



Health Level Seven® International
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May 28, 2015

Dr. Karen DeSalvo, MD, MPH, MSc
Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: 2015 Edition Health IT Certification Criteria Proposed Rule
Hubert Humphrey Building, Suite 729D
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. DeSalvo:

HL7 appreciates the opportunity to provide feedback on the ONC's 2015 Edition Health IT Certification Criteria Proposed Rule. Health Level Seven International (HL7) is the global authority on interoperability for healthcare information technology (IT) and the organizational home and link for Fast Healthcare Interoperability Resources (FHIR) and Consolidated Clinical Document Architecture (C-CDA). HL7 is a not-for-profit, ANSI-accredited standards developing organization (SDO) dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's members represent approximately 500 organizations that comprise more than 90% of the information systems vendors serving healthcare in the U.S.

Given the importance of issues in the 2015 Edition Health IT Certification Criteria Proposed Rule and HL7's core relevance to supporting the development of an interoperable health IT infrastructure that supports a broad scale learning health system over the next ten years, HL7's leadership, Policy Advisory Committee and Work Groups contributed notable time and effort to these comments. We would be happy to provide further information to you.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles Jaffe'.

Charles Jaffe, MD, PhD

Chief Executive Officer

Health Level Seven International

A handwritten signature in black ink, appearing to read 'Stanley M. Huff, MD'.

Stanley M. Huff, MD

Board of Directors, Chair

Health Level Seven International

General Observations

A number of the proposed standards have not yet been published, which creates challenges. For some standards, the publication involves errata or progressive updates to an already deployed standard, while in other cases the standard essentially reflects a first version that has not yet been sufficiently deployed. Regarding the first category of standards HL7 appreciates any update on target availability dates to help its membership bring these updates to conclusion. Regarding the second category HL7 wishes to express concerns with the proposed adoption at this stage.

The introduction of the 2011 Certification Edition and 2014 Certification Edition have demonstrated that it is essential for standards to have a minimum level of maturity to support successful deployment of the capabilities they support. At the same time, waiting for perfect standards will delay deployment unnecessarily, thus not enabling soon enough the potential benefits that interoperability can offer. The HIT-SC has done important work to better assess maturity, while HL7 is progressing with efforts to further quantify maturity of standards for a given use case.

HL7 is concerned however that quite a few standards are being proposed that do not have the basic level of maturity to be considered for deployment. Publication alone is not sufficient to consider a standard mature for national deployment. Pilots and early deployments are essential to validate and solidify the standards, as well as identify gaps in related componentry necessary to make interoperability successful (e.g., supporting directories, trust frameworks, legal frameworks, process improvements, etc.). To that end HL7 urges ONC to work with CMS and other relevant agencies to promote and support such pilots and early deployments in areas where interoperability shows great promise and standards are in early stages of maturation.

While introduction of such a phase may be considered delaying the deployment of capabilities, such an approach would actually improve the quality and efficiency of the deployment when the all interoperability components have been sufficiently exercised first. HL7 provides specific feedback where such a phase would be essential to move interoperability forward.

In this context HL7 appreciates and supports the development of the Interoperability Roadmap that can help introduce standards on their path to national adoption. HL7 notes that where the standards referenced in the 2015 Certification Edition NPRM are also listed in the Interoperability Roadmap, national adoption challenges are generally less. However, proposed standards that are not listed in the Interoperability Roadmap are generally more challenging. This demonstrates that as use cases and supporting standards move through the maturity lifecycle from great idea to widely adopted, the Interoperability Roadmap has a role to begin raising awareness of emerging standards that are worthy of early implementations that in turn can help mature the standards before they are required at a national level through a certification edition.

Backwards Compatibility

HL7 finds the current pattern of alternating standards development and regulation naming those standards difficult for all involved to implement. In standards development, a successor to a specific version of standard is considered to be backwards compatible when existing functionality in older implementations is still served by the information in the new version without change by the old system.

HL7 recommends that the Standards and Certification criteria identify a standard by requiring a minimum version and allow for its backwards compatible successors. This has already been done with vocabulary standards. For example, in section 170.205 (a)(4) Standard. HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1, or successors which are backwards compatible.

HL7 commits to ensuring a transition path for Asynchronous Bilateral Cutover for subsequent versions of HL7 standards named in the Certification regulations.

Line of Sight from Standards to Use Cases and Incentives

HL7 appreciates the extended use of the certification program to support multiple programs such as EHR Incentive Program, Prospective Payment Systems, and other potential programs. While it is possible to review various proposed criteria and standards in context of EHR Incentive Program, that is not yet feasible for other criteria and standards. HL7 suggests that such insight will be very helpful to assess appropriateness of the standards for the intended purposes and urges ONC to provide that proposed relationship when introducing a criterion and its standards. For example:

- As the collection and analysis starts to encompass data from different healthcare organizations as well as patient generated data, data provenance becomes increasingly important. As the proposed criterion and standard are not linked to an EHR Incentive Program objective/measure or another program's objectives, e.g., a patient engagement objective/measure, rather as a consequence an allowable, voluntary criterion/standard, it is unclear whether the standard is adequate, whether further guidance is necessary, and/or how the industry is encouraged to adopt these standards. Without that perspective we cannot fully assess its applicability to the corresponding objective/measure.

