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April 28, 2014

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 EHR Standards and Certification Criteria Proposed Rule
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. DeSalvo:

We appreciate the opportunity to provide feedback to the ONC proposed rule entitled “Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements” published in the February 26, 2014 *Federal Register*. Health Level Seven International (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 2,300+ members represent approximately 500 organizations that comprise more than 90% of the information systems vendors serving healthcare in the U.S.

As the global authority on standards for interoperability of health information technology, HL7 appreciates the opportunity to offer feedback to ONC on this proposed rule. Given the importance of issues in the NPRM and its relevance to our mission and members, HL7’s Policy Advisory Committee and nine of our organization’s Work Groups contributed to and shaped these comments including Work Groups that cover interoperability concerns in the following domains:(1) clinical decision support; (2) clinical quality information; (3) electronic health records; (4) orders and observations; (5) patient care; (6) public health and emergency response; (7) structured documents; (8) security; and (9) vocabulary. Brief general NPRM comments are detailed in this letter. The majority of HL7’s input is being submitted in a second document formatted using the suggested voluntary public comment template. We would be happy to answer questions or provide further information to you.

Sincerely,

A handwritten signature in black ink that reads "Charles Jaffe MD, PhD".

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International

A handwritten signature in black ink that reads "Stanley M. Huff, MD".

Stanley M. Huff, MD
Board of Directors, Chair
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Office of the National Coordinator for Health IT
Proposed Rule Public Comment Template

**Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria;
Interoperability Updates and Regulatory Improvements**

Preface

This document is meant to provide the public with a simple and organized way to submit comments on the proposed certification criteria and associated standards and implementation specifications, and respond to specific questions posed in the preamble of the proposed rule, which is published in the *Federal Register* at 79 FR 10880. While use of this document is entirely voluntary, commenters may find it helpful to use the document in lieu of or in addition to unstructured comments on the certification criteria and associated standards and implementation specifications, or to use it as an addendum to narrative cover pages.

The following tables align with the presentation of the proposed certification criteria in the preamble of the proposed rule. The tables specify where the proposed 2015 Edition EHR certification criterion or criteria would be included in § 170.315. The tables also specify the MU objective that the proposed 2015 Edition EHR certification criterion or criteria and associated standards and implementation specifications support. The tables note the page(s) of the *Federal Register* where we discuss the certification criterion or criteria and whether we request specific comments on certain proposals in the preamble. Last, the tables provide a field for submitting public comments on the proposed criterion or criteria, including responses to specific questions or requests for comments posed in the preamble.

To be considered, all comments (including comments provided through this document) must be submitted according to the instructions in the proposed rule. Electronic comment submissions are strongly encouraged and can be easily completed through the regulations.gov website and by clicking here:

<http://www.regulations.gov/#!submitComment;D=HHS-OS-2014-0002-0001>

Proposed Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria;

Interoperability Updates and Regulatory Improvements

A. Proposed for 2015 Edition¹ Certification Criteria

§ 170.315(a)(1) Computerized physician order entry - medications	
MU Objective Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.	
2015 Edition EHR Certification Criterion (1) <u>Computerized provider order entry – medications</u> . Enable a user to electronically record, change, and access medication orders.	
Preamble FR Citation: 79 FR 10886	Specific questions in preamble? No
Public Comment Field: No HL7 comment	

§ 170.315(a)(2) Computerized physician order entry - laboratory	
MU Objective Use CPOE for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.	
2015 Edition EHR Certification Criterion (2) <u>Computerized provider order entry – laboratory</u> . (i) Enable a user to electronically record, change, and access laboratory orders. (ii) <u>Ambulatory setting only</u> . Enable a user to electronically create laboratory orders for electronic transmission: (A) With all the information for a test requisition as specified at 42 CFR 493.1241(c)(1) through (c)(8); and (B) In accordance with the standard specified at § 170.205(l)(1) and, at a minimum the version of the standard at § 170.207(c)(2).	
Preamble FR Citation: 79 FR 10887	Specific questions in preamble? No

¹ This includes one proposed revision to the 2014 Edition certification criterion for transmission of syndromic surveillance information to public health agencies.

Public Comment Field:

- HL7 expresses concern that the references to LOINC for CPOE – Laboratory are confusing. It comes across in the NPRM that LOINC is mandated and no other code sets are allowed. Depending on the setting, as little as 30% or as high as 80% of the orderable tests have LOINC code. Both the use of non-LOINC test codes and more current versions of LOINC test codes must be clearly accommodated.
- HL7 supports the direction to use the Laboratory Orders Interface Implementation Guide (LOI IG) in communicating orders from ambulatory providers to laboratories. It is important to note however, the published version is incomplete and substantial updates are to be expected over the next 12-18 months. Also, there have not been any implementations yet to validate that the guide is usable and complete. We are concerned that, even though this is suggested to be voluntary, that without a clear understanding of the current state of the guide, software developers will implement the guide and will then be asked to upgrade to the next version, rather than to wait for the more complete version. Specific updates in progress include:
 - Handling of ask-at-order-entry questions and other relevant clinical information as part of the order
 - Clarity on vocabulary requirements
 - Expectations for cardinality constraints
 - Clarity on add-on orders
 - Updates to ensure the Patient Matching data standards are accommodated
- Another challenge is that the LOI IG specifies various optional profiles. Unfortunately it is not clear which profiles are to be supported and which one(s) remain optional.
- To improve on the ordering processes, a test compendium implementation guide (eDOS IG) was created, which started to gain some traction. We suggest that this guide should be included as an optional standard to allow organizations to begin considering implementation of this capability.
- We suggest that various of the CLIA requirements are not appropriate for the provider to forward to the laboratory, e.g., Ordering Provider Address as that information is being made available through other channels. We believe that the LOI IG has appropriately identified the data that is essential to communicate and the remainder that is optional to communication partners to use if both so desire..

§ 170.315(a)(3) (Computerized physician order entry – radiology/imaging)

MU Objective

Use CPOE for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.

2015 Edition EHR Certification Criterion

(3) Computerized provider order entry – radiology/imaging. Enable a user to electronically record, change, and access radiology and imaging orders.

Preamble FR Citation: 79 FR 10887

Specific questions in preamble? No

Public Comment Field: No HL7 comment.

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

MU Objective

Implement drug-drug and drug-allergy interaction checks.

2015 Edition EHR Certification Criterion

(4) Drug-drug, drug-allergy interaction checks. (i) Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.

(ii) Adjustments. (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

Preamble FR Citation: 79 FR 10887

Specific questions in preamble? Yes

Public Comment Field:

- The Drug-Allergy Interaction (DAI) functions described require the use of an allergy list. A known medication allergy has the potential to cause a severe reaction should be named a criticality assessment (condition) vs. a severity assessment which relates to a specific reaction. The Patient Care Work Group Allergy and Intolerance Domain Analysis Model provides a clear differentiation of these two concepts. Please see the Patient Care Work Group Allergy and Intolerance Domain Analysis model for reference: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=308.
- The NPRM question “What factors, definitions, standards, or existing consensus should be considered in determining whether a likely DDI/DAI reaction should be considered severe?” only addresses one single reaction. A system must anticipate whether a future reaction might be severe, hence the concept of criticality. An allergy list of conditions should list for example “allergy to penicillin” with a criticality of high or low. This would be the best approach to determining whether a likely DAI reaction would have the potential for an adverse reaction or adverse event.

§ 170.315(a)(5) (Demographics)

MU Objective

Record the following demographics: preferred language; sex; race; ethnicity; date of birth; and for the inpatient setting only, date and preliminary cause of death in the event of mortality in the EH or CAH.

2015 Edition EHR Certification Criterion

(5) Demographics. (i) Enable a user to electronically record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.

(A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.

(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.

(ii) Inpatient setting only. Enable a user to electronically record, change, and access the preliminary cause of death and date of death in the event of a mortality.

Preamble FR Citation: 79 FR 10888

Specific questions in preamble? Yes

Public Comment Field: No HL7 comment.

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

MU Objective

Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0-20 years, including BMI.

2015 Edition EHR Certification Criterion

(6) Vital signs, body mass index, and growth charts. (i) Vital signs. Enable a user to electronically record, change, and access, at a minimum, a patient's height/length, weight, and blood pressure. Height/length, weight, and blood pressure must be recorded in numerical values only.

(ii) Calculate body mass index. Automatically calculate and electronically display body mass index based on a patient's height and weight.

(iii) Optional—Plot and display growth charts. Plot and electronically display, upon request, growth charts for patients.

Preamble FR Citation: 79 FR 10889

Specific questions in preamble? Yes

Public Comment Field:

- HL7 recommends only supporting “vocabularies (and other metadata)” developed by organizations/initiatives that are accredited and maintain an open consensus process.
- HL7 supports requiring cited option 2 to “require that EHR technology be able to represent data in the aforementioned standards in this section in any certification criterion that references vital signs when such data would be exchanged.” We also support that option1 be recommended best practice presuming we understand the term “natively” as referring to the data being persisted in the system. It is important to note in data capture to use the most humanly consumable representation.

On the questions of adopting LOINC (for observations), SNOMED CT (for qualitative results), and UCUM (for units of measure)) in this certification criterion for the 2017 Edition, HL7 agrees with all three, however recognizes that concerns have been raised with the use of UCUM as members have indicated that laboratories do not support UCUM widely yet. Thus where transactions to laboratories include vital signs using UCUM, certain laboratories may be challenged to process them.

- HL7 questions what the basis is for the suggested change in methodology for gathering and documenting blood pressures.

§ 170.315(a)(7) (Problem list)

MU Objective

Maintain an up-to-date problem list of current and active diagnoses.

2015 Edition EHR Certification Criterion

(7) Problem list. Enable a user to electronically record, change, and access a patient's active problem list:

(i) Ambulatory setting. Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3); or

(ii) Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).

Preamble FR Citation: 79 FR 10890

Specific questions in preamble? No

§ 170.315(a)(7) (Problem list)

Public Comment Field:

- HL7 supports the use of the SNOMED-CT coding system for the problem list. We do not support the use of ICD-10 as an additional coding system as this would require more mappings and add complexity to using the C-CDA document templates.

§ 170.315(a)(8) (Medication list)

MU Objective

Maintain active medication list.

2015 Edition EHR Certification Criterion

(8) Medication list. Enable a user to electronically record, change, and access a patient's active medication list as well as medication history:

- (i) Ambulatory setting. Over multiple encounters; or
- (ii) Inpatient setting. For the duration of an entire hospitalization.

Preamble FR Citation: 79 FR 10890

Specific questions in preamble? *No*

Public Comment Field: No HL7 comment.

§ 170.315(a)(9) (Medication allergy list)

MU Objective

Maintain active medication allergy list.

2015 Edition EHR Certification Criterion

(9) Medication allergy list. Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history:

- (i) Ambulatory setting. Over multiple encounters; or
- (ii) Inpatient setting. For the duration of an entire hospitalization.

