

September 14, 2022

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Dear Dr. Tripathi:

The Health Information Technology Advisory Committee (HITAC) asked the Adopted Standards Task Force to review the existing set of ONC adopted standards and implementation specifications referenced in federal regulations and make recommendations to maintain or phase out such standards and implementation specifications, as required by 42 U.S. Code § 300ji–13 (Setting priorities for standards adoption).

This transmittal letters offers the final report from the HITAC with recommendations therein which are hereby submitted to you for your consideration.

Respectfully submitted,

Aaron Mírí	Denise Webb
/s/	/s/
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Co-chair, Health Information Technology Advisory	Co-chair, Health Information Technology Advisory
Committee	Committee



Final Report of the Health Information Technology Advisory Committee on ONC Adopted Standards and Implementation Specifications

Submitted to the Office of the National Coordinator for Health IT on September 14, 2022

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Background

The 21st Century Cures Act of 2016 (Cures Act) requires the Office of the National Coordinator for Health Information Technology (ONC) to convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to:

- A) maintain the use of such standards and implementation specifications; or
- B) phase out such standards and implementation specifications.

ONC is required to commence this review five (5) years after December 13, 2016, which would be no earlier than December 13, 2021, and every three (3) years thereafter. To meet these requirements, ONC convened an Adopted Standards Task Force (Task Force), consisting of a subset of members of the Health Information Technology Advisory Committee (HITAC) and other relevant stakeholders to make specific recommendations to maintain or phase out the reference to the standards and implementation specifications in regulations implementing the Cures Act, currently the 21st Century Cures Act Final Rule (Cures Act Final Rule).

CHARGE

The HITAC was charged with reviewing the existing set of ONC adopted standards and implementation specifications referenced in federal regulations and making recommendations to maintain or phase out such standards and implementation specifications, as required by 42 U.S. Code § 300jj–13 (Setting priorities for standards adoption). The current set of standards and implementation specifications referenced by ONC in federal regulation is maintained on the ONC Standards Hub.

This charge does not seek recommendations for new standards and implementation specifications for ONC to adopt through rulemaking.

ADDITIONAL BACKGROUND INFORMATION

The Task Force included a diverse collection of subject matter experts across various stakeholder groups, including direct patient care, public health, patient advocacy, health IT development, standards development, and academia. Additionally, other subject matter experts were invited to review specific standards and identify viable alternatives to inform the Task Force's discussions. Appendix A reflects the Task Force roster and invited subject matter experts by topic at the time these recommendations were finalized.

The Task Force established a method to record and utilize individual members' inputs to inform group deliberation and establish consensus for each recommendation for every standard and implementation specification included in the scope of review. Members submitted individual input in advance of discussions to enable productive discussions to occur during Task Force meetings. At the conclusion of Task Force meetings, final group-level recommendations were documented by the co-chairs and Task Force staff.

In addition to review of the adopted standards and implementation specifications referenced in the Cures Act Final Rule, the Task Force reviewed utilized Standards Version Advancement Process (SVAP), Interoperability Standards Advisory (ISA), and Standards Development Organizations' (SDOs) current published standards as input to their recommendations. In the Task Force's review process, it was determined whether there was a more current version of the reviewed standard that could indicate that the version referenced in the Cures Act Final Rule should be considered by ONC for phase-out and replacement

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and consider the more current standard a potential replacement. Where that was the Task Force's finding, the rationale for the proposed disposition in this report indicates that availability. The SVAP permits health IT developers to voluntarily update health IT products certified under the ONC Health IT Certification Program (Certification Program) to utilize newer versions of adopted standards as part of the "Real World Testing" Condition and Maintenance of Certification requirement (§ 170.405) of the Cures Act Final Rule.

Recommendations

INTRODUCTION

The primary objective of the Task Force was to make specific recommendations to maintain or phase-out references to standards and implementation included in the Cures Act Final Rule. A recommendation of phase-out could only be viable when a reference to a standard were to be fully removed from regulation. There are some situations, however, where the current version of a standard or implementation guide is no longer sufficient in meeting business needs. In those circumstances, the Task Force distinguished between a phase out with a replacement or a phase out entirely, i.e., without replacement necessary.

Therefore, this report provides recommended dispositions for each reviewed standard reference in one of three categories:

- Maintain maintain existing reference to the standard as is.
- **Phase-Out with Replacement –** phase out and replace with a reference to a more current version of the standard and/or an alternative standard.
- Phase-Out Entirely phase out the regulatory reference without replacement.

For each reference, the Task Force reviewed whether the use of that standard is still relevant. If the consensus of the Task Force was that the subject the standard addresses still requires specification, the group then considered whether a more current version of the standard was available (e.g., already included in SVAP) or if a suitable alternative industry-developed standard should be considered by ONC as a replacement during an appropriate regulatory update. In instances where the Task Force recommends a standard be phased-out with replacement, the Task Force recommends that the replacement process be an orderly transition using future rulemaking processes to ensure there are no gaps in available standards support, as the underlying need for a standard remains.

In addition to the recommended disposition, the Task Force provided a supporting rationale. In instances where the rationale calls for ONC to consider adoption of "the then most current version" of the standard or implementation specification, the Task Force recommends that ONC consider the six characteristics¹ identified in ONC's Interoperability Standards Advisory (ISA), which may still result in selecting a different version or standard that is more mature or widely adopted. Or in some cases, ONC may decide that it is more appropriate to maintain the current referenced standard or implementation specification or select a newer version (e.g., a normative version that became available after the initial Cures Act Final Rule was finalized) that is more suitable for reference in future regulatory updates. The Task Force suggests that backwards compatibility considerations should be added to the six characteristics as a critical consideration when and how to advance use of more current standards. The Task Force did not provide specific recommendations regarding which standard or implementation specification should be adopted since the timeline of the next regulatory update is unknown and recommending new standards and implementation specifications was out of scope per the Task Force charter.

