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

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

To ONC Leadership:

Thank you for the opportunity to submit comments on the proposed voluntary 2015 Edition EHR Certification Criteria. As Drummond Group is one of the original ONC-ATCBs, we have been grateful to be a part of this ONC certification and testing program since its inception. It has given us a unique opportunity to see its growth and changes over the course of nearly four years. ONC has given the HIT industry both the incentive and structure to grow, and the HIT infrastructure in place with hospitals and providers would not be at the level it is without the work of the ONC.

We believe the direction and purpose behind the voluntary 2015 Edition certification criteria and rules is an appropriate pivot at this junction of the HIT industry and the ONC program. We applaud the effort and intent to introduce a voluntary certification program to allow development and implementation of new criteria over a longer period of time. By "tipping your hand" in these regulations, vendors can be better their development cycles and planning to reduce the challenges which lie ahead.

At the same time, we are concerned about the EHR community in terms of the workload expected from any near-term certification, even one designated as voluntary. The 2014 Edition testing has been a daunting and monumental task for all involved. While we believe this remarkable effort has significantly improved the HIT community and will achieve significant dividends in terms of improving the technology necessary to assist quality health care, we do hope everyone can "catch their breath" so that certification is not always their dominate focus but allow time to meet their individual customer needs.

It is a balance as there is more work to do, and we believe certification testing is a necessary component to improve HIT. Overall, we think there is merit in discussing the potential required 2017 Edition testing as well introducing a voluntary intermediary certification effort in 2015 Edition, with significant Gap-eligible criteria and many other criteria only slightly modified. If done well, it can be lead to a gentler slope for vendors to improve their software which in turn will mean a smaller, but still beneficial, impact to health care providers who adopt and implement the software.

Our comments on the ruling are primarily not from a perspective of what is "best" for HIT use within the hospitals and provider offices across our country simply because that is not where we as a testing and certification body operate. Others can far better comment on these needs. Rather, we wish to make comments from our unique position as a certification and testing body of EHR vendors. Our comments are often more of the nature of trying to describe the testing impact behind the proposed changes or comment requests rather than trying to argue for or against a requirement.

Again, we are excited at the work and direction of the ONC. We look forward to taking this next step with you.

Kyle Meadors
Director of EHR Testing with Drummond Group (ONC-ACB/ONC-ATL)

A. Proposed for 2015 Edition[1] Certification Criteria

§ 170.315(a)(1) Computerized physician order entry - medications	
MU Objective	
Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.	
2015 Edition EHR Certification Criterion	
(1) Computerized provider order entry – medications. Enable a user to electronically record, change, and access medication orders.	
Preamble FR Citation: 79 FR 10886	**Specific questions in preamble?** *No*
Public Comment Field:	
From our experience in working with many vendors targeting specialty practices, separating out the CPOE criteria into three separate ones is an appropriate move. We have seen too many vendors whose target customers don't need one or two of these CPOE options to unnecessarily add functionality simply to meet the criteria (e.g. chiropractors not needing CPOE medication capability). It also supports regulation changes for each one without impacting the others. In this section, the concept of adaptations was referenced with a link to the 2014 Edition ruling where adaptations were discussed in more detail. While not the focus of this rule, we encourage ONC in other venues to better explain and illustrate, including with specific examples, method of adaptations, specifically in the area of mobile access of patient portals. It is our experience that nearly all vendors, including very large market leaders, are confused on this topic regarding what is an adaptation and how it impacts their providers MU reporting. While the concept of adaptations is relatively straight forward, the practical implementation of it seems to need further guidance.	

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

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

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10887	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

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

MU Objective

Implement drug-drug and drug-allergy interaction checks.

2015 Edition EHR Certification Criterion

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

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

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

Preamble FR Citation: 79 FR 10887	**Specific questions in preamble?** *Yes*

Public Comment Field:

Regarding the request for comment on adding future requirements involving the tracking of responses to DDI/DAI, the rational of improved patient safety alluded to by ONC in its reason why this might be consider seems sounds, although other individuals and groups are better able to comment on such clinical matters than a software certification and testing lab. However, we can comment that such capability of logging when DDI/DAI interactions were viewed, accepted, declined, ignored, overrode, or otherwise commented on should be relatively easy to track in most EHRs we have observed. The interaction is typically shown on a specific screen/template provided to the user which should enable for robust logging. This should also be relatively easy to verify in testing.

Guidance would be needed in where this information is tracked - in general EHR audit log, which is often not easily (if at all) seen by most non-security/non-admin users or in a separate medication history log, which could be more easily accessible to physicians and care providers from a patient's chart. If the intent is to improve patient safety and improve notification systems, then those who are most impacted by the notifications should have this information easily available. Therefore, regarding the request for comment on who should be permitted to review this data, we believe it would be most beneficial to be accessible to those who are doing ordering.

Regarding the request for comment on whether EHR technology should be able to track when an adverse event occurs for which a DDI/DAI check was missed or ignored, a concern about this is that it presumes EHRs are able to associate a reaction or medical outcome with an order. That would require some modifications to patient record designs in most EHRs, or at least we have not seen in our testing where this type of information can be clearly captured and linked together. While it may be of value for improved patient safety, it would be likely be a significant undertaking for EHR systems.

§ 170.315(a)(5) (Demographics)

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

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

Preamble FR Citation: 79 FR 10888	**Specific questions in preamble?** *Yes*

Public Comment Field:

In our testing efforts of 2014 Edition, there has been occasional challenges in consistently implementing demographics, specifically race and ethnicity, across other criteria which utilize demographics but in a different way, specifically the public health criteria which use different codes from HL7 which does not necessarily fully align with 314.a.3 (e.g. allowing "Other Race" as an acceptable value). Also, how would multiple races be presented in the CCDA of summary records? While not directly related to the comments requested, we believe it would be of value to consider providing guidance or alignment on demographics across the other criteria where messages are created/exported.

