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May 3, 2012

Farzad Mostashari, MD, ScM
Department of Health and Human Services
Office of the National Coordinator for Health Information
Technology
Attention: 2014 Edition EHR Standards and
Certification Criteria Proposed Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave., SW
Washington, DC 20201

Code RIN 0991-AB82

[Filed Electronically]

Dear Dr. Mostashari,

On behalf of the members of the EHR Association, we are pleased to submit our comments on the Office of the National Coordinator for Health IT's (ONC) Notice of Proposed Rule-Making (NPRM) for Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Proposed 2014 Edition EHR Certification Criteria.

We appreciate ONC's care and thoughtfulness in developing this proposed rule. We especially appreciate the clear and effective efforts by the Center for Medicare and Medicaid Services (CMS) to listen and respond to feedback on Stage 1 and suggestions for Stage 2. The attached responses were developed through the collaborative effort of 138 individuals, representing 25 of the 42 EHR Association member companies, working over the past several weeks to ensure thorough review and consideration of the proposed rule.

1. We strongly support and appreciate CMS' proposed one-year extension of Stage 1 of meaningful use and ONC's support for this change. Along with many others in the industry, we have advocated for many months that ONC and CMS

address the challenges that the current timeline and associated meaningful use and certification requirements create for providers and vendors and the likely impact on the overall success of the HITECH Program. As our members have carefully reviewed the development and operational implications of the proposed rules and reflected on our experience with Stage 1, we have concluded that this challenging situation has been exacerbated in recent months due to the likely timing for release of the Stage 2 final rule, the number and immaturity of the proposed clinical quality measures, the proposed certification criteria, and that ONC calls for all providers to be required to upgrade to the 2014 Edition of their EHR regardless of their stage of meaningful use. Combined with the still tight schedule, this latter requirement would exponentially amplify the number of upgrades required in a very finite period of time for those who attested in 2011 and those who will attest in 2012, 2013, and 2014.

We therefore strongly recommend that additional steps, many of which have been discussed at length over the past months, are taken in the CMS and ONC final rules to more completely address the challenge associated with the start of Stage 2.

Given this continued and now elevated concern, we urge ONC to take these considerations into careful account when making decisions on the scope of the Stage 2 final rules, as well as every possible effort to expedite release of those rules. As was generally agreed across the industry and by the HIT Policy Committee, a full 18 months is needed between release of the final rules and when providers need to upgrade. As of now, however, it is expected that this will be reduced to approximately 12 months for eligible hospitals (EHs) and 15 months for eligible professionals (EPs). We therefore encourage ONC to consider allowing providers who are still in Stage 1 in 2014 to continue to use 2011 Edition certified EHR technology at their discretion. We are also strongly recommending to CMS that providers participating in 2014 be able to do so for a 90- or 180-day reporting period rather than a year.

2. We also applaud the clearly described transition between 2011 to 2013 and 2014, where 2011-certified software remains certified until 2014, while 2014 certified EHRs can be used starting in 2012. Transitioning smoothly between the first and second stages of the program will be essential to its ongoing success. We are pleased to see good alignment on this point between the CMS and ONC proposed rules.
3. The EHR Association is very supportive of ONC's efforts (and strong coordination with CMS) to quickly move toward broad and effective interoperability, including a single clinical summary standard, clinical reconciliation, and specification of transport standards. Given our strong and consistent commitment to interoperability and health information exchange, we are pleased that many elements of both the CMS and ONC proposed rules are aimed at substantially increasing the use and benefit of standards-based interoperability and exchange. We have suggested specific changes to the proposed rule to ensure that healthcare professionals and organizations can effectively interoperate across health systems and vendors before, during, and after the start of MU2, while also ensuring that they get full credit for standards-based electronic exchanges, including Direct, NwHIN Exchange-type standards and models, and community health information exchanges (HIEs) that support the coordination of care for patients.
4. We are strong supporters of increased patient engagement and the inclusion of robust patient engagement objectives and measures in Stage 2 of meaningful use. We specifically support both view, download, and transmit and secure messaging. At the same time, our

detailed comments propose refinements to these provisions, including ensuring that providers have the flexibility that CMS proposes with regard to specific data transport methods and that the proposals for online patient image access be revised to reflect technical realities.

5. We support ONC's proposal to revise the certification process, create a Base EHR, and remove the requirement that all Modular EHRs need to have the security and privacy scripts tested in addition to clinical criteria as part of the Modular EHR certification process. This change will allow vendors to offer more Modular EHR options to better match feature/functions that align with providers' meaningful use Stage 2 goals as well as greater flexibility to eligible professionals (EPs) and eligible hospitals (EHs) as to how to achieve those goals.
6. We are pleased with the elimination of the requirement to "possess" certified EHR technology for menu objectives that EPs or EHs are not pursuing or for which they claim exclusions. The fact that ONC has addressed this weakness from the Stage 1 regulation is very much appreciated by both EHR Association member companies, as well as the healthcare providers we serve.
7. The EHR Association is committed to clinical decision support (CDS), and accurate measurement and reporting on clinical quality. We do, however, make several specific recommendations to improve ONC's proposals regarding CDS and clinical quality measures (CQM). These include:
 - CDS functionality in an EHR should allow providers considerable flexibility in designing CDS, and we support allowing various scenarios within the definition of evidence-based interventions
 - We support the "calculate and transmit" aspects of the CQM criteria, but oppose the requirement to capture all data in the quality data model (QDM) and to export it using the vocabularies in the QDM, a substantial requirement well beyond the rest of meaningful use data capture and information exchange. We recommend that one of the alternatives identified by ONC be adopted, such as a "constrained" QDM, or a focus on only those data elements required for selected quality measures.
8. Although highly supportive of vendors having quality system processes in place and the general approach proposed by ONC of describing the nature of each company's quality processes, we are very concerned that ONC did not release a draft of its Quality Management System document at the time that the proposed rule was issued (and not as of the date of this letter). Such a document will require extensive industry and expert review and feedback before finalization. It is also essential that companies that are currently following existing ISO or FDA standards and processes not in any way be disadvantaged relative to the ONC approach.
9. The EHR Association is very engaged in the broader dialog around reporting potential EHR-related patient safety events, and strongly supports reporting using the Patient Safety Organization (PSO) model. At the same time, we do not agree with using EHRs to gather information and generate reports on safety events for PSOs and other organizations. Many PSOs have their own forms and processes, and to ask EHR vendors to reengineer their systems to perform tasks of this nature would divert important resources away from other MU2-related development work.

10. We appreciate the desire for transparency related to certification results. At the same time, we strongly believe that it would be inappropriate to post detailed test results on any public web site. In fact, such "publication" could compromise intellectual property rights and confidentiality agreements. Our clients can, of course, request such information.
11. The EHR Association also understands why the so-called "pricing transparency" proposal made by ONC might appear to be advantageous to EHR buyers. Based, however, on our collective experiences, although our members strongly support being clear and transparent on prices with our members, we believe that the approach proposed by ONC could be costly, confusing and ultimately not helpful to our customers. Our detailed comments provide further information on our concerns.
12. Our CMS and ONC comments provide detailed suggestions to improve the accuracy and feasibility of reporting on progress against meaningful use measures. Based on Stage 1 experience across vendors and providers, we urge ONC to ensure that: (1) definitions used in the certification process are clear and enable accurate and efficient reporting and testing; (2) definitions of key terms and concepts are explicit in measure specifications and the final rule preambles; and (3) CMS and ONC rethink their intention to require providers and their EHRs to track when functions are enabled or disabled or actions triggered. The need to measure and report on such events could impede clinical flexibility and exceed EHR capabilities.

On behalf of the members of the EHR Association, we appreciate the tremendous effort that went into the development of this important NPRM, especially the work to be responsive to comments received about Stage 1, and look forward to working with ONC staff to clarify certification requirements that will impact all of our member companies. We also congratulate the you and your organization on the success of this important program that is clearly accelerating the adoption of health IT, part of the broader effort to transform and improve healthcare delivery for all Americans.

Sincerely,



Carl Dvorak
Chair, EHR Association
Epic



Charles Jarvis
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee



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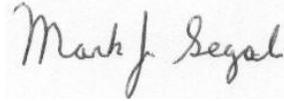


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About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit <http://www.himssehra.org>.



Office of the National Coordinator for Health IT
Proposed Rule Public Comment Template

Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology

Proposed 2014 Edition EHR Certification Criteria

New Certification Criteria

a. Ambulatory and Inpatient Setting

§ 170.314(a)(9) – Electronic notes

MU Objective

Record electronic notes in patient records. *(Not proposed by CMS)*

2014 Edition EHR Certification Criterion

Electronic notes. Enable a user to electronically record, access, and search electronic notes.

Preamble FR Citation: 77 FR 13838

Specific questions in preamble? *No*

Public Comment Field:

We agree with what we believe to be ONC’s intention that the definition of a note for certification should allow a range of options including templates, free text and structured data, and we ask that ONC be more explicit on this point. In general, we do not support certification capabilities extending beyond those needed to support specific meaningful use (MU) objectives and measures; given that CMS has not proposed a note-related objective/measure, therefore, this certification criterion should not require the additional functionality associated with searching across notes, especially across providers and patients. If this search provision is maintained, we ask that ONC provide more clarification on the required search capabilities.

§ 170.314(a)(12) – Imaging

MU Objective

Imaging results and information are accessible through Certified EHR Technology.

2014 Edition EHR Certification Criterion

Imaging. Electronically indicate to a user the availability of a patient’s images and/or narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable immediate electronic access to such images and narrative interpretations.

Preamble FR Citation: 77 FR 13838

Specific questions in preamble? Yes

Public Comment Field:

We support inclusion of a new certification requirement for image access, but we believe that EHR certification capability should be limited to the ability to provide either a context sensitive link to an external application/repository that provides access to images and their associated narrative or a direct link to specific images and their associated narrative within the EHR. Requirements for “immediacy” via additional sign-on capabilities and other system requirements are beyond the control of the EHR and should not be expected to be demonstrated via EHR certification.

§ 170.314(a)(13) - Family health history**MU Objective**

Record patient family health history as structured data.

2014 Edition EHR Certification Criterion

Family health history. Enable a user to electronically record, change, and access a patient’s family health history.

Preamble FR Citation: 77 FR 13838

Specific questions in preamble? Yes

Public Comment Field:

We support inclusion of a family history certification criterion, but we believe that the proposed criterion should be modified to allow for the use of unstructured data to record family health history, as such a format is the most widely used method of data collection. As such, we oppose the requirement in the meaningful use objective for structured data recording. We support the proposal that § 170.314(a)(13) does not specify a standard for family history in MU2. Family history should be able to be collected in human-readable format, but should not require a standard until the standards have been vetted and more widely adopted. We do not support the HL7 standard or the Surgeon General tool, as these are not widely used or available in the marketplace, and instead suggest that they be analyzed for MU3.

Additionally, it is our understanding that family health history can be supported as text in the CCDA.

§ 170.314(d)(4) – Amendments

MU Objective

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

2014 Edition EHR Certification Criterion

Amendments.

- (i) Enable a user to electronically amend a patient’s health record to:
 - (A) Replace existing information in a way that preserves the original information; and
 - (B) Append patient supplied information, in free text or scanned, directly to a patient’s health record or by embedding an electronic link to the location of the content of the amendment.
- (ii) Enable a user to electronically append a response to patient supplied information in a patient’s health record.

Preamble FR Citation: 77 FR 13838

Specific questions in preamble? Yes

Public Comment Field:

We agree that this functionality should be supported by EHR technology. Although the criterion has been associated with the CMS security and privacy objective, we urge ONC to acknowledge that this functionality has importance beyond and primarily in a non-security/privacy context. We also request that ONC and CMS clarify that, as with other security and privacy functionality, this capability need not be used by a provider to attest to meaningful use.

We also ask ONC to clarify that patient-supplied information need not be appended to individual data elements in the health record. Rather, we believe it is acceptable to have a separate section of the record for patient-supplied information.

§ 170.314(e)(1) - View, download, and transmit to 3rd party

MU Objective

EPs

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

EHRs and CAHs

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

2014 Edition EHR Certification Criterion

View, download, and transmit to 3rd party.

- (i) Enable a user to provide patients (and their authorized representatives) with online access to do all of the following:
 - (A) View. Electronically view in accordance with the standard adopted at § 170.204(a), at a

§ 170.314(e)(1) - View, download, and transmit to 3rd party

minimum, the following data elements:

(1) Patient name; gender; date of birth; race; ethnicity; preferred language; smoking status; problem list; medication list; medication allergy list; procedures; vital signs; laboratory tests and values/results; provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; and care plan, including goals and instructions.

(2) Inpatient setting only. Admission and discharge dates and locations; reason(s) for hospitalization; names of providers of care during hospitalization; laboratory tests and values/results (available at time of discharge); and discharge instructions for patient.

(B) Download. Electronically download:

(1) A file in human readable format that includes, at a minimum:

(i) Ambulatory setting only. All of the data elements specified in paragraph

(e)(1)(i)(A)(1).

(ii) Inpatient setting only. All of the data elements specified in paragraphs (e)(1)(i)(A)(1) and (e)(1)(i)(A)(2).

(2) A summary care record formatted according to the standards adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):

(i) Patient name; gender; date of birth; medication allergies; vital signs; the provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions;

(ii) Race and ethnicity. The standard specified in § 170.207(f);

(iii) Preferred language. The standard specified in § 170.207(j);

(iv) Smoking status. The standard specified in § 170.207(l);

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

(vi) Encounter diagnoses. The standard specified in § 170.207(m);

(vii) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);

(viii) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);

(ix) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed;

(x) Medications. At a minimum, the version of the standard specified in § 170.207(h); and

(xi) Inpatient setting only. The data elements specified in paragraph (e)(1)(i)(A)(2).

(3) Images formatted according to the standard adopted at § 170.205(j).

(C) Transmit to third party. Electronically transmit the summary care record created in paragraph (e)(1)(i)(B)(2) or images available to download in paragraph (e)(1)(i)(B)(3) in accordance with:

(1) The standard specified in § 170.202(a)(1); and

(2) The standard specified in § 170.202(a)(2).

(ii) Patient accessible log.

(A) When electronic health information is viewed, downloaded, or transmitted to a third-party

§ 170.314(e)(1) - View, download, and transmit to 3rd party

using the capabilities included in paragraphs (e)(1)(i)(A)-(C), the following information must be recorded and made accessible to the patient:

- (1) The electronic health information affected by the action(s);
 - (2) The date and time each action occurs in accordance with the standard specified at § 170.210(g);
 - (3) The action(s) that occurred; and
 - (4) User identification.
- (B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) if it is also certified to the certification criterion adopted at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

Standard(s) and Implementation Specifications

§ 170.204(a) (Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance); § 170.205(a)(3) (Consolidated CDA); § 170.205(j) (DICOM PS 3—2011); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT[®] International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); § 170.202(a)(1) (Applicability Statement for Secure Health Transport) and § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.210(g) (synchronized clocks).