Preamble FR Citation: 79 FR 10890

Specific questions in preamble? *No*

§ 170.315(a)(9) (Medication allergy list)

Public Comment Field:

- HL7 believes the Medication Allergy list needs to include other types of allergies and intolerances (e.g. food, device) as per HL7 standards. The current requirements fall short, as peanuts and latex would not be included on a medication allergy list, for example.
- The list should be called the Allergy and Intolerance list. This remains a **significant patient safety issue** when all types of allergies and intolerances are not represented in a clinical setting or included in transitions of care. A food allergy can be a life-threatening event, especially in the pediatric population.
- The HL7 Patient Care Work Group has completed a Domain Analysis Model, Clinical Models and FHIR resources to accommodate the documentation and exchange of allergy and intolerance reactions and conditions. The Domain Analysis Model reference can be found here:
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=308
- The C-CDA R2.0 references the documentation and transport of allergies and intolerances including food, latex and environmental allergens. A limitation to only the medication allergy list is therefore inconsistent with use of the C-CDA R2.0.

§ 170.315(a)(10) (Clinical decision support)

MU Objective

Use clinical decision support to improve performance on high-priority health conditions.

2015 Edition EHR Certification Criteria

(10) Clinical decision support. (i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:

- (A) Problem list;
- (B) Medication list;
- (C) Medication allergy list;
- (D) At least one demographic specified in paragraph (a)(5)(i) of this section;
- (E) Laboratory tests; and
- (F) Vital signs.

(ii) Linked referential clinical decision support. (A) EHR technology must be able to:

- (1) Electronically identify for a user diagnostic and therapeutic reference information; or
- (2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard

specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (3).

(B) For paragraph (a)(10)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(10)(i)(A), (B), and (D) of this section.

(iii) Clinical decision support configuration. (A) Enable interventions and reference resources specified in paragraphs (a)(10)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.

(B) EHR technology must enable interventions to be electronically triggered:

- (1) Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section.
- (2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(i)(B) of this section.

(3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4)(i)(A)(1) of this section.

(iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(10)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.

(v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources:

(A) For evidence-based decision support interventions under paragraph (a)(10)(i) of this section:

- (1) Bibliographic citation of the intervention (clinical research/guideline);
- (2) Developer of the intervention (translation from clinical research/guideline);
- (3) Funding source of the intervention development technical implementation; and
- (4) Release and, if applicable, revision date(s) of the intervention or reference source.

(B) For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

(vi) Decision support – knowledge artifact. Electronically process clinical decision support knowledge artifacts in accordance with the standard specified at § 170.204(d).

(vii) Decision support – service. Enable a user to electronically make an information request with patient data and receive in return electronic clinical guidance in accordance with the standard specified at § 170.204(e).

Preamble FR Citation: 79 FR 10890

Specific questions in preamble? Yes

§ 170.315(a)(11) (Electronic notes)

MU Objective

Record electronic notes in patient records.

§ 170.315(a)(10) (Clinical decision support)

2015 Edition EHR Certification Criterion

(11) Electronic notes. Enable a user to electronically:

- (i) Record, change, and access electronic notes; and
- (ii) Search within and across electronic notes stored within EHR technology.

Preamble FR Citation: 79 FR 10891

Specific questions in preamble? Yes

Public Comment Field:

Health eDecisions (HeD) – Knowledge Artifacts and Decision Support Service (DSS)

Given that Meaningful Use of EHRs is ultimately intended to improve the quality, safety and value of patient care, we feel that promoting the adoption of standards such as HQMF and HeD is both necessary and beneficial. However, we note that there is an active effort known as the Clinical Quality Framework (CQF) initiative (www.cqframework.info) which is working to harmonize these standards. The effort, which is sponsored by the ONC and CMS and actively supported by HL7 and its Work Groups, is expected to develop and validate the next generation of the HQMF and HeD standards utilizing a harmonized data model, expression logic, and metadata. The CQF effort is not expected to result in a complete re-write of the HeD and HQMF standards. Indeed, the changes are expected to be evolutionary rather than revolutionary in nature. At the same time, these changes/enhancements are expected to be substantial in nature, in particular with regard to the data model utilized. Our recommendations for moving forward are therefore based on this active work at harmonization, as well as the anticipated update to the data model utilized.

Our primary recommendations are as follows. The remainder of our comments below expands upon these primary recommendations. We also provide secondary recommendations and comments on various aspects for which ONC has requested public comment. Of note, here and throughout these comments, unless otherwise stated, the EHR certification criteria referenced are the 2015 Voluntary EHR Certification Criteria rather than future 2017 EHR Certification Criteria.

- We recommend that the ONC **facilitate the development of tools and resources that reduce the costs and increase the benefits of adopting the relevant standards**. For example, the ONC could facilitate the establishment and initial population of a library of standards-compliant CDS knowledge artifacts that are designed to improve performance on electronic clinical quality measures included within the scope of the Meaningful Use program.
- We suggest that the ONC **prioritize and promote the CQF harmonization work, in particular by making 2015 Voluntary EHR Certification Criteria related to HQMF and HeD fulfillable by participation in CQF pilots**.
- We suggest that **the 2015 Voluntary EHR Certification Criteria related to current HQMF and HeD specifications be narrowed to “simple” and high value functionalities**, so that experience can be gained with the general approach of these standards, while avoiding undue burden to implementers given the expected updates to these standards through the CQF initiative. Such “simple” and high value functionalities might include:
 - o Order sets with no logic specifications beyond groupings, and content nesting limited to 2 levels maximum

- Documentation templates with no logic specifications beyond groupings, and content nesting limited to 2 levels maximum
- Alerts/reminders using a simplified subset of the full capabilities defined in HeD
- Immunization forecasting for decision support as a guidance service, where there are existing production-level implementations as well as open-source, freely available software

For the purposes of voluntary 2015 EHR certification, we recommend the ONC generate test scripts that conform with this goal of simple implementation. Regulations citing these criteria could then allow fulfillment of the requirements through the demonstration of the ability to import/use at least one of each type of artifact. In designing these test scripts, a balance will need to be struck between keeping the requirements simple for the purposes of Voluntary 2015 Certification Criteria and protecting against gaming.

Background

Harmonization of HeD and HQMF Standards – In-Progress HL7 Activities and the Clinical Quality Framework (CQF) Initiative

The HL7 Clinical Quality Improvement (CQI) and Clinical Decision Support (CDS) Work Groups have been working over the past year to harmonize the HQMF and HeD standards, based on very strong feedback received from industry and from the ONC. This effort has since been formalized as an ONC and CMS-sponsored Standards and Interoperability (S&I) Framework Initiative known as the Clinical Quality Framework (CQF) initiative. The CQF initiative, which is working closely with the HL7 CQI and CDS Work Groups, is aiming to have the harmonized standards fully specified and validated via pilots by the fall/winter of 2014, so as to enable potential reference in 2017 EHR certification criteria.

While the functionality supported by the HeD and HQMF R2 standards is not expected to change greatly, the infrastructure and architecture needed to implement the harmonized standards is likely to be different from what would be necessary to use those standards as they exist today. Premature, heavy investment in that infrastructure would be likely to result in a situation which would negatively impact the ability of vendors to respond to changes thereafter. This might present itself through a marketplace that simply cannot adapt to use the newly harmonized standards in 2017 in time for providers to be able to adopt the new technology. It is an age-old adage in software design that making a change is orders of magnitude easier when the requirements are developed than when the code is being tested or after it has shipped. Since significant infrastructure is required to support HQMF and HeD, we believe that the ONC should be very careful about how it commits the market to adoption of these standards. Our recommendations are based on this assessment.

Standards Readiness

One of the challenges in selecting standards is in assessing readiness. The image below is reproduced from a presentation developed by the Clinical Quality Workgroup of the Health IT Standards FACA. We note that the committee felt that this was a viable set of principles for assessing standards readiness, and we would suggest that the ONC consider adopting it as a set of principles that is applied by all HIT Standards FACA workgroups:

	Principles Checklist	Guiding Questions
MUST HAVES	<input type="checkbox"/> GETS THE JOB DONE <ul style="list-style-type: none"> <input type="checkbox"/> Meets program goals and requirements <input type="checkbox"/> Is well-suited and/or designed for the purpose 	<ul style="list-style-type: none"> • What are we trying to do? <ul style="list-style-type: none"> – Does our architecture need to change to support that? • Is this standard designed to do that? <ul style="list-style-type: none"> – If not, why is it still a good fit?
	<input type="checkbox"/> TRIED AND TRUE <ul style="list-style-type: none"> <input type="checkbox"/> Testable and tested <input type="checkbox"/> Has, or is expected to have implementation, adoption and use <input type="checkbox"/> Widely recognized, well-established, mature 	<ul style="list-style-type: none"> • What risks are we willing to take? How mature is it? <ul style="list-style-type: none"> – If new, does it build on previous knowledge? – Has it ever been used in real world environment? – Has it been tested? – Can I get it today?
	<input type="checkbox"/> FORWARD LOOKING <ul style="list-style-type: none"> <input type="checkbox"/> Extensible <input type="checkbox"/> Has SDO support 	<ul style="list-style-type: none"> • Is it future-proof and adaptable to change? • Who maintains it?
NICE TO HAVES	<input type="checkbox"/> PLAYS WELL WITH OTHERS <ul style="list-style-type: none"> <input type="checkbox"/> Fits into the existing/planned architecture 	<ul style="list-style-type: none"> • What is our Architecture?
	<input type="checkbox"/> NOT TOO DIFFICULT <ul style="list-style-type: none"> <input type="checkbox"/> Readily available w/o encumbrances <input type="checkbox"/> Low Complexity 	<ul style="list-style-type: none"> • Is it easily and inexpensively implemented?

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When assessed individually against the above criteria, both HQMF and HeD individually might receive good grades. However, when assessed together they are suboptimal in two places:

- *Meets program goals and requirements*

HeD and HQMF today have two different ways to represent logical criteria which must be evaluated to determine whether an intervention is needed (HeD) or was performed (HQMF). If these criteria are not evaluated in the same way, what is being counted in a measure could wind up being different from what was intended in the implementation of decision support. There should be only one way to do both.

- *Fits into the existing/planned architecture*

Individually, these standards could fit into the planned architecture, but together they do not. As the evaluation of logic is done differently, and as evaluation is essential to both standards, the two different approaches may produce slightly different results. This would not be the case in a carefully designed architecture.

Promoting Adoption

We understand the need and desire to test these standards in the marketplace. We urge the ONC and CMS to work together to find optimal mechanisms by which such tests could be performed. Providers adopting new standards to test their ability to improve patient care are presented with three key challenges today:

1. Availability of implementations
2. Competing needs with other programs such as Meaningful Use which demand resources to be completed
3. Risking incentives because piloting new standards is not recognized by CMS as an allowed mechanism to meet targets used to attain incentives or avoid penalties

Using voluntary regulation to drive adoption addresses these three challenges, but it is not the ideal solution in itself. The market perception of the 2015 Voluntary EHR Certification Criteria is quite mixed. Some understand this rule to be the 2017 criteria, others believe it to be required rather than voluntary, and others will simply assume that newer

is better. These misperceptions are common and likely unavoidable, but they also result in an under-emphasis on the voluntary nature of the criteria. While this creates a demand for implementation and use, it does so without necessarily establishing a demonstrated willingness to perform beyond meeting the basic expectations.

Newer may in fact be more risky for providers, especially given that 2017 requirements follow shortly thereafter. Should the HQMF or HeD standards be comprehensively adopted for 2015 and then changed in 2017, an organization committing either to develop or to use voluntary criteria may incur significant risk that such changes in a following rule may not be implementable by regulatory timelines.