Support of Structured Data Exchange

HL7 supports the direction and intent expressed in various criteria to increase the amount of data exchanged in structured format and recognizes that with the current standards and documentation practices still a substantial data will come across in free text format. As the community identifies opportunities to include structured data at all times, HL7 stands ready to reflect that in updated standards. We have a lot of experience to assist the community to help progress towards improved structured data capture and exchange to enable further advanced uses of data in areas such as decision support.

Criterion Specific Comments

§ 170.315(a)(1) Computerized provider order entry – medications

HL7 suggests that the question whether an “IT Module must be able to include” is not the correct starting point, particularly with the advent of service oriented approaches. The first question must be what the recipient of the order needs to execute on the order. Depending on the interoperability approach, e.g., message transmission, service-based API, or some combination thereof, it must be determined how much the ordering system sends pro-actively vs. makes available for, e.g., query access as needed.

Depending on what is ordered, data requirements will vary. However, the reason of the order and any comments by the provider are typically fields that can be included. HL7 standards, although not proposed for this criterion, do have the ability to convey this data, whether as part of a V2 message transmission or the emerging FHIR based service. The use of secondary diagnosis may not frequently be required and raises the question whether this references a billing diagnosis and its vocabulary, or a clinical diagnoses and its vocabulary addressed through the problem list. Either could be conveyed using HL7 standards. However, we note that appropriateness whether to actually collect and/or require to collect is subject to practice and potentially prevailing state laws.

HL7 is concerned about the statement in the questions, “if they are provided to the ordering provider in their order entry screen”. This may be interpreted as a constraint that data not entered in the order entry screen could not be conveyed with the order as well, or that it may have to be collected with each individual order rather than as collected for multiple orders, e.g., through an order set. There needs to be more clarification about what this means, while leaving flexibility for software developers and providers to establish optimum balance on how to include relevant data with the order being conveyed. The additional data elements relevant to an order may have been entered elsewhere in the EHR. Reason for specific orders could be in multiple places and will typically not be captured in a discrete coded value. We are concerned that adding this as a requirement to CPOE, will force a clinician to enter a reason for each individual order causing additional data capture that is not in the normal workflow. In addition, this is counterintuitive to using order sets to increase efficiency because multiple orders within an order set may contain different reasons for each individual order. In general, we believe it is important for the system to allow the capturing of these data elements, including a reason. However, requiring a specific reason for each order within an order set would be very burdensome

§ 70.315(a)(2) Computerized provider order entry – laboratory

HL7, in collaboration with ONC’s S&I Framework, has made substantial progress to provide implementation guides based on V2 in support of communicating a test compendium and laboratory orders in an ambulatory setting that complement the already deployed laboratory results interface guide. The following provides the current state of these efforts and HL7’s assessment of the readiness to deploy these at a national level.

- The test compendium guide referenced in § 170.205(l)(2), also known as the eDOS guide, is currently going through final ballot reconciliation and is expected to be published by July 2015. The guide is dependent on acceptance of V2.8.2, which is currently going through ballot and is expected to be published in the next couple of months. HL7 does not recommend adoption of currently published eDOS version considering the updates being included.

The guide was developed in conjunction with the laboratory results and orders guides to promote re-use of many concepts. Consequently risk of adoption requiring substantial adjustments is lower. However, while there is an indication of initial deployment considering the nature of DSTU comments to date, it is not yet widely deployed.

- The laboratory orders guide referenced in § 170.205(l)(1), also known as the LOI guide, is going through final ballot reconciliation. The first version was published in 2014, but was incomplete and cannot be deployed. The version referenced in the 2015 Edition NPRM is targeted for July publication, but is at risk to not make that

target. HL7 notes that in that case the eDOS guide could move forward to begin adoption.

There are no implementations using the LOI guide. HL7 recognizes this as a clear risk, that is in part off-set by the fact that the LOI guide is a companion to the laboratory results guide already deployed, thus using the same concepts and many of the components, as well as that many software developers have V2 experience. However, without operational experience a risk remains of running into unexpected issues that impact the ability to achieve the desired interoperability. HL7 considers this risk at the same level when the laboratory results interface guide was introduced, although the LOI guide does include new capabilities that have not yet been exercised through the laboratory results implementation guide either, e.g., the use of expanded acknowledgement schemes to manage receipt of the transactions by the intended recipient.

HL7 suggests given the level of maturity and the need to promote adoption that this element of the criterion is made optional in the absence of another mechanism for ONC and CMS to encourage pilots and early deployment projects to assess readiness for wide, national deployment. However, we urge ONC to sponsor further piloting and early deployment outside of the proposed 2015 Edition to ensure these standards can be successfully deployed at national level in the next iteration.