¹ https://www.healthit.gov/isa/isa-structure: Standards Process Maturity, Implementation Maturity, Adoption Level, Federally Required, Cost, and Test Tool Availability

LIST OF RECOMMENDATIONS

This section provides a detailed explanation of recommendations and associated rationale supporting each recommendation by standard or implementation specification.

Data Scope and Vocabulary Standards

The standards in this section reference the scope of data for specific certification criteria and the vocabulary referenced in the Cures Act Final Rule that in turn are used by standards in the subsequent sections of this report.

Adopted Standards-TF-2022_Recommendation 01 – <u>United States Core Data for Interoperability</u> (<u>USCDI</u>)

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the USCDI standard included in the Cures Act Final Rule and consider referencing the then most current version of the USCDI during the next relevant regulatory update.

The HITAC notes that it is critical that any replacement version of the USCDI that is adopted through rulemaking is fully supported by the necessary supporting standards, in particular HL7 FHIR US Core and HL7 CDA C-CDA, to enable appropriate implementation of the replacement version of the USCDI.

Adopted Standards-TF-2022_Recommendation 02 – <u>Code on Dental Procedures and Nomenclature</u> (<u>CDT</u>)

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the CDT code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the CDT code system in the next relevant regulatory update.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when such a system becomes available, while also acknowledging the need to recognize use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to more current code systems.

Adopted Standards-TF-2022_Recommendation 03 – <u>Current Procedural Terminology, Fourth</u> <u>Edition (CPT-4)/Healthcare Common Procedure Coding System (HCPCS)</u>

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the CPT-4 code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the CPT code system during the next relevant regulatory update.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when such a system becomes available, while also acknowledging the need to recognize use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current version of a code system.

Adopted Standards-TF-2022_Recommendation 04 – <u>ICD-10 CM Encounter Diagnoses: Code Set for the following conditions: Diseases, Injuries, Impairments, Other health problems and their manifestations, Causes of injury, disease, impairment, or health problems</u>

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the ICD-10 CM code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the ICD-10 CM Code system, or a more current ICD CM version, during the next relevant regulatory update.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of the code system when a new version becomes available, while also acknowledging the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

Adopted Standards-TF-2022_Recommendation 05 – <u>International Classification of Diseases ICD-10-PCS 2020</u>

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the ICD-10-PCS 2020 code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the ICD-10 PCS code system, or a more current version of the ICD PCS code system, during the next relevant regulatory update.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when a new version becomes available, while also acknowledging the need to recognize use of code systems and values in historical documentation, i.e., not requiring historical documentation to be converted to a more current code system.

Adopted Standards-TF-2022_Recommendation 06 – RxNorm, September 8, 2015 Full Release Update

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the RxNorm code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the RxNorm code system in the next relevant regulatory update.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when a new version becomes available, while also acknowledging the need to recognize use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

Adopted Standards-TF-2022_Recommendation 07 – <u>SNOMED International, Systematized</u>
Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2019 Release

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the SNOMED code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the SNOMED CT code system during the next relevant regulatory update.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when a new version of the code system becomes available, while also acknowledging the need to recognize use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

For SNOMED CT in particular, the HITAC suggests that only one version of the SNOMED CT code system is referenced throughout federal regulations for the then current exchange. Older SNOMED versions should be addressed as part of general guidance on the use of older versions in the context of historical data.

Adopted Standards-TF-2022_Recommendation 08 – <u>Systematized Nomenclature of Medicine</u>
<u>Clinical Terms (SNOMED CT®) International Release July 31, 2012 and US Extension to SNOMED</u>
CT® March 2012-

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the versions of SNOMED CT code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the SNOMED CT code system during the next relevant regulatory update.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system as it becomes available, while also acknowledging the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

For SNOMED CT in particular, the HITAC suggests that only one version of the SNOMED CT code system is referenced throughout federal regulations for the then current exchange. Older SNOMED CT versions should be addressed as part of general guidance on the use of older versions in the context of historical data.

Adopted Standards-TF-2022_Recommendation 09 – <u>Systematized Nomenclature of Medicine</u> Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the versions of the SNOMED CT code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the SNOMED CT code system during the next relevant regulatory update.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when a new version becomes available, while also acknowledging the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

For SNOMED CT in particular, the HITAC suggests that only one version of the SNOMED CT code system is referenced throughout federal regulations for the then current exchange. Older SNOMED CT versions should be addressed as part of general guidance on the use of older versions in the context of historical data.

Adopted Standards-TF-2022_Recommendation 10 – <u>RFC 5646, "Tags for Identifying Languages,"</u> <u>September 2009</u>

Disposition: Maintain or Phase Out with Replacement

Rationale: Recommend that ONC maintain the reference to the version of the Tags for Identifying Languages standard included in the Cures Act Final Rule and consider the opportunity to further align references to RFC 5646 (referenced in USCDI) with BCP 47 (referenced in HL7 FHIR US Core, which includes RFC 5646), direct references to the IANA language registry listing the language tags conforming to RFC 5646 (referenced in RFC 5646), and/or ISO 639-2 (identified by RFC 5646 and directly referenced in HL7 CDA C-CDA and certification test clarifications), focusing on primary language codes rather than sub-tags as indicated in the certification test clarifications. All references across standards including languages should be aligned with each other, particularly USCDI, HL7 FHIR US Core, and HL7 CDA C-CDA.

Adopted Standards-TF-2022_Recommendation 11 – <u>Logical Observation Identifiers Names and</u> Codes (LOINC®) Database version 2.52, Released June 2015

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the references to the versions of the LOINC code system included in the Cures Act Final Rule and consider adopting references to the then most current version of the LOINC code system during the next relevant regulatory update.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when a version becomes available, while also acknowledging the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

For LOINC in particular, the HITAC suggests that only one version of the LOINC code system is referenced throughout federal regulations for the then current exchange. Older LOINC versions should be addressed as part of general guidance on the use of older versions in the context of historical data.