Preamble FR Citation: 77 FR 13838-41

Specific questions in preamble? Yes

Public Comment Field:

Certification Issues:

View: We are generally supportive of the proposal for the Consolidated CDA (CCDA), but we have suggestions regarding particular aspects. We believe that the proposed data elements exceed those required for this use case and request that the Final Rule be clear that not all those listed need to be provided in every instance. For example, data such as names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider may not always make sense in the View requirement and should be reconsidered for mandatory inclusion.

In addition, CCDA is an implementation guide for nine different document types, and it would not only be inappropriate to require the use of all of these document types from all environments but would in fact not make sense for elements like a discharge summary for an EP). We request more specificity as to what aspects of the CCDA are required for which environments. We recommend that the certification requirement be that the vendor should demonstrate the ability to generate at least one of the available CCDA document types and that providers will be able to use the document type most appropriate to the clinical situation.

The NPRM mentions that there needs to be a confidentiality type included in the CCDA. It is

§ 170.314(e)(1) - View, download, and transmit to 3rd party

unclear what that requirement means in the use case where a patient downloads their information. We request further clarification and guidance on the indication of this element within the contexts of this criterion.

We recommend the additional flexibility of being able to import (save "as is") and view CCD (C32) and CCR documents in order to provide a transition between Stages 1 and 2.

We support § 170.207(h) and also agree with adoption of RxNorm as the standard vocabulary instead of any source vocabulary. It is important to note, however, that not all medications in the source vocabularies have an equivalent RxNorm code. The requirement should state that the RxNorm vocabulary will be utilized when there is an equivalent concept mapping to a drug in a source vocabulary. Use of the RxNorm vocabulary will more readily improve interoperability between systems and will remove the need for receiving systems to understand all source vocabularies in order to do something meaningful with the data.

For *Human Readable*, we suggest that an HTML view of the XML file for the CCDA should be adequate for View and Download.

We discuss images in greater detail below. For *View*, we suggest a revised criterion to support provision of a subset of images, created at the provider's discretion, in reduced matrix non-diagnostic format such as JPG. A patient could identify a study and request that full DICOM images be sent. Even so, we caution that such *View* (and other) access for images not stored in the EHR will be challenging and should probably be deferred to MU3.

We do not support the UAAG standard, which does not apply to web sites like portals; it applies only to web browsers. In addition, adoption of WCAG 2.0 Level AA would be a significant effort even for existing web portals, and we suggest this not be required at this time. If this standard is implemented as proposed, we request that ONC clarify that this applies only to patient viewable information.

Download: Images are specified as being available for Download. As with View, this proposed criterion and standard will be technically and practically difficult to achieve. Providing patient access to images in order to enable download will be a challenge. We suggest for Image Download that the patient should be able to identify the location of a study to be referred to another provider as acceptable certification criterion.

Patient Accessible Log: We support ONC's proposal that this feature not be required for View, Download, and Transmit if an audit log is available to the patient via a Complete EHR. We ask for clarification that this proposed criterion does not imply electronic or immediate access to the general audit trail via either the Complete EHR or portal.

We also request confirmation that the access is not online. We suggest the EHR could produce a document for patient review (i.e., a printed document, not on-line accessibility/ viewing). For the audit log for utilization of the patient portal, we request clarification that the log could provide

§ 170.314(e)(1) - View, download, and transmit to 3rd party

summary information, (e.g., that a patient summary was sent to a third party) and not be required to list all information contained in the summary.

Images: We oppose § 170.205(j) (DICOM PS 3—2011) as a required standard for patient image access. Although we support the principle of patient access to images, the question is whether implementation of that goal is practical for this criterion in a MU2 context. Typically, EHR systems and imaging systems (PACS) are implemented as separate systems with separate data stores. Making EHR system responsible for being the funnel point for such information to patients is a challenge. The functionality of viewing images in the EHR system is often done through opening a viewer hosted by the PACS system, meaning the images are not actually viewed directly in the EHR). These images are not stored in EHR system itself. As such, requiring the EHR system to enable this type of access, and including images in the criterion, is problematic and should be deferred, pending evaluation, to MU3.

Although patients today commonly request and receive their images on CD, those CDs include a special DICOM image viewer that the patient or a third party can use. This type of functionality will not be immediately available through online methods, including view and transmit (unless viewed from within some sort of online portal or the patient seeks out an external viewer). This requirement would likely cause unnecessary confusion and frustration for patients. We recommend that, if images must be provided to patients as part of meaningful use, the images could be provided to the patient on a CD or DVD. The DICOM specification does include this physical transport mechanism (along with USB, though USB has not been widely adopted because of cost and potential for loss). Electronic communication of DICOM images, particularly when possibly needing to allow the patient to see the images, is still a new area and will require more discovery for inclusion in a regulation.

Additionally we recommend that CHERT be required to not only be able to read the DICOM images from a provided CD or DVD but import the images in a form that is acceptable to the environment of care in which it is being utilized. At a minimum this functionality could be something like choosing a particular "significant image" subset and saving it as a JPEG or other widely supported image format to be associated with the patient's record.

Finally, due to image size and complexity, we believe that including images in the Transmit function for this criterion is impractical.

TRANSMIT-§ 170.202(a)(1) (Applicability Statement for Secure Health Transport) - Direct/XDR/XDM – Although the use of Direct for communicating directly from one provider to another provider (or clinician or organization) is an appropriate direction to take, it is not at all clear that this is an appropriate standard, in all cases, for transmission to patients as part of this patient-focused criterion. The "transmit to third party" via Direct should be clarified that the intent is transmission to another provider or a PHR (both of which can be expected to support Direct in MU2). Direct should NOT be required to transmit to other individuals who are not providers (e.g., friends, relatives, etc.). Each Direct address requires a separate certificate, and this requirement would prove a considerable challenge when used for transmission beyond other providers or PHRs as part of this criterion. Although there are methods for reducing the

§ 170.314(e)(1) - View, download, and transmit to 3rd party

complexity (specifically regarding PHRs), this is a fairly new area that still needs to be further explored before putting into regulation.

We support the ONC proposal: *"We have determined that it is not necessary to include in the 2014 Edition EHR certification criteria the "encrypting when exchanging" certification criterion adopted in the 2011 Edition EHR certification criteria (§ 170.302(v)). We believe that to include the 2011 Edition EHR certification criterion would be redundant and that our proposed approach more explicitly ties security to a particular transmission."*

We also agree that additional metadata standards are not needed above those identified by CCDA at this time, as the industry and standards development organizations are still exploring the potential opportunities and methods to develop this area further.

§ 170.314(g)(1) - Automated numerator recording

MU Objective

N/A

2014 Edition EHR Certification Criterion

Automated numerator recording. For each meaningful use objective with a percentage-based measure, electronically record the numerator.

Preamble FR Citation: 77 FR 13841-42

Specific questions in preamble? *No*

Public Comment Field:

We agree that this criterion should not apply to a Complete EHR or a module that supports Automated Measure Calculation, and we also appreciate that ONC states that modules that do not support Automated Measure Calculation need only record numerators. We have addressed the reporting issues with numerator recording. We suggest that this criterion be excluded, or at a minimum the logic must be reevaluated. The capability to record the numerator is based on logic that requires a system to also know the denominator in order for inclusion in the numerator. This requirement exceeds the capabilities of modules, as the full denominator will frequently be unknown. In many cases, programming for a numerator without having the denominator is not possible.

Should this criterion remain, we request clarification on the process that will be used in testing to determine the accuracy of numerators. Will test data be provided and expected to match some predetermined calculations by the tester? If vendors are expected to demonstrate each measure calculation on the report, we are concerned about the extended time that could be required to validate such accuracy.

§ 170.314(g)(3) - Non-percentage-based measure use report

MU Objective

N/A

2014 Edition EHR Certification Criterion

Non-percentage-based measure 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, electronically record the date and time in accordance with the standard specified at § 170.210(g) when the capability was enabled, disabled, and/or executed.
- (ii) Enable a user to electronically create a report of the information recorded as part of paragraph (g)(3)(i).

Standard

§ 170.210(g) (synchronized clocks)

Preamble FR Citation: 77 FR 13842

Specific questions in preamble? *No*

Public Comment Field:

We oppose this criterion and suggest that it not be included in the Final Rule. The complexity of the criterion has been underestimated, as there would likely be several paths or components within a system required to accomplish the tasks associated with the applicable objectives and measures. Most of these actions do not involve simple on/off, enable/disable switches, and it would require significantly complex design and programming to deliver such a report. Development time on reporting that cannot be accomplished otherwise for attestation is a much better use of vendor and provider effort and resources. Providers should be allowed to provide attestation and produce documentation or reports from the system to support their attestation as in MU1.

We do not support applying the standard § 170.210(g) (synchronized clocks) for this criterion given the concerns expressed above.

§ 170.314(g)(4) - Safety-enhanced design

MU Objective

N/A

2014 Edition EHR Certification Criterion

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: § 170.314(a)(1); § 170.314(a)(2); § 170.314(a)(6); § 170.314(a)(7); § 170.314(a)(8); § 170.314(a)(17); § 170.314(b)(3); and § 170.314(b)(4).

Preamble FR Citation: 77 FR 13842-43

Specific questions in preamble? *Yes*

Public Comment:

We applaud the fact that the proposed certification criteria for this topic are not prescriptive with respect to design, and we also support ONC's general approach, given this proposal, to start with a relatively small set of functions, focusing on those with a higher likely impact on patient safety. At the same time, we are very concerned that publishing data on a small set of capabilities under particular configurations would lead to invalid comparisons across systems. As stated in this AHRQ report, *"Usability studies are often difficult to generalize or transfer across settings, in part because MMIT effectiveness is linked strongly to the culture, institutional leadership, and other situation specific factors. Therefore, applicability of findings related to usability is problematic in MMIT applications."*

(<http://www.ahrq.gov/clinic/epcsums/medmgsum.htm>)

Given the concerns outlined above and below, we, suggest an alternative approach in which vendors attest to and document their current processes for incorporating user-centered design (UCD) practices into their software design, as well as any UCD approaches used for currently certified products, but not publicly publish findings from specific tests. We also believe that this type of summative testing, as used in the referenced NIST template, can catch the most basic usability errors, but is unlikely to have a significant impact on patient safety relative to cost. We are, therefore, in favor of broadening the criteria to include other, formative UCD techniques instead of just summative testing as valid for certification.

We have strong objections to the requirement for retrospective UCD analysis and application. In many cases, the core functionality and user interfaces associated with some of the specified applications and features were developed several years ago and continuously refined through user feedback over the ensuing years – feedback that has addressed usability issues, albeit not necessarily according to formal UCD protocols. To be required to go back and redevelop widely-used and user-recommended content as mandatory for certification would be an unnecessary and valueless burden, forcing EHR Association members to pull resources from development work of higher priority to our end users. We strongly object to this requirement.

Therefore, if ONC wishes to retain its requirement for application of UCD, despite our general alternative proposed above, we suggest that this certification requirement should be restricted only to systems that have made significant changes since MU1 to any of the eight medication-related certification criteria that are part of the Safety Enhanced Design criteria.

We also request clarification that the certification criterion is for clinical roles (as opposed to system administration and set-up).

We do appreciate that ONC has identified several applicable UCD standards with respect to the listed established UCD standards, and we have the following comments:

- ISO 13407 is old and has been withdrawn. It has been replaced by ISO 9241-11.
- ISO/IEC 62366 should be included in the list of choices as a valid, accepted standard.
- ISO 9241-210 should be included in the list of choices as a valid, accepted standard (it is more focused on UCD).
- We agree wholeheartedly with the decision not to include NISTIR 7804.

With respect to the CIF template (NISTIR 7742), it is unclear which specific elements are required. For example, we assume all the data elements in the participant demographic table on page 11 are illustrative, as is Path Deviation in the table on page 20. If ONC pursues its general proposed approach, rather than the EHR Association suggestion to attest to a UCD process, we advocate requiring the high-level elements (Introduction, Method, Results expressed in Effectiveness, Efficiency, and Satisfaction) and leaving flexibility on the specific lower-level elements. We do not recommend including Major Findings and Areas for Improvement in reporting results, since those are only useful to the vendor.

b. Ambulatory Setting

§ 170.314(e)(3) - Secure messaging

MU Objective

Use secure electronic messaging to communicate with patients on relevant health information.

2014 Edition EHR Certification Criterion

Ambulatory setting only – secure messaging. Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:

- (i) Both the patient and EHR technology 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).

Standard

§ 170.210(f) Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2.

Preamble FR Citation: 77 FR 13843-44

Specific questions in preamble? *No*

§ 170.314(e)(3) - Secure messaging

Public Comment Field:

Certification Issues:

Based on the CMS proposed rule, we expect that providers will be able to use multiple ways to accomplish secure messaging and that these methods could include the use of a patient portal or secure email. Any test methods and scripts should reflect the diversity of options allowed by CMS and the narrow set of standards proposed for this criterion by ONC.

We agree with the reference to the FIPS 140-2 Annex A. We request further clarification and some examples of common access mechanisms (e.g., secure web site) and acceptable security protocols. Additionally, items in FIPS 140-2 should be tested by having vendors indicate which libraries and/or tools are being used, and how they enable and/or configured for secure implementation. We agree with the proposed meaningful use MU2 decision to continue with SHA-1, which is more mature and widely available than SHA-2. Additionally, functionality such as a patient portal would be handled through normal browser HTTPS functionality. That would be something that should be easily managed through a visual inspection and not require additional verification.

Reporting Issues:

Given that the CMS measure and preamble discussion leave it to the provider to determine "relevance" of information, the capability to assess or document relevance should not be in the automated measure calculation for this item nor be part of its base certification criteria.

§ 170.314(f)(7) - Cancer case information; and (f)(8) - 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.

§ 170.314(f)(7) - Cancer case information; and (f)(8) - Transmission to cancer registries

2014 Edition EHR Certification Criteria

(f)(7) Ambulatory setting only – cancer case information. Enable a user to electronically record, change, and access cancer case information.

(f)(8) Ambulatory setting only – transmission to cancer registries. Enable a user to electronically create cancer case information for electronic transmission in accordance with:
(i) The standard (and applicable implementation specifications) specified in § 170.205(i); and
(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and § 170.207(g).

Standards and Implementation Specifications

§ 170.205(i) (HL7 CDA, Release 2 and Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012); § 170.207(a)(3) (SNOMED CT® International Release January 2012); and § 170.207(g) (LOINC version 2.38).

