substances.**
- **IS-WG-2023_ Recommendation – 02 – Recommend that ONC add Health Status Assessments - Alcohol Use and reference the specific LOINC codes mentioned in the submission. The WG further recommends adding SNOMED CT as an applicable vocabulary standard.**
- **IS-WG-2023_ Recommendation – 03 – Recommend that ONC add Health Status Assessments - Substance Use and reference the specific LOINC codes mentioned in the submission.**
- **IS-WG-2023_ Recommendation – 04 – Recommend that ONC work with CDC, CMS, state, tribal, local, and territorial agencies and other key healthcare and public health authorities to identify and evolve appropriate vocabulary standards for Facility Information - Facility Type.**
    - Standards for Facility Type should be defined to maintain clear differentiation from encounter location and associated standards.
- **IS-WG-2023_ Recommendation – 05 – Recommend that ONC include the following applicable standards for Facility Information - Facility Identifier:**
    - CMS Certification Number (CCN)
    - Provider Transaction Access Number (PTAN)

- National Provider Identifier (NPI)
- Clinical Laboratory Improvement Amendments identification numbers (CLIA)

- **IS-WG-2023_ Recommendation – 06 – Recommend that ONC specify that Vital Signs - Average Blood Pressure includes, at minimum, the following LOINC codes as applicable vocabulary standards:**
  - 96607-7 Blood pressure panel mean systolic and mean diastolic
  - 96608-5 Systolic blood pressure mean
  - 96609-3 Diastolic blood pressure mean
- **IS-WG-2023_ Recommendation – 07 – Recommend that ONC reference the following code system as an applicable vocabulary standard for Laboratory – Result Interpretation:**
  - https://terminology.hl7.org/CodeSystem-v3-ObservationInterpretation.html, as it has been harmonized across HL7 v2, CDA, and FHIR.
  - Result Interpretation is required by CLIA (493.1291) and suggest adding this citation to the definition to emphasize its importance.
- **IS-WG-2023_ Recommendation – 08 – Recommend that ONC add language to the definitions of the following data elements that they are required by CLIA (493.1291):**
  - Reference Range
  - Result Unit of Measure
  - Specimen Source Site
- **IS-WG-2023_ Recommendation – 09 – Recommend that ONC specify in its definition of Laboratory - Specimen Identifier that it is intended to include the accession number assigned to the specimen.**
  - This data element is required by CLIA (493.1276(a))
- **IS-WG-2023_ Recommendation – 10 – Recommend that ONC rename the proposed Laboratory - Specimen Condition and Disposition data element to Specimen Exception Annotation.**
  - Specimen Exception Annotation includes any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability relevant to the performance or non-performance of a test as required by CLIA (493.1291).

- This alternative name would better describe the appropriate purpose and scope of the data element, that can be applied as appropriate to a lab result involving a specimen in a condition that would normally not be acceptable yet is still used for the test. It may also be used when a test is not performed and documented as such, or a test is cancelled with an indication of the specimen's condition being not acceptable.

- **IS-WG-2023_ Recommendation – 11 – Recommend that ONC does not use Procedures – Time of Procedure to represent the specimen collection date/time for a laboratory test.**

- **IS-WG-2023_ Recommendation – 12 – Recommend that ONC make the following changes to the Medications – Medication Instructions data element:**
  - Change the definition to the following:
    - Directions for administering or taking a medication. Including: route of administration (e.g., oral), quantity (e.g., take 1 pill), timing or hours of administration (e.g., once a day or every 12 hours), special instructions (e.g., as needed, for pain, for cough).
  - Include several specific components
    - Route of administration
    - Quantity
    - Timing or hours
    - Special instructions

  These data elements are a small subset of a broader set of data elements included in structure and codified SIG. We recommend the NCPDP superset continue to be reviewed for data elements to be included in future versions.