In 2014 Edition testing, it was our experience that vendors typically did not have a problem implementing a preferred language code other than occasional confusion on terminology vs bibliographic codes as well as the sheer volume of codes to support. Rather, there main interest was just finding the list to support and inserting those codes. Thus, we don't expect any significant challenge with vendors making updates. Rather, the key part is just identifying code to use and they will support this.

Regarding the request for comment on which language vocabulary to use, Option 3 seems to best option given our comments above of being in compliance with other exported messaging standards (CDA/HL7) as RFC 5646 should fit better with CCDA. Option 1 would be the next best choice as it adds some additional languages to what is currently supported. Option 2 with its huge list of languages seems unnecessary in terms of providing real value to EHR systems beyond what is currently adopted.

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

Preamble FR Citation: 79 FR 10889	**Specific questions in preamble?** *Yes*

Public Comment Field:

Regarding the two options, Option 2 choice would be less burdensome for vendors, and in our experiences, many vendors are already implementing some method of standardization in their CCDA or QRDAs. By requiring all vendors to standardized in the data exchange portion, many vendors will also improve their collection methods. We think it would be best first step in standardizing vitals. This model has worked well with medications and medication allergies already, which are standardized in CCDAs but not required by regulation to be in the patient's active list.

§ 170.315(a)(7) (Problem list)

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(a)(8) (Medication list)

MU Objective

Maintain active medication list.

2015 Edition EHR Certification Criterion

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

(i) Ambulatory setting**.** Over multiple encounters; or

(ii) Inpatient setting**.** For the duration of an entire hospitalization.

Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

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

MU Objective

Maintain active medication allergy list.

2015 Edition EHR Certification Criterion

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

(i) Ambulatory setting**.** Over multiple encounters; or

(ii) Inpatient setting**.** For the duration of an entire hospitalization.

Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

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

MU Objective

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

2015 Edition EHR Certification Criteria

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

(A) Problem list;

(B) Medication list;

(C) Medication allergy list;

(D) At least one demographic specified in paragraph (a)(5)(i) of this section;

(E) Laboratory tests; and

(F) Vital signs.

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

(1) Electronically identify for a user diagnostic and therapeutic reference information; or

(2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (3).

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

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

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

(1) Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section.

(2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(i)(B) of this section.

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

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

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

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

(1) Bibliographic citation of the intervention (clinical research/guideline);

(2) Developer of the intervention (translation from clinical research/guideline);

(3) Funding source of the intervention development technical implementation; and

(4) Release and, if applicable, revision date(s) of the intervention or reference source.

§ 170.315(a)(10) (Clinical decision support)	
(B) For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline). (vi) Decision support – knowledge artifact. Electronically process clinical decision support knowledge artifacts in accordance with the standard specified at § 170.204(d). (vii) Decision support – service. Enable a user to electronically make an information request with patient data and receive in return electronic clinical guidance in accordance with the standard specified at § 170.204(e).	
Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *Yes*

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

Public Comment Field:

In the 2014 Edition testing, Clinical Decision Support (CDS) has proven to be more difficult than most vendors' anticipated, although the improvements from the 2011 Edition were valuable. Vendors often struggled understanding what the new CDS implementations should be doing, with respect to areas like diagnostic and therapeutic reference information and user controls. It was often a question of how this should be implemented in a workflow where a provider can utilize the information to make a better decision. In our opinion, it seemed like 2014 Edition requirements were giving more features to implement without necessary an understanding of how they all fit together. Certainly, some vendors were able to put together a very nicely integrated CDS capability within their EHR, but most struggled to make it consistent workflow to truly aid a provider in decision making in an unobtrusive and natural means. That does not mean this was a fault of the 2014 Edition requirements, but it was simply the reality in which they were implemented by the vendor community.

This was also reflected in the actual testing activities. In our opinion as a test lab, the CDS test procedure was without question the most confusing to implement and apply of all the 2014 Edition test procedures. If often seemed we were testing pieces of functionality multiple times, but it was not necessarily clear how it moved together. After many months of experienced, we improved our understanding, and testing became easier to implement. However, it still was considered by vendors as a more challenging criterion. It seems like the authors of the regulation and test procedures as well as CDS industry experts have a clear vision of how CDS should work in EHRs, but the EHR community seems to have a different approach and view.

Challenges withstanding, we believe CDS should be an essential value-add for electronic health records as computer software should be able to do this type of information look-up/processing in way no possible through paper-based/non-electronic health care. The creating of the Health eDecisions group and subsequent work is to be applauded. The continued emphasis by ONC for vendors to invest in CDS design and architecture is important. Too many vendors still maintain rather rudimentary CDS alert systems, typically only notifying providers of "reminders" type activities (e.g. because of high blood pressure, consider ordering high blood pressure medicine) which provider generally already "known".

The proposed additions of a CDS Knowledge Artifact IG and DS Service IG seem to be good idea to help make CDS within EHRs more useful and valuable to providers and provide time to market of informing new clinical trends and care suggestions. Also, "trying out" these new standards in voluntary certification criteria also has some merit so we can learn from the early adopters and adjust as necessary for the required 2017 Edition. Finally, as vendors generally will not implement new standards until there is some requirement, Because of that, we tentatively support the inclusion of these requirements for 2015 Edition. However, we stress that much more education AND EXAMPLES (specific case studies, scenarios, etc.) are needed for more robust implementations. Without a clear design goal, the CDS in EHRs can be cumbersome and unwieldy, like children's building blocks scattered across the floor rather than constructed in an elegant structure. Also, these efforts, while important, should take slow steps to now further overwhelm the vendors. Regarding the should focus on when it comes to testing and certification for acceptance and incorporation of CDS Knowledge Artifacts, we encourage to develop with specific scenarios in mind and use defined HeD Working Group CDS guidance supplier scenarios with clear expected results to verify the EHR can produce the defined care decision support guidance.