Regarding the specific questions on the ability to communicate the reason for the order, comments, and secondary diagnosis, HL7 notes that the laboratory orders interface guide does accommodate and requires support for the communication of comments from the ordering provider, as well as relevant diagnoses, including secondary diagnosis. Currently the use of either ICD-9 or ICD-10 is proposed, thus focusing on the diagnoses in support of subsequent billing workflow.

Note that the reason for the order is currently not required to be supported. At this point the community did not identify this as a requirement, but it can be considered for a future release if there is a need for laboratory orders. HL7 urges ONC not to mandate optional fields outside of an implementation guide or standard through rule making, rather to work with the community to address the need as part of a subsequent version in support of the OMB-119 circular that promotes consensus bases standards. This becomes of particular concern as optional components in the guide have no guidance on vocabulary and data type restrictions, thus leading to inconsistent implementation, where currently the guide requires that optional components can only be implemented after trading partners have specific agreements on its use (which may vary from one trading partner combination to another).

§ 170.315(a)(3) Computerized provider order entry – diagnostic imaging

While HL7 provides the V2 standard that is capable of communicating imaging orders and that is capable of conveying the data highlighted in ONC's questions (reason for study, secondary diagnosis, and comments), there is no known implementation guide targeted to US use cases and vocabulary. HL7 believes this to be an important area to progress and is ready to engage with ONC to establish such guidance

§ 170.315(a)(4) Drug-drug, drug-allergy interaction checks for CPOE

No comments.

§ 170.315(a)(5) Demographics

HL7 is concerned that this criterion does not provide a standard way of expressing situations where the patient declined to provide race/ethnicity information. It is important that such as statement is communicated using consistent vocabulary. HL7 suggests working with the relevant vocabulary standards organization(s), including HL7, to arrive at such guidance. HL7 suggests this guidance to be consistent across other data, e.g., the socio-economic data addressed in a later criterion

While the criterion is focused on Demographics, HL7 observes confusion whether the sex collected under this criterion is to be used for administrative purposes only, or also to be used for clinical purposes as it references birth sex. HL7 suggests in the laboratory orders guide that gender be communicated through ask-at-order-entry questions for clinical interpretations, thus not using the administrative sex that the proposed demographic values would reflect.

HL7 suggests that the verb “change” in this criterion be replaced with “amended” to reflect that prior values should be maintained. All of the states have legal requirements regarding health records and none of them permit eliminating one value and replacing it with another for any field – regardless of the specific piece of information. That is, whether correcting date of birth or creatinine level, a new value can be added and the prior value flagged as obsolete but NOT eliminated. (Also see the HL7 EHR Functional Model hierarchy of suggested verbs.)

§ 170.315(a)(6) Vital signs, body mass index, and growth charts

HL7 is concerned where to draw the line on what are considered vital signs. It is unclear in this criterion what the source is for the proposed attributes. It is important on what basis these particular clinical measures were selected as, depending on setting, a single set is not appropriate for all situations. Collection need not be required at times, but one should be able to collect one or more of these. Without a model or framework to work against, plus changes to standards of practice that occur from time to time, it is not clear how this list is to be constructed. For example, for patients less than three years of age should “gestational age” be considered a vital sign or not? Should additional metadata be included or not for blood pressure (e.g., position, site)? While pulse oximetry is included, should additional ABG results be considered part of vital signs as well as metadata? Rather we suggest addressing these questions for the specific exchange standard (e.g., C-CDA document type, V2 message, FHIR service) rather than attempting to create a superset and implying it be exchanged at all times.

HL7 notes that LOINC for body weight is not methodless and therefore suggests using [29463-7](#) instead.

HL7 requests clarification on what standard to be used for authoring source. Should this be based on the Rosetta Terminology Mapping Management System? Should the UDI of the measuring device be included when available? The latter would introduce substantial challenges as the industry is not ready yet to capture and communicate UDIs on measuring/monitoring devices.

§ 170.315(a)(7) Problem list

HL7 believes that the distinction between inpatient and ambulatory records should be dropped in favor of a “patient” record. Several major healthcare systems have dropped the distinction and are focusing on a patient problem list where one or more problems on the problem list are addressed in a particular encounter (outpatient visit or inpatient stay).

HL7 suggests that rather than pointing to the full SNOMED CT code system, that the reference be explicit to a concept and its value set relevant to this criterion, e.g., the Core Problem List.

§ 170.315(a)(8) Medication list

HL7 believes that the distinction between inpatient and ambulatory records should be dropped in favor of a “patient” record. Several major healthcare systems have dropped the distinction and are focusing on a patient medication list.

§ 170.315(a)(9) Medication allergy list

HL7 believes that the distinction between inpatient and ambulatory records should be dropped in favor of a “patient” record. Several major healthcare systems have dropped the distinction and are focusing on a patient medication allergy list.

§ 170.315(a)(10) Clinical decision support

HL7 recommends that (E) be included in the list in ii(B) which currently includes only (A), (B), and (D).

§ 170.315(a)(11) Drug-formulary and preferred drug list checks

The HL7 Decision Support Service standard and associated implementation guide, as well as the HL7 Clinical Decision Support Knowledge Artifact Specification, could potentially be used for individual-level, realtime (at the point of care) formulary benefit checking.