Preamble FR Citation: 77 FR 13844

Specific questions in preamble? *No*

Public Comment Field:

Certification Issues:

We request that this criterion be *optional* for Complete EHR certification testing and reporting. We do not believe this criterion is appropriate for inclusion in EHRs that are not focused on meeting the needs of EPs who will report to cancer registries, as some of the cancer case information data utilizes extensive cancer-specific specialized fields and vocabularies (e.g., NAACCR data standards, which in turn refer to ICD-O-3) that are not typically captured in EHRs beyond those specifically marketed as oncology specialty products. It is clear that it may not be a good use of resources for general EHRs to be required to add specialty-requirements when the providers needing this functionality would most often be using a specialty product.

c. Inpatient Setting

§ 170.314(a)(17) - 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).

§ 170.314(a)(17) - Electronic medication administration record

2014 Edition EHR Certification Criterion

Inpatient setting only – electronic medication administration record.

- (i) In combination with an assistive technology that provides automated information on the "rights" specified in paragraphs (i)(A) through (i)(D), 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.
- (ii) Right time. Electronically record the time and date in accordance with the standard specified at § 170.210(g), and user identification when a medication is administered.

Standard

§ 170.210(g) (synchronized clocks).

Preamble FR Citation: 77 FR 13844

Specific questions in preamble? *No*

Public Comment Field:

Certification Issues:

Please clarify what "electronically confirm" means for certification. We suggest that it be specifically stated that the EHR is not required to provide messaging to the user unless one of the "rights" is compromised in the medication administration process. Current systems typically do not message user when all the five rights of administration are in compliance. If there is a future requirement to progress towards RFID, a "heads up" would be appropriate as we consider that all technologies are currently acceptable, including various bar code formats.

§ 170.314(b)(3) - Electronic prescribing

MU Objective

Generate and transmit permissible discharge prescriptions electronically (eRx).

§ 170.314(b)(3) - Electronic prescribing

2014 Edition EHR Certification Criterion

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(h).

Standards

§ 170.205(b)((2) (NCPDP SCRIPT version 10.6) and § 170.207(h) (RxNorm February 6, 2012 Release).

Preamble FR Citation: 77 FR 13844-45

Specific questions in preamble? *No*

Public Comment Field:

Certification Issues:

We agree with the usage of NCPDP 10.6, and we also propose that Surescripts certification should be one basis for meeting this criterion. We support NCPDP without any changes for certification that would compromise the Surescripts certification. We also agree with § 170.207(h), the adoption of RxNorm as the standard vocabulary instead of any source vocabulary. It is important to note, however, that not all medications in the source vocabularies have an equivalent RxNorm code. The requirement should state that the RxNorm vocabulary will be utilized when there is accurate mapping to the prescribed drug. Use of the RxNorm vocabulary will more readily improve interoperability between systems and will remove the need for receiving systems to understand all source vocabularies in order to do something meaningful with the data. We also agree with the ONC proposal not to accept the Health IT Standards Committee recommendation to require a specific standard for communicating prescriptions within an individual legal entity

We note that the same eRx certification criterion applies to both ambulatory and inpatient settings. It will be important, however, for the Final Rule and the testing criteria to identify any difference in application between the two settings.

Reporting Issues:

We have identified issues related to exclusion criteria for paper prescriptions, however reporting accuracy for drug formulary inclusion will be difficult to determine. Therefore, we suggest an attestation on part of meaningful use formulary utilization. The transition to use of RxNorm, as opposed to a vocabulary contained in RxNorm, can be complicated for providers. Version changes to RxNorm can become complicated because the older vocabulary values must be stored for historical storage for reporting on CQM, as well.

§ 170.314(b)(6) - Transmission of electronic laboratory tests and values/results to ambulatory providers

MU Objective

Provide structured electronic laboratory results to eligible professionals.

2014 Edition EHR Certification Criteria

Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers. Enable a user to electronically create laboratory tests and values/results for electronic transmission in accordance with:

- (i) The standard (and applicable implementation specifications) specified in § 170.205(k); and
- (ii) At a minimum, the version of the standard specified in § 170.207(g).

Standards and Implementation Specifications

§ 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm); and § 170.207(g) (LOINC version 2.38).

Preamble FR Citation: 77 FR 13845

Specific questions in preamble? *No*

Public Comment Field:

CMS did not propose an objective or measure for this item, and we do not believe that it should be a certification criterion unless CMS ultimately adopts a corresponding objective and measure in the Final Rule. If, however, this criterion becomes a requirement, we support using the same specification for transmission of electronic labs from the hospital to ambulatory provider as whatever standard is chosen for the incorporation of lab results in the ambulatory care environment.

The use cases and trigger events for these lab results are unclear. Already, transitions of care support exchange of laboratory results as part of the appropriate documentation that enables a clinician to include the relevant laboratory data in context. Either the lab already sent copies to the appropriate EP, or the EHR would have to determine what relevant lab data may or may not be and for whom. We believe that alternative exchange methods at this point are sufficient, until a clearer use case can be provided.

Labs produce the reportable results. Implementation experience has shown that most labs have the capability of identifying reportable results; many of them own the responsibility of submitting this information to public health authorities (PHA) today. It is redundant to send this data back to the EHR and have the EHR implement the reporting rules again.

MU1 experience showed that many customers either did not elect this menu option or reported to the PHA directly via their lab systems. There are lab vendors that have been certified to perform such submissions. Labs also seem to feel ownership of reporting this data and sometimes do it even in cases where the EHR attempts to report the data as well.

Revised Certification Criteria

a. Ambulatory and Inpatient Setting

§ 170.314(a)(2) - Drug-drug, drug-allergy interaction checks

CMU Objective

Implement drug-drug and drug-allergy interaction checks.

2014 Edition EHR Certification Criteria

Drug-drug, drug-allergy interaction checks.

(i) Interventions. Before a medication order is placed during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user at the point of care of drug-drug and drug-allergy contraindications based on 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: 77 FR 13846

Specific questions in preamble? *No*

Public Comment Field:

Certification Issues:

We suggest that the language for this criterion be changed to indicate that, "Before an order is completed and acted upon..." instead of "Before a medication order is placed...", so that it is clear for addressing the real-time notification definition in order for the licensed provider to see the decision support information.

Reporting Issues:

In the case of a scribe entering the order, and a provider signing or transmitting the order, the display of CDS warnings will occur in the normal system workflow.

§ 170.314(a)(3) - Demographics

MU Objective

Record the following demographics: preferred language; gender; 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.

§ 170.314(a)(3) - Demographics

2014 Edition EHR Certification Criterion

Demographics.

- (i) Enable a user to electronically record, change, and access patient demographic data including preferred language, gender, 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(j) and whether a patient declines to specify a preferred language.
- (ii) Inpatient setting only. Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality in accordance with the standard specified in § 170.207(k).

Standards

§ 170.207(f)(OMB standards); § 170.207(j) (ISO 639-1:2002); and § 170.207(k) (ICD-10-CM).

Preamble FR Citation: 77 FR 13846

Specific questions in preamble? *No*

Public Comment Field:

Certification Issues:

The proposed approach adds flexibility, as well as additional complexity, to know what is and what is not mapped if vendors provide clients the capability to use additional data entry approaches, as has been suggested. Given some remaining uncertainty, please clarify the use of the OMB race/ethnicity from a product standpoint, as the NPRM allows other entries by a user than the standard. From a product certification standpoint, we ask for clarification as to whether this information is to be stored as aggregated to the standard (i.e., it must be done this way), or could it be aggregated to the standard by a third party and not the EHR? Also, is the aggregation to the OMB standard only to produce reports? If user interface options are used, what must be shown to demonstrate and certify?

It would also be helpful to have a focused ONC summary of the OMB standard regarding race and ethnicity, as the OMB document can be confusing to the reader and sometimes ambiguous.

We expect customer complaints about the length of the standard list for preferred language. For this element, we request clarification as to whether all languages in the standard must be visible for customer selection? In other words, for certification testing and product deployment, will we need to present the complete list, or could vendors display a limited list for end user selection based upon user needs?

Finally, we prefer that preliminary cause of death be able to be entered as text and not require an ICD 10-coded field. Customer education to enter an appropriate code could complicate the use of this data field.

§ 170.314(a)(5) - Problem list

MU Objective

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

2014 Edition EHR Certification Criterion

Problem list. Enable a user to electronically record, change, and access a patient's problem list for longitudinal care in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).

Standards

§ 170.207(a)(3)(SNOMED CT® International Release January 2012).

Preamble FR Citation: 77 FR 13846-47

Specific questions in preamble? Yes

Public Comment Field:

We support the use of SNOMED CT for problem list. In doing so, we wish to clarify that the capability to map to these standards to meet the requirement is sufficient, versus presenting SNOMED CT codes or descriptors in the user interface. Our expectation is that systems will continue to enable entry in terminology of the provider's choice, with the ability to export data using the standard as required in the CCDA.

We request analysis of the implications for accurate computation of clinical quality measures through use of SNOMED CT for problem lists and ICD-10 for diagnoses.

§ 170.314(a)(8) - Clinical decision support

MU Objective

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

2014 Edition EHR Certification Criterion

Clinical decision support.

- (i) Evidence-based decision support interventions. Enable a user to select (or activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in each one or any combination of the following:
 - (A) Problem list;
 - (B) Medication list;
 - (C) Medication allergy list;
 - (D) Demographics;
 - (E) Laboratory tests and values/results; and
 - (F) Vital signs.
- (ii) Linked referential clinical decision support.
 - (A) Enable a user to retrieve diagnostic or therapeutic reference information in accordance with the standard specified at § 170.204(b)(1).

§ 170.314(a)(8) - Clinical decision support

- (B)** Enable a user to access the reference information specified in paragraph (ii)(A) relevant to patient context based on the data elements included in each one or any combination of the following:
- (1) Problem list;
 - (2) Medication list;
 - (3) Medication allergy list;
 - (4) Demographics;
 - (5) Laboratory tests and values/results; and
 - (6) Vital signs.
- (iii) Configure clinical decision support.
- (A)** Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) to be configured by an identified set of users (e.g., system administrator) based on each one of the following:
- (1) A user's role;
 - (2) Clinical setting; and
 - (3) Identified points in the clinical workflow.
- (B)** Enable interventions to be triggered, based on the data elements specified in paragraph (a)(8)(i), when a summary record is incorporated pursuant to § 170.314(b)(1).
- (iv) Automatically and electronically interact. Interventions selected and configured in accordance with paragraphs (a)(8)(i)-(iii) must automatically and electronically occur when a user is interacting with EHR technology.
- (v) Source attributes. Enable a user to review the attributes for each intervention or reference source for all clinical decision support resources including:
- (A)** Bibliographic citation (clinical research/guideline) including publication;
 - (B)** Developer of the intervention (translation from clinical research/guideline);
 - (C)** Funding source of the intervention development technical implementation; and
 - (D)** Release and, if applicable, revision date of the intervention.

Standards

§ 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval ("Infobutton") Standard, International Normative Edition 2010).

Preamble FR Citation: 77 FR 13847

Specific questions in preamble? Yes

Public Comment Field:

Certification Issues:

We approve of the terminology change from "Clinical Decision Support Rule" to "Clinical Decision Support Intervention". We would like to note some challenges this terminology change introduces in the companion CMS incentives rule with regard to counting "interventions". Although it is easy to identify and count "rules" within a clinical decision support implementation, it is much more difficult to count interventions given the CMS definition of an "intervention". For example, a clinical decision support implementation that ensures that patients with diabetes get annual A1C and cholesterol measures could be counted as either a single intervention, or as two

§ 170.314(a)(8) - Clinical decision support

separate interventions, depending upon how it was implemented in an EHR.

The phrase “in each one or any combination of the following” found in subsection (i) and (ii)(B) is confusing. It could mean one or more of the following, all of the following, or anything in between. We would suggest that this section should read “utilizing any of the following data elements used alone or in any combination.”

ONC requests comment on the use of HL7 Common Terminology Services, Revision 1, standard (CTS 1). Although many EHR systems today utilize CTS or functional equivalents to access value sets and terminology, interfaces to the terminology management system are not necessarily exposed outside of the EHR environment. Furthermore, we note that CTS 1 enables systems to look up and access value sets, but it does not provide APIs to update those value sets. We do not believe that it would be appropriate to expose or use these interfaces to update value sets.

Evidence-based decision support interventions: CDS features with an EHR should allow EPs and hospitals as much flexibility in designing CDS as possible. By allowing them to customize their own CDS alerts and advisories, they can create customized and targeted decision support based on criteria specific to their patient population. It would be inefficient for an EHR vendor to hard-code specific CDS rules into the system, which should instead be designed to provide a framework that allows EPs and hospitals to quickly create their own clinical decision support rules. We support various scenarios allowed within the definition of evidence-based interventions —those from an EHR database or reference source if provided, along with those developed directly by the EP or EH. There should be no bias towards one method or the other required for certification. Within such a context, it would be impossible for an EHR to control whether a CDS is “authenticated” or “evidence-based”, as it would remain the EPs’ or EHs’ choice. Such information would come from the entity creating the CDS rule and its contents and be entirely dependent upon them. The EHR could, however, provide a method of displaying a source to a clinician.

Linked referential clinical decision support: The requirement for the Infobutton for CDS should be an *optional* additional certification criterion as it relates to reference information not typically in an EHR. Current CDS implementations address the alerts and appropriate references for those system alerts. This capacity to provide Infobutton exceeds the requirements to meet the meaningful use objectives and should not be required for certification. The use of Infobutton, although potentially very useful, is not currently widespread among EHRs. Also, when available for specific reference materials, Infobutton may only address a specific category of reference information such as medications or problems but not necessarily all the areas required for CDS interventions. For example, even where MedLine Plus implements InfoButton, they only code for problems, not for medications and laboratory tests (see http://www.nlm.nih.gov/pubs/techbull/nd10/nd10_medlineplus_connect.html).

If this standard is retained, CMS should be clear that providers need not use the Infobutton capabilities in meeting the CDS meaningful use objective and measure. Timing constraints should be considered for MU2 certification and with a focus placed on supporting the meaningful

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use objective for CDS with vendor-supplied CDS rather than InfoButton. In addition, if a provider utilizes InfoButton capabilities of an EHR, that use should be able to count that towards the objective for CDS interventions as one of the five CDS interventions.

We also point out it is not possible for the EHR to "know" if the external access via InfoButton access was relevant to a particular CQM. It should be the vendor's responsibility to supply appropriate CDS monitoring in consideration of the requirements for the provider to meet meaningful use with the EHR system in the manner they define, and but the vendor should not be required to provide outside reference tools except as an *optional* certification criterion.

If this standard is ultimately required for certification, much more information must be supplied regarding how its use should be captured in the workflow and reported accurately. We suggest the addition of the HL7 Context-aware Information Retrieval (InfoButton) URL-based Implementation Guide as the implementation guide to accompany the InfoButton standard. This guide is the basis for most InfoButton implementations currently supported in EHR products and has been implemented in MedLine Plus (see http://www.nlm.nih.gov/pubs/techbull/nd10/nd10_medlineplus_connect.html).

