

April 28, 2022

Micky Tripathi, Ph.D. M.P.P.  
National Coordinator for Health Information Technology  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

RE: 2022 Standards Version Advancement Process (SVAP)

Dear Dr. Tripathi,

Cerner Corporation appreciates the opportunity to submit public comment on the Standards Version Advancement Process (SVAP) for 2022. As a leading supplier of clinical and management information systems and a market leader in health information interoperability, we believe our experience provides us with valuable insight in this subject area and are grateful for the ability to share that insight.

If you have any questions or if we can provide any additional information, please do not hesitate to contact me at (816) 201-1465.

Sincerely,

John Travis  
Vice President & Regulatory Strategy Executive  
Cerner Corporation

## General Standards Version Advancement Process (SVAP) Recommendations

In addition to our comments and recommendations on the proposed standards for the 2022 SVAP comment period put forth in this comment letter, we offer the following important recommendations for the future of the SVAP.

### **Hardening of the SVAP process and standards versions proposals**

Current state, the process for proposing new versions of adopted standards and opening them up for comment is too informal. New versions of standards are added to the [healthit.gov/svap](https://healthit.gov/svap) page as they pop up and could easily be missed by stakeholders or mistaken for being ineligible given timing. A more structured process by which a defined set of standards is presented as proposed for the annual SVAP comment period as of a particular date would help to ensure all stakeholders are operating on a clear, consistent, and even basis.

### **Alignment of SVAP timeline to USCDI expansion and standards development timeline**

As our comments provided later specific to the USCDI V2 standard version will further illustrate, the timing of the standards development of specifications to accommodate new versions of USCDI – in this case specifically the publication of HL7 FHIR® US Core R5.0.0 and HL7 CDA® C-CDA Companion Guide R3 in support of USCDI V2 – is still misaligned with the revised SVAP timeline. At present, HL7 estimates these to be available by the end of May. This timing leaves insufficient time for their consideration by the public for inclusion in SVAP given the current comment period end.

We appreciate that in what ONC did in 2021 to adjust the SVAP comment period to what is true now, ONC was trying to allow sufficient time for exactly this kind of circumstance. However, we believe this is still a matter of calibration that needs some more tuning. If the desire is to maintain an annual cadence for the SVAP, a logical adjustment to the timeline to adopt would be the following:

- Cutoff for new versions of standards to be considered for the SVAP comment period = June 30
- Comment period = July 1 – August 31
- Announcement of approved standards = October 1

This cadence would provide for assurances that new versions of USCDI and their corresponding exchange standard specifications could be adopted via SVAP (if appropriate based on stakeholder input) within ~15 months of the new version of SVAP being published. In our comments on the USCDI V2 standard version below, we recommend immediate

actions to take regarding the current cycle for the SVAP. We recommend the above timing be considered as a permanent change to the SVAP cycle.

## **Applicability Statement for Secure Health Transport Version 1.3, May 2021 (Direct)**

We highly recommend the approval of the new 1.3 version of the Applicability Statement for Secure Health Transport standard under the Standards Version Advancement Process (SVAP). For many reasons, the new Direct messaging standard version represents a perfect fit for the intent of the SVAP.

For starters, it is highly backwards compatible with the 1.2 version currently in place, meaning that there would be no perceivable issues or gaps that would create potential exchange issues between Direct messaging Health Information Service Providers (HISP) using the different versions. This was a very intentional strategy from Direct Trust in developing the update.

The new version also raises the bar from a security perspective. For example, the obsolete SHA-1 hashing algorithm for ensuring integrity of data exchange is now disallowed. Additionally, message wrapping has been elevated to required. This places MIME header content (e.g., the subject line of a Direct message) in an encrypted envelope to ensure that it is protected in cases where protected health information such as a patient's name or demographics might be included.

Finally, the new version adds some necessary clarifications to sections of the standard that were previously ambiguous. For example, support for domain-bound certificates is explicitly stated as required, which is something that was generally understood as required under the 1.2 version but was technically only recommended. Similarly, modes of AES encryption are now specified and textual descriptions of the reason for message bounces are required, which is important for troubleshooting purposes.

## **CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2022 (July 2021)**

We highly recommend the approval of the new QRDA Category I Hospital Quality Reporting IG standard for 2022 reporting under the SVAP. The annual cadence for uplift of QRDA specifications for the Centers for Medicare and Medicaid Services (CMS) eCQM reporting is well established and is something that both certified developers and healthcare providers have been accommodating each year long before the HIT Certification Program (the Program) was amended to enable alignment to that annual uplift process via the SVAP. This

also creates the opportunity for HIT developers to do something CMS has long advocated for which is to assert compliance with the updated specification versions through certification. Given that claiming support for updated QRDA specification versions through SVAP will be subject to Real World Testing, (RWT) HIT developers that claim such support for the new versions are also transparently held accountable for proving that claim.