Adopted Standards-TF-2022_Recommendation 12 – <u>Logical Observation Identifiers Names and</u> Codes (LOINC®) Database version 2.40, Released July 2012

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the references to the versions of the LOINC code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the LOINC code system during the next relevant regulatory update.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when a new version becomes available, while also acknowledging the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

For LOINC in particular, the HITAC suggests that only one version of the LOINC code system is referenced throughout federal regulations for the then current exchange. Older LOINC versions should be addressed as part of general guidance on the use of older versions in the context of historical data.

Adopted Standards-TF-2022_Recommendation 13 – <u>HL7® Standard Code Set CVX— Vaccines</u> Administered, updates through August 17, 2015

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the CVX code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update. The standard as referenced is no longer current, nor is it available on the CDC web page, even as an archived file. Of note, the instructions on the CDC web page instruct the reader to use a particular file for certification purposes. This version predates the August 17th version specified in current regulation. The generation of current files appears to be on demand, so there is not a particular version with a recent (last 18 months) publication date that the committee can specify. Stakeholder input may help clarify the best approach for ensuring the use of up-to-date information.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when the version becomes available, while also acknowledging the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

Adopted Standards-TF-2022_Recommendation 14 – <u>Public Health Data Standards Consortium</u> Source of Payment Typology Code Set Version 5.0 (October 2011)

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the Payment Typology code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the payment typology code set during the next relevant regulatory update. The HITAC recommends that ONC consult with stakeholder groups when considering a change to ensure stakeholders are prepared to support structural changes in the code set as noted in the description of Version 9.2, December 2020, at www.nahdo.org/sopt.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when the version becomes available, while also acknowledging the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

Adopted Standards-TF-2022_Recommendation 15 – <u>National Drug Code (NDC) Directory–Vaccine NDC Linker</u>, updates through August 17, 2015

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the NDC Linker included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the NDC Linker or a potential replacement if available during the next relevant regulatory update.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when a new version becomes available, while also acknowledging the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

Adopted Standards-TF-2022_Recommendation 16 – <u>CDC Race and Ethnicity Code Set Version 1.0</u> (March 2000)

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the version of the CDC Race and Ethnicity code system included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the CDC Race and Ethnicity code system or its equivalent during the next relevant regulatory update. The HITAC notes that USCDI V3 references CDC Race and Ethnicity Code Set Version 1.2 (July 2021).

At the same time, the HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when a new version becomes available. The HITAC also acknowledges the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

Adopted Standards-TF-2022_Recommendation 17 – <u>HL7® Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor</u>

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the Administrative Gender and NullFlavor value set included in the Cures Act Final Rule during the next relevant regulatory update to address and continue to support current approaches to describing the applicable sex for administrative purposes.

The HITAC notes that the HL7 v2, CDA, and FHIR standards are being updated through the Gender Harmony project to include additional sex and gender identity related attributes. The HITAC suggests reviewing the resulting vocabulary in the HL7 v2, CDA, and FHIR standards and assess which standards and guidance references in the Cures Act Final Rule, such as the Administrative Gender and NullFlavor value sets and USCDI, should be upgraded and/or replaced accordingly. Note that the Gender Harmony project does not address the legal sex for administrative purposes.

The HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when a new version becomes available while also acknowledging the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

Adopted Standards-TF-2022_Recommendation 18 – Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997

Disposition: Phase-Out with Replacement

Rationale: Recommend that regardless of whether the Office of Management and Budget (OMB) makes updates to this standard, the HITAC suggests ONC, in relevant future rulemaking, address any ambiguities regarding the specific version of the material that is intended to be used.

The HITAC also recommends that ONC phase out and replace the version of the Federal Data on Race and Ethnicity publication of 1997 referenced in the Cures Act Final Rule and consider adopting a reference to the then most current version in the next relevant regulatory update. It is the HITAC's understanding that this standard is currently being revised by the OMB.

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The HITAC supports the current regulatory process to enable HIT to be certified to a more current version of the code set when the version becomes available, while also recognizing the need to recognize use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to more current code systems.

Adopted Standards-TF-2022_Recommendation 19 – <u>The Unified Code of Units of Measure, Revision</u> 1.9

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the version of the UCUM standard included in the Cures Act Final Rule and consider adopting a reference to the then most recent version during the next relevant regulatory update.

At the same time, the HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system when a new version becomes available while also acknowledging the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

Adopted Standards-TF-2022_Recommendation 20 – <u>E.123: Notation for national and international telephone numbers</u>, e-mail addresses and web addresses

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the E.123 standard included in the Cures Act Final Rule. The HITAC was unable to identify an existing, potential alternative or a standard in development for ONC to consider.

Adopted Standards-TF-2022_Recommendation 21 – <u>E.164: The international public telecommunication numbering plan</u>

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the E.164 standard included in the Cures Act Final Rule. The HITAC was unable to identify an existing, potential known suitable alternative or a standard in development for ONC to consider.

General Data Access Standards

The standards in this section reference the ability to generally access data using FHIR based Application Programming Interfaces (APIs).

Adopted Standards-TF-2022_Recommendation 22 – <u>HL7® Version 4.0.1 FHIR® Release 4, October 30, 2019</u>

Disposition: Maintain

Rationale: Recommend that ONC starts considering when adoption of a new version of the FHIR standard should be implemented as it will require substantial time to prepare for such transition. Particularly as any implementation guides referenced in regulation using FHIR R4 would have to be updated and reasonably implemented to enable an organized transition of all dependent standards and systems. Moving some, but not all, would create substantial complexities.

New capabilities have been introduced with FHIR R4B and even more capabilities will be introduced with FHIR R5 (upcoming), such as a data subscription method, enhanced data definitions, and new data definitions, while FHIR R6 is expected to contain more normative, thus more stable definitions. This creates a challenge in considering when to advance to a new version, or even skip a version versus staying current on the latest version.