Regarding the question of the feasibility of implementing the interface requirements of the DSS IG, the major question which is begged in introducing a service to request and receive CDS is where will the service/source of this information be so that EHR vendors have a reliable and robust service to utilize in developing and testing this feature, not to mention real-world implementation? It is difficult to support this proposal without knowing there is/will be some infrastructure to support it.

Regarding the ease with which EHR technology could be developed to consume CDS Knowledge Artifacts, we believe it would require a fairly significant redesign for most EHR systems. As mentioned above, many EHR systems have relatively simply CDS alert systems. However, they can potentially leverage them by tying the current CDS engine/template tool to support CDS Knowledge Artifacts.

Regarding the request for comment on whether we should work to distinguish between complex CDS Knowledge Artifacts and simple Knowledge Artifacts and to require only acceptance and incorporation of simple Knowledge Artifacts in the 2015 Edition, with increasing expectations of more complex capabilities in future editions, we definitely recommend starting "slowly" to minimize the initial challenges at the same time learning from these new efforts. Therefore, we recommend using simple Knowledge Artifacts in the 2015 Edition.

Regarding the request for comment on the ability to store and auto-configure a CDS Knowledge Artifact within the EHR and also the request for comment on ability to map the CDS Knowledge Artifact standard to data within the EHR technology (including medications, laboratory, and allergies information), this would likely be a major architectural change for the majority of current EHRs, especially if they wanted to do it "right".

§ 170.315(a)(11) (Electronic notes)

MU Objective

Record electronic notes in patient records.

2015 Edition EHR Certification Criterion

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

(i) Record, change, and access electronic notes; and

(ii) Search within and across electronic notes stored within EHR technology.

Preamble FR Citation: 79 FR 10891	**Specific questions in preamble?** *Yes*

Public Comment Field:

In our testing experience, very few vendors allowed for a robust note searching capability across multiple notes. By far most vendors implemented a rather "simple" search within the single note itself, which typically provides little value to a provide who can easily see the note itself and likely not need to search for a word or phrase. Adding search capabilities across multiple notes as well as multiple patients would likely be a valuable addition to most health care providers given we live in a world of "search" and expectations of our software to enable this capability in a robust manner.

However, as we mentioned, this advance search across multiple notes of the same patient would be a new feature for most vendors. From our testing experience, we estimate less than 40% of vendors demonstrated this type of capability. Expanding that to note searching across all patients, we estimate less than 10% of vendors demonstrated this type of capability. Of course, just because a vendor did not demonstrate that specific functionality may not mean the EHR does not have the functionality. The vendor could have elected to use the simpler search method of within a single note as that was all that was required, and therefore, those estimated percentages above may be higher.

Still, this would be a significant change for most vendors. ONC will need to weigh the value in requiring this. The request in this section for health care provider to weigh in on the value/need of note searching should be a critical factor in determining if this updated capability should be required in 2015 Edition.

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

MU Objective

Implement drug formulary checks.

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10892	**Specific questions in preamble?** *Yes*

Public Comment Field:

We offer no comment on the consideration of the NCPDP Telecommunications Standard or NCPDP Formulary and Benefit Standard as we are not as familiar with these standards to given a sufficient opinion. From a testing perspective, EHRs rarely fail Drug Formulary testing so it is considered an "easy" criteria to pass, and the test procedure requirements are rather straight forward in simply showing formulary query results. Nothing is required to show setup of formulary, either at patient level or practice level. ONC may want to consider expanding the test procedure to capture more of the real-world setup, even if the "testing" is just collecting an attestation letter which is part of the public test report so users better understand how formulary is setup and maintained. However, since we as an ONC-ACB have never received any user surveillance complains on certified EHR's formulary features, it may also be a capability which is working fine as is and not need any further changes.

§ 170.315(a)(13) (Smoking status)

MU Objective

Record smoking status for patients 13 years old or older.

2015 Edition EHR Certification Criteria

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

Preamble FR Citation: 79 FR 10892	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(a)(14) (Image results)

MU Objective

Imaging results and information are accessible through Certified EHR Technology.

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10893	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

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

MU Objective

Record patient family health history as structured data.

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10893	**Specific questions in preamble?** *No*

Public Comment Field:

In our review of the voluntary 2015 Edition criteria, nothing surprised us more than seeing the proposed requirement to use HL7 Clinical Genomic standard rather than just SNOMED. In our 2014Edition testing, only two EHR vendors have actually utilized the HL7 Clinical Genomic standard. The SNOMED option is the overwhelming choice among EHR vendors. As a result and if this criteria was adopted as proposed, virtually every EHR vendor would have to re-do their Family Health History functionality to support this. In our testing experience, most vendors had well designed means of recording diagnosis/problems for FHH via SNOMED. Also, the HL7 Clinical Genomic standard is more of a model for recording FHH as opposed to a very tightly defined specification. As well, it is complicated and require significant re-working from EHR vendors.

Our preference as a testing and certification body is to keep their criteria unchanged from 2014 Edition. As a testing body, we will test whatever the ONC determines is appropriate, and we are cautious in recommending against a proposed method. However, we do want the ONC to be aware that this proposed criteria would require a re-design of the current approach implemented by the 2014 Edition EHR community. The approach of just using SNOMED seemed to be effective and well received. Also, it seems to lend itself to inclusion of Family Health History into the CCDA summary records if that element is ever required by the ONC, and many vendors did voluntarily include FHH in their CCDAs.