Accordingly, it is in the best interest of all impacted parties for each new annual specification to be adopted under SVAP. Doing so enables HIT developers the opportunity to formally assert their ability to support the new annual specification updates, which also provides healthcare providers with necessary confidence that their software will support their reporting needs. For these reasons, the annual QRDA specification uplifts make for an ideal use-case for the SVAP.

## **CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2022 (May 2021)**

For the same reasons outlined under the CMS IG for QRDA I Hospital Quality Reporting IG for 2022 (July 2021), we highly recommend the approval of the new QRDA Category III Eligible Clinicians and Eligible Professionals Quality Reporting IG standard for 2022 reporting under the Standards Version Advancement Process (SVAP).

## **United States Core Data for Interoperability (USCDI), Version 2, July 2021**

We fully recognize the value of the annual USCDI version updates and have a strong desire to maintain currency with supporting exchange of each new version (including V2) independent of mandatory requirements under the Program. However, we feel strongly that inclusion of new versions of USCDI in the Program – starting with their inclusion for voluntary certification under the SVAP – should only occur once associated standard specifications (i.e., HL7 FHIR® US Core R5.0.0 and HL7 CDA® C-CDA Companion Guide R3) and vocabulary standards/value sets have been published to accommodate all new data classes/elements adopted in USCDI v2.

Adopting new versions of USCDI – even for only voluntary certification under SVAP – before the appropriate associated standard specifications are available will lead to wide variances in how those data classes/elements are exchanged in the real world. This will inevitably create unintended challenges with interoperability (most notably for effectively consuming data from external sources for use within the receiving system workflow) and would ultimately represent a direct step backwards from the standardized data exchange via consensus

standards that the program has been so effective at establishing. This is especially true in the API space where the recent Cures Update introduced FHIR standards conformance as a requirement under the 170.315(g)(10) criterion after initially easing into API-based exchange requirements with standards-agnostic requirements under the 170.315(g)(7)-(9) criteria. Introducing new versions of USCDI into the program without associated standards will directly contradict that progress and direction.

Furthermore, adopting the new version of USCDI as part of SVAP without those associated exchange standards tied-in would also appear to contradict ONC's statements in the Cures Act final rule on their intent for the SVAP: "We do recognize the importance of ensuring that updated versions of standards are approved and available for use in the Program only when such use is consistent with the Program's purposes. We do not anticipate that the National Coordinator would approve a newer version of a standard for use in the Program where that is inconsistent with the Program's purposes, notably including the maintenance and advancement of interoperability."<sup>1</sup>

Accordingly, we make the following specific recommendations regarding adoption of USCDI V2 (and future versions of USCDI) under the SVAP:

**In all scenarios of USCDI consideration under SVAP, the new version should only be approved if the corresponding new versions of exchange standards for representing newly adopted USCDI data classes/elements are also approved alongside it.**

Because the RWT process calls for proof of the production capability of the certified HIT to which a claim of support for a new standard applies, we believe that asserting support for a new version of the USCDI under SVAP also means certifying to the corresponding new version of the applicable exchange standard(s) for the given criterion that the new USCDI version applies to. For example, if a new version of USCDI is available for certifying to the 170.315(g)(10) criterion, it would also require the HIT developer to certify to the corresponding new version of HL7 FHIR® US Core. Similarly, if a new version of USCDI is able to be certified to for the 170.315(b)(1) criterion, it would also require the HIT developer to certify to the corresponding new version of HL7 CDA® C-CDA IG.

**Given that the necessary standard specifications for representing the new USCDI V2 data classes/elements via certified capabilities (i.e., HL7 CDA® C-CDA Companion Guide R3 and HL7 FHIR® US Core R5.0.0) have not yet been published, we recommend against adoption of USCDI V2 for the current SVAP comment period. However, since these new standard specifications are currently going through final review for likely publication in May 2022, we recommend that ONC open a special additional 2022 SVAP comment**

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<sup>1</sup> <https://www.federalregister.gov/d/2020-07419/p-1521>

**period exclusive to these three new versions of standards (i.e., USCDI V2, HL7 CDA® C-CDA Companion Guide R3 and HL7 FHIR® US Core R5.0.0).**

The adoption of USCDI V2 under SVAP is an important step to allow developers to move forward to supporting the new data elements without risk of creating a noncompliance of their software with the existing standards and should not be delayed to next year's SVAP. However, it would be wholly inappropriate to automatically adopt these new versions of supporting standards for USCDI V2 without providing suitable opportunity for public stakeholders to weigh-in on their potential adoption for the SVAP. And furthermore, delaying the adoption of the other standards being considered in this comment period solely for the consideration of these three outliers would also be inappropriate, and they should proceed to be made available for the SVAP. Therefore, a special dedicated comment period for these three outliers is warranted.