- **IS-WG-2023_ Recommendation – 13 –Recommend that ONC make the following changes to the Medications – Medication Adherence data element:**
  - Change the definition to the following:
    - Medication is consumed according to instructions as captured by provider, pharmacist, or clinician.
  - Include two specific components
    - Adherence codes (e.g., taking, not taking as directed, stopped, discontinued)
    - Reason for patient non-adherence. Examples of reasons for non-adherence include: (1) Indication e.g., duplicate therapy (2) Effectiveness e.g., medication not effective (3) Safety e.g., adverse effect (4) Adherence e.g., cost too much, etc.

  Both adherence (as defined above) and reason for non-adherence use existing SNOMED CT codes in medication history assessments today, including the reason for why the patient is non-adherent. By including the reason codes/data elements, we will also help address concerns brought up by patient advocates during WG discussions.

- **IS-WG-2023_ Recommendation – 14 – Recommend that ONC rename the Goals Data Class to Goals and Preferences.**
    - This change will better accommodate the range of concepts therein including Patient Goals, SDOH Goals, and the new data elements Treatment Intervention Preference and Care Experience Preference.

- **IS-WG-2023_ Recommendation – 15 – Recommend that ONC add Health Status Assessments - Physical Activity and reference the specific LOINC codes of the base measures mentioned in the submission.**

Level 2 Data Elements Not Included in Draft USCDI v4

- **IS-WG-2023_ Recommendation – 16 – Recommend that ONC rename the Patient Summary and Plan Data Class to Patient Care Plan, and the Assessment and Plan of Treatment data element to Care Plan Summary.**
    - ONC listed Care Plan as a data element at Level 2. IS WG sees Care Plan as a data class (whether named “Care Plan” or “Patient Summary and Plan”) – a structured package of core, common data elements, most already in USCDI, not a separate, individual data element.
    - ONC should work with interested parties to quickly develop these core structured data elements beyond a narrative summary into a Care Plan data class, to include in USCDI v5 in order to help meet immediate needs. This makes a critical advance, moving Care Plan to a more shareable data class.
    - ONC should add a data element for Care Plan Type.
    - The basic, common data elements already in USCDI, are recommended to be included as key components of a Care Plan:
        - Health Concerns
        - Patient Goals
        - Problems [e.g., diagnoses]
        - Procedures [e.g., interventions]
        - Care Team Member(s)
        - Care Plan Summary, the renamed Assessment and Plan of Treatment, would remain a narrative

- **IS-WG-2023_ Recommendation – 17 – Recommend that ONC include Advance Directive in USCDI v4, with an immediate priority focused on establishing an on-ramp for access to currently available unstructured advance directive documents (e.g., PDFs and scanned images), and include Advance Directive as a care plan type in the Care Plan data class, as per Recommendation 16, to enable access to structured data from advance directives.**

ONC should consider the following:

- An Advance Directive is not a singular data element, but rather a data class that can range from a simple scan to a well-structured, computable document that can be interpreted for a variety of decision support capabilities. It should cover the range of like documents, such as advance directives, durable powers of attorney for health care, do not resuscitate (DNR) orders, preferred interventions, and may also include resulting standing provider's orders for life-sustaining treatment (POLST), and medical orders for life-sustaining treatment (MOLST). From implementation, exchange, and care coordination perspectives, it is therefore logical to consider Advance Directives as a type of Care Plan typically authored by the patient, that may include practitioner-authored content, or be referenced by other practitioner-authored care plans, that address encounter-centric or and Portable Orders for Life-Sustaining Treatment (POLST).
- Current standards focusing on Advanced Directives, such as the PACIO HL7 Advance Directive Interoperability (ADI) FHIR implementation guide consider advanced directives a type or category of a care plan. One reflecting the patient's goals, preferred interventions to perform and avoid, including their care team and living will. The guidance emerging enables a narrative only capability, as well as the ability to further structure the care plan, as well as include relevant documents such as .pdf-s and scanned documents. This would enable more effective use of structured advance directive information but would also carry additional implementation burden.
- Immediate goals should be to make existing advance directive documents (e.g., PDFs or scanned images) available as quickly and easily as possible using currently available mechanisms. Thus, the workgroup recommends considering progressing the Advanced Directive Level 2 proposal in conjunction with the workgroup's Care Plan Level 2 recommendation and introduce not only the type of care plan in addition to the narrative already made available through the currently named Assessment and Plan of Treatment data element in USCDI v3, but also introduce a data element for supporting documentation, in particular those available through .pdfs or scanned images.
- We suggest that the proposed Treatment Intervention Preferences and Care Experience Preferences are considered in this context, specifically the progression towards structured content in a Care Plan as recommended in Recommendation 16.