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

Preamble FR Citation: 79 FR 10893	**Specific questions in preamble?** *Yes*

Public Comment Field:

Regarding the request for comment on a minimum list of patient communication preferences, we have often been asked by vendors to give a "minimum" list. Of course, we have been unable to give that as it was not defined in the regulations or test procedures. However, we have always required vendors to have at least two options, whatever they choose for them to be. We think it would be of value to offer a recommend minimum of communication preferences to represent an industry baseline. However, we do not think that should necessarily be a certification requirement. Rather, if ONC can just offer a recommendation, that could help vendors in their decision making and lead the industry to naturally standardize on a common list.

Regarding the request for comment whether to require EHRs to be able to provide patient reminders according to identified patient preferences and preferred language, we have long found it odd that the ONC criteria in this case (i.e. building a list of patients) was so different from the corresponding CMS MU measure (i.e. sending out a reminder). We understand there are obvious challenges with requiring an EHR to make the reminder per the preference as many communication methods are non-electronic, specifically phone and postal mail.

Still, the patient reminder/patient list creation could have a requirement to RECORD that the reminder was sent, even if the action of sending the reminder was not demonstrated. This "record" capability is an indirect requirement with the testing of g.1/g.2 as the EHR must be able to record if a reminder was produce to count in the Automated Measure reporting. Given that, we recommend ONC consider adding a requirement in Patient List Creation to show the EHR can allow a provider to record, either manual or automatic, that patient reminder has been sent and consider making an optional requirement to allow for generating electronic reminders, specifically email and/or portal notification). While this documenting of patient reminders is done as part of g.1/g.2 testing, calling out explicitly to test in Patient List Creation would allow test proctors (and vendors) to give it more of the attention it deserves.

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

(i) In accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (3); and

(ii) By any means other than using the standard specified in § 170.204(b).

Preamble FR Citation: 79 FR 10893	**Specific questions in preamble?** *Yes*

Public Comment Field:

Regarding the comment on whether to require Infobutton method AND an alternative method, we observed in our testing that several vendors found this scenario "odd" in why should the keep an out dated model (the alternative method) when they had the newer Infobutton method available. Since they had to support both for 2014 Edition testing, the result was often a complicated user interface, with Infobutton triggering icons/buttons at one section and then in another section of the EHR the buttons/links to trigger query of the non-Infobutton method. The requirement to support both methods likely impacted usability for many systems.

Given that, we would lean toward option #2 (require Infobutton, but permit EHR technology to be certified to other methods) as it would allow EHR vendors to drop the alternative method unless their users truly needed, which some vendors did indicate their user community definitely preferred their non-Infobutton alternative. However, we see value in both option #1 and option #3. For Option #2, the ONC public Test Report Summary may need to be altered to allow capturing of these non-Infobutton methods.

Also, one area we would ask ONC to consider is whether EHRs should allow the user to configure the Inbutton server to provide the education resources. Most EHRs seem to have hard-coded in the Infobutton server to provide education content (MedLinePlus Connect has been the overwhelmingly popular choice of vendors). The problem with hard-coding the content source as it locks in the users to that content source. We would not believe this a significant program nor a huge need for ONC's focus as most content providers, including MedLinePlus provide sufficient patient education for a majority of all patient use cases, but it should something to at least consider.

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

(A) Right patient**.** The patient to whom the medication is to be administered matches the medication to be administered.

(B) Right medication**.** The medication to be administered matches the medication ordered for the patient.

(C) Right dose**.** The dose of the medication to be administered matches the dose of the medication ordered for the patient.

(D) Right route**.** The route of medication delivery matches the route specified in the medication order.

(E) Right time**.** The time that the medication was ordered to be administered compared to the current time.

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

Preamble FR Citation: 79 FR 10894	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(a)(19) (Inpatient setting only – advance directives)	
MU Objective Record whether a patient 65 years old or older has an advance directive.	
2015 Edition EHR Certification Criteria (19) Inpatient setting only—advance directives**.** Enable a user to electronically record whether a patient has an advance directive.	
Preamble FR Citation: 79 FR 10894	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

§ 170.315(a)(20) (Implantable Device list)	
MU Objective N/A	
2015 Edition EHR Certification Criteria (20) Implantable device list**.** (i) Enable a user to electronically access and view a list of Unique Device Identifiers and other relevant information associated with a patient's Implantable Device(s). (ii) Enable a user to electronically record in a patient's Implantable Device list the following information at the time the Device is implanted or removed: (A) The Unique Device Identifier associated with the Implantable Device; and (B) Other relevant information about the Implantable Device or procedure. (iii) For each Unique Device Identifier in a patient's Implantable Device list, allow a user to separately access and view electronically the Device Identifier and Production Identifier portions of the Unique Device Identifier.	
Preamble FR Citation: 79 FR 10894	**Specific questions in preamble?** *Yes*
Public Comment Field: Regarding this criteria, others are more knowledgeable on the use of Implantable Devices and the clinical needs to record their information and those individuals or group can offer better comments on whether to include or exclude this criteria. From a testing perspective, we would add the following comments based on the proposed ruling. One, it seems like a rather easy criteria to test as it is essentially just recording data in discrete fields without any additional checking or analysis done. Two, supporting AIDC via methods like a bar code scanner seems reasonable given the item in question is a device and aligns with recording capabilities of the eMAR criteria. Three, the ability to do a UDI search or generated list seems to be a natural requirement to support the meaningful use of this criteria. If the information is collected as discrete data, it makes sense for software to be able to search for it. Also, this is how providers would expect their EHR to support them if they need to identify patients who have a specific device which is to be recalled.	

§ 170.315(b)(1) (Transitions of care)

MU Objective

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

2015 Edition EHR Certification Criteria

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

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

(B) Receive transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(e) from a service that has implemented the standard specified in §170.202(a).

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

(iii) Display.