We believe that both the ONC and CMS should recognize cases where providers and vendors are contributing to adoption efforts to promote the use of new standards which will benefit health care in new ways, such as those which HQMF and HeD are attempting. To that effect, we suggest that CMS and ONC collaborate in promoting these efforts by recognizing pilot programs in such a way so as to:

1. Make it easier for EHR developers to certify products under newly adopted criteria after participation in a recognized pilot program, noting that the demands of participating in a pilot are more stringent and based in real-world use than certification testing, and
2. Allow providers who participate in a recognized pilot program to count that participation towards the goal of meeting targets necessary to attain incentives or avoid penalties under Meaningful Use, for example by naming Recognized Pilot Participation in the menu set of options for Meaningful Use participation.

This addresses the challenges presented above by:

1. Presenting EHR developers with an incentive to participate in pilot testing of new standards without sacrificing the quality of the certification program,
2. Presenting eligible providers and hospitals with an incentive to move the bar up as an option to meeting Meaningful Use requirements, and
3. Eliminating disincentives to move the bar up for eligible providers and hospitals.

We believe that this alternative will create both a demand, and willingness on the participants not to just meet, but even to exceed ONC's program goals in the use of standards. We recognize that such an approach would take some time to develop, but we feel that this would be a better way to test the waters with new standards. It may well be that the harmonized HQMF and HeD standards that HL7 is presently working on would be the perfect test case for executing such a pilot. In other words, we believe that meaningful pilots of new standards should be encouraged, supported, and incentivized in a holistic manner that may include but is not limited to Voluntary EHR Certification Criteria.

The Inadequacy of the Current State and the Need for Forward Movement

Since the 1970s, randomized controlled trials have shown that CDS interventions can significantly improve care. 40 years later, we have made relatively little progress in the widespread adoption of advanced CDS capabilities, such that we are still at a point where CDS is quite difficult to share across institutions. If we do not seize the opportunity to make strides in this area, we may be in the same situation in 40 additional years. Thus, beginning on a path towards shareable CDS harmonized with clinical quality measurement is critical for moving the industry forward towards improved care quality, patient safety, and healthcare outcomes.

Validation to Date of HeD Standards

As noted above, an important consideration for standards maturity is the degree to which such standards have been vetted through implementation and piloting.

One set of HeD standards pertains to the delivery of CDS Guidance Services (HeD Use Case 2), with the relevant standards consisting of the Decision Support Service (DSS) Implementation Guide, Virtual Medical Record (vMR) standards, and DSS standard. Here, we note that the DSS and vMR standards have been implemented by a variety of groups. For example, the vMR and DSS standards are in production-level use by a major EHR system (eClinicalWorks) for immunization CDS using the Immunization Calculation Engine (ICE) product (<https://www.hln.com/ice/>). Similarly, the vMR and DSS standards are in production use by the OpenCDS platform (www.opencds.org), which is being used for operational CDS and quality measurement at institutions such as University of Utah Health Care.

With regard to the HL7 CDS Knowledge Artifact Implementation Guide (HeD Use Case 1), the HeD initiative conducted several pilot implementations of this specification. This included an order set exchange pilot by Zynx Health and Design Clinicals; a documentation template exchange pilot by Wolters Kluwer Health and the Veterans Health Administration; and an event-condition-action rule exchange pilot by Motive Medical Intelligence and Allscripts. For example, in the Motive-Allscripts pilot, a CDS rule expressed in the CDS Knowledge Artifact format was translated automatically into the Allscripts native rules execution format and successfully executed against test cases.

In summary, HeD-related standards are either in successful production use or have been piloted significantly.

Primary Recommendations

1. Provide Tools and Resources to Reduce Costs and Increase Benefits of Standards Adoption

We recommend that the ONC facilitate the development of tools and resources that reduce the costs and increase the benefits of adopting the relevant standards. Specifically, we make the following recommendations:

- Provide a large library of standards-compliant CDS knowledge artifacts to “seed” the CDS domain, similar to the way that electronic clinical quality measures are currently provisioned. For example, provide access to a library of vetted event-condition-action rules, order sets, and documentation templates compliant with the proposed standards and aligned with the electronic clinical quality measures included within the Meaningful Use program.
- Make available a fully functional reference DSS implementation including the following:
 - A DSS compliant with the DSS IG and available for test usage
 - An underlying DSS evaluation engine
 - Integration with an open source EHR that interoperates with the DSS by requesting guidance and consuming the resulting recommendations
- Provide tooling for authoring CDS knowledge artifacts and services
- Provide support resources such as documentation, tutorials, etc.

2. Allow CQF Pilots to Fulfill Voluntary 2015 EHR Certification Criteria

We suggest that the ONC prioritize and promote the CQF harmonization work, in particular by making 2015 Voluntary EHR Certification Criteria related to HQMF and HeD fulfillable by participating in CQF pilots. Moreover, as noted above, we recommend that additional mechanisms outside of EHR Certification Criteria be used by the ONC and CMS to incentivize vendor participation in meaningful CQF pilots.

3. Constrain Voluntary 2015 EHR Certification Criteria to “Simple” and High Value Functionalities

We suggest that the 2015 Voluntary EHR Certification Criteria related to current HQMF and HeD specifications be narrowed to “simple” and high value functionalities, so that experience can be gained with the general approach of these standards, while avoiding undue burden to implementers given the expected updates to these standards through the CQF initiative. Such “simple” and high value functionalities might include:

- Order sets with no logic specifications beyond groupings, and content nesting limited to 2 levels maximum
- Documentation templates with no logic specifications beyond groupings, and content nesting limited to 2 levels maximum
- Alerts/reminders using a simplified subset of the full capabilities defined in HeD
- Immunization forecasting for decision support as a guidance service, where there are existing production-level implementations as well as open-source, freely available software

For the purposes of voluntary 2015 EHR certification, we recommend the ONC generate test scripts that conform to this goal of simple implementation. Regulations citing these criteria could then allow fulfillment of the requirements through the demonstration of the ability to import/use at least one of each type of artifact. In designing these test scripts, a balance will need to be struck between keeping the requirements simple for the purposes of Voluntary 2015 Certification Criteria and protecting against gaming.

Secondary Recommendations

1. Consider Bidirectional Exchange

The current NPRM proposes only the import of CDS knowledge artifacts. For optimal interoperability, we recommend considering the export of CDS knowledge artifacts using the HeD format for CQF pilots and/or 2017 EHR Certification Criteria. Without such export capabilities, the ability to share and standardize on useful CDS knowledge artifacts will be limited.

2. Update References

We recommend that the references to the HeD standards be updated to the following. Of note, the locations of these and other HL7 CDS Work Group standards can be obtained from the HL7 CDS Work Group co-chairs and from http://wiki.hl7.org/index.php?title=HL7_CDS_Standards:

- HL7 Implementation Guide: Decision Support Service, Release 1.1
- HL7 Version 3 Standard: Clinical Decision Support Knowledge Artifact Specification, Release 1.1 (note revised name)

3. Explore Potential Overlap with Related Use Cases

To the extent that the HeD standards could be useful for “non-CDS” use cases, such as those being pursued by the Electronic Submission of Medical Documentation (esMD) initiative, we encourage exploration of potential cross-use of these standards in related areas.

Comments on Specific Questions Posed by ONC with regard to HeD Standards

- What specifically ONC should focus on when it comes to testing and certification for acceptance and incorporation of CDS Knowledge Artifacts
 - Please see Primary Recommendations # 2 and 3 above.
- The feasibility of implementing the interface requirements defined in the Decision Support Service IG to make an information request, send patient data, and receive CDS guidance in near real-time
 - As described above, we note that the DSS IG approach has been validated for specific use cases as noted above, e.g., by ICE, eClinicalWorks, and OpenCDS.
 - We also note that the general approach of using services for CDS has been adopted by some large vendors such as Epic and Allscripts. Adapting these custom interfaces to a standard DSS IG interface should be feasible according to discussions with several such vendors.
 - We note that if focused on defined interaction types with specific input and output requirements (e.g. for immunization CDS, drug-drug interaction checking, etc.), the approach is even more simple to implement and feasible.
- The ease with which EHR technology could be developed to consume CDS Knowledge Artifacts
 - We note that in general, the approach has been demonstrated to be feasible with pilots, as well as by the adoption of HeD-based (or similar) formats in production. For example, Allscripts uses CREF, one of the input specifications for HeD, and Motive Medical Intelligence has developed an HeD-based implementation of CDS artifacts that is working in production with an EHR vendor.
 - We note, however, that the feasibility so far demonstrated has been point-to-point, and that in a highly interoperable sharing environment, there will be challenges in terms of aligning terminologies and data models. Ideally, there would be tooling and resources to facilitate these mappings. For example, value set definitions, template definitions, a national order catalog, etc., will be important to achieve truly uncoordinated interoperability.
 - We further note that more complex interaction types will of course be more challenging. We would therefore recommend starting with simpler use cases initially (see Primary Recommendation #3), with a phased increase in capability and complexity.
- Whether we should work to distinguish between complex CDS Knowledge Artifacts and simple Knowledge Artifacts and to require only acceptance and incorporation of simple Knowledge Artifacts in the 2015 Edition, with increasing expectations of more complex capabilities in future editions
 - Please see Primary Recommendation # 3 above. Additional comments are as follows:
 - We agree that further clarity on the distinction between “simple” and “complex” knowledge artifacts would be useful.
 - We agree that focusing on lower-hanging, higher “bang for the buck” scenarios is desirable. While more advanced clinical logic is certainly valuable, significant value can be achieved with simple interventions using basic, commonly available data. For example, high-value, relatively simple use cases may utilize billing information, medications, lab results, problem lists, allergies, and other data that are already required by regulations as a part of Meaningful Use and represented using relatively uniform approaches.
 - High-value use cases may include those involving common but complex CDS logic requirements (e.g., immunization), high cost populations (e.g., individuals with congestive heart failure, acute myocardial infarction,

diabetes, or asthma), CDS aligned with electronic clinical quality measures, and/or simple/common/“bread and butter” clinical cases and use scenarios (e.g., “simple” order sets vs. complex ones).

- We note that a challenge to making such a distinction is that the standards involved do not currently provide clear delineations along these lines. Such distinctions would need to either be added into the current standards or defined outside of these standards.
- The ability to store and auto-configure a CDS Knowledge Artifact in EHR technology
 - As noted above with regard to the feasibility of the CDS Knowledge Artifact IG, we believe that storing and auto-configuring a CDS Knowledge Artifact in EHR technologies is feasible.
- The ability to map the CDS Knowledge Artifact standard to data within the EHR technology (including medications, laboratory, and allergies information)
 - As noted above, the underlying data model for the HeD standards (vMR) is already being used to map data from EHR technologies for use in CDS. A core requirement for CDS is the ability to unambiguously and efficiently map EHR data to the CDS data model. The vMR was specifically designed to enable such mappings in real-world environments. Therefore, we believe this ability to map data definitely exists and is a strength of the HeD approach.
 - The widespread adoption of standardized terminologies and value sets will be critical to enabling such mappings in an unambiguous and efficient manner. Convergence on standard information models as well as convergence on standard terminologies and value sets used within those information models will be critical to achieving true semantic interoperability. The NLM Value Set Authority Center (VSAC) has the potential to greatly facilitate such interoperability, and we encourage continued investment in this area.

Conclusions

We fully support the ONC’s goal of advancing interoperable electronic clinical quality measurement and clinical decision support. We believe interoperability in these areas is critical for making Meaningful Use of EHR technologies to improve health and health care.