End-of-life care information is critical to patient care to prevent harmful, unnecessary medical treatment against an individual's specified wishes. Inclusion of Advance Directive

documents meets USCDI draft v4 prioritization criteria of: (1) mitigated health and health care inequities and disparities; (2) address the needs of underserved communities; and (3) represents important additions over previous USCDI versions. The COVID-19 pandemic taught us that a lack of Advance Directives may cause suffering and inequity when making critical end-of-life care decisions.

- **IS-WG-2023_ Recommendation – 18 – Recommend that ONC add the following Clinical Notes to USCDI v4:**
    - Operative Note
        - LOINC 11504-8 as the generic or minimum operative note code
    - Emergency Department Notes
        - LOINC 15507-7 Emergency Department Progress Note and LOINC 59258-4 Emergency Department Discharge Summary as the generic or minimum emergency department note codes

- **IS-WG-2023_ Recommendation – 19 – Recommend that ONC add the following data elements, definitions, and value sets from the Gender Harmony Project to USCDI v4:**
    - Gender Identity
        - Female
        - Male
        - Nonbinary
        - Unknown
        - USCDI defined values:
            1. Additional gender category or other, please specify
            2. Choose not to disclose
    - Sex for Clinical Use
    - Recorded Sex or Gender
    - Name to Use
    - Pronouns

  These data elements along with their minimum value sets work together to represent sex and gender diversity for improved care and outcomes for gender-marginalized people.

- **IS-WG-2023_ Recommendation – 20 – Recommend that ONC change the name and definition of Sex to become an example of a Recorded Sex or Gender, e.g., recorded at birth.**

- **IS-WG-2023_ Recommendation – 21 – Recommend that Gender Identity remain in the Patient Demographics/Information data class. When added, Name to Use and Pronouns should be in the Patient Demographics/Information Data Class. Gender Identity, Name to Use, and Pronouns should be self-reported by the individual.**

- **IS-WG-2023_ Recommendation – 22 – Recommend that ONC add metadata that captures source for the data elements Sex for Clinical Use and Recorded Sex or Gender (e.g., individual self-report, clinical observation) and method of collecting values for each data element.**

- **IS-WG-2023_ Recommendation – 23 – Recommend that ONC change the name of the Laboratory - Test Performed Date/Time data element to Specimen Collection Date/Time (Clinically Relevant Observation Time) and add Specimen Collection Date/Time (Clinically Relevant Observation Time) as a data element in USCDI v4.**
    - This data element represents the most clinically relevant time point in which to interpret the result. In the case of observations taken directly from a subject, it is the actual date and time the observation was obtained. In the case of a specimen-associated study, this field represents the date and time the specimen was obtained from a patient and collected into a container or obtained.
    - This alternative name would better describe the appropriate purpose and scope of the data element.
    - This data element should accommodate time zone differences**.**
    - The above data elements should be combined**.**

- **IS-WG-2023_ Recommendation – 24 – Recommend that ONC change the name of the Lab Test Report Date/Time data element to Laboratory Result Report Date/Time and add Laboratory Result Report Date/Time as a data element in USCDI v4.**
    - This data element is intended to represent the most recent timestamp associated with completion of all components.
    - This alternative name would better describe the appropriate purpose and scope of the data element
    - This data element should accommodate time zone differences.
    - This data element is required by CLIA (493.1276(a)).