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

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

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

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

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

(3) Cognitive status;

(4) Functional status;

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

(6) Inpatient setting only. Discharge instructions; and

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

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

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

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

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

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

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

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

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

Preamble FR Citation: 79 FR 10896	**Specific questions in preamble?** *Yes*

Public Comment Field:

First, decoupling the Direct protocol transmission is a good idea and should be adopted. We approximate nearly half of the EHRs which were certified as Complete EHRs used HISPs so this TOC and Direct functionality was already separated for most EHRs across different systems. Explicitly separating it out within the ONC criteria will save testing time as HISPs will not have to repeat the

demonstration of the same features multiple times across different EHR systems. Also, it will allow EHR vendors to more easily move to different HISPs if necessary as the HISPs will not be part of their additional software listing.

Second, regarding the new Direct Edge protocol requirement, this seems to be an unnecessary step. In the current 2014 Edition testing, EHR systems have already been successfully exchanging CCDA data with their HISPs without significant issues. Creating a standard and certification require would produce an unnecessary burden to address an issue which is already solved by EHRs and their HISPs. Also, if you are adding a criterion for the Direct edge protocol for this TOC criteria, you would also need to add the Direct Edge protocol to the new Direct/transport protocols of 315.h.1-h.3. That is, if an EHR must use one of the Direct Edge to connect with a HISP (e.g. EHR support 314.h.1) then it stands to reason that a HISP must also support ALL of the possible Direct Edge protocols to cover this end-to-end requirement or otherwise you will have certified system which are technically incompatible with each other per their certification.

Also, we would ask that you consider dropping C32/CCR or at least make plans for its eventual removal as an obsolete content standard as vendors now adopt CCDA. Unlike in 2014 Edition, where you could potentially have the overlap of certified 2011 Edition systems interoperating with certified 2014 Edition during FY/CY 2013 and thus needed backwards compatibility, all MU-compliant EHRs should now be using CCDA.

Regarding backwards compatibility, we have some concerns if the proposed CCDA 2.0 specifications would be sufficient backwards compatible with the current CCDA 1.0 requirements (i.e. EHRs certified to 2014 Edition). Other subject matter experts can better comment on this, but we ask that ONC consider this backwards compatibility decision carefully.

We support the decision to move incorporation to the Clinical Information Reconciliation criterion as it is a more natural fit, and in our experience most 2014 Edition vendors certifying to 314.b.1 and 314.b.4 used the CCDA as their data source to demonstrate reconciliation.

Regarding the proposal for the “performance standard”, we find merit in the goal of requirement (i.e. support of variation of CCDA content and coding) although we do have some questions on the approach. First, it requires clear definitions and guidelines on these rules. Yes, there is the HL7 specification itself, but more guidance is needed. Information such as defining what sections of the CCDA syntax to use in extracting out information (e.g. take RxNorm code of medication listed and look up its value or use the HTML textual representation), defining where a where a problem (or allergy) is active (e.g. problemAct status or observation status or both). For encounter diagnosis, some vendors have challenges with support findings within SNOMED code set.

Second, large supplies of different messages are needed from different sources, preferable real systems. If ONC or another single group generates out a large number of messages from an engine/template, they will bear the mark of an artificial creation. While of some value, it will be better to find “real-world” messages and use them. In our experience, the best method to “solve” this problem is to utilize community involvement to share files as part of a public repository for use.

Third, we are concerned about the practical nature of testing this. If the expectation was for an EHR to successfully process 95% of their CCDAs, the certification testing for this would involve a significant amount of time simple receiving and incorporation CCDA files. To have confidence of 95%, the vendor would at a minimum have to receive 20 CCDAs and successfully process at least 19 of them. A single Direct transmission from the TTT, receipt by the EHR under test, display of received results and then ATL inspection to verify successful receipt accuracy would likely require 10-15 minutes based on experience doing this in 2014 Edition testing. Even if we went with the low end of time, 20 CCDA test would require over 3 hours of testing. If this is what is needed, then it can be done, but it would impact pricing of testing activity.

Given that, we do not recommend this requirement be part of the 2015 Edition criterion. However, we do recommend ONC begin a leading a “crowdsourcing” effort among EHR vendors to collect and catalog various CCDA data used both in certification as well as public submissions. The ONC-ACBs/ATLs can work with their EHR vendor community to collect CCDAs and share those in a public repository of such and also do some basic cataloging of these files to note differences between. Also, ONC/community can begin creating specific types of CCDAs which are “unusual” but complaint and would serve as “extremes” of what may be received.

With this repository, vendor can conduct their own quality testing to develop their performance standards compliance. If ONC wishes to revisit this in 2017 Edition, we now have a source of information from which to pull. In terms of actually testing it, we can do some manner of attestation+sample testing. So we have vendor attest they did quality testing on a large number of CCDAs from the approved CCDA repository and share that information (made part of public test report). Then in test event itself, the ATL would sample test a small number of CCDAs from the repository to verify the EHR can in fact properly receive them.

Regarding the patient matching, we support this concept to better define and improve methods of patient matching. However, we recommend not adoption this requirement for 2015 Edition criteria for precisely the same reasons of delaying the performance standard requirements. We need a large repository of CCDAs which have various of patient identification which to fully test an EHRs ability to match a variety of potential test patients.

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

MU Objective

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

2015 Edition EHR Certification Criteria

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

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

(A) Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date;

(B) Enable a user to create a single reconciled list of medications, medication allergies, or problems;

(C) Enable a user to review and validate the accuracy of a final set of data; and

(D) Upon a user's confirmation, automatically update the list, and electronically incorporate the following data expressed according to the specified standard(s):

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

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

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

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *Yes*

Public Comment Field:

Regarding request for comment for 2017 Edition rulemaking to broaden the criteria to be reconciled beyond just medications, allergies and problems, we believe this would be a good addition to the current work. Items such as procedures or lab results would be clinical data which are a natural additional to the reconciliation capabilities. Some clinical data like vitals or smoking status would not need to be included as they are easily captured within the EHR system and likely more current than what would be in the TOC.