§ 170.315(a)(12) Smoking status

HL7 suggests that rather than pointing to the full SNOMED CT code system, that the reference be explicit to a concept and its value set relevant to this criterion.

§ 170.315(a)(13) Image results

We note that the HL7 standards are available to support communication of results and clinical documentation that are further profiled in IHE using DICOM standards for the image itself. HL7 is ready to work with ONC and other SDOs to provide further guides that can be used in future certification editions.

§ 170.315(a)(14) Family health history

HL7 suggests that rather than pointing to the full SNOMED CT code system, that the reference be explicit to a concept and its value set relevant to this criterion.

§ 170.315(a)(15) Family health history – pedigree

No comments.

§ 170.315(a)(16) Patient list creation

The HL7 Decision Support Service standard and associated implementation guide, as well as the HL7 Clinical Decision Support Knowledge Artifact Specification, could potentially be used to support this use case. Such an approach may be useful if the logical criteria are complicated and difficult to manage using standard approaches such as database queries.

§ 170.315(a)(17) Patient-specific education resources

HL7 supports this proposal but suggest to re-state (17)(i) as follows: “

Request that the language patient-specific education resources are presented in, be identified in accordance with the standard in § 170.207(g)(2)”.

§ 170.315(a)(18) Electronic medication administration record

No comments.

§ 170.315(a)(19) Patient health information capture

No comments.

§ 170.315(a)(20) Implantable device list

HL7 notes concerns with the deployment of the UDI that currently allows for 4 formats referenced in the FDA guidance and 6 other formats used in the DoD, while internationally other formats may be deployed as well. Discussions are in

progress to consider a UDI Canonical Format (UCF) to harmonize these formats and enable uniform interpretation of a UDI that is exchanged. HL7 urges ONC to work with FDA to establish UCF as the format to use for communication.

HL7 further notes the lack of clarity on what comprises an implantable devices list beyond the fields listed in the proposed criterion, e.g., date of implantation, procedure, surgeon, etc. Depending on the source this information may be more or less available with more or less accuracy. There is currently no guidance on how to implement these variants consistently in a C-CDA or other standard (e.g., V2).

Until these topics have been addressed through development of the necessary standards and implementation guidance, HL7 is concerned that deployment of only recording of the UDI itself and including that UDI list into a C-CDA will not result in the projected benefits, rather lead to inconsistency and confusion during the implementation.

§ 170.315(a)(21) Social, psychological, and behavioral data

§ 170.207(o)(3), § 170.207(o)(5), § 170.207(o)(9), and § 170.207(o)(10) require use of LOINC and respective answer list but specific codes are not listed. If included in the final rule these should be clearly identified to avoid variances in implementations.

If SNOMED CT is chosen to represent occupation codes, it should mention the parent concept and allowed descendants or reference a value set instead

§ 170.315(a)(22) Decision support – knowledge artifact

HL7 supports enabling a user to both send and receive clinical decision support (CDS) knowledge artifacts.

HL7 notes that the CDS Knowledge Artifact Specification (KAS) is currently being updated to harmonize with electronic clinical quality measurement (eCQM) standards through the Clinical Quality Framework (CQF) initiative. In particular, the CDS KAS is being updated to utilize the Clinical Quality Language (CQL) expression language. In the near future, we anticipate that the CDS KAS will be updated to utilize a data model harmonized with the eCQM domain. This updated data model is anticipated to consist of HL7 FHIR profiles as the physical models (QICore FHIR Profiles and potentially additional domain-specific profiles that build upon QICore), as well as logical models corresponding to these physical models (Quality Improvement and Clinical Knowledge – QUICK – model and potentially additional domain-specific models that build upon QUICK).

Based on the above context, HL7 recommend the following:

- Reference the most up-to-date version of the CDS KAS standard available at the time of publication of the final rule.
- Continue to encourage support for this type of interoperability functionality.
- Consider postponing requirement of a specific set of standards until the CDS-eCQM standards harmonization effort has been completed.

Other comments regarding corrections needed for the proposed language found at <http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-06612.pdf>:

- p. 16830, column 3: "... and requesting/receiving knowledge artifacts from a CDS service provider (UC2)." → underlined text should be "guidance". Same issue is repeated on p. 16831, column 2.
- p.16831, column 1: "(1) and offer testing and certification for health IT demonstrate it can electronically send and receive a CDS artifact formatted in the HeD standard Release 1.2." → This seems grammatically incorrect (missing a verb).

§ 170.315(a)(23) Decision support – service

HL7 notes that the statement “(6)Decision support – service. Enable a user to send and receive electronic clinical guidance in accordance with the standard specified in § 170.204(e)(1).” Is inaccurate. This statement should only state “receive” rather than “send and receive”.