Infobutton

We offer the following responses to the specific questions raised on Infobutton.

- Re: As a result, we propose that the 2015 Edition CDS certification criterion will not require compliance with the Infobutton-enabled capability for vital signs nor medication allergies data. “
 - Release 4 of the HL7 Infobutton URL-based Implementation Guide was approved as a normative specification in January 2014. This release does provide support to represent vital signs and medication allergies. Yet, we agree with the proposal above since there is little experience with the implementation and usefulness of infobuttons with vital signs and medication allergies. Therefore, we agree that these should not be required for certification.
- Re: “We also propose to discontinue referencing “laboratory values/results” data as we understand from stakeholder feedback that the Infobutton standard cannot support this specific data. “
 - Release 4 of the HL7 Infobutton URL-based Implementation Guide does support laboratory test values/results. Based on experience at early adopter sites, infobutton usage from laboratory test results data is fairly high and there are online reference resources that support this kind of data. Therefore, we recommend not discontinuing laboratory test results data as a requirement for

certification.

- Re: “..we propose to adopt the HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1, August 2013 (at § 170.204(b)(3)) in place of the older version referenced by the 2014 Edition certification criterion.”
 - We agree with this proposal. We also recommend referencing the latest release of the HL7 Infobutton URL-based Implementation Guide, which was approved in January 2014 and is officially entitled “HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain, Release 4”. We also recommend referencing the following parent specification, which was also approved in January 2014: “HL7 Version 3 Standard: Context-Aware Knowledge Retrieval Application (Infobutton); Knowledge Request, Release 2”.

Other Comments

Additionally we offer the following comments as well.

- HL7 suggest to consistently support the use of one terminology (e.g. SNOMED-CT) for the problem list, regardless of its use in CDS, CQM, C-CDA, transactions, or other capabilities.
- We note that an Allergy list needs to be called an Allergy and Intolerance list to more appropriately reflect the scope.
- We suggest that while lab results/values are not as useful when obtaining patient-education resources using Infobutton, they should not be excluded as parameters for CDS in general. as actual values influence decision making most of the time, not just absence/presence of a test.

§ 170.315(a)(12) (Drug formulary checks)

MU Objective

Implement drug formulary checks.

2015 Edition EHR Certification Criterion

(12) Drug-formulary checks. EHR technology must automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication.

Preamble FR Citation: 79 FR 10892

Specific questions in preamble? Yes

Public Comment Field:

- HL7 recommends to “leave this certification criterion as-is (in its flexible form).”

§ 170.315(a)(13) (Smoking status)

MU Objective

Record smoking status for patients 13 years old or older.

§ 170.315(a)(13) (Smoking status)

2015 Edition EHR Certification Criteria

(13) Smoking status. Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(h).

Preamble FR Citation: 79 FR 10892

Specific questions in preamble? *No*

Public Comment Field: No HL7 comment.

§ 170.315(a)(14) (Image results)

MU Objective

Imaging results and information are accessible through Certified EHR Technology.

2015 Edition EHR Certification Criterion

(14) Image results. Electronically indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

Preamble FR Citation: 79 FR 10893

Specific questions in preamble? *No*

Public Comment Field: No HL7 comment.

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

MU Objective

Record patient family health history as structured data.

2015 Edition EHR Certification Criterion

(15) Family health history. Enable a user to electronically record, change, and access a patient's family health history according to the standard and implementation specification specified at § 170.205(m)(1).

Preamble FR Citation: 79 FR 10893

Specific questions in preamble? *No*

Public Comment Field:

- HL7 supports the use of the HL7 V3 Genomics Standard: Clinical Genomics, Pedigree, and the implementation specifications guide. In addition, HL7 recommends that there should be criterion guiding the use of family history for patient health risk assessment and management.

§ 170.315(a)(16) (Patient list creation)

MU Objective

Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.

§ 170.315(a)(16) (Patient list creation)

2015 Edition EHR Certification Criterion

(16) Patient list creation. Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data:

- (i) Problems;
- (ii) Medications;
- (iii) Medication allergies;
- (iv) At least one demographic specified in paragraph (a)(5)(i) of this section;
- (v) Laboratory tests and values/results; and
- (vi) Ambulatory setting only. Patient communication preferences.

Preamble FR Citation: 79 FR 10893

Specific questions in preamble? Yes

Public Comment Field:

- HL7 supports the use of RIM-based models for documenting patient preference details. This work is detailed in the HL7 Clinical Model for Patient Preferences (work done through Orders and Observations).
- HL7 supports the documentation and use of communication preferences – and recommends facilitating care coordination that these same preferences be recognized across the continuum of care. HL7 recommends these communication preferences lists have shared care plan functionality.

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

MU Objective

Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

2015 Edition EHR Certification Criterion

(17) Patient-specific education resources. EHR technology must be able to electronically identify for a user patient-specific education resources based on data included in the patient's problem list, medication list, and laboratory tests:

- (i) In accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (3); and
- (ii) By any means other than using the standard specified in § 170.204(b).

Preamble FR Citaion: 79 FR 10893

Specific questions in preamble? Yes

Public Comment Field:

Re: “Our first proposal is to adopt this certification without the requirement that EHR technology be capable of electronically identifying patient-specific education resources based on “laboratory values/results.””

As mentioned in response on Clinical Decision Support above, Release 4 of the HL7 Infobutton URL-based Implementation Guide does support laboratory test values/results. However, unlike provider reference information, there are important reasons not to require identifying patient-specific education resources based on “laboratory values/results”.

- Patient education vendors typically do not maintain reference ranges or the clinical rules to be able to interpret whether a lab value would be considered high/low/normal.
- There are few if any patient education reference libraries with sufficient granularity to differentiate between instructions for a lab test with abnormal results versus a lab test with normal results.
- Knowing that a lab test is abnormal does not automatically mean that education would be appropriate. Instead, it's preferable to wait until a diagnosis has been assigned by a qualified professional (e.g. hyperlipidemia) – and provide education based on the diagnosis, not the test results.

Therefore, we agree with the proposal above not to require identifying patient-specific education resources based on laboratory values/results. Yet, we still recommend requiring identifying patient-specific education resources based on laboratory tests (regardless of the results). This kind of laboratory test education could describe the test, its purpose, experiential factors, typical ranges, the meaning of different results, but without interpreting the specific patient's results.

Re: “Our second proposal is to adopt the HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1, August 2013.”

We agree with this proposal. Please note that the specification referenced above (HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1, August 2013) is now a normative specification and no longer a DSTU.

We recommend referencing the latest release of the HL7 Infobutton URL-based Implementation Guide, which was approved in January 2014 and is officially entitled “HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain, Release 4”.

We also recommend referencing the following parent specification, which was also approved in January 2014: “HL7 Version 3 Standard: Context-Aware Knowledge Retrieval Application (Infobutton); Knowledge Request, Release 2”.

Re: “We request comment on whether we should adopt a different approach related to the methods EHR technology uses to electronically identify patient-specific education resources for the 2015 Edition, a potential 2017 Edition “patient-specific education resources” certification criterion, or both.

We propose the adoption of option #2 above. Option #1 has generated substantial confusion among implementers and should be discontinued. Option #3 leaves in-place the current proprietary barriers that have hindered the spread of this needed functionality.

Re: We also seek comment on whether we should require that EHR technology be capable of providing patient-specific education resources in a patient's preferred language in the 2015 Edition, in a potential 2017 Edition certification criterion, or in both.

We agree with the proposal above. Language preference is not difficult to implement and several online patient education resources have the capability to provide patient education content in the patient's preferred language. We recommend this capability as a certification criterion both in the 2015 and in the 2017 Edition. Because several patient education resources provide content in both English and Spanish, we suggest support for these two languages as the minimum requirement for certification.

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

§ 170.315(a)(18) (Inpatient setting only – electronic medication administration record)

MU Objective

Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

2015 Edition EHR Certification Criterion

(18) Inpatient setting only—electronic medication administration record. (i) In combination with an assistive technology that provides automated information on the “rights” specified in paragraphs (a)(18)(i)(A) through (E) of this section, enable a user to electronically verify the following before administering medication(s):

- (A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered.
- (B) Right medication. The medication to be administered matches the medication ordered for the patient.
- (C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient.
- (D) Right route. The route of medication delivery matches the route specified in the medication order.
- (E) Right time. The time that the medication was ordered to be administered compared to the current time.

(ii) Right documentation. Electronically record the time and date in accordance with the standard specified in §170.210(g), and user identification when a medication is administered.

Preamble FR Citation: 79 FR 10894

Specific questions in preamble? *No*

Public Comment Field: No HL7 comment.

§ 170.315(a)(19) (Inpatient setting only – advance directives)

MU Objective

Record whether a patient 65 years old or older has an advance directive.

2015 Edition EHR Certification Criteria

(19) Inpatient setting only—advance directives. Enable a user to electronically record whether a patient has an advance directive.

Preamble FR Citation: 79 FR 10894

Specific questions in preamble? *No*

Public Comment Field: No HL7 comment.

§ 170.315(a)(20) (Implantable Device list)

MU Objective

N/A

2015 Edition EHR Certification Criteria

(20) Implantable device list. (i) Enable a user to electronically access and view a list of Unique Device Identifiers and other relevant information associated with a patient’s Implantable Device(s).

(ii) Enable a user to electronically record in a patient’s Implantable Device list the following information at the time the Device is implanted or removed:

- (A) The Unique Device Identifier associated with the Implantable Device; and
- (B) Other relevant information about the Implantable Device or procedure.

(iii) For each Unique Device Identifier in a patient’s Implantable Device list, allow a user to separately access and view electronically the Device Identifier and Production Identifier portions of the Unique Device Identifier.

Preamble FR Citation: 79 FR 10894

Specific questions in preamble? *Yes*

§ 170.315(a)(20) (Implantable Device list)

Public Comment Field:

- HL7 recommends that ONC facilitates an initiative to establish clearly defined use cases where UDI needs to be exchanged beyond Transitions of Care to enable standards development organizations to assess their inventory of standards, determine whether they need to be adjusted or not, and make updates accordingly to support a future Edition.

§ 170.315(b)(1) (Transitions of care)

MU Objective

The EP, EH, or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

§ 170.315(b)(1) (Transitions of care)

2015 Edition EHR Certification Criteria

(1) Transitions of care. (i) Send and receive via edge protocol. EHR technology must be able to electronically:

- (A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(e) and that leads to such summaries being processed by a service that has implemented the standard specified in §170.202(a); and
- (B) Receive transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(e) from a service that has implemented the standard specified in §170.202(a).

(ii) Receiving accuracy. EHR technology must meet or exceed the standard specified at §170.212(a)

(iii) Display.

(A) EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: §170.205(a)(1) through (4).

(B) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at §170.205(a)(3).

(iv) Create. (A) Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at §170.205(a)(4) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(1) Encounter diagnoses. The standard specified in §170.207(i) or, at a minimum, the version of the standard specified §170.207(a)(3);

(2) Immunizations. The standard specified in §170.207(e)(2);

(3) Cognitive status;

(4) Functional status;

(5) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information;

(6) Inpatient setting only. Discharge instructions; and

(7) Unique Device Identifier(s) for a patient's implantable device(s).