Beyond that, some other suggestions for the ONC to consider is better defining where data goes in relevant CCDA sections. The Companion Guide to CCDA for MU by the S&I Framework is a very useful document, but making it more “official” may help interoperability.

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

MU Objective

Generate and transmit permissible prescriptions electronically (eRx).

2015 Edition EHR Certification Criterion

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

(i) The standard specified in § 170.205(b)(2); and

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

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

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

MU Objective

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

2015 Edition EHR Certification Criteria

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

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

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

(ii) Electronically display the test report information:

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

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

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

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

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

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *No*

Public Comment Field:

No comments.

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

MU Objective

Provide structured electronic laboratory results to eligible professionals.

2015 Edition EHR Certification Criteria

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

(i) That includes the information:

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

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

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

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

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

Preamble FR Citation: 79 FR 10901	**Specific questions in preamble?** *No*

Public Comment Field:

No comments.

§ 170.315(b)(6) (Data portability)

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

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

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

(iii) Cognitive status;

(iv) Functional status;

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

(vi) Inpatient setting only**.** Discharge instructions; and

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

Preamble FR Citation: 79 FR 10902	**Specific questions in preamble?** *Yes*

Public Comment Field:

Regarding the request for comment on remaining the criteria to data migration, that name is a better description for the purpose of the criteria.

Regarding the request for comment on expanding the requirements of this criterion for the 2017 Edition rulemaking, we believe expanding to allow more refined selection of data, such as per provider or patients seen during a certain period of time, would be of benefit as one "risk" of this criteria as currently written is producing too much patient data to be useful. Of course, to make this requirement fully useful EHRs would need to support a more mass import feature as well, although there are significant challenges with that feature which require significant and careful thought.

Regarding the request for comment on a broader range of use cases, we have no comment.

Clinical Quality Measures – Electronically Processing eMeasures

Preamble FR Citation: 79 FR 10902 | **Specific questions in preamble?** *Yes*

Public Comment Field:

Others in the healthcare field can better comment on the value of implementing HQMF as we have not followed this standard as closely as others in terms of its readiness for wide spread adoption. However, we can offer some insight into the workings of vendors for the certification testing of CQMs in the 2014 Edition to give some backdrop on this. First, CQM testing was very hard. If we have to be grade it on a scale, it would top at 100 (being the hardest) and the next most challenging criteria, probably Automated Measures (g.2) would score at a 50 (1-100 scale). Thus, it is truly twice as challenging as any other criteria. The Cypress test tool with its exacting requirements and detailed test data certainly improved the quality of the CQM functionality, but it was not an easy road to travel. Second, and related to the first point, EHR vendors was very confused regarding CQM implementation. Certainly the large vendors, e.g. McKesson, MEDITECH, Allscripts, MEDHOST, GE, were more familiar with the requirements given they often have individuals on these standards groups as well as large teams available to do development. Yet for the vast majority of EHR vendors, they did not have these advantages were struggling to understand where even to find the CQM specifications without our assistance.

The latter point is key. In our opinion, based on our testing experiencing, we expect that less than half of all vendors who certified in CQMs can currently tell you anything about HQMF. We expect less than 10% have any real work knowledge of HQMF. Therefore, it will be a major undertaking in terms of knowledge and experience to implement this requirement.

We stress this point as it is natural for policy makers and stakeholders to lose sight of the vast majority of other individuals and companies who are in this case virtually clueless. We do need policy makers and stakeholders to lead us and share their expertise to push the industry forward. Along with that point, we are excited about HQMF and hope it will be adopted at some point within the EHR industry. We are just concerned about the majority of vendors being able to keep up in the CQM space.

Clinical Quality Measures – Functions and Standards for CQM Certification

Preamble FR Citation: 79 FR 10903 | **Specific questions in preamble?** *Yes*

Public Comment Field:

We agree on the need to align the CQM requirements of CMS, the HL7 specification and the ONC test procedure and test tool Cypress so that EHR vendors can develop CQM functionality “one time”. As it stands, there is often competing requirements, especially with the need to create QRDA-I reports on a per encounter basis for CMS rather than per patient, as had been required for certification. To put it another way, the CQM requirements should be such that the material produced by an EHR system within a certification even could be directly ported to CMS submission by its provider customers.

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

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

Preamble FR Citation: 79 FR 10903 | **Specific questions in preamble?** *Yes*

Public Comment Field:

Others in the healthcare field can better comment on the value of implementing QRDA Cat II reports as we are not personally familiar with that version of QRDA. However, given the immense challenge vendors faced with developing compliance to the current QRDA Cat I and Cat III standards, it would be very frustrating to have to move to another new standard, especially after starting with PQRS in 2011 Edition and moving to a new standard in 2014 Edition.

§ 170.315(c)(2) (Clinical quality measures – import and calculate)	
MU Objective	
N/A	
2015 Edition EHR Certification Criterion	
(2) Clinical quality measures—import and calculate**.** (i) Import**.** EHR technology must be able to electronically import a data file formatted in accordance with the standard specified at § 170.205(h) and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. EHR technology presented for certification to all three of the certification criteria adopted in paragraphs (c)(1) through (3) of this section is not required to meet paragraph (c)(2)(i). (ii) Calculate**.** EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.	
Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment.	

§ 170.315(c)(3) (Clinical quality measures – electronic submission)	
MU Objective	
N/A	
2015 Edition EHR Certification Criteria	
(3) Clinical quality measures—electronic submission**.** Enable a user to electronically create a data file for transmission of clinical quality measurement data: (i) In accordance with the standards specified at § 170.205(h) and (k); and (ii) That can be electronically accepted by CMS.	
Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment.	