HL7 notes that the Decision Support Service (DSS) Implementation Guide (IG) is currently being updated to harmonize with electronic clinical quality measurement (eCQM) standards through the Clinical Quality Framework (CQF) initiative. In the near future, we anticipate that the DSS IG will be updated to utilize a data model harmonized with the eCQM domain. This updated data model is anticipated to consist of HL7 FHIR profiles as the physical models (QICore FHIR Profiles and potentially additional domain-specific profiles that build upon QICore).

Based on the above context, we recommend the following:

- Continue to encourage support for this type of interoperability functionality.
- Consider postponing requirement of a specific set of standards until the CDS-eCQM standards harmonization effort has been completed.

We identified the following potential corrections if this text is carried forward into the final rule:

- p.16831, column 2: “accordance with ~~the standard in accordance with~~ an HeD standard.” → strikethrough seems to be redundant.

§ 170.315(b)(1) Transitions of care

HL7 is pleased with the continued utilization of C-CDA and supports the expansion of document types that must be supported to enable communicating the right amount of data (not too much, not too little) to the right person at the right time. However, since the requirements between the certification edition and the EHR Incentive Program that at the time of transition the full Common Clinical Data Set must be sent, a number of document types cannot be used even though they would be more suitable for specific transitions. HL7 suggests ONC and CMS to reconsider this requirement and allow for the flexibility that the provider can choose which document type is most appropriate for the specific transition at hand and that this consequently can count towards the objectives/measures.

HL7 supports the requirement that HIT must be able to render the human readable format for display. This is a fundamental CDA requirement that cannot be enforced strongly enough and ensures new versions of a document are at least readable by the clinician.

HL7 recognizes that introduction of C-CDA R2.0 in its current state introduces backwards compatibility challenges, particularly the following:

- To maintain interoperability at the current level, it is also important that at least the problems, medication allergies, and medications contained in a C-CDA R2 document can be extracted without changes by a system that has not yet upgraded to full C-CDA R2 support. HL7 is concerned that without availability of critical C-CDA R2 guidance and updates this is not attainable.
- Additionally, to maintain interoperability at the current level, data included that can be used for quality measures remains consistently available as well for those systems not yet upgraded to full C-CDA R2 support. As value sets are being updated and changed, this cannot be fully achieved without further updates to C-CDA R2.0.

There are two perspectives on how to proceed that have support in the HL7 community:

- Encourage quick adoption of C-CDA R2.0 so systems will be able to manage both. In that case, HL7 recommends:
 - A 2015 certified system will send documents conformant to C-CDA R2.0.
 - A 2015 certified system will be able to process either a document conformant to C-CDA R1.1/R2.0
 - A 2014 certified system will be able to process a C-CDA R1.1, and display R2.0 until that system becomes a 2015 certified system.
- Provide an update to C-CDA R2.0, e.g., “C-CDA R2.1”, that addresses the backwards compatibility issues
 - HL7 is actively exploring the opportunity to create an update in the July 2015 timeframe
 - It is not clear at this point whether this is feasible to achieve in that timeframe.

HL7 recommends the final rule name a specific version in the context of our general comment on backwards compatibility, thus allowing for the use of subsequent minor or major releases (e.g., C-CDA R2.*) that are backwards compatible. This gives HL7 the ability to perform maintenance releases to address these types of issues and have them recognized and deployed more quickly. In case that recommendation is not possible, HL7 recognizes that during CMS’ proposed 2017 reporting year, when providers are proposed to be able to attest to Stage 1, Stage 2, or Stage 3 using a mix of 2014 Edition and/or 2015 Edition, that not all providers will have 2015 Edition software for a significant period of time during 2017. The mix of software would result in increased integration efforts and gaps impacting the efficiency and effectiveness of clinical information reconciliation workflows. If the reporting period were shortened, as some in the industry argue, this impact can be mitigated and may make the first option more attainable and workable for the providers.

HL7 does not recommend the creation and transmission of a document in two different versions to support Asynchronous Bilateral Cutover. The industry is best served by transmission of a single document using the latest version of the standard where:

- functionality supported by both versions of the standard is transmitted in a backwards compatible way, and
- functionality supported only by the later version of the standard is transmitted without attention to backwards compatibility.

There are a number of reasons why sending multiple documents is problematic.

- It is challenging for the recipient to manage multiple documents.
- Use of multiple documents can also introduce patient safety issues.
- As the newer version allows for more content it is unclear how to create the two documents:
 - Only the content that can be rendered in both versions. This does not take advantage of the new version and raises the question why to support the new version.
 - Generate the full content for the new version and limited content for the old version. This effectively creates two different documents and adds to the challenge on how to manage multiple documents. Considering the discrepancy in content this may introduce patient safety issues as well.
- Additional content supported by new standards cannot be taken advantage of when a receiver on an older system forwards the document to a newer system.

HL7 suggests that rather than pointing to the full SNOMED CT code system, that the reference be explicit to the concepts and their value sets relevant to this criterion.

HL7 is concerned that current validators of C-CDA are not managing null values correctly, thus creating confusion on the appropriate way to convey null values. HL7 has produced examples on proper use and is happy to review these further with the validator developers.