(B) Patient matching data quality. EHR technology must be capable of creating a transition of care/referral summary that includes the following data and, where applicable, represent such data according to the additional constraints specified below:

(1) Data. first name, last name, middle name (or middle initial in cases where only it exists/is used), suffix, date of birth, place of birth, maiden name, current address, historical address, phone number, and sex.

(2) Constraint. Represent last/family name according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0.

(3) Constraint. Represent suffix according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, PHD, ESQ). If no suffix exists, the field should be entered as null.

(4) Constraint. Represent the year, month and date of birth are required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in latter local time is assumed. If date of birth is unknown, the field should be marked as null.

(5) Constraint. Represent current and historical address information, including the street address, city, state, zip code, according to the United States Postal Service format;

(6) Constraint. Represent phone number (home, business, cell) in the ITU format specified in ITU-T E.123 and ITU-T E.164. If multiple phone numbers are present, all should be included.

(7) Constraint. Represent sex according to the HL7 Version 3 ValueSet for Administrative Gender.

Preamble FR Citation: 79 FR 10896

Specific questions in preamble? Yes

Public Comment Field:

- It is important to note that C-CDA R2.0 has not yet been published, thus it is not available for public review and people have not had a chance to review the document in its entirety. While HL7 strongly supports the move to C-CDA R2, we also must acknowledge the need to provide adequate time for everybody to consider the readiness of the next version. HL7 therefore suggests to move the adoption to the 2017 Edition, also considering the need to address interoperability compatibility and backwards compatibility issues.
- In relation to Consolidated CDA, HL7 requests that the name be changed to the intended name that HL7 is planning to use to publish.

§ 170.315(b)(1) (Transitions of care)

- Patient matching is a critical concept for reconciliation. However, this should not only be applied to ToC, but to all transactions where patient data is conveyed.
- HL7 supports the use of § 170.205(a)(1) - HL7 CDA R2, CCD + HITSP Summary Doc using HL7 CCD Component HITSP/C32.
- Regarding the best ways to identify additional Consolidated CDA guidance that will further reduce its implementations variability is below.

Major variability in EHR's contributes to the variability in implementations of C-CDA. Another contributing factor is C-CDA's use of open templates, allowing EHR's to express that variability in the C-CDA instance. Alternate solutions to this include:

- Closing many of the C-CDA Entry templates to eliminate variability
 - Tighter conformance testing for example the SMART CDA Scorecard. See: <http://ccda-scorecard.smartplatforms.org/static/ccdaScorecard/#/>
 - Applying existing EHR functionality criteria as, recently, potentially problematic EHR system function variability's have been highlighted by OIG (ex: <http://oig.hhs.gov/oei/reports/oei-01-11-00570.asp> and GAO (ex: <http://www.gao.gov/products/GAO-14-207>) reports. These reports address the reliability of the source systems' data and impact on Quality Reporting and Health Care Reform. Variability in the source records systems themselves introduces additional variability in C-CDA implementations. This can be reduced by applying existing Normative Standards for EHR Functionality. In particular, see "Electronic Health Record System Functional Model, Release 2". The Request for Publication has been submitted to HL7, publication should be "imminent".
- **Re: “We seek comment on whether the performance level should be set to 95% and request that commenters provide accompanying rationale for why it should be lower or higher.”**
 - HL7 believes setting the level at 95% without empiric evidence is problematic and should not be done. Focus on obtaining the evidence of the proper level before specifying an exact figure.
 - **Re: “We seek input on and suggestions on the best way(s) to test this proposal.”**
 - HL7 believes funding should be provided for proofs of concept in an open source way for others to see how to do it in their own system.
 - **Re: “We also seek input from industry stakeholders on the best ways to identify additional guidance for the Consolidated CDA that will further reduce its implementation variability and, ultimately, make achieving this performance standard simply a byproduct of implementing a tightly specified implementation guide.”**
 - A new version of CDA (not CCD R2) should be released with templates and models for continuity of care and all the other needs (emergency care, public health etc.). Budget should be created for the ongoing sustainability of all these tools that need maintenance of the standards we become dependent on.
 - **Re: “We seek comment on additional patient matching data to include and other constraints that could be applied to this data to improve its quality”**
 - HL7 recommends criterion should be included to match patients to clinical context (why something is being done).
 - **Re: “We seek comment on the proposed standardized data to improve patient matching, including whether other data or constraints on proposed data should be modified to better support patient matching practices and work flow.”**
 - Accurate patient matching is important. HL7 supports the definition of a standard for patient matching and requiring the surfacing of the confidence (i.e. 80%match) of the match to the user.
 - **Re: “We request comment on how to best handle or anticipate changes to the way in which data may be represented in other rapidly evolving standards approaches”**

§ 170.315(b)(1) (Transitions of care)

- HL7 believes there should be the concept of “alignment as we go”. An example is CDA templates could be used to inform FHIR profiles.
- **Re: “We would be interested in stakeholder feedback regarding what standards could best support international addresses”**
 - HL7 suggest looking at and contributing to the current ISO work in this area.
- **Re: “We seek comment on methods that leverage the certification program, ways to test and measure data quality, and approaches to sharing best practices for improving data quality.”**

“We seek comment on additional findings from the 2013 Patient Matching Initiative that include studying non-traditional attributes to understand the potential for matching improvement, developing open source algorithms for testing purposes or use by EHR technology developers, the development of a formalized structure for establishing best practices, advancing consumer engagement with and access to their demographic data and attributes for correction or approval, and developing and/or disseminating options and training materials that improve data quality.”

- HL7 supports the definition of a standard for patient matching and require the surfacing of the confidence (i.e. 80%match) of the match to the user.

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

MU Objective

The EP, EH, or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

2015 Edition EHR Certification Criteria

(2) Clinical information reconciliation and incorporation. (i) Correct patient. Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(4), EHR technology must be able to demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

(ii) Reconciliation. Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:

- (A) Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date;
- (B) Enable a user to create a single reconciled list of medications, medication allergies, or problems;
- (C) Enable a user to review and validate the accuracy of a final set of data; and
- (D) Upon a user's confirmation, automatically update the list, and electronically incorporate the following data expressed according to the specified standard(s):

(1) Medications. At a minimum, the version of the standard specified in § 170.207(d)(2);

(2) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);

(3) Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(2).

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

Preamble FR Citation: 79 FR 10901

Specific questions in preamble? *Yes*

Public Comment Field:

- HL7 looks forward to working with S&I Framework and team on the newly formed Data Provenance initiative. We recognize the need for clear propagation of provenance in areas such as CDS, security, patient safety and records management.
- HL7 recommends that EHR technology should be required to retain the outside/external data source's provenance as part of the incorporation process.
- HL7 observes that Rx Norm is not specific enough for medication allergies and that NDFRT, RxNorm or UNII should be available for coding medication allergies. An allergy to a specific ingredient (multiple ingredient drug(e.g. sulfa in Bactrim) cannot be expressed with current standards. An excipient (e.g. egg) or diluent cannot be expressed with Rx Norm.
- Food and environmental allergens (substances) should be included using SNOMED-CT.

§ 170.315(b)(3) (Electronic prescribing)

MU Objective

Generate and transmit permissible prescriptions electronically (eRx).

2015 Edition EHR Certification Criterion

(3) Electronic prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:

- (i) The standard specified in § 170.205(b)(2); and
- (ii) At a minimum, the version of the standard specified in § 170.207(d)(2).

Preamble FR Citation: 79 FR 10901

Specific questions in preamble? *No*

Public Comment Field:

- HL7 supports the use of its standards for this use case.

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

MU Objective

Incorporate clinical laboratory test results into Certified EHR Technology as structured data.

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

2015 Edition EHR Certification Criteria

(4) Incorporate laboratory tests and values/results. (i) Receive results. (A) Ambulatory setting only. (1) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j)(2) and, at a minimum, the version of the standard specified in § 170.207(c)(2).

(2) Electronically display the tests and values/results received in human readable format.

(B) Inpatient setting only. Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.

(ii) Electronically display the test report information:

(A) Specified in 42 CFR 493.1291 (a)(1) through (a)(3) and (c)(1) through (c)(7);

(B) Related to reference values as specified in 42 CFR 493.1291(d);

(C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h); and

(D) For corrected reports as specified in 42 CFR 493.1291(k)(2).

(iii) Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

Preamble FR Citation: 79 FR 10901

Specific questions in preamble? No

Public Comment Field:

- HL7 recommends use of this non-hospital based lab reporting to an Eligible Hospital.

§ 170.315(b)(5) (Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers)

MU Objective

Provide structured electronic laboratory results to eligible professionals.

2015 Edition EHR Certification Criteria

(5) Inpatient setting only—transmission of electronic laboratory tests and values/results to ambulatory providers. EHR technology must be able to electronically create laboratory test reports for electronic transmission:

(i) That includes the information:

(A) For a test report as specified in 42 CFR 493.1291 (a)(1) through (a)(3) and (c)(1) through (c)(7);

(B) Related to reference values as specified in 42 CFR 493.1291(d);

(C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h); and

(D) For corrected reports as specified in 42 CFR 493.1291(k)(2); and

(ii) In accordance with the standard specified in § 170.205(j)(2) and with laboratory tests expressed in accordance with, at a minimum, the version of the standard specified in § 170.207(c)(2).

Preamble FR Citation: 79 FR 10901

Specific questions in preamble? No

Public Comment Field:

- HL7 agrees with use of the proposed HL7 standard with errata.

§ 170.315(b)(6) (Data portability)

MU Objective

N/A

§ 170.315(b)(6) (Data portability)

2015 Edition EHR Certification Criterion

(6) Data portability. Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(4) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(i) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);

(ii) Immunizations. The standard specified in § 170.207(e)(2);

(iii) Cognitive status;

(iv) Functional status;

(v) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information;

(vi) Inpatient setting only. Discharge instructions; and

(vii) Unique Device Identifier(s) for a patient's Implantable Device(s).

Preamble FR Citation: 79 FR 10902

Specific questions in preamble? Yes

Public Comment Field:

- Activities in this domain should focus on the sender providing clarity on the data available (export tools, documentation), be XML based and use C-CDA tags where available.
- Narrowing this to just data migration seems to restrict the utility of C-CDA in other data portability scenarios. Data migration appears to imply moving the source of truth of the packet of data whereas data portability accommodates sharing of data without regards to transfer of data source of truth. Both are needed, eliminating one in favor of the other does not seem useful. Data migration is one use case for data portability.

Clinical Quality Measures – Electronically Processing eMeasures

Preamble FR Citation: 79 FR 10902

Specific questions in preamble? Yes

Public Comment Field: No HL7 comment.

Public Comment Field:**Specific recommendations and comments of HL7's Clinical Quality Information Work Group are below.**

- The CQI Work Group supports the idea of unified CDS and CQM standards, and reiterates our wish that standards not be required before such alignment occurs.

However the following may be some starting points for classifying measures that may be similar to each other in terms of how difficult they are to implement:

- Rating measures in terms of cyclomatic complexity, although keep in mind cyclomatic complexity is not necessarily the same as implementation complexity. For more info on MITRE's cyclomatic complexity analysis of measures, see www.projectkamira.org
- Rating measures based on feasibility or the ability to matching internal EHR system data model to QDM
- Rating measures based on how frequently the data elements are captured as standardized, discrete elements in EHRs. For example, procedures which are not ordered (such as foot examinations for diabetic patients) are often not captured in the EHR as a discrete data element (instead being part of the free-text note) and as a result measures using these elements are difficult to implement.