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

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

Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *Yes*

Public Comment Field:

While not necessarily speaking out against this proposal to require filtering CQMs by patient population characteristics, it is hard to be supportive of it given that the healthcare benefits of adopting this criterion are not clear. Meaning, it is hard to see how this would truly help provide better patient care or even reduce healthcare costs. Others in the healthcare field can better identify its value. From a testing standpoint, this would not necessarily be challenging to execute the test event day activities to verify data is properly searched and queried. However, it would like require significant and detail test data to load which provides a significant burden on vendors. The Cypress test data for 2014 Edition requires approximately 16 to 800 man-hours to enter in, depending on the complexity of the system and number of CQMs to be tested.

We are not as familiar with the metadata for the characteristics of the QRDA Category I and Category III to reasonably comment on the usefulness of using those standards for this population filtering, but if they can be used, we certainly recommend that approach to leverage existing work performed by the EHR vendors.

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

Preamble FR Citation: 79 FR 10904	**Specific questions in preamble?** *Yes*

Public Comment Field:

Regarding the request for comment on whether we should adopt a general two-factor authentication capability requirement for authentication and access control criteria.

As one of the DEA approved 3rd party assessors for certification of e-prescribing of controlled substances, we are very familiar with two-factor authentication (2FA), and especially the DEA EPCS requirements for 2FA, and the challenges in doing this. The DEA EPCS requirements are more comprehensive than solely requiring 2FA. Complementary to the DEA 2FA requirement is Identity Proofing and digitally signing e-prescriptions with controlled substances. Even if ONC would require that 2FA be a part of the 2015 Edition Criteria, the 2FA solution chosen by EHR vendors may not meet the DEA EPCS requirements and thus not be complementary to meeting DEA EPCS requirements. In situations where EHR implement 2FA without consulting the DEA EPCS 2FA requirements would be implementing a non-compliant application to the DEA EPCS 2FA requirements. In this scenario the EHR vendor would be required to select a 2FA technology that meets DEA requirements, then re-implementing their EHR application 2FA offering so as to meet DEA EPCS Rule -- a costly endeavor. Given that, we would not recommend changing the Authentication, Access Control, and Authorization criteria to require multi-factor authentication. To achieve the complementary goal the EPCS DEA Rule must be strictly followed. We suggest considering making multi-factor authentication an optional requirement and alert EHR vendors to consult with the two ONC-ACBs or other 3rd party assessors before choosing to implement 2FA. In addition, some EHRs may not need this level of security so multi-factor authentication may not always been needed. However, as an optional requirement is may be utilized as a value-added service for EHR vendors which can be used to support their specific customer needs.

Regarding the request for comment on whether the HITPC's recommendations (multi-factor authentication (meeting LOA 3) by provider users who remotely access protected health information by MU Stage 3).

We agree that many organizations may want to use a two-factor authentication (2FA) when their provider-users are seeking remote access to their EHR technology from unsecure sites to improve security. However, there are challenges in making this a certification requirement. First of which is EHR vendors may choose to not offer any remote access to their EHR technology but only allow access from controlled client systems. Therefore, it may be more of a conditional or optional requirement.

Second, two types of EHR applications exist: Practice Installed and Cloud-based. Remote access to Installed EHR Applications is typically implemented using Remote Access technology already built in to the OS (like Windows OS's and VPN) which can and should secure remote access already. Further, for Cloud-based EHR applications, Remote Access is not an option as the application is accessed over the Web. 2FA may make sense for user login of Cloud-based EHR applications but keep in mind that it would not necessarily meet EPCS DEA requirements as stated above. LOA3 as defined in NIST SP 800-63-1 and NIST SP 800-63-2 are slightly different so please keep that in mind and make sure to specify the latest version. (DEA EPCS does not allow the latest version it reference 800-63-1). Instead of singling out remote access as a point of emphasis, we recommend that a ONC make a statement on Security which would be more comprehensive. We recommend that such a statement reinforce that Practitioners must have a 3rd Party Security Audit to ensure HIPPA Security Rule compliance. The HIPPA Security Rule addresses Access Control (which would include Remote Access) among many other security requirements.

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

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

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

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

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

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

Preamble FR Citation: 79 FR 10904	**Specific questions in preamble?** *Yes*

Public Comment Field:

We support the recommendation to prevent audit logs from being disabled given the vital importance of the audit log. However, we should add that in our experience in 2014 Edition testing only a handful of vendors allowed this. The overwhelming majority do not allow an audit log to be disabled which they clearly indicate in their attestation letters we included in their public test reports.

One suggestion we offer is for ONC to consider requiring vendors to demonstrate sub-section (v) Detection in the course of testing rather than just satisfying via attestation letter. While it may be a significant undertaking, vendors should have objectively confirmed that log alterations can be detected and prove this. However, if this approach was adopted by the ONC, it is likely further guidance would be needed to explain means of which an audit log can be altered by outside efforts including some specific examples. As a testing body, we recognize this would be a difficult feature to demonstrate in the course of a test event so we are open to alternative methods, such as submission of letter of compliance from a security risk group or simply an attestation of the steps the vendors to took to conduct their own Audit Log detection test internally. We too often see vendors include just a single line or two with a brief description of the attestation and frankly wonder if they have objectively verified this through internal testing.

§ 170.315(d)(3) (Audit report(s))

MU Objective

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

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *Yes*

Public Comment Field:

We support the ONC interpretation of the certification criterion requirement to mean that if the EHR technology does not include a capability for which an "action" is listed (e.g. copy) that testing and certification can proceed for the audit log process without EHR technology showing that it can record actions related to a non-existent capability. This is the interpretation and process we have followed for the 2014 Edition testing, and we have never require an EHR vendor to specifically add functionality just to satisfy all of these actions. However, we have applied a broader interpretation to these actions in some cases, as noted below.

