EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

June 9, 2025

Dr. Thomas Keane
Assistant Secretary for Technology Policy and
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Keane,

On behalf of our nearly 30 member companies, the HIMSS Electronic Health Record (EHR) Association provides the following feedback to the ASTP/ONC regarding the 2025 Standards Version Advancement Process (SVAP). As the national trade association of EHR developers, we appreciate this opportunity to contribute input on the ASTP/ONC's efforts to create a healthcare system that enhances accessibility, quality, affordability, empowerment, and innovation.

Broadly, there are four key points of feedback that the Association has provided regarding previous versions, which the ONC has yet to address and that remain relevant to the new standard version:

- **Comment Period Alignment:** To align SVAP more directly with the cadence for publishing the annual FHIR US Core and C-CDA Companion Guide releases that support each annual version of USCDI, the EHR Association recommends that the SVAP comment period begin and end later. For example, a comment period running from mid-May through mid-July with an approval announcement in August and a 60-day delayed effective date falling in October. As it currently stands, there is insufficient time to review and provide feedback on the FHIR US Core and C-CDA Companion Guide releases when their publication coincides with the closing of the SVAP comment period.

- **Partial Implementation Clarity:** We request confirmation from ASTP/ONC on the EHR developer community's current understanding of policy related to partial implementation of a new version of a standard approved under SVAP without claiming support for that version under the SVAP. For example, a scenario in which a developer wishes to add a new field or element from a new version of USCDI and the corresponding FHIR US Core or C-CDA Companion Guide standard but does not wish to advance to the full newer version. This is commonly done when a developer is

working on advancing to a full new version of USCDI and FHIR US Core/C-CDA Companion Guide but wants to release updates incrementally.

Releasing updates piece by piece allows customers and users, including patients, to benefit from each new feature as it becomes available. The current understanding is that this is perfectly acceptable, so long as what is introduced is additive and/or passive and does not create a direct nonconformity with the version of the standard that is currently claimed in certification (i.e., either the minimum version adopted in regulation or a newer version approved in a previous round of SVAP).

We would like to highlight that developers are already implementing this approach and have not encountered any issues with client use in production environments. Therefore, we seek confirmation that our understanding aligns with ONC's policy and expectations.

- **Concurrently Available Versions**: The current SVAP structure, which permits only one newly approved version of a standard to be available at any given time, is unnecessarily restrictive and does not align with typical development cycles or timelines.
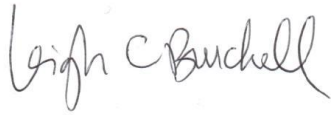
  The EHR Association recommends the SVAP Fact Sheet be updated to allow two new versions of the same standard (e.g., USCDI v3 and USCDI v4, WCAG 2.1 and WCAG 2.2, etc.) to be available under SVAP at a time. This is needed to accommodate the development timeline experienced by EHR developers. As it currently stands, EHR developers may be unable to complete development updates and SVAP activities by the August effective date on an upgraded standard they have been working on for the prior year. This is particularly limiting for standards that are generally updated annually, such as USCDI and associated FHIR/C-CDA specifications.

  Furthermore, allowing just two versions at a time is a reasonable compromise compared to requiring developers to maintain the availability of all SVAP-approved versions of a standard in perpetuity.
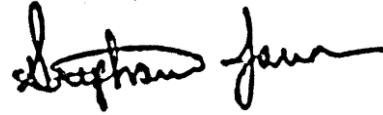
- **Clear Guidelines on Conditional Version Standards**: The EHR Association recommends providing a more precise and formal explanation of the dependencies between new standard versions. Specifically, we recommend a declaration on the SVAP page outlining the prerequisites for claiming a new version (e.g., to claim USCDI v3, one must also claim C-CDA Companion Guide R4.1 or US Core v6.1.0 – depending on the specific criteria for which it is being claimed).