The CQI workgroup appreciates the request for input on EHR requirements and has the following comments:

- We have given several areas in which we are concerned that the existing standards do not have the capabilities required to meet the desired requirements (e.g. the proposed §170.315(c)(4) criterion). We note that if such criteria are put in place, it will be impossible for EHRs to simultaneously satisfy these standards while still electronically processing the standardized file, since these additional criteria must come in the form of free-text guidance.
 1. As the proposed rule notes in §170.315(c)(4), programs such as PQRS GPRO already have similar requirements which may not be standards-compliant. We remark that EHRs who support such programs may have a difficult time supporting such programs while still having an eCQM engine based on the electronic processing of HQMF, even if the MU requirements are standards-compliant.
- We request clarification on the criterion that EHRs “store and incorporate an eCQM in HQMF R2.” We are unclear what the intent of requiring EHRs to store eCQMs is.
- We request clarification on the intent of the requirement that EHRs “map the HQMF R2 standard to data within the EHR technology (including medications, laboratory, allergies information)” and are uncertain how such an ability would be demonstrated beyond the ability to process and evaluate eCQMs written in HQMF R2 standard. We further consider that the Quality Data Model (QDM) is the recommended standard for requirements regarding the data model used in quality measurement, and suggest that data model requirements be based on the QDM instead of HQMF.

Lastly, the CQI Work Group wishes to draw attention to our recent comment-only ballot “FHIR as a Potential Common Logical Model for Clinical Quality Measures and Decision Support” which is an initial investigation into the use of FHIR to align CQM and CDS standards. We point readers to the ballot itself for full details, but wish to quote the concluding paragraph:

In terms of moving towards convergence, if the path forward involves FHIR, a considerable amount of work to harmonize FHIR with QIDAM will be required. Because the requirements of QIDAM have been validated (albeit indirectly) through the use of vMR and QDM, FHIR is likely to benefit from this analysis in terms of completeness and maturity. Ultimately, adoption of FHIR in this area will require reworking on several levels, authoring tools, artifact formats, and execution engines. Whether this investment is worthwhile remains to be seen.

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

(1) Clinical quality measures—capture and export. (i) Capture. For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at § 170.204(c) that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of “patient reason,” “system reason,” or “medical reason.”

(ii) Export. EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at § 170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section.

Preamble FR Citation: 79 FR 10903

Specific questions in preamble? Yes

Public Comment Field:

HL7 appreciates that the NPRM provides requirements for a possible QRDA Category 2 standard, however HL7 requests clarification on the proposed requirements and has the following concerns:

- The QRDA Category II standard has only been passed on a “for comment” ballot as part of the original QRDA DSTU. We are concerned that the standard has not been fleshed out enough yet for commenters to give constructive feedback .
- Category 2 reports will be more difficult for document generators to create than either the Category I or III reports as they combine all the elements from both formats
- QRDA Category 2 reports may be more trouble than its worth; simply collecting multiple QRDA Category 1 reports may be easier since it wouldn’t force implementers to learn and adopt yet another QRDA specification. Many widely-used formats such as zip already exist and are capable of combining multiple reports into one file.
- Some implementers of QRDA, such as CMS, are already creating a “wrapper” for QRDA Category 1. If various implementers are creating similar “wrappers”, that may make the case for supporting a standardized approach to wrapping the QRDA Category 1 with a potential QRDA Category 2 specification.
- If QRDA category 2 is intended as an interim step between taking QRDA category 1 reports and aggregating up to a QRDA category 3 report, it should account for the fact that the aggregation is not always simple once reporting stratification is factored in.
- Based on the experience of the Cypress project, the most difficult part of CQMs for implementers currently is the QRDA standards and adding a new standard will only exacerbate that.

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

MU Objective

N/A

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

2015 Edition EHR Certification Criterion

(2) Clinical quality measures—import and calculate. (i) Import. EHR technology must be able to electronically import a data file formatted in accordance with the standard specified at § 170.205(h) and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. EHR technology presented for certification to all three of the certification criteria adopted in paragraphs (c)(1) through (3) of this section is not required to meet paragraph (c)(2)(i).

(ii) Calculate. EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.

Preamble FR Citation: 79 FR 10903

Specific questions in preamble? *No*

Public Comment Field:

- HL7 supports the continued use of the current HL7 standard for this criterion.

§ 170.315(c)(3) (Clinical quality measures – electronic submission)

MU Objective

N/A

2015 Edition EHR Certification Criteria

(3) Clinical quality measures—electronic submission. Enable a user to electronically create a data file for transmission of clinical quality measurement data:

- (i) In accordance with the standards specified at § 170.205(h) and (k); and
- (ii) That can be electronically accepted by CMS.

Preamble FR Citation: 79 FR 10903

Specific questions in preamble? *No*

Public Comment Field: No HL7 comment.

§ 170.315(c)(4) (Clinical quality measures – patient population filtering)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(4) Clinical quality measures – patient population filtering. EHR technology must be able to record structured data for the purposes of being able to filter CQM results to create different patient population grouping by one or a combination of the following patient characteristics:

- (i) Practice site and address;
- (ii) Tax Identification Number (TIN), National Provider Identifier (NPI), and TIN/PIN combination;
- (iii) Diagnosis;
- (iv) Primary and secondary health insurance, including identification of Medicare and Medicaid dual eligibles; and
- (v) Demographics including age, sex, preferred language, education level, and socioeconomic status.

Preamble FR Citation: 79 FR 10903

Specific questions in preamble? *Yes*

Public Comment Field:

Overarching comments

- Standards vocabulary is needed, particularly around supporting proper filtering of sensitive data.

§ 170.315(c)(4) (Clinical quality measures – patient population filtering)

HL7 requests clarification on what it means to “filter” a report. As an example, consider measure CMS 138: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention. For this measure a patient must have 2 office visits with the EP to be included.

- Scenario 1: A patient is seen by Provider A during the measurement period for one office visit. Later, and also during the measurement period, the patient is seen by Provider B for one office visit. Both encounters are billed under the same TIN.
 - Option A: We would evaluate the measures at the provider level (following the MU specifications). Because of this, the patient would not be included in the measure’s initial patient population because they had neither 2 office visits with Provider A nor 2 office visits with Provider B.
 - Option B: We would evaluate the measures at the TIN level. Because of this, the patient would be included in the initial patient population for the group because they had 2 office visits with providers within the TIN.
- Scenario 2: A patient is seen by Provider A during the measurement period for two office visits. The patient is also seen during the measurement period for two office visits with Provider B.
 - Option A: We would evaluate the measures at the provider level and summarize at the group level. This would mean the patient would be in the initial patient population for Provider A and also in the initial patient population for Provider B. When summarizing the data at the group level, the patient would only be included once because both providers are part of the TIN.
 - Option B: We would evaluate the measures at the TIN level. This would mean the patient would be in the initial patient population for the TIN because they were seen for 4 office visits by providers within the TIN, which is greater than the requirement of 2.

We request clarification on which of these options EHRs would be required to support. We believe that current standards are able to support options (A) in the above two scenarios, but not options (B).

Additionally, we have the following comments on the ability of current standards to support these requirements:

- HQMF supports some patient characteristics, such as diagnosis, via supplemental data elements, but it does not, in general, support provider characteristics.
- QRDA-I and III support many patient and provider characteristics (the latter through program-specific Implementation Guides)
- We have several concerns with filtering by socioeconomic status:
 - It is unclear what data would be used to indicate socioeconomic status. Is this measured by income? Education level? Occupation? The CQI workgroup requests clarification on which specific data elements would be used.
 - We do not believe that indicators such as income are currently recorded in EHRs and would often not be provided by patients, even if they were asked.
 - Furthermore, we don’t believe that standardized terminologies for these indicators exist, and for example in the case of income it is even unclear whether we should have “categories” of income levels or if this should be a numeric value.
- We also believe that education level is not regularly captured in EHRs today. However, there is a possible value set 2.16.840.1.113883.5.1077 which could be used to standardize these values, if captured. The granularity of this value set may or may not be appropriate for the goals of the program.

The CQI workgroup also requests clarification on how Continuous Variable Measures will function under these filtering requirements.

§ 170.315(c)(4) (Clinical quality measures – patient population filtering)

HL7 recommends that the the population filters are based on interoperable codes that are sufficiently detailed, because the same filtering capability could be used for other purposes such as analytics, public health, and for access control purposes. These additional uses could be considered in evaluating the benefits of this certification criterion.

With respect to leveraging content filtering capabilities for privacy and security, diagnosis codes are indicative of sensitive information such as alcohol and drug abuse or HIV, and can therefore be used to ensure that only authorized end users can access the data. If facility type codes are used for practice sites, then care settings for sensitive conditions can indicate that the services are governed by more restrictive privacy laws such as 42 CFR Part 2 and Title 38 Section 7332. If HL7 Coverage Type codes are used for primary and secondary health insurance, the coverage for the service can also be used to determine governing privacy law.

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

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(1) Authentication, access control, and authorization. (i) Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and

(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the EHR technology.

Preamble FR Citation: 79 FR 10904

Specific questions in preamble? Yes

Public Comment Field: No HL7 comment.

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

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(2) Auditable events and tamper-resistance. (i) Record actions. EHR technology must be able to:

(A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1); and

(B) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by EHR technology in accordance with the standard specified in § 170.210(e)(3) unless the EHR technology prevents electronic health information from being locally stored on end-user devices (see 170.314(d)(7) of this section).

(ii) Default setting. EHR technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraph (d)(2)(i)(B).

(iii) Prevent disabling. EHR technology must prevent all users from being able to disable the capabilities specified in paragraphs (d)(2)(i)(A) and (B) of this section through the EHR technology.

(iv) Audit log protection. Actions and statuses recorded in accordance with paragraph (d)(2)(i) of this section must not be capable of being changed, overwritten, or deleted by the EHR technology.

(v) Detection. EHR technology must be able to detect whether the audit log has been altered.

Preamble FR Citation: 79 FR 10904

Specific questions in preamble? Yes

Public Comment Field:

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

- HL7 agrees that the current set of EHR actions defined or discussed in ASTM E2147 are deficient. HL7 recommends that the ASTM E2147 definitions be updated for 2017 MU or that a more robust standard vocabulary be selected such as the one being developed by HL7 to standardize EHR action terminology used in the HL7 EHR Functional Model and the HL7 Security and Privacy Ontology.

§ 170.315(d)(3) (Audit report(s))

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(3) Audit report(s). Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards at § 170.210(e).

Preamble FR Citation: 79 FR 10905

Specific questions in preamble? *Yes*

Public Comment Field: No HL7 comment.

§ 170.315(d)(4) (Amendments)

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(4) Amendments. Enable a user to electronically select the record affected by a patient's request for amendment and perform the capabilities specified in paragraphs (d)(4)(i) or (ii) of this section.

(i) Accepted amendment. For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.

(ii) Denied amendment. For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.

Preamble FR Citation: 79 FR 10905

Specific questions in preamble? *No*

Public Comment Field: No HL7 comment.

§ 170.315(d)(5) (Automatic Log-Off)

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(5) Automatic log-off. Prevent a user from gaining further access to an electronic session after a predetermined time of inactivity.

Preamble FR Citation: 79 FR 10905

Specific questions in preamble? *No*

Public Comment Field: No HL7 comment.