Regarding the question on data provenance, HL7 suggests given the level of maturity and the need to promote adoption that this element of the criterion is at most made optional in the absence of another mechanism for ONC and CMS to

encourage pilots and early deployment projects to assess readiness for wide, national deployment. However, we urge ONC to sponsor further piloting and early deployment outside of the proposed 2015 Edition to ensure these standards can be successfully deployed at national level in the next iteration.

The absence of a standard for the API component of this criterion may lead to wide variety and conflicting implementations and, therefore, may be costly and inefficient. HL7 agrees with FHIR as a target standard and that FHIR is not yet mature for market-wide regulatory requirements. HL7 stands ready to work with the market on the maturation of appropriate standards. In support of that, HL7 is defining a maturity classification of FHIR at the component level that will enable a good understanding of what can be widely adopted sooner rather than later. This maturity classification will be essential to the industry and regulatory bodies to assert readiness for wide adoption even before FHIR may be fully normative.

§ 170.315(b)(2) Clinical information reconciliation and incorporation

HL7 notes that RXNorm Feb 2015 is already available and should be referenced.

HL7 suggests that rather than pointing to the full SNOMED CT code system, that the reference be explicit to the concept and its value set relevant to this criterion.

§ 170.315(b)(3) Electronic prescribing

HL7 notes that RXNorm Feb 2015 is already available and should be referenced.

§ 170.315(b)(4) Incorporate laboratory tests and values/results

HL7 agrees that the upcoming EHR-S Functional Requirements should be the basis for certification testing of incorporate, but the guide is not yet published, nor sufficiently mature to deploy in this edition. Once available, HL7 suggests using the specific user stories as guidelines for testing – result progression handling (initial, prelim to final, partial to final, final to corrected, final to amended), error handling of malformed messages or inconsistent content following the definitions for hard and soft error handling.

Regarding the use of the laboratory results implementation guide, HL7 notes that:

- The updated version is targeted to be published in July.
- Improvements include clarification, harmonization with other Lab guides, as well as new capabilities (micro, acknowledgements). The value sets used went through a substantial review and clean-up based on implementation feedback, and have been separately packaged to allow for more frequent, incremental updates.
- There are concerns with the enhancements to the acknowledgement requirements. While necessary to support improved confirmations of receipt, these capabilities have typically not been implemented in any V2 based implementations, thus there is no implementation experience at this time.

Considering the risks, HL7 supports the adoption of the new laboratory results implementation guide version as soon as it is published.

§ 170.315(b)(5) Transmission of laboratory test reports

See our comments on § 170.315(b)(5)

§ 170.315(b)(6) Data portability

HL7 suggests that rather than pointing to the full SNOMED CT code system, that the reference be explicit to the concepts and their value sets relevant to this criterion.

§ 170.315(b)(7) Data segmentation for privacy – send

HL7 notes that it is unclear whether the proposed data segmentation standard is only to be applied to the C-CDA CCD document type, or other document types referenced in this guide. HL7 suggests this should be applied to any document type.

Considering the pre-amble indicates only support for Level 1 is required, HL7 suggests that this be explicitly included in the rule language.

§ 170.315(b)(8) Data segmentation for privacy – receive

See comment on § 170.315(b)(7).

§ 170.315(b)(9) Care plan

No comments.

§ 170.315(c)(1) Clinical quality measures – record and export

Regarding the timing of introducing this requirement, HL7 believes that any criterion required for EHR incentive program should be required in the same timeframe for certified HIT.

HL7 suggests that RELEASE 3 (Category 1) of the CDA QRDA implementation guide, which is being published summer 2015, should be adopted rather than either of the other two versions (July 2012, or July 2012 + September 2014 Errata). The anticipated FHIR-based QUICK implementation guide should be considered for adoption in a future Edition of Certification Criteria once the guide is complete and has matured sufficiently through operational deployments.

HL7 notes the quality data model is still evolving and not stable or mature for adoption yet. Therefore, adopting quality data model standards such as those related to the vMR, which has not been adopted by EHRs, would be premature.

HL7 strongly agrees that all export be done without further developer assistance. The ability to validate the accuracy of the QRDA-I files is severely hindered without the ability to generate the files on demand. In addition, many of the errors found in the QRDA-I files can be due to local settings rather than vendor issues and it can take multiple weeks to months for an end-user to determine the problem while waiting for the vendor to investigate. This lengthy waiting period could be easily remedied by empowering the end users to generate the QRDA-I files as needed allowing them to do their own independent troubleshooting.

§ 170.315(c)(2) Clinical quality measures – import and calculate

Regarding the timing of introducing this requirement, HL7 believes that any criterion required for EHR incentive program should be required in the same timeframe for certified HIT.

HL7 notes that the same standard should be chosen as in § 170.315(c)(1) Clinical quality measures – record and export

HL7 agrees with ONC's overall intended direction for testing and certifying health IT and agrees with the proposed plan to test a larger number of test records for certification purposes. HL7 believes it is important to ensure that the system is tested on the multiple different ways in which a patient can appear in the numerator for a quality metric. So, we

believe it will be important to ensure that there are enough cases to cover each of various pathways for patients to appear in each of the measured populations. In addition, while duplicate records are a well-known occurrence in large databases, we also support the requirement that the certified EHR has the ability to de-duplicate the records. We would add to this requirement, the ability and flexibility for the end-users to define the de-duplication parameters for the records without the assistance from the vendor.