Until there is clarity among stakeholders on the appropriate timing to migrate to a new version and which one, the HITAC recommends that ONC maintain the reference to the FHIR R4 standard as included in the current Cures Act Final Rule.

Adopted Standards-TF-2022_Recommendation 23 – FHIR® US Core Implementation Guide STU V3.1.1

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the FHIR US Core implementation guide included in the Cures Act Final Rule and consider adopting a reference to the then most current version in the next relevant regulatory update while ensuring that the version identified by ONC for adoption aligns with and fully supports the version of the USCDI standard in place at the time any regulatory change is finalized.

Adopted Standards-TF-2022_Recommendation 24 – <u>HL7® FHIR® Bulk Data Access (Flat FHIR®)</u> (V1.0.0:STU 1)

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the FHIR Bulk Data implementation guide included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update as a more current version is already adopted through the SVAP process.

Adopted Standards-TF-2022_Recommendation 25 – <u>HL7® SMART Application Launch Framework</u> <u>Implementation Guide Release 1.0.0</u>

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the SMART Application Launch Framework standard included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update as a more current version of the standard is available through the SVAP process.

Care Coordination Standards

The standards in this section reference the ability to support coordination of care specific transactions. Some are used for general access as well, but the HITAC opted to only list them in this section to avoid redundancy.

Adopted Standards-TF-2022_Recommendation 26 – <u>HL7® CDA R2 IG: C-CDA Templates for Clinical</u> Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5)

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the C-CDA Companion Guide implementation guide included in the Cures Act Final Rule and consider adopting the then most current version of the C-CDA Companion Guide that supports the scope of USCDI that should be supported by a C-CDA document type during the next relevant regulatory update.

Adopted Standards-TF-2022_Recommendation 27 – <u>HL7® Implementation Guide (IG) for CDA</u>

Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use
Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata)

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the C-CDA 2.1 implementation guide with errata included in the Cures Act Final Rule as the HITAC is not aware of a more current C-CDA implementation guide in development that could be considered. Updates to support USCDI and other initiatives primarily occur through the C-CDA Companion Guide.

Adopted Standards-TF-2022_Recommendation 28 – <u>HL7® Implementation Guide for CDA® Release</u>
2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July
2012

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the IHE Health Story Consolidation standard included in the current Cures Act Final Rule in the next relevant regulatory update. The continued inclusion of the reference to the IHE Health Story standard enables support of viewing, reconciling, and incorporating of data communicated through older documents formatted according to this implementation guide. ONC should continue to clarify that generating new content using this standard is not required. Alternatively, ONC could consider referencing HL7 CDA R2 for view, reconciliation, and incorporation requirements for CDA based documents, but not generation. The HITAC notes that only the most current C-CDA Implementation Guide plus associated Companion Guide Implementation Guide referenced in current regulation, or a future FHIR Document Implementation Guide once available and accepted, should be utilized for generating the appropriate new documents.

Adopted Standards-TF-2022_Recommendation 29 – <u>Direct Project: ONC Applicability Statement for Secure Health Transport, Version 1.2 August 2015</u>

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the Direct Project Applicability Statement for Secure Health Transport standard included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update. The HITAC notes that a more current version, Version 1.3, is already available and referenced in SVAP. Version 1.3 is also the first ANSI approved version, reflecting the maturity and adoption of the standard.

The HITAC notes the need to address any dependencies between the currently referenced version 1.2 and the ONC Implementation Guide for Direct Edge Protocols, Version 1.1, as that is also currently being updated to address a variety of undesired interpretation variances.

Adopted Standards-TF-2022_Recommendation 30 – <u>ONC Implementation Guide for Direct Edge</u> Protocols, Version 1.1, June 25, 2014

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the Direct Edge Protocols standard included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the Direct Edge Protocols during the next relevant regulatory update.

The HITAC notes that an update to the standard that addresses a variety of undesired interpretation variances is currently being developed. The updated Implementation Guide for Direct Edge standard is anticipated to be available in the next 6-12 months as an ANSI standard. Until available, the referenced version cannot be retired (phased out).

Adopted Standards-TF-2022_Recommendation 31 – <u>IHE IT Infrastructure Technical Framework</u> Volume 2b (ITI TF- 2b)

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the IHE ITI Technical Framework standard included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update. The HITAC notes that many clarifications have been identified and are in use across numerous networks already. Additionally, the HITAC recommends that ONC consider formally including references to Volume 1 in the regulatory text where Volume 2b is currently referenced.

Adopted Standards-TF-2022_Recommendation 32 – NCPDP SCRIPT Standard, Implementation Guide, Version 2017071

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of NCPDP SCRIPT standard included in the Cures Act Final Rule and consider adopting a reference to the then most current version of the NCPDP SCRIPT standard during the next relevant regulatory update. The HITAC notes that NCPDP has started the process to update SCRIPT to the 2022011 version for Medicare Part D and Electronic Prescribing of Controlled Substances (EPCS) and, depending on timing, this may go to the even more current 2022071 version. There is a concern as to alignment with PDMP use cases using ASAP as there is a desire to utilize a single, common standard wherever possible, while recognizing resource constraints to achieve that goal. Consequently, ONC should consider the PDMP interoperability use cases and interaction as part of considering the most current SCRIPT version.

The HITAC notes that the NCPDP SCRIPT standard may also impact public health exchange. Most discussion of public health exchange standards appears in the section below.

Public Health Exchange Standards

The standards in this section reference the ability to exchange data with public health authorities.

Adopted Standards-TF-2022_Recommendation 33 – <u>HL7® Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015</u>

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the Immunization Messaging implementation guide plus addendum included in the Cures Act Final Rule until such time as public health, health care providers, and other stakeholders have developed and tested replacement standards and that immunization registries and trading partners are prepared and resourced to support.