- **IS-WG-2023_ Recommendation – 25 – Recommend that ONC add Laboratory - Test Kit device name and manufacturer name to USCDI v4.**

  ONC should initially include the device name and manufacturer component of the test kit/device(s) and address the barriers to including the full UDI in the next USCDI version.
  Rationale: Test kit/device information is essential to analysis and interpretation of test results where different devices are used for the same/similar test that may or may not be comparable in trend analysis, and/or fully interpret the results. Yet availability of the full UDI in accordance with the FDA definition to ease these capabilities remains a challenge for systems outside the LIS. Documentation and inclusion of a test kit/device is still problematic as the UDI is not yet widely communicated by devices when they produce a test result,

thus the UDI needs to be inserted through configuration in the LIS or documented at the time of resulting the test. Or test kits are read manually, thus the relevant data needs to be documented at the time of resulting the test as well. To advance the ability to know the device(s) used to perform the test, focus should initially be on the device name and manufacturer creates a steppingstone, while the HITAC IS WG urges ONC to work with FDA, CMS, IVD and HIT suppliers, and laboratories to encourage inclusion of the full UDI as part of test results.

- **IS-WG-2023_ Recommendation – 26 – Recommend that ONC add Provenance - Author in USCDI v4.**

  This data element is especially relevant in conjunction with patient-generated health data (PGHD) and patient-reported outcomes (PROs).

  If ONC thinks that Author should not be included across the board, we recommend at the very least that ONC include Author in USCDI v4 for the following USCDI and draft USCDI v4 data elements that emphasize self-reported data and thus warrant capturing the individual as the author:
  - Race
  - Ethnicity
  - Gender Identity
  - Sexual Orientation
  - Disability Status
  - Pregnancy Status

  and the following Level 2 data elements that capture important PGHD and, further, advancing these Level 2 data elements to USCDI v4:
  - Family Health History
  - Problems: Date of Onset
  - Allergies: Substance (non-medication) [e.g., latex]
  - Allergies: Substance (food)
  - Travel Information [e.g., COVID-19, Zika]

- **IS-WG-2023_ Recommendation – 27 – Recommend data elements that may be used to capture patient-generated health data (PGHD) and support its bidirectional exchange in USCDI v4:**
  - Family Health History
  - Reported Medication
  - Problems: Date of Onset
  - Pregnancy Status (intent to become pregnant)
  - Nutrition & Diet
  - Substance Use (draft v4)
  - Allergies: Substance (non-medication) (draft v4)
  - Allergies: Substance (food)
  - Social History
  - Travel Information

- **IS-WG-2023_ Recommendation – 28 – Recommend including the following three Diagnostic Imaging data elements in USCDI V4:**
    - Imaging Reference
    - Requested Procedure Identifier
    - Accession Number

  While not all Health IT systems currently capture, maintain, or share information to access and view DICOM images, the requirement to exchange it when available would significantly advance the ability for individuals and providers to access and use diagnostic images and data files utilizing broadly available technology and would support current implementations of DICOM image file access and use within or outside networks such as Carequality and the Trusted Exchange Framework (TEFCA).

  The WG acknowledges that inclusion of these data elements in USCDI is not sufficient to achieve access to the DICOM images for all stakeholders. Specifically:
  - Sharing of image references by the PACS/image services needs further advancement to ensure consistent and universal access opportunities.
  - Exchange of full DICOM image files for complex diagnostic images requires broadband infrastructure that may not exist in some rural areas.
  - The Argonaut Project is working to identify and address critical next steps to include standards-based access to referenced DICOM images.
  - Current access to and sharing of DICOM image files require an agreed to sharing, trust, and security framework that to date has been point-to-point, thus limiting portability of image references, leading to inaccessible images. Efforts, such as Carequality, are advancing cross-network sharing, but do not address non-network based direct access.