HL7 agrees with not including this in the base EHR definition, as 170.315 (c) (1) provides for a method of integrating with other health IT which provides this functionality. Enabling users to use multiple systems to fulfill all of the CQM objectives will advance interoperability standards. Because of this, we see no reason why this criterion needs to be included in the CEHRT definition.

In addition to the “import” we also strongly support the same ability for the end users to import the CQM data to any certified vendor. The inability for the end user to do this without the assistance of multiple vendors imposes the extraneous costs associated with data exchange between vendors on the end user community. In the current environment where numerous institutions employ a best-of-breed approach in utilizing multiple software programs, the associated cost of aggregating data together to capture a CQM can quickly become very costly. Enabling the ability for the end-user to import their QRDA files along with the ability to export the files, would address this costly barrier for the end-users.

Reserved for § 170.315(c)(3) Clinical quality measures – report

Regarding the timing of introducing this requirement, HL7 believes that any criterion required for EHR incentive program should be required in the same timeframe for certified HIT.

HL7 agrees with not including this in the base EHR definition, as 170.315 (c) (1) provides for a method of integrating with other health IT which provides this functionality. Enabling users to use multiple systems to fulfill all of the CQM objectives will advance interoperability standards. Because of this, we see no reason why this criterion needs to be included in the CEHRT definition.

§ 170.315(c)(4) Clinical quality measures – filter

HL7 suggests that rather than pointing to the full SNOMED CT code system, that the reference be explicit to the concept and its value set relevant to this criterion.

The list of data elements for filtering purposes seems to be a good starting point, and most of the data elements have mature code sets, except perhaps for provider type and patient insurance type. HL7 suggests for those two to postpone introduction as consistent application of the same criteria for the filter between organizations cannot be guaranteed. Until standards have been identified, they should not be used as a filter element with the exception of identifiers. HL7 notes that such standards are introduced in the data capture process first before introducing them for this criterion.

HL7 suggests that a payer code set used in administrative transactions and public health reporting to aid filtering should be considered for this purpose.

In the NPI provider enumeration system, a provider can select one or multiple Provider Taxonomy codes. Many individual providers choose one – often the one that reflect the largest type of clinical practice they perform. However, because of its relatively limited use in administrative transactions, this code has relatively low reliability. Still, this code set is perhaps the only specialty code set that is widely available, at least within the US Realm. ISO TC215 has developed a provider code set but is much less granular and much less used than NPI (at least in the US Realm)

At this point HL7 does not have any additional filtering data elements to consider.

§ 170.315(d)(1) Authentication, access control, and authorization

No comments.

§ 170.315(d)(2) Auditable events and tamper-resistance

No comments.

§ 170.315(d)(3) Audit report(s)

No comments.

§ 170.315(d)(4) Amendments

No comments.

§ 170.315(d)(5) Automatic access time-out

No comments.

§ 170.315(d)(6) Emergency access

No comments.

§ 170.315(d)(7) End-user device encryption

No comments.

§ 170.315(d)(8) Integrity

No comments.

§ 170.315(d)(9) Accounting of disclosures

No comments.

§ 170.315(e)(1) View, download, and transmit to a third party

Please see our comments on C-CDA R2.0 vs. C-CDA R2.1.

HL7 suggests that the questions 2, 3, and 6 are best addressed through market pressures to determine the variety of access methods most suitable to meet a patient's needs.

§ 170.315(e)(2) Secure messaging

No comments.

§ 170.315(f)(1) Transmission to immunization registries

HL7 encourages ONC to work with the CDC and states to arrive at a common implementation guide that enable consistent exchange with the registries. HL7 is ready to work with the ONC, CDC, and the states to establish such guidance

§ 170.315(f)(2) Transmission to public health agencies – syndromic surveillance

HL7 suggests improving consistency by using the proposed standard for both inpatient and ambulatory settings.

HL7 encourages ONC to work with the CDC and states to arrive at a common implementation guide that enable consistent exchange with the agencies. HL7 is ready to work with the ONC, CDC, and the states to establish such guidance.

§ 170.314(f)(3) Transmission to public health agencies – reportable laboratory tests and values/results

HL7 suggests that rather than pointing to the full SNOMED CT code system, that the reference be explicit to the concept and its value set relevant to this criterion.

HL7 encourages ONC to work with the CDC and states to arrive at a common implementation guide that enable consistent exchange with the agencies. HL7 is ready to work with the ONC, CDC, and the states to establish such guidance.

§ 170.315(f)(4) Transmission to cancer registries

HL7 encourages ONC to work with the registries to arrive at a common implementation guide that enable consistent exchange with the registries. While HL7 recognizes variations across registries are appropriate, a C-CDA document type/section approach may help ease the ability of HIT to communicate with the various registries. HL7 is ready to work with the ONC and the registries to establish such guidance.