The HITAC recognizes that immunization data and interfaces with immunization registries impact a wide variety of stakeholders, not all of which utilize electronic health records systems using Certified Electronic Health Record Technology and consequently, do not receive related system updates from vendors. Considerable effort may be required to ensure all relevant systems utilize relevant, up-to-date standards to facilitate the secure, efficient exchange of all required information.

Adopted Standards-TF-2022_Recommendation 34 – PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Care, Inpatient and Ambulatory Care, and Inpatient Settings, Release 2.0, April 21, 2015

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the Syndromic Surveillance standard included in the Cures Act Final Rule and consider adoption of a reference to the then most current version during the next relevant regulatory update. The HITAC specifically suggests collaborating with stakeholders including state and local public health agencies, national public health organizations, the Centers for Disease Control and Prevention, laboratories, health care providers, and HL7 to determine whether the then most current version indeed provides sufficient updates to warrant a transition and that any transition plan addresses the availability of resources to ensure that both sending and receiving systems are capable of supporting any standards change. Similar to immunization messaging, some stakeholders may not utilize systems that incorporate Certified Electronic Health Record Technology and, as such, do not receive automatic updates from vendors.

Adopted Standards-TF-2022_Recommendation 35 – <u>HL7® Version 2.5.1 Implementation Guide:</u> <u>Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)</u>

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the Electronic Laboratory Reporting (ELR) implementation guide included in the Cures Act Final Rule and considers adopting either 1) a reference to the then most current version of the ELR implementation guide and also reference the relevant pandemic response sections in the most current Laboratory Results Interface (LRI) implementation guide that is in the process of being published, or 2) the ELR specific sections in the then most current version of the LRI implementation guide during the next relevant regulatory update. The HITAC specifically suggests collaborating with stakeholders including state and local public health agencies, national public health organizations, CDC, laboratories, health care providers, and HL7 to determine which alternative is most suitable.

Additionally, ONC should consult with state and local public health agencies and organizations, to explore whether electronic case reporting is sufficient in meeting laboratory results reporting from entities supplying eCR reports in full (i.e., instead of these same institutions additionally submitting electronic laboratory reporting), or in part (i.e., only for such data that is not relevant to the performance of the tests but critical context from other parts of the patient's record that electronic case reporting is already addressing). Using

electronic case reporting for such additional data could address future needs associated with the surveillance of emerging conditions such as monkeypox in a manner that fully addresses public health's surveillance and data needs and can serve as a method for reducing unhelpful duplicative reporting. However, where the case reporting method is being considered, one must consider that organizations currently not capable or required to submit case reports to now be included where they take on the role of the ordering/initiating provider. Such an approach requires critical participation by all stakeholders to ensure all relevant data can be shared with public health through the combined data flows. It is critical that any change ensures that public health continues to receive essential accurate, high-quality, and complete data in a timely manner. There may be opportunities to also improve data exchange processes that minimize unnecessary exchange of data and associated expenses.

Adopted Standards-TF-2022_Recommendation 36 – <u>Electronic Laboratory Reporting (ELR) 2.5.1</u>
<u>Clarification Document for EHR Technology Certification</u>

Disposition: Maintain or Phase-Out with Replacement

Rationale: Recommend that ONC phase out the reference to the version of the Electronic Laboratory Reporting Errata document included in the Cures Act Final Rule and consider adopting a reference to the then most current Electronic Laboratory Reporting version that has all the errata incorporated or, as a potential replacement, the LRI standards, as discussed above, during the next relevant regulatory update. See the recommendation on Electronic Laboratory Reporting above for further details. Note that if a more current ELR version or alternative standard that addresses the errata is not adopted, the reference to the errata document should be maintained.

Adopted Standards-TF-2022_Recommendation 37 – <u>HL7® Implementation Guide for CDA© Release</u> 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, <u>DSTU Release 1.1, April 2015</u>

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the Reporting to Public Health Cancer Registries implementation guide included in the Cures Act Final Rule.

The HITAC suggests ONC collaborates with state and local public health agencies receiving cancer data, public health professional organizations, CDC, NACCR, and other stakeholders regarding future, updated standards for the exchange of cancer-related information.

Adopted Standards-TF-2022_Recommendation 38 – <u>HL7® Implementation Guide for CDA® Release</u> 2 – Level 3: Healthcare Associated Infection Reports

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the Healthcare Associated Infection Reports implementation guide included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update.

The HITAC notes that the version in the Cures Act Final Rule is not aligned with the version(s) that NHSN requires for healthcare associated infection reports and suggests ONC collaborates with NHSN to determine a single version, or set of versions, that can be used both for certification and NHSN reporting. Until such alignment has been achieved, adoption of a newer version for certification seems premature.

Adopted Standards-TF-2022_Recommendation 39 – <u>HL7® Implementation Guide for CDA Release 2:</u>
National Health Care Surveys (NHCS), Release 1 – US Realm, Draft Standard for Trial Use,
December 2014

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the National Health Care Surveys implementation guide included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update as a more current version is already adopted through the SVAP process.

Clinical Quality Measure Reporting Standards

The standards in this section support the various clinical quality measure reporting requirements, primarily to the Centers for Medicare and Medicaid Services (CMS).

Adopted Standards-TF-2022_Recommendation 40 – <u>HL7® CDA® Release 2 Implementation Guide</u> for: Quality Reporting Document Architecture – Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1 and 2

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the QRDA Category I implementation guide included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update that is necessary to support the then most current CMS QRDA implementation guidance for QRDA Category I.

Adopted Standards-TF-2022_Recommendation 41 – Quality Reporting Document Architecture

Category III, Implementation Guide for CDA Release 2

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the QRDA Category III implementation guide included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update relevant to support the CMS QRDA implementation guidance for QRDA Category III.