**Clarification should be provided regarding whether new versions of USCDI approved under SVAP can be certified for only individual criteria a developer may select, or if a developer must certify to all applicable criteria for which they hold an existing certification if they want to claim certification to a new USCDI version.**

This is technically a question that could apply to any standard under SVAP that applies to multiple Program criteria, but it is most glaring for the USCDI. On the surface, developers should have the flexibility to choose to certify to only individual criteria that cite USCDI as a required standard if they so desire. For example, even if certified for both the C-CDA criterion at 170.315(b)(1) and API criterion at 170.315(g)(10), a developer could choose to certify a new version of USCDI to only one and maintain certification to only USCDI V1 for the other. However, if a developer claims support for USCDI V2 without doing so for the full scope of criteria for which they hold a certification, that could be misleading to the market as to their support for USCDI V2. We appreciate ONC's clarification on this point.

**Enable stratification of USCDI when cited in regulation for the HIT Certification Program.**

This recommendation reaches beyond the scope of the SVAP but we feel it is critical for consideration in how the USCDI (and new versions of it) are incorporated into the HIT Certification Program in the future.

The reality of the USCDI in its current state is that it is inextricably linked with the Base EHR and Certified EHR Technology (CEHRT) concepts applicable primarily to healthcare providers in acute and ambulatory care venues. This is problematic as it effectively does not recognize the reality that certified HIT comes in many different shapes, sizes, and forms that have different needs/purposes, and it compels certified HIT developers (and the healthcare providers they serve) to support data that may be of little applicability to intended use of

their certified products. The result is questionable requirements for these products, problematic usability and workflow challenges given that certification requires data capture capability for any included elements, and data overload for clinicians and other EHR/HIT users instead of simplifying use as interoperability is intended to do.

As a resolution for this, we recommend that when cited as a standard in the HIT Certification Program, the USCDI should transition from being a single standard cited as an "all or nothing" requirement for applicable criteria to a model where defined subsets of the USCDI can be cited for individual criteria based on what elements from the full USCDI data library are appropriate. This would both solve the issues with Base EHR/CEHRT criteria we have called out, as well as opening opportunity for more specialized HIT to be able to be certified in the future in the Program.

## **HL7 FHIR® US Core Implementation Guide STU 4.0.0, June 28, 2021**

Cerner Corporation highly recommends the approval of the new HL7 FHIR® US Core Implementation Guide STU 4.0.0 version under the SVAP. There are several enhancements adopted with this new version, which we've outlined briefly below, that represent notable improvements and clarifications that should be made available as part of the program. But most importantly, it is critical for ONC to consistently adopt new releases of HL7 FHIR® and HL7 FHIR® US Core standards as part of the SVAP to enable the industry to continue to move forward with standardized API-based data exchange.

Among the notable enhancements adopted with the new 4.0.0 release of HL7 FHIR® US Core IG are:

- The clarification of specific references and/or data type choices required for applicable "must support" attributes. This update provides a hardened specification for what ONC adopted as policy in the 170.315(g)(10) criterion Certification Companion Guide which will create better alignment of the specifications to promote strong consistency of understanding and requirement across developers.
- Individual Profiles for each data element under the USCDI VI Vital Signs data class, whereas the 3.1.1 version simply references the FHIR Core Profile for most vital signs.
- Numerous updates providing necessary flexibility in data representation, such as the DocumentReference Profile's flexibility in representing the responsible organization to avoid duplication of data, and the update to Observation resource Profiles to allow systems that never provide an observation without a value to be exempt from having to support an unnecessary Observation.dataAbsentReason.

These are just a few of the examples from the more than seventy changes adopted in the new version which illustrate why it is appropriate to be made available for voluntary

certification through the SVAP. Furthermore, necessary conformance validation for certification is already on-track considering that a US Core R4.0.0 test suite has already been made available in the Inferno validation platform.

As a final point, we note that it is important to adopt this R4.0.0 of the IG even if the successor R5.0.0 is also eventually adopted this year (see comments above on USCDI V2 for reference). This is because R4.0.0 aligns with USCDI V1 to provide the necessary enhancements outlined above for representing that version of the data set, whereas R5.0.0 aligns with USCDI V2 to provide specifications for representing the expanded set of data elements adopted with the newer version of the data set. To be clear, adopting R5.0.0 does not alleviate the need to also adopt R4.0.0.