HL7 suggests that rather than pointing to the full SNOMED CT code system, that the reference be explicit to the concept and its value set relevant to this criterion

§ 170.315(f)(5) Transmission to public health agencies – case reporting

HL7 is unsure if public health agencies have been sufficiently involved in creation of this IG to warrant implementation in the 2015 Edition as it is primarily driven by clinical research requirements. It has not been adopted in the public health community.

§ 170.315(f)(6) Transmission to public health agencies – antimicrobial use and resistance reporting

HL7 supports this certification criterion as it supports a national registry using a broadly adopted, mature standard.

§ 170.315(f)(7) Transmission to public health agencies – health care surveys

No comments.

§ 170.315(g)(1) Automated numerator recording

Regarding the timing of introducing this requirement, HL7 believes that any criterion required for EHR incentive program should be required in the same timeframe for certified HIT.

§ 170.315(g)(2) Automated measure calculation

Regarding the timing of introducing this requirement, HL7 believes that any criterion required for EHR incentive program should be required in the same timeframe for certified HIT.

§ 170.315(g)(3) Safety-enhanced design

No comments.

§ 170.315(g)(4) Quality management system

No comments.

§ 170.315(g)(5) Accessibility technology compatibility

No comments.

§ 170.315(g)(6) Consolidated CDA creation performance

HL7 agrees that there is a need for certification of C-CDA documents. However, a certification edition should focus on only one C-CDA version as there is no need to continue to generate older versions. As indicated earlier, creation of multiple versions to support backwards compatibility is strongly discouraged.

The challenge to evaluate the “completeness” of the data and deciding “equivalence” is to arrive at a consensus of these definitions. Considering that the objective is to communicate the right information at the right time to the right person, content of one document to another will vary (see our earlier comments on inappropriateness of requiring the full Common Clinical Data Set for all document types.) Consequently the HIT may have more data available that could be sent in a document but is not relevant to be sent in that case, or could be requested using, e.g., FHIR based services, as needed later. Therefore, the focus should be on the ability to populate all sections and its required fields

§ 170.315(g)(7) Application access to Common Clinical Data Set

HL7 suggest that the All Request should utilize a fully populated C-CDA CCD. Use of the term “summary record” is ambiguous and could yield use of a different document type or less populated document. However, fully populated should not mean all data on the patient for each section. For a patient with multiple inpatient stays and outpatient encounters this could be huge. HIT should be allowed to provide alternative approaches that enable access to all data without providing it through one document

§ 170.315(g)(8) Accessibility - centered design

No comments.

§ 170.315(h)(1) Direct Project

No comments.

§ 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM

No comments.

§ 170.315(h)(3) SOAP Transport and Security Specification and XDR/XDM for Direct Messaging

No comments.

§ 170.315(h)(4) Healthcare Provider Directory – query request

No comments.

§ 170.315(h)(5) Healthcare Provider Directory – query response

No comments.

§ 170.315(i)(1) Electronic submission of medical documentation

No comments.

Gap Certification Eligibility Table for 2015 Edition Health IT Certification Criteria

No comments.

Pharmacogenomics Data – Request for Comment

No comments.

Base EHR Definitions

No comments.

Common Clinical Data Set Definition

No comments.

Cross Referenced FDA Definitions

No comments.

Subpart E – ONC Health IT Certification Program

No comments.

Health IT Modules

HL7 supports for the notion of some form of field-testing of certified HIT, but notes the complexities as the tests in the field cannot necessarily use the same tests as the certification tests and must address the challenges of the PHI that is involved. Additionally, it is not reasonable to upgrade operational transactions that may not be according to the standards in the certification edition. Thus testing of those capabilities is not feasible.

“Removal” of Meaningful Use Measurement Certification Requirements

No comments.

Types of Care and Practice Settings

No comments.

Referencing the ONC Health IT Certification Program

No comments.

Privacy and Security

No comments.

Design and Performance (§ 170.315(g))

No comments.

“In-the-Field” Surveillance and Maintenance of Certification

HL7 supports the notion of surveillance but urges ONC to recognize that methods used in certification are not easily transferrable to surveillance as the configured capabilities may not use all certified capabilities yet still enable the provider to achieve all their objectives and is fully interoperable.

Transparency and Disclosure Requirements

No comments.

Open Data Certified Health IT Product List (CHPL)

No comments.

Records Retention

No comments.

Complaints Reporting

No comments.

Adaptations and Updates of Certified Health IT

No comments.

“Decertification” of Health IT – Request for Comment

HL7 suggests that any decertification process must enable due process to determine whether the variance between certification test and in-the-field testing or surveillance is the result of configuration or due to unavailability of the certified capabilities. Certification criteria and standards must be considered minimum capabilities, thus allowing space for new, innovative approaches that are not yet certified (e.g., new versions of standards), as well as continued use of interoperability that is not certified yet achieves the same goals (assuming certified capabilities are available to be implemented).

Collections of Information – Paperwork Reduction Act

No comments.

Regulatory Impact Statement

No comments.