Adopted Standards-TF-2022_Recommendation 42 – <u>Errata to the HL7® Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm), September 2014</u>

Disposition: Maintain or Phase-Out with Replacement

Rationale: Recommend that ONC phase out the reference to the version of the QRDA Category III Errata document and consider adopting a reference to the then most current QRDA Category III version during the next relevant regulatory update that includes these errata and is necessary to support the then most current CMS QRDA implementation guidance for QRDA Category III. Note that if a more current QRDA Category III version is not adopted that addresses the errata, the errata should be maintained.

Adopted Standards-TF-2022_Recommendation 43 – <u>Crosswalk: Medicare Provider/Supplier to</u> Healthcare Provider Taxonomy, April 2, 2015

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the Supplier to Healthcare Provider Taxonomy standard in the current Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update. At the same time, the HITAC supports the current regulatory process enabling HIT to be certified to a more current version of a code system as it becomes available, while also acknowledging the need to recognize the use of code systems and values in historical documentation, i.e., not requiring historical data to be converted to a more current code system.

Adopted Standards-TF-2022_Recommendation 44 – <u>CMS Implementation Guide for Quality</u>
Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of QRDA I Hospital Quality Reporting standard in the current Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update. ONC should also continue to utilize yearly SVAP updates referencing the applicable CMS guides for the upcoming reporting year enabling certification to the version required by CMS.

Adopted Standards-TF-2022_Recommendation 45 – <u>CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020</u>

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the QRDA III Eligible Clinicians and Eligible Professionals Program implementation guide included in the Cures Act Final Rule. ONC should also consider adopting a reference to the then most current version during the next relevant regulatory update while continuing to utilize yearly SVAP updates referencing the applicable CMS guides for the reporting year until a subsequent regulatory update.

Privacy / Security Standards

The standards in this section support the ability to communicate various privacy and security related capabilities and attributes, while providing a consistent audit log.

Adopted Standards-TF-2022_Recommendation 46 – <u>HL7® Implementation Guide: Data</u> Segmentation for Privacy (DS4P), Release 1

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the DS4P implementation guide included in the Cures Act Final Rule during the next relevant regulatory update. ONC also should consider: 1) complementary standards necessary to fully enable management of privacy policies and patient consent directives consistently at a national level, 2) guidance on how to tag and interpret data given specific policies, and 3) alignment on maintenance and access to such policies within and across stakeholders.

Adopted Standards-TF-2022_Recommendation 47 – (RFC 5905) Network Time Protocol Version 4

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the Network Time Protocol standard included in the Cures Act Final Rule during the next relevant regulatory update, while evaluating whether RFC 7822, RFC 8573, and RFC 9109 should be considered as they provide specific updates to RFC 5905.

Adopted Standards-TF-2022_Recommendation 48 – <u>Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2, October 8, 2014 (incorporated by reference in § 170.299)</u>

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of FIPS publication 140-2 included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update.

Adopted Standards-TF-2022_Recommendation 49 – <u>ASTM E2147-18 Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems</u>

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the ASTM E2147-18 standard included in the Cures Act Final Rule during the next relevant regulatory update as there is no known more current version nor suitable alternative.

Adopted Standards-TF-2022_Recommendation 50 – OpenID Connect Core 1.0 incorporating errata set 1

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the OpenID Connect standard, including errata, included in the Cures Act Final Rule during the next relevant regulatory update as there is no known more current version nor suitable alternative.

Adopted Standards-TF-2022 Recommendation 51 - Secure Hash Standard, 180-4 (August 2015)

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the Secure Hash standard in the current Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update.

The HITAC notes that at the time of these recommendations NIST is holding a public comment period after which the new version will be finalized. If the updated edition is not available at the time when ONC will be proposing updates to the Cures Act Final Rule, then the reference to the August 2015 edition should continue to be maintained, including a note that SHA-1 is disallowed (one of the updates the new edition would address).

Accessibility Standards

The standards in this section address accessibility guidelines to ensuring individuals with disabilities have the ability to successfully interact with HIT.

Adopted Standards-TF-2022_Recommendation 52 – <u>Web Content Accessibility Guidelines (WCAG)</u> 2.0, Level A Conformance

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the WCAG Level A Conformance guidelines included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update, as a more current version is already adopted through the SVAP process. The HITAC suggests that ONC reach out to the Office of Civil Rights (OCR) to align with any other initiatives that may further inform the appropriate version to consider while noting that version 2.2 is in draft that may address those considerations.

Adopted Standards-TF-2022_Recommendation 53 – <u>Web Content Accessibility Guidelines (WCAG)</u> 2.0, Level AA Conformance

Disposition: Phase-Out with Replacement

Rationale: Recommend that ONC phase out and replace the reference to the version of the WCAG Level AA Conformance guidelines included in the Cures Act Final Rule and consider adopting a reference to the then most current version during the next relevant regulatory update, as a more current version is already adopted through the SVAP process. The HITAC suggests that ONC reach out to OCR to align with any other initiatives that may further inform the appropriate version to consider while noting that version 2.2 is in draft that may address those considerations.

Certification Process Standards

The standards in this section address the ability to establish the necessary processes and controls to implement ONC HIT certification program.

Adopted Standards-TF-2022_Recommendation 54 – <u>ISO/IEC 17025:2017(E)—General Requirements</u> for the Competence of Testing and Calibration Laboratories, (Third Edition), November 2017

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the General Requirements for Competence of testing and Calibration Laboratories standard included in the Cures Act Final Rule during the next relevant regulatory update and only consider adopting a newer version if it becomes available.

Adopted Standards-TF-2022_Recommendation 55 – <u>ISO/IEC 17065:2012 (E)—Conformity</u>
<u>Assessment—Requirements for Bodies Certifying Products, Processes and Services (First Edition),</u>
September 2012

Disposition: Maintain

Rationale: Recommend that ONC maintain the reference to the version of the Requirements for Bodies Certifying Products, Processes and Services standard included in the Cures Act Final Rule during the next relevant regulatory update and only consider adopting a newer version if it becomes available.