8(iii)B: We suggest elimination of this certification step. Providing CDS alerts as defined from the *incorporation* of the data elements received via a CCDA is beyond the scope of proposed meaningful use objectives and measures. At most, we anticipate the incorporation of the medication list, medication allergy list and problem list (those elements subject to the proposed clinical reconciliation certification criterion), and that any CDS rules triggered would only be those that use such information, not all CDS rules as specified in the criterion. Moreover, it is not practical to trigger these alerts until the complete reconciliation process is finished.

It is unclear what is meant here with regards to the timing of these alerts from this incorporation. Also, we ask ONC to clarify that the stated timing is not to be interpreted literally. We would point out that once an EHR is updated with relevant information, drug-drug and drug-allergy notifications would occur without the need to include this additional required certification criterion. In general, we would expect the EHR CDS to function normally once the data is entered into the EHR after any needed reconciliation without the need for this additional specified requirement.

Reporting Issues:

Tracking CDS interventions or meaningful use reporting will be very difficult, beyond attestation by the provider. Interventions may arise in many different workflows within an EHR, so tracking these can be difficult to report – that is, a "turned on" or "turned off" flag or date/time may not exist. Many interventions are in workflow set up throughout the EHR, so there is not necessarily a location where all interventions reside to be easily tracked into a single report. In order to adequately track, we request a clear understanding for "intervention", defined in a manner consistent between CMS and ONC such that meaningful use and certification can track beyond a provider's ability to simply attest to use within the reporting period.

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Regarding the proposed source attributes, we suggest clarification that the information be available but not a requirement for the CDS intervention display for the provider unless providers wish to see it. We also suggest that the source attributes can be displayed as a linked resources that *may* contain the listed information (as the EHR vendor cannot assure that all attributes are provided by the linked resource), and that users creating their own interventions be given a format to enter free-text information to satisfy the requirements for interventions they create themselves.

§ 170.314(a)(16) - 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.

2014 Edition EHR Certification Criterion

Patient-specific education resources. Enable a user to electronically identify and provide patient-specific education resources according to:

- (i) At a minimum, each one of the data elements included in the patient's: problem list; medication list; and laboratory tests and values/results; and
- (ii) The standard specified at § 170.204(b)(1).

Standard

§ 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard, International Normative Edition 2010).

Preamble FR Citation: 77 FR 13847-48

Specific questions in preamble? *No*

Public Comment Field:

Reporting Issues:

We suggest editing the descriptions of both the numerator and the denominator to clarify unique patients and patients with at least one office visit.

Certification Issues:

Infobutton should be an *optional standard*, as many systems have their own patient education functionality and/or content. Although InfoButton implementations may be widely available, and useful in some settings, they are not consistently available across the full spectrum of data elements (even problems, medications, lab results) as suggested in the rule; they are most typically available for problems. Again, we recommend identification of the HL7 Context-aware Information Retrieval (InfoButton) URL-based Implementation Guide as the implementation guide to accompany the standard.

We also recommend that the wording at (i) be changed to: "One or more of the data elements included in the patient's problem list, medication list and laboratory tests and values/results".

§ 170.314(a)(16) - Patient-specific education resources

We also point out that searches for patient education might be performed in different ways depending on what data element is being searched. If a system has multiple ways to identify patient education, which may or may not include Infobutton, how are these to be shown for testing? Finally, as written, and combined with the CMS requirement that certified capabilities and standards must be used, this criterion seems to imply that the patient education must always be provided using the Infobutton. We believe strongly that, regardless of whether the current proposed standard is retained, there should be no expectation that this should be used each time for querying patient education.

Finally, please clarify how documentation for meaningful use reporting would reflect both methods if Infobutton is not optional.

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record

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.

2014 Edition EHR Certification Criteria

(1) Transitions of care – incorporate summary care record. Upon receipt of a summary care record formatted according to the standard adopted at § 170.205(a)(3), electronically incorporate, at a minimum, the following data elements: Patient name; gender; race; ethnicity; preferred language; date of birth; smoking status; vital signs; medications; medication allergies; problems; procedures; laboratory tests and values/results; the referring or transitioning provider's name and contact information; hospital admission and discharge dates and locations; discharge instructions; reason(s) for hospitalization; care plan, including goals and instructions; names of providers of care during hospitalization; and names and contact information of any additional known care team members beyond the referring or transitioning provider and the receiving provider.

(2) Transitions of care – create and transmit summary care record.

(i) Enable a user to electronically create a summary care record formatted according to the standard adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):

(A) Patient name; gender; date of birth; medication allergies; vital signs; laboratory tests and values/results; the referring or transitioning provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions;

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record

- (B) Race and ethnicity. The standard specified in § 170.207(f);
 - (C) Preferred language. The standard specified in § 170.207(j);
 - (D) Smoking status. The standard specified in § 170.207(1);
 - (E) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);
 - (F) Encounter diagnoses. The standard specified in § 170.207(m);
 - (G) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);
 - (H) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);
 - (I) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed;
 - (J) Medications. At a minimum, the version of the standard specified in § 170.207(h); and
 - (K) Inpatient setting only. Hospital admission and discharge dates and location; names of providers of care during hospitalization; discharge instructions; reason(s) for hospitalization; and indication of whether an advance directive exists.
- (ii) Transmit. Enable a user to electronically transmit the summary care record created in paragraph (i) in accordance with:
- (A) The standards specified in § 170.202(a)(1) and (2).
 - (B) Optional. The standard specified in § 170.202(a)(3).

Standards

§ 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); and § 170.202(a)(1) (Applicability Statement for Secure Health Transport); § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.202(a)(3) (SOAP-Based Secure Transport RTM version 1.0).

Preamble FR Citation: 77 FR 13848-49

Specific questions in preamble? Yes

Public Comment Field:

Summary Care Record: We suggest adding a definition of a Summary of Care Record to the ONC proposed rule and referencing it at appropriate places in the proposed rule, as in the following:

"§170.208 Summary Care Record: The secretary adopts the following as the definition of a Summary Care Record:

(a) Content A summary care record contains the following information:

Subsections would include relevant data elements

Describe the Data Elements that should appear in the Summary Care Record when known:

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record

- (1) Patient Name
- (2) Patient Demographics, including
 - (i) Gender,
 - (ii) Date of Birth,
 - (iii) Race and Ethnicity
- (3) The patient's preferred language
- (4) The date and location of care, including:
 - (i) Ambulatory Only -- The date of the visit
 - (ii) Inpatient Only -- The admit and discharge date of the hospital stay
- (5) Contact information for the provider(s) responsible for the patient's care during the visit or inpatient stay.
- (6) Contact information for other providers on the patient's care team when known
- (7) The reason for receiving care (e.g., Chief complaint, reason for visit, or admission diagnosis)
- (8) The Patient's smoking status
- (9) Most recent vital signs, including Blood Pressure, Height and Weight where applicable (Not including BMI or growth charts as they are calculable given heights and weights).
- (10) A list of current and relevant past problems.
- (11) A list of currently active medications.
- (12) A list of currently active medication allergies.
- (13) A list of procedures performed during the visit or inpatient stay, when procedures have been done.
- (14) A list of immunizations given during the visit or inpatient stay, when immunizations have been given.
- (15) A list of medications given during the visit or inpatient stay, when medications have been given.
- (16) A list of lab tests and results provided during the visit, or tests and results on discharge for an inpatient stay, including any results still pending, when tests have been initiated.

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(17) Any diagnoses produced as a result of the visit or inpatient stay, when there is a diagnosis.

(18) Care Plan, including Patient Instructions, Decision Aids; Goals; and any future scheduled tests, visits or referrals.

(b) Standards When supplied in an electronic form, the summary care record shall be formatted according to the standards specified in §170.205(a)(3)."

Subsections would reference relevant standards associated with the data elements above.

Describe the Vocabulary Standards that should be used with each data element when known:

- (1) Race and ethnicity. The standard specified in § 170.207(f)
- (2) Preferred language. The standard specified in § 170.207(j)
- (3) Smoking status. The standard specified in § 170.207(l)
- (4) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3)
- (5) Encounter diagnoses. The standard specified in § 170.207(m)
- (6) Medications. At a minimum, the version of the standard specified in § 170.207(h); and
- (7) Reserved (For Allergies)
- (8) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3)
- (9) Immunizations. The standard specified in § 170.207(i)
- (10) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g)

Elsewhere in this proposed rule, reference the appropriate parts of this section:

- 170.314(b)(1) Transitions of care—incorporate summary care record. Upon receipt of a summary care record formatted according to the standard adopted at § 170.208(b), electronically incorporate the data elements found in § 170.208(a).
- 170.314(b)(2) Transitions of care—create and transmit summary care record.
 - (i) Enable a user to electronically create a summary care record formatted according to the standards as described in § 170.208(b) and that includes the data elements expressed in § 170.208(a) according to the specified standard(s)

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record

- 170.314 (e)(1) View, download, and transmit to 3rd party.
 - (i) Enable a user to provide patients (and their authorized representatives) with online access to do all of the following:
 - (A) View. Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the data elements expressed in § 170.208(a)
- 170.314(e)(1)(B)(2) A summary care record formatted according to the standards adopted at § 170.208(b) and that includes, at a minimum, the data elements expressed in 170.208(a).
- 170.314(e)(2) Ambulatory setting only—clinical summaries. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, the data elements expressed in 170.208(a).

Incorporate: We ask ONC to clarify what they mean by “incorporate” and whether the individual referenced data elements in the CCDA must be incorporated as structured data as opposed to the MU1 approach of displaying the contents of a received CCD or CCR. We also have concerns regarding hospitalizations with large volumes of data, such as voluminous lab results, and how this information would display in a summary document of considerable length.

We propose that incorporation be limited to the three data elements included in clinical reconciliation, problems, medications and medication allergies and that the MU1 requirement to receive and display the clinical summary be retained as well. Finally, we suggest that the same data transport standards referenced under “Transmit” be referenced under Incorporate, which should be revised as “Receive and Incorporate,” to ensure that we can have an effective system of transmission and receipt of clinical summaries. The criterion should be revised to indicate that the system shall have the capability to receive and display a summary of care record formatted according to the standard adopted at § 170.205(a)(3) and using the transport standards specified at § 170.202, with incorporation of problems, medications and medication allergies.

Create: We support the use of SNOMED CT for problem list and ICD-10 for encounter diagnosis. There is confusion regarding the RTM 1.0 specification, as other specifications using SOAP should not be disallowed for certification.

Reporting Issue:

We are unsure how to address the reporting complexity that should be considered regarding the ability for *only* exchanges outside the organization with a separate vendor and certified to count in the reporting process. How can the EHR be expected to calculate such subjective information?

Clarification on Practical EHR Compliance with Direct Applicability Statement:

Transmit-§ 170.202(a)(1) (Applicability Statement for Secure Health Transport) - Direct/XDR/XDM

The current 2014 certification criteria pose several challenges in the certification of an EHR in

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terms of testing and deployment. The Direct Applicability Statement essentially describes how the existing SMTP infrastructure can be used to securely exchange information between message submission and user agents, utilizing a message transfer agent. This infrastructure uses several standards to exchange messages, including SMTP, POP3 and IMAP, and it can also be bridged using the IHE XDR and XDM profiles through an additional specification provided by the Direct Project.

E-mail clients make the mechanics of the exchange and what standards are being used to facilitate and secure that exchange completely transparent to the end user. An e-mail receiver need not know whether the transmitter integrated to the infrastructure through IMAP, SMTP or even the web or web services. The Direct Applicability Statement attempts to use the same infrastructure.

The challenge in testing such integration is that testing of the EHR without further specification provides a number of different options, which could be used appropriately in a variety of configurations.

1. Does the system appropriately connect to an SMTP MTA?
2. Does the system appropriately connect to an IMAP based MSA?
3. Does the system appropriately transmit using the IHE XDR profile?
4. Does the system appropriately receive from a POP3 based MSA?

Only one of these tests of the EHR in fact would be necessary to verify that that an appropriate SMTP + S/MIME communication as described in the applicability statement appears and is correctly structured, however all would rely on that capability being present. The SMTP + S/MIME infrastructure is ubiquitous, and many equivalents exist in the marketplace, some open source. There is little incentive for the suppliers of this infrastructure to validate or certify it for meaningful use, which leaves it to vendors to certify their products with specific infrastructure components. Deploying the product with another infrastructure component with equal capabilities would leave the end user in the unenviable position of using an uncertified solution, but testing with all of the alternatives is equally untenable for product certification.

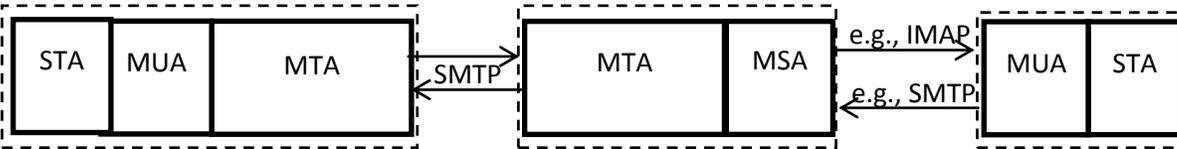
To support Direct, there are a number of alternative deployment models (as outlined on the Direct wiki at <http://wiki.Directproject.org/Deployment+Models>):

1. The EHR could implement SMTP and Certificate management capabilities, eliminating the need for a HISP.
2. The EHR could implement using one of the e-mail transmission standards (e.g., IMAP or SMTP), and leave certificate management to a third party HISP.
3. The EHR could implement using the NWHIN XDR interface, expecting to a HISP that supports the XDR to XDR/XDM Gateway capabilities.

This simplified architecture diagram illustrates two deployment variants for the Direct Applicability Statement:



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Any of these would meet the requirements and support the exchange of communications using the Direct Protocol. As presently stated, however, the proposed regulation is ambiguous, and it is not clear in the specification of the standards whether the EHR must support one or all of these options, or if it is restricted from implementing any one of them. Furthermore, it is unclear what must be tested or what the outcome would be for the end user with respect to certification if a component is changed.

We recommend that the standards and certification criteria be modified to make it clear that the EHR be capable of communicating as specified according to the Direct Applicability Statement with respect to the creation and receipt of messages; providing for the EHR to be tested to any one (or more) of the identified Deployment Models (<http://wiki.Directproject.org/Deployment+Models>); but that modules supporting e-mail infrastructure need NOT be subject to certification under the 2014 criteria. This approach will enable providers to utilize other e-mail infrastructures without requiring EHR vendors to test with multiple infrastructures.