§ 170.315(d)(5) (Automatic Log-Off)

§ 170.315(d)(6) (Emergency access)

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(6) Emergency access. Permit an identified set of users to access electronic health information during an emergency.

Preamble FR Citation: 79 FR 10905

Specific questions in preamble? No

Public Comment Field: No HL7 comment.

§ 170.315(d)(7) (End-User Device Encryption)

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(7) End-user device encryption. Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion.

(i) EHR technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of EHR technology on those devices stops.

(A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(1).

(B) Default setting. EHR technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.

(ii) EHR technology is designed to prevent electronic health information from being locally stored on end-user devices after use of EHR technology on those devices stops.

Preamble FR Citation: 79 FR 10905

Specific questions in preamble? No

Public Comment Field: No HL7 comment.

§ 170.315(d)(8) (Integrity)

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(8) Integrity. (i) Create a message digest in accordance with the standard specified in § 170.210(c).

(ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

Preamble FR Citation: 79 FR 10905

Specific questions in preamble? No

§ 170.315(d)(8) (Integrity)

Public Comment Field:

HL7 does not concur with the use of “a hashing algorithm with a security strength equal to or greater than SHA-1 (Secure Hash Algorithm (SHA-1) as specified by the National Institute of Standards and Technology (NIST) in FIPS PUB 180-3 (October, 2008)) to verify that electronic health information has not been altered” as it is deprecated for use in digital signature generation per the NIST SP 800-131A publication.

Per [NIST SP 800-131A](#) (January 2011 page 13), use of “SHA-1 for digital signature generation: SHA-1 is acceptable for digital signature generation through December 31, 2010.

From January 1, 2011 through December 31, 2013, the use of SHA-1 is deprecated for digital signature generation. The user must accept risk when SHA-1 is used, particularly when approaching the December 31, 2013 upper limit. This is especially critical for digital signatures on data for which the signature is required to be valid beyond this date. See Section 5.6.2 of [SP 800-57] for further guidance.

SHA-1 shall not be used for digital signature generation after December 31, 2013.

SHA-1 for digital signature verification:

For digital signature verification, the use of SHA-1 is acceptable through December 31, 2010.

For digital signature verification, SHA-1 is allowed for legacy-use after December 31, 2010.”

The transition schedule for hash functions is provided in the following Table.

Table: Hash Function Transitions Hash Function	Use	
SHA-1	Digital signature generation	Acceptable through 2010 Deprecated from 2011 through 2013 Disallowed after 2013
	Digital signature verification	Acceptable through 2010 Legacy-use after 2010
	Non-digital signature generation applications	Acceptable
SHA-224	Acceptable for all hash function applications	
SHA-256		
SHA-384		
SHA-512		

§ 170.315(d)(9) (Accounting of Disclosures)

MU Objective

§ 170.315(d)(9) (Accounting of Disclosures)

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

2015 Edition EHR Certification Criterion

(9) Accounting of disclosures. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

Preamble FR Citation: 79 FR 10905

Specific questions in preamble? No

Public Comment Field: No HL7 comment.

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

MU Objective

EPs

Provide patients, and their authorized representatives, the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

EHs and CAHs

Provide patients, and their authorized representative, the ability to view online, download, and transmit information about a hospital admission.

2015 Edition EHR Certification Criterion

(1) View, download, and transmit to 3rd party. (i) Patients (and their authorized representatives) must be able to use EHR technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Access to these capabilities must be online and through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(A) View. Patients (and their authorized representatives) must be able to use EHR technology to electronically view in accordance with the standard adopted at § 170.204(a)(2), at a minimum, the following data:

(1) The Common MU Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).

(2) Ambulatory setting only. Provider's name and office contact information.

(3) Inpatient setting only. Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(B) Download.

(1) Patients (and their authorized representatives) must be able to use EHR technology to electronically download an ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) in only human readable format, in only the format specified in accordance to the standard adopted at § 170.205(a)(4), or in both formats.

(2) When downloaded according to the standard adopted at § 170.205(a)(4), the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(i) Ambulatory setting only. All of the data specified in paragraph (e)(1)(i)(A)(1) and (2) of this section and Unique Device Identifier(s) for a patient's implantable device(s).

(ii) Inpatient setting only. All of the data specified in paragraphs (e)(1)(i)(A)(1) and (3) of this section and Unique Device Identifier(s) for a patient's implantable device(s).

(3) Inpatient setting only. Patients (and their authorized representatives) must be able to electronically download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion adopted at paragraph (b)(1) of this section).

(C) Transmit to third party. Patients (and their authorized representatives) must be able to:

(1) Enter a 3rd party destination of their choice to electronically transmit:

(i) The ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) created in paragraph (e)(1)(i)(B)(1) of this section in accordance with the standard specified in § 170.202(a).

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

(ii) Inpatient setting only. Electronically transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with the standard specified in § 170.202(a).

(2) Accomplish a transmission of their ambulatory summary or inpatient summary through a method that conforms to the standard specified at §170.202(e) and that leads to such summary being processed by a service that has implemented the standard specified in §170.202(a).

(ii) Activity history log. (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient:

- (1) The action(s) (i.e., view, download, transmission) that occurred;
- (2) The date and time each action occurred in accordance with the standard specified at § 170.210(g);
- (3) The user who took the action; and
- (4) The addressee to whom an ambulatory summary or inpatient summary was transmitted and whether that transmission was successful (or failed).

(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at §170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

Preamble FR Citation: 79 FR 10906

Specific questions in preamble? Yes

Public Comment Field:

- The CDA standard supports including images directly or as references, but industry support for this is lacking. Clear guidance in the C-CDA IG would be ideal, providing guidance to industry on how to support this if it becomes a requirement.
- When using references, IHE has a number of profiles available to address the ability to incorporate viewers into HIT, although we understand that to some standards are still missing to fully address easy of sign-on. We suggest ONC works with IHE to establish guidance on how best to integrate images through references and viewers.

§ 170.315(e)(2) (Ambulatory setting only – clinical summary)

MU Objective

Provide clinical summaries for patients for each office visit.

2015 Edition EHR Certification Criterion

(2) Ambulatory setting only—clinical summary. (i) Create Enable a user to create a clinical summary for a patient in human readable format and formatted according to the standards adopted at § 170.205(a)(4).

(ii) Customization Enable a user to customize the data included in the clinical summary.

(iii) Minimum data from which to select EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary:

(A) Common MU Data Set (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set);

(B) Medications administered during the visit At a minimum, the version of the standard specified in § 170.207(d)(2);

(C) Immunizations administered during the visit At a minimum, the version of the standard specified in § 170.207(e)(2);

(D) Diagnostic tests pending and future scheduled tests At a minimum, the version of the standard specified in § 170.207(c)(2);

(E) The provider’s name and office contact information; date and location of visit; reason for visit; clinical instructions; future appointments; referrals to other providers; and recommended patient decision aids; and

(F) Unique Device Identifier(s) for a patient’s Implantable Device(s).

Preamble FR Citation: 79 FR 10907	Specific questions in preamble? Yes
Public Comment Field:	
<ul style="list-style-type: none"> • Since many diagnostic tests lack a suitable LOINC code, the pending and future scheduled test capability should state something such as " if a suitable representation of the concept exists in the standard." • Regarding the references "at a minimum" for the vocabulary: This phrase seems to only means "minimum version." However, we are concerned that even the latest version does not contain the proper value. It needs to be clear that "at a minimum" means version or local. Both can be done. Vocabulary should allow for locally adopted or text. Note that local could take on another system, e.g., PLT. 	

§ 170.315(e)(3) (Ambulatory setting only – secure messaging)	
MU Objective	
Use secure electronic messaging to communicate with patients on relevant health information.	
2015 Edition EHR Certification Criterion	
(3) <u>Ambulatory setting only—secure messaging</u> Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures: <ul style="list-style-type: none"> (i) Both the patient (or authorized representative) and EHR technology user are authenticated; and (ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f). 	
Preamble FR Citation: 79 FR 10908	Specific questions in preamble? No
Public Comment Field: No HL7 comment.	

§ 170.315(f)(1) (Immunization information)	
MU Objective	
Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.	
2015 Edition EHR Certification Criterion	
(1) <u>Immunization information</u> . Enable a user to electronically record, change, and access immunization information.	
Preamble FR Citation: 79 FR 10908	Specific questions in preamble? No
Public Comment Field: No HL7 comment.	

§ 170.315(f)(2) (Transmission to immunization registries)
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MU Objective	
Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.	
2015 Edition EHR Certification Criterion	
(2) <u>Transmission to immunization registries</u> EHR technology must be able to electronically create immunization information for electronic transmission in accordance with: <ul style="list-style-type: none"> (i) The standard and applicable implementation specifications specified in § 170.205(e)(4); and (ii) At a minimum, the version of the standard specified in § 170.207(e)(2). 	
Preamble FR Citation: 79 FR 10908	Specific questions in preamble? Yes
Public Comment Field: No HL7 comment.	

§ 170.314(f)(3) (Transmission to public health agencies – syndromic surveillance) and § 170.315(f)(3) (Transmission to public health agencies – syndromic surveillance)	
MU Objective	
Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.	
Revised 2014 Edition EHR Certification Criterion	
§ 170.314(f)(3) (Transmission to public health agencies – syndromic surveillance)	
2015 Edition EHR Certification Criterion	
§ 170.315(f)(3) (Transmission to public health agencies – syndromic surveillance)	
(3) <u>Transmission to public health agencies – syndromic surveillance</u> . EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with: <ul style="list-style-type: none"> (i) <u>Ambulatory setting only</u>. (A) The standard specified in § 170.205(d)(2), (d)(5), or (k). (B) <u>Optional</u>. The standard (and applicable implementation specifications) specified in § 170.205(d)(4). (ii) <u>Inpatient setting only</u>. The standard (and applicable implementation specifications) specified in § 170.205(d)(4). 	
Preamble FR Citation: 79 FR 10909	Specific questions in preamble? Yes

Public Comment Field:

- We suggest that this criterion should not reference only the base standard V2.5.1. Rather it should point to the appropriate implementation guide only of either PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data, ADT Messages A01, A03, A04, and A08, HL7 Version 2.5.1, Release 1.1, HL7 V1.1 and/or PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, and Inpatient Settings, Release 1.9. The use of V2.5.1 should be eliminated as soon as possible but certainly by the 2017 Edition.
- The rationale for use of Quality Reporting Document Architecture Category III is not clear.
- Unconstrained CDA Release 2.0 is not sufficient to properly convey information necessary for Syndromic Surveillance. A CDA implementation guide would need to be developed to make it work.
- HL7 appreciates consideration of the QRDA Category I standard, and has the following comments on the feasibility of the requirements:
 - While the QRDA standard has received use in the CQM domain, we are concerned that the standard has had limited implementations in the syndromic surveillance domain, and is too immature to be implemented as a requirement.
 - We are unclear why the Category I standard was chosen for this requirement, and request clarification why alternative standards were not considered.
 - We request clarification on which data elements will be required in the submitted files, the submission mechanism, and whether a standard like HQMF will be used to provide guidance to implementers.

In answer to the question asked in the NPRM: HL7 is not aware of any public health agencies using the QRDA-I standard to receive query-based syndromic surveillance data.