Key Takeaways

- All the regulated areas supported by the 55 referenced standards have ongoing need for continued support through established standards.
 - No standard references should be retired without a suitable replacement and transition plan.
 - Regular reviews and updates are necessary to continue advancing capabilities for these regulated areas.
- Recommending only whether to Maintain or Phase-Out a reference to a standard would have been
 insufficient to address the intent of the Task Force's charter. This led the Task Force including a
 rationale for the recommendation with a focus on viable alternatives for ONC to consider in future
 rulemaking. The Task Force also added sub-categories distinguishing between phasing out because
 there is a viable alternative or that no reference to a standard is further necessary. The Task Force
 recommends this approach to be part of future task force assignments.
- The Cures Act review process results in duplicative reviews: one review to identify references that may need updates and for which a reasonable update is available to determine whether to maintain the reference or not, and a second review at the time of preparing a subsequent rulemaking update to specifically identify the standard that should then be referenced in regulation. It is inefficient to only be able to discuss retiring references to standards without considering viable replacements at the same time.
- The Task Force understands that the SVAP process enables voluntary adoption of interoperability standards by certified HIT developers before future regulations would raise the floor for all. This process may inadvertently create interoperability challenges where a new version is not fully backwards-compatible and/or not all trading partners adopt the same SVAP-included interoperability standards.
- A couple of referenced standards and viable alternatives were not available at no cost to Task Force
 members, limiting the ability to perform a review by all members. Presentations by subject matter
 experts enabled productive discussions and review.

Appendix A – Rosters

TASK FORCE MEMBERS

Name	Organization
Hans Buitendijk (Co-Chair)	Oracle Cerner
Steven (Ike) Eichner (Co-Chair)	Texas Department of State Health Services
Jeffrey Danford	Altera Digital Health
Rajesh Godavarthi	MCG Health, part of the Hearst Health network
Jim Jirjis	HCA Healthcare
John Kilbourne	Department of Veterans Health Affairs
Hung S. Luu	Children's Health
Clem McDonald	National Library of Medicine
Deven McGraw	Invitae
Eliel Oliveira	Dell Medical School, University of Texas at Austin
Vassil Peytchev	Epic
Samantha Pitts	Johns Hopkins University School of Medicine
Alexis Snyder	Individual
Fillipe Southerland	Yardi Systems, Inc.
Ram Sriram	National Institute of Standards and Technology
Raymonde Uy	National Association of Community Health Centers (NACHC)
Debi Willis	PatientLink Enterprises

PRESENTER ROSTER

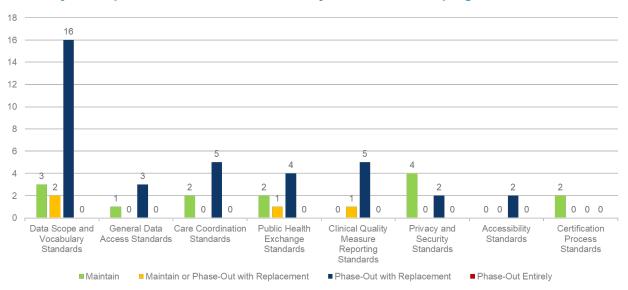
Presenter Name	Organization	Topic
Laura Conn	CDC	Electronic Laboratory Reporting and Case Reporting
Carmela Couderc	ONC	CDC Race and Ethnicity Code Set differences between v1.0 and v1.2 USCDI
Rosa Ergas	MA Department of Health	Syndromic Surveillance
Riki Merrick	APHL	Electronic Laboratory Reporting
Al Taylor	ONC	USCDI
Caleb Wiedeman	TN Dept of Health	Syndromic Surveillance
Margaret Weiker	NCPDP	SCRIPT for ePrescribing

Appendix B – Disposition Summary of Reviewed Standards and Implementation Specifications

Number of Standards by Recommendation

Recommendation	Number of Standards
Maintain – maintain existing standard as is	14
Maintain or Phase-Out with Replacement	4
Phase-Out with Replacement – phase out and replace with a reference to a more current version and/or alternative	37
Phase-Out Entirely – phase out without replacement	0

Summary of Disposition Recommendations by Standards Grouping



Data Scope and Vocabulary Standards

#	Standard	Disposition Recommendation
1	United States Core Data for Interoperability (USCDI)	Phase-Out with Replacement
2	Code on Dental Procedures and Nomenclature (CDT)	Phase-Out with Replacement
3	Current Procedural Terminology, Fourth Edition (CPT-4)/Healthcare Common Procedure Coding System (HCPCS)	Phase-Out with Replacement
4	ICD-10 CM Encounter Diagnoses: Code Set for the following conditions: Diseases, Injuries, Impairments, Other health problems and their manifestations, Causes of injury, disease, impairment, or health problems.	Phase-Out with Replacement
5	International Classification of Diseases ICD-10-PCS 2020	Phase-Out with Replacement
6	RxNorm, September 8, 2015 Full Release Update	Phase-Out with Replacement
7	SNOMED International, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2019 Release	Phase-Out with Replacement
8	Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012 and US Extension to SNOMED CT® March 2012	Phase-Out with Replacement
9	Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release	Phase-Out with Replacement
10	RFC 5646, "Tags for Identifying Languages," September 2009	Maintain or Phase-Out with Replacement
11	Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015.	Phase-Out with Replacement
12	Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, Released July 2012.	Phase-Out with Replacement
13	HL7® Standard Code Set CVX— Vaccines Administered, updates through August 17, 2015	Phase-Out with Replacement
14	Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011)	Phase-Out with Replacement
15	National Drug Code (NDC) Directory–Vaccine NDC Linker, updates through August 17, 2015	Phase-Out with Replacement
16	CDC Race and Ethnicity Code Set Version 1.0 (March 2000)	Phase-Out with Replacement
17	HL7® Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor	Maintain
18	Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997	Maintain or Phase-Out with Replacement
19	The Unified Code of Units of Measure, Revision 1.9	Phase-Out with Replacement
20	E.123: Notation for national and international telephone numbers, e-mail addresses and web addresses	Maintain
21	E.164: The international public telecommunication numbering plan	Maintain