Align the SOAP-based transport option with the XDR and XDM for Direct messaging:

The EHR Association suggests adding an implementation guide (IHE-XDR profile) to the standards criteria requirements for the Optional SOAP-based transport (Transport Requirements Traceability Matrix (RTM) version 1.0). This step will increase transport harmony by achieving two critical objectives:

- First, this approach ensures that directed SOAP-based transport can be bridged into the SMTP-based transport of the Direct Applicability Statement per the XDR and XDM for Direct messaging specification, thus giving full meaning to the reference of this standard.
- Second, this approach ensures compatibility with the Exchange Document Submission production specification (a subset of XDR) that is already deployed in production by the Social Security Administration, CMS, and others.

Increase the NPRM consistency by stating in § 170.202 Transport standards: (3)

Standard. Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 (incorporated by reference in § 170.299). Implementation Specifications. Integrating the Healthcare Enterprise – Cross-Enterprise Document Reliable Sharing profile (XDR), IHE IT Infrastructure Technical Framework (2011)

Clarify that the SOAP-based transport option can support query-based exchange:

It is too restrictive to limit the SOAP option to directed exchange, as implied by placing it under "§ 170.202(a). Directed exchange". A significant number of deployments are using SOAP-based

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record

transports not in a Directed Exchange transport Mode, but in a Query mode (NwHIN Exchange, Care Continuity Consortium, EHR/HIE, Interoperability Workgroup participants, etc.). We believe that this is an unintended limitation that should be removed for providers that have already deployed the more advanced access by query to transfer of care information. We suggest taking a more forward-looking approach by adding a new usage for the already-proposed SOAP-based transport in § 170.202 Transport standards by replacing (b) reserved by:

(a) Query based exchange. (1) Standard. Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 (incorporated by reference in § 170.299).

Question on opportunities for additional transport standards: *ONC states: "While we would only permit EHR technology to be certified to these two transport standards, we intend to monitor innovation around transport and would consider including additional transport standards, such as a RESTful implementation, in this certification criterion. The inclusion of additional standards in this certification criterion would permit EHR technology to be certified to added transport standard(s) and could ultimately enable EPs, EHs, and CAHs to meet MU using EHR technology certified with the added transport standard(s)."*

We have also reviewed a number of potential RESTful transport alternatives, including new work from HL7 (hData) and under development from IHE (mHealth for Documents). We have found that these specifications lack the testing and maturity necessary for use in the timeframe of the 2014 certification criteria.

§ 170.314(b)(4) - Clinical information reconciliation

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.

2014 Edition EHR Certification Criterion

Clinical information reconciliation. Enable a user to electronically reconcile the data elements that represent a patient's active medication, problem, and medication allergy list as follows.

For each list type:

- (i) Electronically display the data elements from two or more sources in a manner that allows a user to view the data elements and their attributes, which must include, at a minimum, the source and last modification date.
- (ii) Enable a user to merge and remove individual data elements.
- (iii) Enable a user to review and validate the accuracy of a final set of data elements and, upon a user's confirmation, automatically update the list.

Preamble FR Citation: 77 FR 13849

Specific questions in preamble? Yes

Public Comment Field:

Certification Issues:

We recommend a change in the wording from "display the data elements from two or more sources" to "display the data elements from at least two sources". This wording change will make it clear that the minimum number of sources is two and, though permissible, there is no requirement to display more than two.

We seek clarification on the statement "the last modification date of the information associated with those medications". Is this the last date of medication reconciliation or the date that the medication was added or updated? The CCDA only supports dates for certain concepts/events.

We also request clarification that not all required functions will occur in the reconciliation process, and that multiple screens are allowed for the reconciliation process for the certification testing script. . We realize this proposed criterion exceeds the functionality needed for the proposed meaningful use medication reconciliation objective and measure but understand and support the benefits of broader clinical reconciliation for interoperability.

We recommend that reconciliation testing use care summary documents that meet the certification requirements for such documents (i.e., properly formatted CCDA with applicable date elements.). Further, We recommend language in the final rule that specifies that any reconciliation from a CCDA received focus only on those items with standard structure that appear in reconciliation screens. For example, a document received as a CCDA must contain structured data for each medication appearing on the CCD. Where data elements are not in such a format, certification does not require appearance of an item on the reconciliation screen.

We recommend a change in the wording from "display the data elements from two or more sources" to "display the data elements from at least two sources". This wording change will make it clear that the minimum number of sources is two and, though permissible, there is no

requirement to display more than two.

We seek clarification on the statement "the last modification date of the information associated with those medications". Is this last date of medication reconciliation or the date that the medication was added or updated? The CCD A only supports dates for certain concepts/events.

§ 170.314(b)(5) - Incorporate laboratory tests and values/results

MU Objective

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

2014 Edition EHR Certification Criteria

Incorporate laboratory tests and values/results.

(i) Receive results.

(A) Ambulatory setting only.

(1) Electronically receive clinical laboratory tests and values/results formatted in accordance with the standard (and implementation specifications) specified at § 170.205(k) and, at a minimum, the version of the standard specified in § 170.207(g).

(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) Display test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(iii) Incorporate tests and values/results. Electronically incorporate a laboratory test and value/result with a laboratory order or patient record.

Standards and Implementation Specifications

§ 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm); and § 170.207(g) (LOINC version 2.38).

Preamble FR Citation: 77 FR 13849-50

Specific questions in preamble? Yes

Public Comment Field:

Certification Issues:

We support § 170.314(b)(5). The HL7 LRI specification cited has been through the S&I Framework process and is further being improved as it continues through the HL7 ballot process. This specification is, however, still actively a work in progress and has not been finalized; therefore, it is difficult to fully comment on its suitability for this requirement. That being said, we recognize that this specification is likely to be the most definitive and applicable for the use case of communicating outpatient-based lab results, so support its link to this certification criterion.

We agree with ONC that hospital labs should not have to meet the LRI specification at this time.

§ 170.314(b)(5) - Incorporate laboratory tests and values/results

We emphasize that the LRI specification contains a number of profiles that provide options for users. This approach was taken because the authors recognized that not all systems or users would or should be able to meet a single set of requirements. We recommend that the choice of which combinations of profiles is to be used should be left up to system developers or that a base combination of profiles be determined as recommended for certification, leaving the other possible combinations as optional.

We do not recommend that all combinations of profiles be required, particularly since this specification and approach is new and untested in real world applications.

In conclusion, we recognize that standards specifications (e.g., LRI) and vocabularies (e.g., LOINC) will go a long way toward improving interoperability while reducing costs and effort, and they can also potentially improve quality through consistent implementations. We are, therefore, supportive of this proposal. At the same time, it is important that all trading partners, and particularly the information source, follow the same specifications. We strongly encourage ONC to work with CMS through CLIA or some other mechanism to increase adoption from laboratory systems.

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

MU Objective

N/A

2014 Edition EHR Certification Criteria

(1) Clinical quality measures – capture and export.

- (i) Capture. Electronically record all of the data elements that are represented in the standard specified in § 170.204(c).
- (ii) Export. Electronically export a data file that includes all of the data elements that are represented in the standard specified in § 170.204(c).

(2) Clinical quality measures – incorporate and calculate.

1. Incorporate. Electronically incorporate all of the data elements necessary to calculate each of the clinical quality measures included in the EHR technology.
2. Calculate. Electronically calculate each clinical quality measure that is included in the EHR technology.

(3) Clinical quality measures – reporting. Enable a user to electronically create for transmission clinical quality measurement results in a data file defined by CMS.

Standard

§ 170.204(c) (NQF Quality Data Model).

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

Preamble FR Citation: 77 FR 13850-53

Specific questions in preamble? Yes

Public Comment Field:

ONC states, *"For both MU1 and MU2 EPs, starting in calendar year (CY) 2014, must use the 2014 version of ONC Certified EHR Technology (CEHRT), including the latest Clinical Quality Measures"*

Because of the challenges of moving large numbers of providers to 2014 Edition CEHRT in a compressed time period, we do not agree with the ONC proposal requiring use of the 2014 version of the CEHRT for providers still in MU1. We believe that providers who are in MU1 during 2014 should be able to use 2011 Edition CEHRT at their discretion, including the 2011 Edition CQMs, but with updated specifications if available for FY/CY 2014. Note also that in our comments to the CMS NPRM, we recommend retaining the number of measures that providers in MU1 must submit.

ONC also states the following in this section: *"By explicitly separating the certification of CQMs into these discrete criteria, we believe that user experiences relative to CQMs can be enhanced, the burden of capturing data elements necessary for CQMs can be reduced, and ultimately, EPs, EHS, and CAHs would be better positioned to assess in real-time the quality of care they provide."*

We agree that clarity around the required functions for CQMs is beneficial to both providers and vendors, and we appreciate the thoughtfulness that is evident in the proposed approach. We agree that supporting a model in which the computation of the measures can be separated from data capture for measurement allows greater flexibility for EHR technology development and may result in better choices for providers. We do not believe, however, that this approach reduces the burden of data capture. Neither will it better position providers for real-time quality assessment, as calculation remains critical to real-time assessment and is part of Base EHR functionality.

ONC also asks if Complete EHRs should be required to be able to perform data export functionality; we believe that this should not be a requirement for the reasons stated by ONC.

ONC states the following: *"The CQM lifecycle starts with the determination of data elements to be captured and the subsequent capture of clinical or demographic data. Thus, the first specific capability we propose for CQM certification (§ 170.314 (c)(1)(i)) focuses on the capability of EHR technology to electronically record all of the data elements that are represented in the QDM"* Related to the gap between the data defined by the QDM and the data captured in EHR technology we request comments regarding (1) industry readiness for the expansion of EHR technology data capture; (2) how this would impact system quality, usability, safety, and workflow; and (3) how long the industry believes it would take to close this gap.

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

Requesting Public Comment on whether EHR technology must be able to capture all of the data elements represented in the QDM, or only the data elements for those CQMs the EHR vendor believed its EHR technology would need to support."

We respectfully disagree that the CQM lifecycle starts with identifying what data elements must be captured. For the measure developer, this process starts with a consensus of what needs to be measured (based on priorities and identified measure gaps), research on whether there is evidence-based information relative to the measurement, and development of the measure concept and a narrative draft of the measure, as well as testing of the measure concept.

During the development of the CQM, there also needs to be an assessment and validation that required data elements can be efficiently and accurately gathered in the healthcare provider workflow, if at all possible using data elements that are already collected and stored in the EHR in the natural course of the care process. Some measure development requires the creation of new standard data types or formats which must be deployed and adopted prior to use in measurement.

We recommend that an assessment is done of the QDM standard and its applicability to represent the requirements of data capture and workflow in an EHR. In addition, ONC/NQF needs to perform a full assessment of the data elements and associated attributes that are required by the QDM today, as well as whether all of these are appropriate and required for CQM capture. We do not believe it is feasible that EHR technology be certified to capture all of the data elements represented in the QDM, and we recommend that certification only includes those data elements for CQMs that the EHR technology will (and should) support.

ONC states: "Related to either adding specific CQM data capture requirements to already existing certification criteria or adopt new certification criteria in order to explicitly require the data that is specified by the QDM to be captured, requesting public comment on whether this approach would be preferred, which certification criteria should be expanded, and where new certification criteria would be appropriate."

We agree that it would be most efficient to add specific CQM data capture requirements to existing certification criteria where applicable, and we urge ONC to ensure that these requirements are harmonized around similar data and value sets required in other objectives. At the same time, because not all vendors will support all CQMs, especially in the ambulatory space, we do not believe that all CQM-relevant data elements should be specified in certification criteria.

ONC states: "Request public comment regarding negation exclusion, EHR technology would not be required to capture the "reason" justification attribute of any data element in an encoded way but permit "reason" to allow for free text entries, specifically on the impact this flexibility would have on the accuracy of CQM reporting."

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

Although we support not using a required code set for exclusions, if an EHR vendor has already implemented this using a coded structure, we do not feel this should require the need to allow free text. We also urge ONC to work with CMS and the measure developers in defining a rational approach when considering the need for negation exclusion for any measure. Documenting the negation information for multiple clinical quality measures, regardless of whether via free text or coded entry, presents an extraordinary documentation and workflow burden on the providers.

ONC states: *"We believe that it is prudent to propose that EHR technology presented for certification not only be able to capture data for CQMs based on the QDM, but be able to export this data as it is represented in the QDM in the event that an EP, EH, or CAH chooses to use another certified Modular EHR to perform the calculation of CQM results."*

We support the "calculate and transmit" parts of this criterion. But the requirement to capture all data in the QDM and export it all according to the vocabularies in the QDM is a huge additional requirement beyond the rest of meaningful use data capture and information exchange requirements. Many of the elements are captured in unstructured formats or in structured formats not using the QDM vocabularies. Among the elements that are burdensome are: device (SNOMED), Experience, Family History, physical exam and risk evaluation (LOINC and SNOMED) and Care Goal (SNOMED).

Although the QDM is useful for some things (e.g., authoring measures), we do not believe it is appropriate for certification, either for data capture or for export.

For data capture, it is both too granular (in that it requires information that is often not practical to capture, such as that a patient declined allergies, or a patient's preference in regards to system resources) and too broad (an example being "system resources" such as nursing ratios, power outages, availability of durable medical equipment, invasive-procedure capabilities) that are grouped together. This proposed use of the QDM reflects the misconception that if you could capture one of those elements, you could capture all of them, and that the information about each one would be the same, and it disregards the point that it is likely that few of these would be in the EHR).

For export, because the QDM is so detailed, we feel it would inflate an export file with information of minimal importance that could potentially introduce errors, as the most critical information of interest (e.g., a shortage of nurses in a particular unit that night) is lost in the effort to format disparate things in a common table with the same attributes.

The QDM is based around a vision that if the EHR could just capture something – say a system resource – with the right attributes, then additional system resources could be documented in the same fashion and reported on in the same fashion without need for new EHR development. This makes sense for things like allergies – if you can capture an allergy to aspirin you can likely capture an allergy to any other drug in the same fashion. But for the more broad categories (characteristics, for example, or health record artifacts), it is not practical, and it would not meet

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

user requirements for usability.

Finally, and of great importance, we recommend that one of the alternatives identified by ONC be adopted instead of a requirement for 100% data capture of the QDM. We suggest either the constrained QDM as described by ONC based on the final CQMs chosen or a focus on only those data elements required for selected quality measures are the most promising.

ONC states: *"We request comment on whether any standards (e.g., QRDA category 1 or 2, or Consolidated CDA) would be adequate for CQM data export as well as whether Complete EHRs (that by definition would include calculation and reporting capabilities) should be required to be capable of data export."*

We agree with ONC's belief that there is no widely adopted standard to export captured CQM data. We urge ONC and CMS to harmonize on one standard for all quality measure data submission. Until a standard is defined and readily available, we feel that certification of any standard for CQM data export should be considered optional.