  ONC should continue efforts to identify and mitigate infrastructure gaps that limit the access to and exchange of large data files that support high value care and recommends that ONC, in collaboration with CMS and other applicable agencies, should incent and support ongoing industry efforts to advance scalable trust frameworks to support the exchange of full image files.

- **IS-WG-2023_ Recommendation – 29 – Recommend that ONC add Facility Information - Facility Address to USCDI v4.**
    - Facility address is part of a core set of facility-level data elements needed to link data to a specific physical place of service or resource.

- **IS-WG-2023_ Recommendation – 30 – Recommend that ONC add Medications - Medication Prescribed Code and Medication Route to USCDI v4 as they are important data elements for quality measurement and public health.**

    - Medication Prescribed Code

        - Change the element definition to “A code (or set of codes) that specify medication prescribed or ordered, and to include textual description if no code is available." In addition, the applicable vocabulary standard would be RxNorm and NDC.

    - Medication Route

    - ONC should work with stakeholders to define elements for documenting data elements for medication administration statuses.

- **IS-WG-2023_ Recommendation – 31 – Recommend that ONC add Vaccinations - Vaccination Event Record Type data element to USCDI v4.**

- **IS-WG-2023_ Recommendation – 32 – Recommend that ONC add Orders - Orders for End of Life Care data element to USCDI v4**

- **IS-WG-2023_ Recommendation – 32 – Recommend that ONC add Orders - Orders for End of Life Care data element to USCDI v4.**

- **IS-WG-2023_ Recommendation – 33 – Recommend that ONC expand the definitions of the following Health Status Assessments data elements to include not only the specified assessment questions but also the responses or results of the assessments:**
    - Functional Status
    - Disability Status
    - Mental/Cognitive Status

  These changes would better align with the PACIO Project IGs. It is important to include the necessary information on responses since assessment data collected by health professionals, as well as patient generated health data collected from surveys or questionnaires, may be used for multiple purposes: including quality reporting, prior authorization, payments, utilization review, survey and certification, and more. Information garnered via patient health assessments is critical for planning patient-centered care and should be exchanged between providers during transitions of care to support care coordination.

Recommendations for Future Consideration

- **IS-WG-2023_ Recommendation – 34 – Recommend that ONC re-evaluate Organization – Organization Identifier as a Level 2 data element for consideration for addition to future versions of USCDI.**
    - Update the definition and/or the applicable standards to include NHSN Org ID as one of the applicable, widely used national standards.

- ONC should collaborate with CMS to evaluate moving the CCN from the currently proposed Facility Information data class to the Organization data class.

Appendix

WORKGROUP ROSTER

NAME	ORGANIZATION
Sarah DeSilvey* (Co-Chair)	Gravity Project, Larner College of Medicine at the University of Vermont
Naresh Sundar Rajan* (Co-Chair)	CyncHealth
Pooja Babbrah	Point-of-Care Partners
Shila Blend*	North Dakota Health Information Network
Ricky Bloomfield	Apple
Hans Buitendijk*	Oracle Health
Christina Caraballo	HIMSS
Grace Cordovano	Enlightening Results
Raj Dash	College of American Pathologists
Steven Eichner*	Texas Department of State Health Services
Nedra Garrett**	Centers for Disease Control and Prevention
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network
Bryant Thomas Karras*	Washington State Department of Health
Steven Lane*	Health Gorilla
Hung Luu*	Children's Health
Margaret Marshall**	Department of Veterans Affairs
Anna McCollister*	Individual
Clem McDonald*	National Library of Medicine
Deven McGraw*	Invitae Corporation
Aaron Miri*	Baptist Health
Aaron Neinstein*	UCSF Health
Kikelomo Oshunkentan*	Pegasystems
Mark Savage	Savage & Savage LLC
Michelle Schreiber**	Centers for Medicare and Medicaid Services
Shelly Spiro	Pharmacy HIT Collaborative

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