General Data Access Standards

#	Standard	Disposition Recommendation
22	HL7® Version 4.0.1 FHIR® Release 4, October 30, 2019	Maintain
23	FHIR® US Core Implementation Guide STU V3.1.1	Phase-Out with Replacement

#	Standard	Disposition Recommendation
24	HL7® FHIR® Bulk Data Access (Flat FHIR®) (V1.0.0:STU 1)	Phase-Out with Replacement
25	HL7® SMART Application Launch Framework Implementation Guide Release 1.0.0	Phase-Out with Replacement

Care Coordination Standards

#	Standard	Disposition Recommendation
26	HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5).	Phase-Out with Replacement
27	HL7® Implementation Guide (IG) for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata).	Maintain
28	HL7® Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012	Maintain
29	Direct Project: ONC Applicability Statement for Secure Health Transport, Version 1.2 August 2015	Phase-Out with Replacement
30	ONC Implementation Guide for Direct Edge Protocols, Version 1.1, June 25, 2014	Phase-Out with Replacement
31	IHE IT Infrastructure Technical Framework Volume 2b (ITI TF- 2b)	Phase-Out with Replacement
32	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Phase-Out with Replacement

Public Health Exchange Standards

#	Standard	Disposition Recommendation
33	HL7® Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015	Maintain
34	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Care, Inpatient and Ambulatory Care, and Inpatient Settings, Release 2.0, April 21, 2015	Phase-Out with Replacement
35	HL7® Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)	Phase-Out with Replacement
36	Electronic Laboratory Reporting (ELR) 2.5.1 Clarification Document for EHR Technology Certification	Maintain or Phase-Out with Replacement
37	HL7® Implementation Guide for CDA© Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1, April 2015	Maintain
38	HL7® Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports	Phase-Out with Replacement
39	HL7® Implementation Guide for CDA Release 2: National Health Care Surveys (NHCS), Release 1 – US Realm, Draft Standard for Trial Use, December 2014	Phase-Out with Replacement

Clinical Quality Measure Reporting Standards

#	Standard	Disposition Recommendation
40	HL7® CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1 and 2	Phase-Out with Replacement

#	Standard	Disposition Recommendation
41	Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2	Phase-Out with Replacement
42	Errata to the HL7® Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm), September 2014	Maintain or Phase-Out with Replacement
43	Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015	Phase-Out with Replacement
44	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020	Phase-Out with Replacement
45	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020	Phase-Out with Replacement

Privacy and Security Standards

#	Standard	Disposition Recommendation
46	HL7® Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1	Maintain
47	(RFC 5905) Network Time Protocol Version 4	Maintain
48	Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2, October 8, 2014 (incorporated by reference in § 170.299).	Phase-Out with Replacement
49	ASTM E2147-18 Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems.	Maintain
50	OpenID Connect Core 1.0 incorporating errata set 1	Maintain
51	Secure Hash Standard, 180-4 (August 2015).	Phase-Out with Replacement

Accessibility Standards

#	Standard	Disposition Recommendation
52	Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance	Phase-Out with Replacement
53	Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance	Phase-Out with Replacement

Certification Process Standards

#	Standard	Disposition Recommendation
54	ISO/IEC 17025:2017(E)—General Requirements for the Competence of Testing and Calibration Laboratories, (Third Edition), November 2017	Maintain
55	ISO/IEC 17065:2012 (E)—Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services (First Edition), September 2012	Maintain

Appendix C – Glossary of Acronyms

ANSI American National Standards Institute
API Application Programming Interface

ASAP American Society for Automation in Pharmacy
ASTM American Society for Testing and Materials

BCP Best Current Practices

C-CDA Consolidated Clinical Document Architecture

CDA Clinical Document Architecture

CDC Centers for Disease Control and Prevention

CDT Current Dental Terminology

CMS Centers for Medicare & Medicaid Services

CPT Current Procedural Terminology

CVX Vaccine Administered

DS4P Data Segmentation for Privacy
DSTU Draft Standard for Trial Use
ELR Electronic Lab Reporting

EPCS Electronic Prescriptions for Controlled Substances

FHIR Fast Healthcare Interoperability Resources FIPS Federal Information Processing Standards

HCPCS Healthcare Common Procedure Coding System

HIT Health Information Technology

HITAC Health Information Technology Advisory Committee

HL7 Health Level 7

IANA Internet Assigned Numbers Authority

IBR Incorporation by Reference

ICD International Classification of Diseases

ICD CM International Classification of Diseases Clinical Modification

ICD PCS International Classification of Diseases Procedure Coding System

IEC International Electrotechnical Commission
IHE Integrating the Healthcare Enterprise
ISA Interoperability Standards Advisory

ISO International Organization for Standardization

ITI IHE IT Infrastructure

LOINC Logical Observation Identifiers Names and Codes

NACCR North American Association of Central Cancer Registries

NCPDP National Council for Prescription Drug Programs

NDC National Drug Code

NHSN National Healthcare Safety Network

ONC HITAC Recommendations on ONC Adopted Standards and Implementation Specifications

NIST National Institute of Standards and Technology

OCR HHS Office for Civil Rights

OMB United States Office of Management and Budget

ONC Office of the National Coordinator for Health Information Technology

PDMP Prescription Drug Monitoring Programs
PHIN Public Health Information Network

QRDA Quality Reporting Document Architecture

RFC Request for Comments

SDOs Standards Development Organizations

SMART Substitutable Medical Applications and Reusable Technologies

SNOMED Systematized Nomenclature of Medicine

SNOMED CT Systematized Nomenclature of Medicine Clinical Terms

STU Standard for Trial Use

SVAP Standards Version Advancement Process

UCUM Unified Code for Units of Measure

USCDI United States Core Data for Interoperability WCAG Web Content Accessibility Guidelines