Although we recognize that a number of organizations, including CMS, are considering QRDA Category I for this standard, we believe this approach is problematic for a number of reasons:

- It is explicitly tied to the measure specifications. This linkage creates an ongoing need to update the EHR filtering and format logic with each release of measure specifications, perpetuating the very dependency ONC is trying to eliminate.
- Requiring a separate export format and process purely to support clinical quality measurement is an extra step in the healthcare process with little added value. It increases maintenance costs and represents an additional potential point of failure.
- As discussed in other comments, many EHRs are, in fact, highly modularized, particularly in the inpatient setting. It is rare for a single module to include all the data for a complete QRDA1 record.
- Finally, one of the stated goals for MU2 of the EHR incentive program is support for continuous quality improvement. This requires more than numerator, denominator and exclusion data. It requires a robust set of demographics and clinical documentation that is consistent across the entire patient population to support the evaluation not just of which patients met or failed a measure, but why they did so. The QRDA1 format is too narrow in focus to support such analytics.

We encourage investigation during MU2 to determine the feasibility of using the Consolidated CDA summary of care record or other applicable standard to support the required export.

ONC requests public comment, especially from measure stewards and EHR technology developers, on the best way for CQM test data sets to be developed.

We are encouraged by the stated intention to provide a testing mechanism to verify the

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

accuracy of measure calculations. Given the immaturity of eMeasurement specifications and the lack of robust implementation guidelines, it has been challenging to verify measures for MU1. We note, however, that this situation also creates challenges for any testing approach. If a measure result produced by an EHR differs from the "expected" result, the fault is just as likely to be in the specification or implementation guide as in the EHR software. This implies that there will need to be a "soft" introduction of any new testing mechanism, with a grace period to allow resolution of errors in specifications, implementation guides, testing tools and software.

We are also concerned that there is, at present, no public mechanism for testing any of the inpatient measures. The Cypress project work being done by MITRE represents a promising direction, but does not address the data requirements and calculations of the inpatient measures. In addition, we do not feel that in its current state, the Cypress project represents an accurate depiction of quality measure accuracy.

We urge ONC to consider a more straightforward method of developing CQM test data sets. ONC should provide sample test data set(s) as well as testing examples and an implementation guide as early as possible that can be used by vendors in order to validate their implementation of each quality measures. We urge ONC to refer to the HIMSS eMeasures recommendations sent to HHS in January 2012, which recommend that both controlled testing and field testing of the eMeasure specification should be part of the measure development and endorsement process. Controlled testing of the eMeasure specification should ensure the feasibility, validity and accuracy of each eMeasure when implemented in an EHR. The eMeasure testing process should also include a testing site with a set of sample data, testing examples and an implementation guide that can be used by vendors during their implementation and testing.

Field testing of the eMeasure specification should be done in order to validate at least the following:

- The eMeasures specifications are accurate, with the correct clinical category defined and mapped to the correct vocabulary standards (taxonomy) and codes, along with the correct attributes and state(s).
- The eMeasures are tested for validity and reliability against the measures intent.
- Required data elements can be efficiently and accurately gathered in the healthcare provider workflow, if at all possible using data elements that are already collected as a byproduct of the care process and stored in the EHR.
- CQM reports based on eMeasures accurately reflect the care given by the applicable healthcare provider(s).

ONC states: *"Clinical quality measures – reporting. Enable a user to electronically create for transmission clinical quality measurement results in a data file defined by CMS. Proposes a CMS-defined XML data file of measurement results for transmission."*

We support the proposed reporting approach, and we endorse a consolidated approach to reporting across multiple programs, specifically the PQRS and ACO programs. We are concerned

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

about the additional burden on EHR vendors of dual certification/qualification for participation in both PQRS and the EHR incentive program, and we point out the mismatched application timelines, which is a point of confusion for providers. Thus, we encourage CMS and ONC to work together on some form of joint certification that would remove this additional burden which represents a significant barrier to program entry.

ONC states: *"We request public comment regarding how certification can accommodate specialty EHR technology developers so that they would not have to take on development work (solely to get certified) for functionality that their customers may not require."*

We propose that EHR technology vendors should only be required to certify the quality measures that are applicable to their users.

ONC requests comments on *"changes to measure specifications and impact to certification."*

If there are cases when there are changes to the quality measure specifications, we recommend that only new certifications of EHRs are required to certify on the revised specifications and with a minimum of six months lead time. EHRs that are already certified to the existing measure specifications should not have to recertify whether they update to the new specifications or not. An example of such frequent updates can be found on Quality Net, which frequently updates measure specifications.

§ 170.314(d)(2) - Auditable events and tamper-resistance; and (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.

2014 Edition EHR Certification Criteria

(d)(2) Auditable events and tamper-resistance.

- (i) Enabled by default. The capability specified in paragraph (d)(2)(ii) must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users.
- (ii) Record actions. Record actions related to electronic health information and audit log status in accordance with the standard specified in § 170.210(e).
- (iii) Audit log protection. Actions recorded in accordance with paragraph (d)(3)(ii) must not be capable of being changed, overwritten, or deleted.
- (iv) Detection. Detect the alteration of audit logs.

(d)(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 elements specified in the standard at § 170.210(e).

§ 170.314(d)(2) - Auditable events and tamper-resistance; and (d)(3) - Audit report(s)

Standards

§ 170.210(e) Record actions related to electronic health information, audit log status, and encryption of end-user devices.

- (1)** When EHR technology is used to record, create, change, access, or delete electronic health information, the following information must be recorded:
 - (i) The electronic health information affected by the action(s);
 - (ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g);
 - (iii) The actions(s) that occurred;
 - (iv) Patient identification; and
 - (v) User identification.
- (2)** When the audit log is enabled or disabled, the following must be recorded:
 - (i) The date and time each action occurs in accordance with the standard specified at § 170.210(g); and
 - (ii) User identification.
- (3)** As applicable, when encryption of electronic health information managed by EHR technology on end-user devices is enabled or disabled, the following must be recorded:
 - (i)** The date and time in accordance with the standard specified at § 170.210(g); and
 - (ii)** User identification.

Preamble FR Citation: 77 FR 13853-54

Specific questions in preamble? *No*

Public Comment Field:

We agree that knowing the context of a user's create, read, update or delete actions is important information for a security audit and support its inclusion as a certification criterion. For example, it is important to audit that a user accesses a patient's medication list. However, we are concerned that (e)(1)(i) may be interpreted to require granular auditing, for example, of which medications in the medication list were viewed by the user. Requiring this type of very granular auditing may introduce a burden on EHR adopters because of the amount of disk space required to store these audit logs. It may also adversely affect system performance and place undue burden on security auditors who may not be able to find the information they need. Therefore, we ask HHS to clarify the granularity of information that must be logged to satisfy (e)(1)(i).

In addition, if protected health information (PHI, such as the medications that are in the patient's medication list) is included in an audit log, we are concerned this violates separation of duties and the minimum necessary requirements under HIPAA, as security auditors typically do not need this information to perform an audit. Although we agree that EHR technology should track the changes made to a clinical record, such as modifications made to the medication list, we do not feel the security audit log is the appropriate place to store this information. Instead, we encourage HHS to adopt a "medical record history and completeness" objective that is not

§ 170.314(d)(2) - Auditable events and tamper-resistance; and (d)(3) - Audit report(s)

related to the security auditing objective.

Also, we would like to clarify that we view (d)(2)(ii) and (e) to apply to actions performed through the EHR. For example, if an authorized user views PHI on disk or through the database, we hold that this is beyond what can be reasonably expected to be logged in the EHR's audit logs. Similarly, if a user disables auditing functionality outside of the EHR, such as turning off the auditing service through the operating system (similar to Task Manager in a Windows environment), these actions would be unreasonable to log in the EHR audit logs.

We seek to clarify that the "enabled by default" certification criteria does not preclude one-time configuration of the audit log at installation (e.g., to select the location to store the audit logs). We suggest the language be updated to read, "When certified EHR technology is installed and configured according to vendor specifications, the capability specified by paragraph (d)(2)(ii) must be..."

The goal of (d)(2)(iii) is to provide separation of duties, so that a user who is able to access or make changes to PHI is not also able to modify the audit log to remove traces of suspicious activity. We applaud this goal. However, we seek clarity on the extent to which EHR technology is responsible for preventing changes, overwrites or deletions to the audit log. For example, if the EHR technology writes audit logs to a file or to a database, it is outside the control of an EHR vendor to prevent authorized users from modifying files in the operating system or modifying tables in the database. We suggest that this criterion be reworded to state that the audit log should not be able to be changed, overwritten or deleted through the EHR application.

We ask clarification on the interplay of (d)(2)(iii) and (d)(2)(iv). If audit logs are not capable of being modified through the EHR, to what extent do changes need to be detected?

We also point out that many systems do not allow disabling of audit logs if it does not suit their customer base or technologies. We recommend a change to the wording, "*If the system provides the capability of disabling the logging...*" then, "*The ability to enable and disable the recording of actions be limited to an identified set of users...*"; and "*When the audit log is enabled or disabled, the date and time (in accordance with the standard specified at § 170.210(g) (synchronized clocks), user identification, and the action(s) that occurred must be recorded. "*

§ 170.314(d)(7) - Encryption of data at rest

MU Objective

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

2014 Edition EHR Certification Criterion

Encryption of data at rest. Paragraph (d)(7)(i) or (d)(7)(ii) must be met to satisfy this certification criterion.

- (i) If EHR technology manages electronic health information on an end-user device and the electronic health information remains stored on the device after use of the EHR technology on that device has stopped, the electronic health information must be encrypted in accordance with the standard specified in § 170.210(a)(1). This capability must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users.
- (ii) Electronic health information managed by EHR technology never remains stored on end-user devices after use of the EHR technology on those devices has stopped.

Preamble FR Citation: 77 FR 13854-55

Specific questions in preamble? *No*

Public Comment Field:

We applaud inclusion of this certification criterion. Lost end-user devices represent a significant data breach risk to covered entities. We applaud the decision to allow the option to either encrypt end user devices or make sure no data remains on end user devices (managed by the technology).

We do, however, seek clarity on when electronic health information is “managed” by the EHR. Operating systems and other technology on the end-user device may cache PHI and retain it outside of the EHR technology. For example, swap files, sleep and hibernate features of laptops, and application context switching in Windows 8 Metro applications or iOS, may all cause electronic health information in memory to be cached to disk. We believe it is unreasonable to expect EHR technology to control how operating systems perform memory management and consider this information to not be managed by the EHR or subject to EHR encryption. Likewise, we consider information that has been sent to a print queue or exported by the user into a report (such as downloading a PDF report) to no longer be managed by the EHR.

We ask ONC to consider the certification test steps that will be required for (d)(7)(ii). We feel it is difficult to test that an EHR never leaves electronic health information on an end-user device when it terminated in the prescribed or non-prescribed manner, and we encourage HHS to consider attestation for the test procedure.

§ 170.314(f)(1) - Immunization information; and (f)(2) - Transmission to immunization registries

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.

2014 Edition EHR Certification Criteria

§ 170.314(f)(1) - Immunization information; and (f)(2) - Transmission to immunization registries

(f)(1) Immunization information. Enable a user to electronically record, change, and access immunization information.

(f)(2) Transmission to immunization registries. Enable a user to electronically create immunization information for electronic transmission in accordance with:

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

Standards and Implementation Specifications

§ 170.205(e)(3) (HL7 2.5.1 and Implementation Guide for Immunization Messaging Release 1.3); and § 170.207(i) (CVX code set: August 15, 2011 version).

Preamble FR Citation: 77 FR 13855

Specific questions in preamble? *No*

Public Comment Field:

We believe that ONC should be clear that alternative submission methods can be used for an EHR system to meet the purpose of the objective. For example, it may be possible for an EHR system to utilize the capabilities of an HIE to report immunization data in the HL7 format after it is extracted from a CCDAs provided by the EHR system.

We believe that CMS is clear that an HIE can be used to transport, or transform and transport, the data. It would be helpful if ONC confirms that, "If the HIE does the data transformation from "non-standard" format to standard format, then the HIE module should be certified and the provider should be able to claim that as part of their Certified EHR portfolio".

It is important to note that while the standardization of these reports for EHR technology certification is in general a good thing, variances at the local level (e.g., additional requirements or proprietary specifications) in the content and transmission specifications continues to cause challenges and incur costs associated with adoption of immunization reporting. These challenges are further exacerbated by the fact that there are no standard specifications for the transmission of immunization reports. We recommend that the ONC work with the CDC to identify ways to improve the adoption of the CDC implementation guides (content and transmission specifications) by the state immunization registries. See <http://www.cdc.gov/vaccines/programs/iis/enhance-projects.htm>.

Additionally, we have concerns about the meaning of the language regarding reporting immunizations after receipt of a CCDAs. It should be the responsibility of the EHR sending the CCDAs to report the original immunization information. Requiring EHRs to report immunizations not administered within the context of the EHR may lead to duplicate results and additional reconciliation at state levels.

There should be no requirement to report immunizations provided elsewhere in the

§ 170.314(f)(1) - Immunization information; and (f)(2) - Transmission to immunization registries

immunization message. In the EHR incentive NPRM from CMS, it states, "In order to achieve improved population health, providers who administer immunizations must share that data electronically, to avoid missed opportunities or duplicative vaccinations". This statement would be consistent with our viewpoint noted above.

§ 170.314(f)(3) - Public health surveillance; and (f)(4) - Transmission to public health agencies

MU Objective

Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.

2014 Edition EHR Certification Criteria

(f)(3) Public health surveillance. Enable a user to electronically record, change, and access syndrome-based public health surveillance information.

(f)(4) Transmission to public health agencies. Enable a user to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

(i) Ambulatory setting only.

(A) The standard specified in § 170.205(d)(2).

(B) Optional. The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

(ii) Inpatient setting only. The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

Standards and Implementation Specifications

§ 170.205(d)(2) (HL7 2.5.1) and § 170.205(d)(3) (HL7 2.5.1 and the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data HL7 Version 2.5.1)

Preamble FR Citation: 77 FR 13855-56

Specific questions in preamble? *No*

Public Comment Field:

We support the proposed selection of HL7 2.5.1, but addition of the Messaging Guide will require further evaluation.

§ 170.314(g)(2) - Automated measure calculation

MU Objective

N/A

2014 Edition EHR Certification Criterion

§ 170.314(g)(2) - Automated measure calculation

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: 77 FR 13856

Specific questions in preamble? *No*

Public Comment Field:

We understand that vendors will be expected to demonstrate each measure calculation on the report and are concerned about the extended time that could be required in set up and testing of this criterion to validate such accuracy.

We request clarification on the process that will be used in testing to determine the accuracy of numerators and denominators. There are many challenges with the current MITRE tool being tested for this purpose, and these should be addressed if this approach is what is expected to be used for certification. In addition, we oppose vendors only being given a set of CCDAs for import to be used for verification of the accuracy of measure calculations and believe that ACBs should offer multiple ways for vendors to import test data if such data are used to verify measure calculations. As EHRs are generally not set up to import all pertinent elements of a CCD or CCDa, the data import process could itself introduce measurement inaccuracies to the test process.