§ 170.315(f)(4) (Inpatient setting only – Transmission of reportable laboratory tests and values/results)

MU Objective

Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

2015 Edition EHR Certification Criterion

(4) *Inpatient setting only—transmission of reportable laboratory tests and values/results* EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:

- (i) The standard (and applicable implementation specifications) specified in § 170.205(g)(2); and
- (ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

Preamble FR Citation: 79 FR 10910

Specific questions in preamble? *No*

Public Comment Field:

- The NPRM text incorrectly states: “Since the publication of the 2014 Edition Final Rule, CDC has issued an updated implementation guide (HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, DSTU, Release 2 (US Realm), 2013)”. It was not CDC, but HL7 that created the new release. Therefore, we recommend a text change to: “Since the publication of the 2014 Edition Final Rule, HL7 Public Health and Emergency Response (PHER) Workgroup has issued an updated implementation guide (HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, DSTU, Release 2 (US Realm), 2013)”
- We also recommend a language change in the NPRM text from:
 § 170.205(g)(1) - HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Draft Standard for Trial Use, Release 2
To:
 § 170.205(g)(1) - HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, R2, US Realm - Draft Standard for Trial Use

§ 170.315(f)(5) (Ambulatory setting only – cancer case information)

MU Objective

Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.

2015 Edition EHR Certification Criterion

(5) Ambulatory setting only—cancer case information. Enable a user to electronically record, change, and access cancer case information.

Preamble FR Citation: 79 FR 10910

Specific questions in preamble? No

Public Comment Field: No HL7 comment.

§ 170.315(f)(6) (Ambulatory setting only – transmission to cancer registries)

MU Objective

Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.

2015 Edition EHR Certification Criterion

(6) Ambulatory setting only—transmission to cancer registries. EHR technology must be able to electronically create cancer case information for electronic transmission in accordance with:

- (i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2); and
- (ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

Preamble FR Citation: 79 FR 10910

Specific questions in preamble? No

Public Comment Field:

- HL7 notes that there is a proposed HL7 project to more closely align the Cancer Reporting CDA implementation guide with C-CDA. This would not be directly incorporated in C-CDA as some have suggested, rather it will be reusing a number of C-CDA templates.

§ 170.315(g)(1) (Automated numerator recording)**MU Objective**

N/A

2015 Edition EHR Certification Criterion

(1) Automated numerator recording. For each meaningful use objective with a percentage-based measure, EHR technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

Preamble FR Citation: 79 FR 10911**Specific questions in preamble?** *No***Public Comment Field:** No HL7 comment.**§ 170.315(g)(2) (Automated measure calculation)****MU Objective**

N/A

2015 Edition EHR Certification Criterion

(2) Automated measure calculation. For each meaningful use objective with a percentage-based measure that is supported by a capability included in an EHR technology, electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

Preamble FR Citation: 79 FR 10911**Specific questions in preamble?** *No***Public Comment Field:** No HL7 comment.**§ 170.315(g)(3) (Safety-Enhanced Design)****MU Objective**

N/A

2015 Edition EHR Certification Criterion

(3) Safety-enhanced design User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.315(a)(1) through (4), (8) through (10), and (18) and (b)(2) and (3).

Preamble FR Citation: 79 FR 10911**Specific questions in preamble?** *Yes***Public Comment Field:** No HL7 comment.

§ 170.315(g)(4) (Quality Management System)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(4) Quality management system. For each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability must be identified.

- (i) If a single QMS was used for applicable capabilities, it would only need to be identified once.
- (ii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified. This would include the application of a QMS to some capabilities and none to others.
- (iii) If no QMS was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Preamble FR Citation: 79 FR 10911

Specific questions in preamble? Yes

Public Comment Field: No HL7 comment.

§ 170.315(g)(5) (Non-percentage-based measures report)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(5) Non-percentage-based measures use report (i) For each capability included in EHR technology that is also associated with a meaningful use objective and measure that is not percentage-based (except for the capabilities specified in § 170.315(a)(12), (b)(1), and (d)) electronically record evidence that a user used or interacted with the capability and the date and time that such use or interaction occurred, in accordance with the standard specified at § 170.210(g).

- (ii) Enable a user to electronically create a report of the information recorded as part of paragraph (g)(5)(i) of this section for the user's identified Medicare or Medicaid EHR reporting period.

Preamble FR Citation: 79 FR 10911

Specific questions in preamble? Yes

Public Comment Field:

- HL7 recommends to "maintain the word 'evidence' and use the final rule's preamble to provide more examples of what evidence would be acceptable". Option 1 mentioned in this section to "require the EHR technology to record evidence of use each time a particular capability was used during the reporting period," would require more work. In addition, there currently are no standards exist to support reporting for this type of information.

§ 170.315(h)(1) (Transmit – Applicability Statement for Secure Health Transport)

MU Objective

N/A

2015 Edition EHR Certification Criterion

1) Transmit – Applicability Statement for Secure Health Transport Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(a).

Preamble FR Citation: 79 FR 10914

Specific questions in preamble? No

Public Comment Field: No HL7 comment.

§ 170.315(h)(2) (Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(2) Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(b).

Preamble FR Citation: 79 FR 10914

Specific questions in preamble? *No*

Public Comment Field:

- **No HL7 comment.**

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

(3) Transmit – SOAP Transport and Security Specification & XDR/XDM for Direct Messaging Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(c).

Preamble FR Citation: 79 FR 10914

Specific questions in preamble? *No*

Public Comment Field: No HL7 comment.

§ 170.315(h)(4) (Transmit – Applicability Statement for Secure Health Transport & Delivery Notification in Direct)

MU Objective

N/A

2015 Edition EHR Certification Criterion

(4) Transmit – Applicability Statement for Secure Health Transport & Delivery Notification in Direct Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(d).

Preamble FR Citation: 79 FR 10914

Specific questions in preamble? *No*

- HL7 reviewed use of ONC Implementation Guide for Delivery Notification in Direct standard (§ 170.202(d)) and found no privacy/security impacts.

B. Provisions of the Proposed Rule Affecting the ONC HIT Certification Program

The following comment tables are meant to capture proposals relevant to the ONC HIT Program.

Non-MU EHR Technology Certification	
Preamble FR Citation: 79 FR 10918	Specific questions in preamble? <i>Yes</i>
Public Comment Field: No HL7 comment.	

ONC Regulations FAQ 28	
Preamble FR Citation: 79 FR 10920	Specific questions in preamble? <i>No</i>
Public Comment Field:	
<ul style="list-style-type: none"> • HL7 believes the removal of “Complete EHRs” is appropriate as this Edition is intended to support HIT in general, not just EHRs. 	

Patient List Creation Certification Criteria	
Preamble FR Citation: 79 FR 10920	Specific questions in preamble? <i>No</i>
Public Comment Field: No HL7 comment.	

ISO/IEC 17065 (§ 170.503(b)(1))	
Preamble FR Citation: 79 FR 10920	Specific questions in preamble? <i>No</i>
Public Comment Field: No HL7 comment.	

ONC Certification Mark (§ 170.523(k)(1))	
Preamble FR Citation: 79 FR 10921	Specific questions in preamble? <i>No</i>
Public Comment Field: No HL7 comment	

Certification Packages for EHR Modules	
Preamble FR Citation: 79 FR 10921	Specific questions in preamble? Yes
Public Comment Field: <ul style="list-style-type: none"> HL7 notes concern with the approach of creating packages as another layer, rather than having programs reference relevant criteria directly. 	

C. Other Topics for Consideration for the 2017 Edition Certification Criteria Rulemaking

The following comment tables are meant to capture proposals relevant to the 2017 Edition of Certification Criteria. Please note that although we will consider the comments we receive on these issues as we develop proposals for future rulemaking, we do not plan to respond to those comments in the final rule for the 2015 Edition that we expect will follow this proposed rule.

Additional Patient Data Collection	
Preamble FR Citation: 79 FR 10922	Specific questions in preamble? Yes
Public Comment Field: <ul style="list-style-type: none"> Regarding sexual orientation and gender identity, there is confusion around how many different gender/sex expressions there are between Demographics, this one, and the one to be communicated with a Lab Order. The code/system /value sets are not in sync and may not need to be in sync, but it is unclear what is what. HL7 could have a project to identify different purposes of sex/gender with associated vocabulary. Regarding the EHR functions and elements mentioned under <i>US Military Service</i>, it would take an HL7 project to support this in C-CDA via new templates. 	

Medication Allergy Coding	
Preamble FR Citation: 79 FR 10925	Specific questions in preamble? Yes
Public Comment Field: <ul style="list-style-type: none"> HL7 do support the adoption of additional vocabularies to code medication allergies to drug ingredients. Note the substances also need terminology bindings. The Patient Care Work Group recommends the use of SNOMED-CT for food and environmental 	

Certification Policy for EHR Modules and Privacy and Security Certification Criteria

Preamble FR Citation: 79 FR 10925

Specific questions in preamble? Yes

Public Comment Field:

- HL7 concurs with Option 3 in this section to adopt the HITSC recommendation, and views the more detailed requirements for security capabilities included in the HITSC March 26, 2013 transmittal letter as reasonable capabilities for meeting baseline US health privacy laws.
- HL7 encourages ONC to include the HITSC Privacy and Security certification criteria necessary, which are necessary EHR module capabilities for compliance with other overarching federal privacy and health privacy requirements such as 42 CFR Part 2 and Title 38 Section 7332 as well.

Provider Directories

Preamble FR Citation: 79 FR 10926

Specific questions in preamble? No

Public Comment Field: No HL7 comment.

Oral Liquid Medication Dosing

Preamble FR Citation: 79 FR 10926

Specific questions in preamble? Yes

Public Comment Field: No HL7 comment.

Medication History

Preamble FR Citation: 79 FR 10927

Specific questions in preamble? Yes

Public Comment Field:

- HL7 supports the criterion that would lead to better management of medication lists and medication history capabilities. This is a very important area to patient safety, coordination of care, and quality of care.
- The medication list should be more than a comprehensive list of medications. It should include information such as a prescription has been filled and a filled prescription has been picked-up/taken/administered. The list should have the capability to identify the clinical reasons for the medication. The list should acknowledge any compliance issues (such as financial, patient preferences, or conflicting information) impeding the use of the medication as intended. The medication history should be closely related to the medication reconciliation process. The medication history would benefit from significant patient engagement towards having the list relevant to what is actually being taken – not just prescribed.

Blue Button +

Preamble FR Citation: 79 FR 10927

Specific questions in preamble? Yes

Public Comment Field:

- HL7 recommends harmonization of View, Download and Transmit and Blue Button / Blue Button + standards. It is confusing to keep them separate.

2D Barcoding**Preamble FR Citation:** 79 FR 10928**Specific questions in preamble?** *Yes***Public Comment Field:** No HL7 comment.**Duplicate Patient Records****Preamble FR Citation:** 79 FR 10928**Specific questions in preamble?** *Yes***Public Comment Field:**

- HL7 notes that proposed standards are helpful, but are not expected to substantially improve on the patient matching and duplicate record issues. Other improvements needed are better data entry and use with a unique identifier.

Disaster Preparedness**Preamble FR Citation:** 79 FR 10928**Specific questions in preamble?** *Yes***Public Comment Field:** No HL7 comment.**Certification of Other Types of HIT and for Other Health Care Settings****Preamble FR Citation:** 79 FR 10929**Specific questions in preamble?** *No***Public Comment Field:**

- HL7 believes it is good that this and future Editions can support multiple programs to help close the interoperability loop.