- **SITE and Conformance Test Tools:** Conformance tools are essential for ensuring compliance with necessary rules, standards, and requirements. However, the timeliness of these tools poses a significant challenge. The Edge Test Tool (ETT), for instance, consistently fails to provide timely validation for new versions; USCDI v4 was not incorporated into ETT until November 2024. To address this, we must adopt a more efficient approach to tool updates and problem resolution, ideally by aligning the release of conformance test tools directly with the release of the SVAP standard.

As always, the EHR Association stands ready to assist. Our specific comments follow.

Sincerely,

Leigh Burchell
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CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians Programs; Implementation Guide for 2025 v1.1 (December 2024)

These annual updates are mandatory for developers and providers participating in CMS and TJC quality reporting programs. The EHR Association fully supports their adoption and recommends that the CMS Implementation Guide (IG) for QRDA Category III for Eligible Clinicians be automatically approved as part of each SVAP cycle, given its essential role in ensuring provider compliance with CMS quality reporting requirements.

CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2025 v1.1 (May 2025)

The EHR Association supports the adoption of the CMS Implementation Guide (IG) for QRDA Category I for Hospital Quality Reporting and recommends that it be automatically approved with each SVAP cycle, as it is required for hospitals to meet CMS quality reporting requirements.

United States Core Data for Interoperability (USCDI), Version 5

The EHR Association supports the continued adoption of updated USCDI versions with each annual SVAP cycle. As noted in our general comments, we also recommend adjusting the SVAP comment timeline to better align with the annual publication of the HL7 implementation guides that support USCDI exchange. Additionally, we urge ONC to apply clearer rules regarding the conditionality between USCDI versions and their associated HL7 FHIR and HL7 CDA C-CDA implementation guides as part of the SVAP process.

Accordingly, our support for the inclusion of USCDI v5 is conditional on the concurrent adoption of HL7 FHIR US Core Implementation Guide STU 8.0.0 (FHIR US Core v8.0.0) and HL7 CDA C-CDA Companion Guide Edition 4.0 (C-CDA Edition 4.0) as the required specifications for applicable program criteria.

We also want to express our appreciation for the inclusion of approved patches and additional guidance for USCDI versions in the Certification Companion Guide (CCG) for the §170.315(g)(10) Standardized API criterion. This approach allows developers to apply important corrections and enhancements from later HL7 FHIR US Core releases (e.g., FHIR US Core v8.0.0 associated with USCDI v5) to earlier implementations (e.g., USCDI v4 supported with FHIR US Core v7.0.0). This flexibility is vital to maintaining the binding between specific FHIR US Core versions and USCDI versions, and reinforces the integrity and practicality of the SVAP framework.

We understand that a similar patching and guidance process is planned for C-CDA-based USCDI criteria, and we look forward to its availability.

Finally, the EHR Association reiterates a key recommendation we have shared in past communications: to re-envision USCDI as a flexible library of data elements, from which developers are only required to

support those elements their systems actively manage, based on the needs of their customer base and market segment. In its current form, USCDI imposes unnecessary burdens, particularly on specialty EHR developers, by requiring support for data elements irrelevant to their clinical focus. Addressing this structural issue would make it significantly easier for developers to adopt new USCDI versions as they are introduced through SVAP.

HL7® FHIR® US Core Implementation Guide STU 8.0.0

As noted above, the EHR Association supports the adoption of HL7 FHIR US Core Implementation Guide STU 8.0.0 as the required implementation specification for program criteria involving FHIR API-based exchange of USCDI v5. We understand that this release has completed the HL7 ballot process and is expected to be published shortly, making it well-positioned for inclusion in ONC's August 2025 announcement of approved SVAP standards.

HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes Edition 4.0

As noted above, the EHR Association supports the adoption of C-CDA Edition 4.0 as the required implementation specification for program criteria involving C–CDA–based exchange of USCDI v5. We understand that this release has completed the HL7 ballot process and is expected to be published shortly, making it appropriate for inclusion in ONC's August 2025 SVAP standards announcement.