Reporting Issues:

Relative to the applicable criteria expected to be included in this report, we have noted throughout our comments, reporting issues that apply to specific certification criteria and meaningful use measures. . We request clarification to improve the accuracy of the reporting process.

b. Ambulatory Setting

§ 170.314(b)(3) - Electronic prescribing [*Note: this is a revised certification criterion for the ambulatory setting and why this table appears twice, see page 7*]

MU Objective

Generate and transmit permissible prescriptions electronically (eRx).

2014 Edition EHR Certification Criterion

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(h).

Standards

§ 170.314(b)(3) - Electronic prescribing [Note: this is a revised certification criterion for the ambulatory setting and why this table appears twice, see page 7]

§ 170.205(b)(2) (NCPDP SCRIPT version 10.6) and § 170.207(h)(RxNorm February 6, 2012 Release)

Preamble FR Citation: 77 FR 13856

Specific questions in preamble? No

Public Comment Field:

Certification Issues:

We support use of NCPDP 10.6 and believe that a valid Surescripts certification for NCPDP 10.6 should be sufficient to meet the criterion without any additional certification requirements. We also agree with the adoption of RxNorm as the standard vocabulary instead of any source vocabulary. It is important to note, however, that not all medications in the source vocabularies have an equivalent RxNorm code. The requirement should state that the RxNorm vocabulary will be utilized when there is an equivalent concept mapping to the prescribed drug. Use of the RxNorm vocabulary will improve interoperability among systems and will remove the need for receiving systems to understand all source vocabularies in order to successfully process the data.

Reporting Issues:

We have continuing concerns regarding how vendors report on exclusion criteria for paper prescriptions. We also believe that reporting accuracy for drug formulary as a part of ePrescribing will be difficult to determine and suggest that attestation suffice for reporting. Requesting an update to RxNorm, as opposed to a formulary supporting RxNorm, can be complicated for providers to update. Customers are obligated to use the standard certified in their system, thus their formulary names are listed in RxNorm. This process can also become complicated because the old values for RxNorm versions must be stored for historical storage for reporting on CQM.

§ 170.314(e)(2) - Clinical summaries

MU Objective

Provide clinical summaries for patients for each office visit.

2014 Edition EHR Certification Criterion

Ambulatory setting only – clinical summaries. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, the following data elements: provider's name and office contact information; date and location of visit; reason for visit; patient's name; gender; race; ethnicity; date of birth; preferred language; smoking status; vital signs and any updates; problem list and any updates; medication list and any updates; medication allergy list and any updates; immunizations and/or medications administered during the visit; procedures performed during the visit; laboratory tests and values/results, including any tests and values/results pending; clinical instructions; care plan, including goals and instructions; recommended patient decision aids (if applicable to the visit); future scheduled tests; future

§ 170.314(e)(2) - Clinical summaries

appointments; and referrals to other providers. If the clinical summary is provided electronically, it must be:

- (i) Provided in human readable format; and
- (ii) Provided in a summary care record formatted according to the standard adopted at § 170.205(a)(3) with the following data elements expressed, where applicable, according to the specified standard(s):
 - (A) Race and ethnicity. The standard specified in § 170.207(f);
 - (B) Preferred language. The standard specified in § 170.207(j);
 - (C) Smoking status. The standard specified in § 170.207(l);
 - (D) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);
 - (E) Encounter diagnoses. The standard specified in § 170.207(m);
 - (F) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);
 - (G) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);
 - (H) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed; and
 - (I) Medications. At a minimum, the version of the standard specified in § 170.207(h).

Standards

§ 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT[®] International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release).

Preamble FR Citation: 77 FR 13856-57

Specific questions in preamble? Yes

Public Comment Field:

Certification Issues:

We request a definition for "patient decision aids" and "clinical instructions" for inclusion in the summary. Are these not the same as "care plan," which includes instructions?

We also suggest wording the criterion to reflect "current" as the status, as opposed to "current problem list, medication list, medication allergy list and any updates". Is this latter proposed wording intended to imply that the EHR must show the changes specific to this visit? We suggest including *only* the lists inclusive in the EHR at the end of the visit. We do not expect to show any highlighted difference between the previous and current visits.

We also request a clear definition of "pending" lab test results. Are these preliminary, yet to be released, or simply orders sent out? These will be difficult to differentiate for inclusion, as well. We assume the summary only includes tests ordered in this visit, and we do not expect all results in the record to be available in the clinical summary. We expect the provider to define

§ 170.314(e)(2) - Clinical summaries

the care team provider and members so the EHR certification criterion enables the provider to input this information. If additional info is required for certification, please specify.

We also have concerns with inclusion of future appointments and future referrals, as these could be a part of scheduling system and not readily available to the EHR to include in summary. This gap could require certification of additional applications, which is not desirable.. We also request that you consider workflow relative to these proposed criteria, as appointments may be scheduled *after* the patient is given a clinical summary so would not be available at the time the provider produces the summary for the patient. Finally, we support the position that all vocabulary standards apply universally to all documents.

CCDA is an implementation guide for nine different document types. We request more specificity as to what aspects of the CCDA are required for this criterion.

We recommend that the certification requirement be that the vendor should demonstrate the ability to generate at least one of the available CCDA document types and that providers will be able to use the document type most appropriate to the clinical situation.

In our comments on § 170.314(b)(1), we make several recommendations about how to express the definition of Summary Care Record more clearly and propose that those suggestions be applied to this criterion, as well, and other criteria as applicable that reference such summaries.

To the Incentive Rule, replace the text describing a Summary Care Record in the preface with:

- All summary of care documents used to meet this objective must meet the definition in §170.208(a).
- And add the following definition at 495.4:
- Summary Care Record
- A document containing the data elements found in §170.208(a) and formatted according to the standards at § 170.208(b) when exchanged electronically.

§ 170.207(h) - We also agree with the adoption of RxNorm as the standard vocabulary instead of any source vocabulary. It is important to note, however, that not all medications in the source vocabularies have an equivalent RxNorm code. The requirement should state that the RxNorm vocabulary will be utilized when there is an equivalent concept mapping. Use of the RxNorm vocabulary will more readily improve interoperability among systems and will remove the need for receiving systems to understand all source vocabularies in order to do successfully process the data.

c. Inpatient Setting

§ 170.314(f)(5) - Reportable laboratory tests and values/results; and (f)(6) -

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.

2014 Edition EHR Certification Criteria

(f)(5) Inpatient setting only – reportable laboratory tests and values/results. Enable a user to electronically record, change, and access reportable clinical laboratory tests and values/results.

(f)(6) Inpatient setting only – transmission of reportable laboratory tests and values/results. Enable a user 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); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and § 170.207(g).

Standards and Implementation Specifications

§ 170.205(g) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with errata); § 170.207(a)(3) (SNOMED CT[®] International Release January 2012); and § 170.207(g) (LOINC version 2.38).

Preamble FR Citation: 77 FR 13857

Specific questions in preamble? *No*

Public Comment Field:

We believe that this criterion represents a lab function and not an EHR function, and we request that it be deleted. Reportable results should be determined by the local, state requirements for the lab and not be deemed the responsibility of the EHR to determine.

Unchanged Certification Criteria

a. Refinements to Unchanged Certification Criteria

§ 170.314(a)(1) - Computerized provider order entry

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.

2014 Edition EHR Certification Criterion

Computerized provider order entry. Enable a user to electronically record, change, and access the following order types, at a minimum:

(i) Medications;

§ 170.314(a)(1) - Computerized provider order entry

- (ii) Laboratory; and
- (iii) Radiology/imaging.

Preamble FR Citation: 77 FR 13858

Specific questions in preamble? *No*

Public Comment Field:

Certification Issues: We assume no recertification for the CPOE function as listed as unchanged criterion, but we do note that the meaningful use reports will need to be updated to reflect the additional categories of orders to be addressed in the report for meaningful use statistics.

§ 170.314(a)(4) - 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.

2014 Edition EHR Certification Criterion

Vital signs, body mass index, and growth charts.

- (i) Vital signs. Enable a user to electronically record and change, and access recordings of a patient's vital signs including, at a minimum, height/length, weight, and blood pressure.
- (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: 77 FR 13858

Specific questions in preamble? *No*

Public Comment Field:

Certification Issues:

We generally agree with this criterion.

If an EHR vendor does not sell product to clients requiring growth charts, we understand this is optional for certification and that meaningful use attestation does not require any documentation for growth charts. If an EHR vendor chooses not to implement growth charts, we request guidance as to how this omission from certification can be indicated from a vendor marketing perspective?

§ 170.314(a)(11) - Smoking status

MU Objective

§ 170.314(a)(11) - Smoking status

Record smoking status for patients 13 years old or older.

2014 Edition EHR Certification Criterion

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(l).

Standard

§ 170.207(l) (smoking status types)

Preamble FR Citation: 77 FR 13858

Specific questions in preamble? *No*

Public Comment Field:

Certification Issues:

What should be shown in the certification test if the EHR maps to these specified standards from alternate categories presented to users? The certification criteria should be more explicit to this ability to use additional terms if this option is acceptable. Vendors are currently compelled to make literal interpretations of standard terms to pass certification. If an option, does mapping apply only to cigarettes or other forms of tobacco as well? We note that the smoking status types, now identified as standards, do not specify what types of tobacco are smoked or otherwise used, although this issue was addressed in the MU1 Final Rule. We ask that ONC be explicit on the definition of this standard.

We are unsure if EHRs will be required to capture other tobacco uses to satisfy tobacco-related CQMs. If so, we request information on specific data elements and value sets that must be incorporated to satisfy the CQM requirements related to tobacco use and that, as possible, these be harmonized with this certification criterion.

§ 170.314(a)(15) - Patient reminders

MU Objective

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

2014 Edition EHR Certification Criterion

Ambulatory setting only – patient reminders. Enable a user to electronically create a patient reminder list for preventive or follow-up care according to patient preferences based on, at a minimum, the data elements included in:

- (i) Problem list;
- (ii) Medication list;
- (iii) Medication allergy list;
- (iv) Demographics; and
- (v) Laboratory tests and values/results.

Preamble FR Citation: 77 FR 13858

Specific questions in preamble? *No*

§ 170.314(a)(15) - Patient reminders

Public Comment Field:

We agree that this criterion should remain unchanged.

§ 170.314(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.

2014 Edition EHR Certification Criterion

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 (d)(1)(i), and the actions the user is permitted to perform with the EHR technology.

Preamble FR Citation: 77 FR 13858-59

Specific questions in preamble? *No*

Public Comment Field:

We agree that this criterion should remain unchanged.

170.314(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.

2014 Edition EHR Certification Criterion

Automatic log-off. Terminate an electronic session after a predetermined time of inactivity.

Preamble FR Citation: 77 FR 13859

Specific questions in preamble? *No*

Public Comment Field:

We agree that this criterion should remain unchanged.

§ 170.314(d)(6) - Emergency access

MU Objective

Protect electronic health information created or maintained by the Certified EHR Technology

§ 170.314(d)(6) - Emergency access

through the implementation of appropriate technical capabilities.

2014 Edition EHR Certification Criterion

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

Preamble FR Citation: 77 FR 13859

Specific questions in preamble? *No*

Public Comment Field:

We agree that this criterion should remain unchanged.

§ 170.314(d)(8) – Integrity

MU Objective

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

2014 Edition EHR Certification Criterion

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.

Standard

§ 170.210(c) (verification that electronic health information has not been altered)

Preamble FR Citation: 77 FR 13859

Specific questions in preamble? *Yes*

Public Comment Field:

We agree that this criterion should remain unchanged.

b. Unchanged Certification Criteria Without Refinements

§ 170.314(a)(10) - Drug-formulary checks

MU Objective

Implement drug-formulary checks.

2014 Edition EHR Certification Criterion

Drug-formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list.

Preamble FR Citation: 77 FR 13859

Specific questions in preamble? *No*

§ 170.314(a)(10) - Drug-formulary checks

Public Comment Field:

Reporting Issues:

We suggest simple attestation for the use of formularies by providers or, potentially, Surescripts certification for certification. We have concerns with the statement in the NPRM, which indicates that, if no formulary is available, the check still counts. We request clarification as to how this unavailability will be "known" by the EHR, beyond attestation to the use of formularies. Also, what is meant by "generic formulary"? Formulary maintenance is very important and difficult.

§ 170.314(a)(6) - Medication list

MU Objective

Maintain active medication list.

2014 Edition EHR Certification Criterion

Medication list. Enable a user to electronically record, change, and access a patient's active medication list as well as medication history for longitudinal care.

Preamble FR Citation: 77 FR 13859

Specific questions in preamble? *No*

Public Comment Field:

We support the definition of "longitudinal care" offered in the proposed rule. In addition, however, additional meanings of "longitudinal care" should be allowed, and the definition should be stated as a minimum, not a maximum.

§ 170.314(a)(7) - Medication allergy list

MU Objective

Maintain active medication allergy list.

2014 Edition EHR Certification Criterion

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 for longitudinal care.

Preamble FR Citation: 77 FR 13859

Specific questions in preamble? *No*

Public Comment Field:

Certification Issues: We support the definition of "longitudinal care" offered in the proposed rule. In addition, however, additional meanings of longitudinal care should be allowed, and the definition should be stated as a minimum, not a maximum.

No allergy standard vocabulary is indicated in the NPRM, nor are severity and reaction

§ 170.314(a)(7) - Medication allergy list

vocabularies specified. Will these be addressed through CCDA requirements for vocabulary? We believe that such vocabularies, if required, should be separately specified by regulation.

§ 170.314(a)(14) - Patient Lists

MU Objective

Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

2014 Edition EHR Certification Criterion

Patient lists. Enable a user to electronically select, sort, access, and create lists of patients according to, at a minimum, the data elements included in:

- (i) Problem list;
- (ii) Medication list;
- (iii) Demographics; and
- (iv) Laboratory tests and values/results.

Preamble FR Citation: 77 FR 13859

Specific questions in preamble? *No*

Public Comment Field:

We agree that the criteria should remain unchanged.

§ 170.314(d)(9) - Accounting of disclosures

MU Objective

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

2014 Edition EHR Certification Criterion

Optional – 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: 77 FR 13859, 13871-72

Specific questions in preamble? *Yes*

Public Comment Field:

We agree that this criterion should remain optional.

§ 170.314(a)(18) - Advance Directives

MU Objective

§ 170.314(a)(18) - Advance Directives

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

2014 Edition EHR Certification Criterion

Inpatient setting only – advance directives. Enable a user to electronically record whether a patient has an advance directive.

Preamble FR Citation: 77 FR 13860

Specific questions in preamble? *No*

Public Comment Field:

We suggest clarification that "yes" or "no" responses are considered "structured" data.

Topic/Section: Patient Safety Events (FR 77 p. 13843)

ONC states that it is considering adopting a certification criterion (as mandatory or optional) that would require EHR technology to enable a user to generate a file in accordance with the data required by the Agency for Healthcare Research and Quality (AHRQ) Common Format, including the "Device or Medical/Surgical Supply, including HIT v1.1a." The Common Formats are designed to capture information about patient safety events. ONC states that, in line with IOM's recommendations, it believes that requiring this capability for certification could be a first step in creating the infrastructure that would support the reporting of potential adverse events involving EHR technology to patient safety organizations (PSOs). ONC requests public comment on whether it should adopt such a certification criterion and what, if any, challenges EHR technology developers would encounter in implementing this capability.

EHR Association Comment:

The EHR Association is a strong supporter of provider reporting of patient safety events, including health IT associated events, through PSOs. Although it is technically feasible to include a reporting tool in EHRs that could be used to collect and transmit information on potential health IT related patient safety conditions, there are a number of problematic technical and policy issues that surround such reporting in general and more specifically, via EHR-collected data. As a result, we do not believe that ONC should adopt such a certification criterion.

First, it is our understanding that many PSOs have their own web-based reporting interfaces, so it seems both duplicative and sub-optimal to require EHRs to add detailed event capture and reporting to EHRs when superior alternatives exist. Vendors are already being asked to add new or revised functionality under extremely short timelines in this scenario, too, so again, the duplication seems unnecessary.

In addition, many patient safety events and near misses manifest themselves only downstream from the EHR activity associated with that event -- e.g., a physician-generated order creates a potential safety event, but it is not discovered until two hours later when hospital staff executes that order. In such cases, there would be nothing that the EHR could capture either at the time of CPOE or at the time the safety event was observed. We therefore caution that the

assumption underlying the proposal for the EHR to capture the context of the potential patient safety event at the time of the related system activity would not be a valid assumption.

Moreover, the current version of the AHRQ Common Format includes information that may be beyond the capability of the end user to understand. Collaborative work should be done to refine this data collection tool to assure capture of information appropriate to the context of the individual reporting. We also ask that ONC clarify its intention that this tool will be used to collect all data in the Common Format and not just those data elements contained in the EHR.

Most events would likely be reported using narrative text, which would require in-depth analysis and follow-up to determine if there was an actual incident and the details necessary to appropriately categorize that incident, report to a PSO and the vendor as applicable, and perform a root cause analysis.

We also have identified several questions that ONC should address as it evaluates comments on this proposal. Who would be the intended recipient of these reports? If it is the involved healthcare organization, what if they do not have patient safety resources or processes to evaluate the report/mitigate any issues, such as is typically the case in small practices? If a PSO is to receive reports, what if the practice/organization does not belong to a PSO?

In addition, who would be expected to filter these reports to reduce the "noise" that could potentially occur? If the practice/organization does not screen these prior to being reported to a vendor/PSO, there may be impractical volumes of material to review that could be largely unrelated to health IT but initially labeled as the proximate cause of the problem. Many issues are specific to the situation and might be related to training deficits, hardware problems, issues with the physical layout, misuse of the system and other factors beyond EHR functionality.

We also believe that it is important to understand the expected and desirable circumstances where users report both to the PSO and the vendor, and where they might compromise their legal protections under the PSO's enabling statute, the Patient Safety Act. The EHR Association has been told that the Office for Civil Rights (OCR) is currently reviewing this issue, but it needs to be resolved prior to Final Rule publication in order to avoid a potential conflict of regulations. For this model to be successful, we must ensure that a focus on PSO-based reporting of health IT-associated safety events can also ensure rapid and widespread reporting of any such issues to the involved vendor(s) while also mitigating applicable legal protection associated with PSO reporting.

Topic/Section: Quality Systems (FR 77 p. 13843)

ONC states that it is considering inclusion in the Final Rule of an additional certification criterion that would require EHR technology developers to document how their EHR technology development processes either align with or deviate from the quality management principles and processes that would be expressed in a health IT-focused quality management system document to be developed by ONC. ONC emphasizes that this certification criterion would not require EHR technology developers to comply with all of the ONC quality management principles and processes in order to be certified. Rather, to satisfy the certification criterion, EHR technology

developers would need to review their current processes and document how they do or do not meet principles and processes specified in the document (and where they do not, what alternative processes they use, if any). ONC states its expectation that this documentation would be submitted as part of testing and would become a component of the publicly available testing results on which a certification is based.

EHR Association Comment:

The EHR Association supports the concept of vendors having quality system processes in place and the general approach proposed of describing that nature of each company's quality processes. We also believe that the current proposal is preferable to a specific requirement for vendors to adopt a quality management system. However, we are very concerned that ONC did not release a draft of its QMS document at the time that the proposed rule was issued (and not as of April 23); such a document will need extensive industry and expert review and feedback before finalization, and if there is not sufficient time for such review, this proposed measure should not be included. It is also essential that companies that are currently following existing ISO or FDA standards and processes not in any way be disadvantaged relative to the ONC view on this issue.

Topic/Section: EHR Technology Price Transparency (FR 77 p. 13872)

Issue:

ONC proposes that price transparency could be achieved through a requirement that ONC-ACBs ensure that EHR technology developers include clear pricing of the full cost of their certified Complete EHR and/or certified Modular EHR on their websites and in all marketing materials, communications, statements and other assertions related to a Complete EHRs or Modular EHRs certified. This provision would require EHR technology developers to disclose the full cost of a certified Complete EHR or certified Modular EHR.

According to ONC, it would not dictate the price an EHR technology developer could assign to its EHR technology, but would help to ensure that a single price for all the capabilities in the certified Complete EHR or certified Modular EHR be made publicly available. ONC states its belief that price transparency would provide purchasing clarity for healthcare providers and lead to more competitive EHR technology pricing. ONC requests comment on the feasibility and value of price transparency for certified Complete EHRs and certified Modular EHRs in the manner described.

EHR Association Comment:

The EHR Association strongly opposes this proposal. Fundamentally, this provision is inconsistent with the way in which complex software and other technology is priced and does not reflect the reality of enterprise or organization-level sales involving multiple components. From the vendor and purchaser standpoint, although we identify CEHRT, we are actually selling a complex mix of software and services to meet specific customer needs.

We also believe that this proposal would hinder innovation and flexibility in product development, pricing, and go-to-market strategies. There is simply no compelling rationale for

such a single price to be used as proposed, and this would actually result in an artificial construct that is not fully reflective of actual market dynamics.

What our members sell is not always just the minimally-certified product. Our customers buy products and services in addition to certified applications, so there is not an apples-to-apples comparison between the products that are sold and implemented by different EHR vendors. One vendor's "Complete EHR" does not equate to a "Complete EHR" from a different vendor, and forcing such pricing transparency could actually end up confusing buyers and be a disincentive to companies in their efforts to differentiate their solutions and supporting services.

Additionally, EHRs will have more capabilities than are required for certification. The concept of publishing test results seems to be attempting to compare, for example, a module that captures 20 demographics with a module that captures 50 demographics. No vendor sells an EHR demographics module that only captures the five demographic data elements required for certification, and most EHR vendors would not sell a product that just included the ability to capture those five demographics.

Finally, ONC's assumption that a single price exists is not accurate even for CEHRT. Pricing is a very complex area, subject to a number of considerations.

- Prices can be regularly adjusted in consideration of new features and capabilities.
- Pricing can be affected by VAR arrangements.
- Pricing formulas and constructs vary widely from company to company, and often include third party component costs.

Two systems might cost exactly the same amount but not deliver the same functionality. That is, price is not a good basis for comparison among EHRs because pricing is affected by customization, which options/modules are selected, interfaces to various regional or local organizations, etc. Additionally, pricing is largely driven by contracting for services, not just the software as a "commodity" that can be compared.

We are not aware of any other industry with these pricing dimensions and complexities that are required by the federal government to post their pricing, and we would be interested if any examples could be stated. There are several dimensions of complex software configurations and related technologies that are supplemented with a range of professional service fees. In addition, the purchasing process for EHRs is more complex than a simple "click" / "check out", especially for EHRs that hire consultants and manage purchasing processes with RFPs that require voluminous content. The complexities of EHRs, as evidenced by "Complete, Modular, Base, Core and Menu EHRs", are not comparable to a simpler commodity like a TV whose pricing could be posted on a public site like Amazon.com.

In addition, having to include prices in marketing materials would be an expensive proposition and require significant expenditures in the instance of pricing changes that involve some element of CEHRT. This provision could add rigidity to pricing in such a way that will be harmful to clients.

Our members apply customary, ethical practices in pricing and marketing, and we are clear and transparent with our customers in presenting prices that they will be required to pay. This

proposal seems to be an effort to facilitate pricing comparisons in a way that will not actually reflect the actual pricing or the total cost of ownership for the purchaser.

Finally, it is well established in the area of EHRs and other software that pricing is far less important than total cost of ownership (TCO) over the life of the product. For example, the RECs have taken extensive steps to identify the true cost inclusive of software (in-house vs. hosted), services, training, maintenance, etc., to help their constituents compare vendors. This proposal appears to be inconsistent with that effort.

Topic/Section: [ONC-ACB Reporting Requirements \(FR 77 p. 13869\)](#)

Issue:

ONC proposes to require that ONC-ACBs include an additional data element in the set of data they are required to provide regarding the Complete EHRs and/or Modular EHRs they report as certified to ONC under § 170.523(f). Specifically, ONC proposes that an ONC-ACB would need to provide to ONC a hyperlink (which would be displayed on the CHPL website of certified EHR technology) for each Complete EHR and Modular EHR it certifies that would enable the public to access the test results that the ONC-ACB used to certify the EHR technology. ONC believes that this additional element is important to increase transparency in the testing and certification processes, and it would serve to make more information available to prospective purchasers of certified Complete EHRs and certified Modular EHRs as well as other stakeholders.

EHR Association Comment:

We do not believe that the results of certification testing would be particularly useful or relevant to a purchaser. Moreover, as proposed, this criterion could require disclosure of information that constitutes trade secrets or proprietary information that otherwise would not be publicly released.

Fundamentally, the results of the certification test are what matters, not the process or experience of testing each individual product. The certification process and most testing aspects are pass/fail. The end result is what matters, and this end result is already available on the ONC's CHPL.

An alternative might be that purchasers could request similar information during the purchase negotiation, to be shared internally, but not be posted publicly through certification.

We respectfully ask for clarification regarding ONC's intent for this proposal. The proposal states that test results only would be shared, but we have other indications from ONC officials that signal that all materials submitted for the certification process would be subject to release. If so, this proposed criterion, which seems intended to evaluate workflow and/or usability, is a wholly inefficient means of evaluating these factors as the ONC-ACB test scripts unlikely to be workflow-based. The test scripts include very unrealistic testing steps that do not mirror real-world provider workflow, such as updating a patient's smoking status five times in a row. We have significant concerns that disclosing such information would not benefit consumers in the way that it seems to be intended, as well as having the unintended dangerous consequence of revealing proprietary software design features to competitors.

Finally, although the EHR Association supports the concept of transparency, that transparency should not force intentional or inadvertent public disclosure of product-specific intellectual property (IP) or trade secrets. We recommend that public posting be limited to attestations and documentation around processes, and it should not delve into product-specific content (e.g., screen shots, coding, etc.). Should either ONC or subsequent certification scripts venture into such specifics, vendors should have the right to request redaction of specific product details that violate IP or other rights, similar to how such rights are protected in federal contracting processes.

Topic/Section: New Certification Framework (FR 77 p. 13861)

ONC proposes a new approach to certification, involving a Base EHR, a Core EHR, and Menu EHR items, with providers needing to have a Base EHR regardless of their MU stage and then only those elements of the Core and Menu applicable based on their current MU stage, any exclusions, and the menu items pursued.

The EHR Association supports the ONC proposed approach, including the proposal that the security criteria are applied only to the Base EHR, as an excellent attempt to be responsive to comments received to-date from the vendor and provider communities regarding the need to possess a Complete EHR and the challenges that this requirement has posed for providers and vendors.

We do, however, have two seemingly unanswered questions from our review of the NPRM.

- First, we ask that ONC provide clarity on the situation where a provider has a module that duplicates functionality in the Base EHR and whether that module requires additional separate security certification. We understand that it would not require such additional certification but would appreciate ONC clarification on this point.
- Second, it is not clear what happens if a vendor presents EHR technology for modular certification that addresses only some but not all of what the Base EHR definition includes. Does that then require the vendor to certify each of these modules for all security criteria, or is the responsibility that of the provider to have a Base EHR that has had all elements certified for security criteria? If the same vendor has previously certified at least to a scope of Base EHR capability, has certified to the security criteria as a part of that effort, and then presents EHR technology for modular certification (CPOE alone, for example) that had been part of the Base certification, does the vendor have to certify for the security criteria for the CPOE modular certification? If a vendor were to certify on a modular level for CPOE as one effort and electronic prescribing as another without having previously certified at least the scope of a Base EHR, would the vendor have to certify for security each time given that they did not present a scope of product capability at one time that covers the full scope of a Base EHR?

We suggest that if a vendor has presented at least a full scope of a Base EHR for certification and has attained certification for that scope of capability, the vendor would not have to go through testing for the security criteria again, no matter what the modular

scope of capability presented for subsequent certification, for modules that were part of these Base certification. But we are unclear on some of the derivative scenarios that are possible, as it is important to inform any vendor's planning. Alternatively, perhaps a vendor could attest to the integrated nature of what they present for modular certification, whether or not they have certified for the scope of a Base EHR before. We request ONC's clarification on this.

Is the intent that automated numerator recording (170.314(g)(1)), non-percentage-based measure use report (170.314(g)(3)), and safety-enhanced design (170.314(g)(4)) be required as criteria to be performed in conjunction with some of the criteria identified in Base EHR or rather would these be required to be included in either the Complete EHR or by the provider given their overall requirements for CEHRT? Is it correct to assume that automated measure calculation (170.314(g) (2)), clinical quality measures (170.314(c) (3)), and electronic notes (170.314(a) (9)) would not be required for a Base EHR?

Topic/Section: Definition of a Base EHR 170.102

General EHR Association Comments:

Base EHR Representation - An EHR technology developer's Complete EHR, single Modular EHR or combination of Modular EHRs could constitute a Base EHR by meeting all the certification criteria required by the definition of Base EHR for the ambulatory setting or inpatient setting. We believe EPs, EHs and critical access hospitals (CAHs) would benefit from knowing which certified EHR technologies on the market constitute a Base EHR because they need to have a Base EHR to satisfy the proposed revised definition of CEHRT beginning with FY/CY 2014.

In response to ONC's questions, we believe that ONC-ACBs should be able to indicate on their sites (and the CHPL) the Base status of specific CEHRT. Although many EHR technology developers would likely identify on their websites and in marketing materials, communications, statements, and other assertions whether their certified Complete EHR or Modular EHR(s) meet the definition of a Base EHR, information availability on the CHPL would be also be very beneficial.