We have found the ASTM E2147 “frustrating” to implement in regards to its actions do not seem to align with those of modern EHR systems. In our work in 2014 Edition testing, we have interpreted “query” to be akin to viewing/access as in the EHR user is “querying” the information from system to view. Obviously, there is as much risk of a nefarious individual reading but not changing a health record so the EHR should log when users have access or “queried” a patient’s record to view.

We believe the actions of “transmit” or “download” should absolutely be logged as there is no greater risk of security breach than full extraction of a patient’s record. If an EHR cannot track when patient data has “left” its system, then users will be challenged to account for claims that they did or did not protect patient information.

In our work in 2014 Edition testing, we have broadly interpreted “copy” for a download/transmit activity as the EHR is in this case making a copy of the patient record outside the record itself.

As mentioned, we have found ASTM E2147 difficult, and that is the feedback we have received from vendors as well. We believe ONC can just as well define their own requirements of actions to be logged as in ASTM E2147. Also, we would encourage developers of the ONC test procedures to include in the individual criterion test procedure information which should be logged in an audit log, or at least an example of this to illustrate the auditable events which would be captured by an EHR implementing this criterion. This may be more detail and scope that intended for this audit log criterion discussion, but an audit log is a key security tool within an EHR and must not be undersold.

§ 170.315(d)(4) (Amendments)

MU Objective

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

2015 Edition EHR Certification Criterion

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

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

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

Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(d)(5) (Automatic Log-Off)	
MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	
2015 Edition EHR Certification Criterion (5) Automatic log-off**.** Prevent a user from gaining further access to an electronic session after a predetermined time of inactivity.	
Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

§ 170.315(d)(6) (Emergency access)	
MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	
2015 Edition EHR Certification Criterion (6) Emergency access**.** Permit an identified set of users to access electronic health information during an emergency.	
Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

§ 170.315(d)(7) (End-User Device Encryption)	
MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	
2015 Edition EHR Certification Criterion (7) End-user device encryption**.** Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion. (i) EHR technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of EHR technology on those devices stops. (A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(1). (B**)** Default setting**.** EHR technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users. (ii) EHR technology is designed to prevent electronic health information from being locally stored on end-user devices after use of EHR technology on those devices stops.	
Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

§ 170.315(d)(8) (Integrity)	
MU Objective	
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	
2015 Edition EHR Certification Criterion	
(8) Integrity**.** (i) Create a message digest in accordance with the standard specified in § 170.210(c). (ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.	
Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment.	

§ 170.315(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.	
2015 Edition EHR Certification Criterion	
(9) Accounting of disclosures**.** Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).	
Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment.	

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

MU Objective

EPs

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

EHs and CAHs

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

2015 Edition EHR Certification Criterion

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

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

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

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

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

(B) Download.

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

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

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

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

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

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

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

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

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

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

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

(1) The action(s) (i.e., view, download, transmission) that occurred;

(2) The date and time each action occurred in accordance with the standard specified at § 170.210(g);

(3) The user who took the action; and

(4) The addressee to whom an ambulatory summary or inpatient summary was transmitted and whether that transmission was successful (or failed).

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

§ 170.315(e)(1) (View, download, and transmit to third party)	
(e)(1)(ii)(A) is accessible by the patient.	
Preamble FR Citation: 79 FR 10906	**Specific questions in preamble?** *Yes*

Public Comment Field:

We support the clarification on the introductory text. To share from our experience as a test lab, we have conducted our 2014 Edition testing with the expectation that the portal is patient facing and for patients to use and tested accordingly.

We support the clarification on removing ambiguity from “Download”. To share from our experience as a test lab, we have conducted our 2014 Edition testing to require both download of human readable and also CCDA for compliance.

We support decoupling of Transport from content, but we do not support the inclusion of the Direct Edge protocol for the same reasons expected in our comments on criterion 315.b.1.

We are concerned about the move to CCDA Release 2.0 for the same reasons expected in our comments on criterion 315.b.1.

We support the two new data points proposed for the Activity History Log.

We support moving to WCAG 2.0 Level AA for improvement in design. However, we want to note from our experience in testing that WCAG conformance tools are somewhat sparse, and vendors often found difficulty finding viable tools. Those on the W3C site were often very outdate or not focused on web browser pages.

We have no specific comment on the value or lack thereof in adding support of Images and Non-Text Data for VDT. However, if these images were to be transmitted via Direct, more guidance is needed on MIME fields to use to proper identify the content. This would also be true for handling more common scenarios such as including a stylesheet along with the CCDA. Likewise, some guidance is needed on how systems should parse the payload to properly extract the potential data payloads as identified by their MIME types.

We have no specific comment on the value or lack thereof in adding support of OpenNotes.

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

MU Objective

Provide clinical summaries for patients for each office visit.

2015 Edition EHR Certification Criterion

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

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

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

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

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

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

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

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

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

Preamble FR Citation: 79 FR 10907	**Specific questions in preamble?** *Yes*

Public Comment Field:

We support the changes to clarify medications and immunizations administered specifically for the encounter visit as well as relevant lab tests. We would suggest clarifying that "medications administered" include new medications ordered/prescribed. For many EHR systems, and in our testing experience we would say the majority, they create the clinical summary as simply complete patient summary record containing all possible historical patient data rather than data specifically targeting the visit in question. Very few EHRs demonstrated the ability to limit information to just that around the encounter visit, and the test procedure did not require this. We encourage to further define this criterion to have the EHR limit or allow customization on just updated information for that visit, for example new problem diagnosed. Otherwise, this criterion looks much like the summary available in the VDT criterion (315.e.1) which make is somewhat redundant.

We are concerned about the move to CCDA Release 2.0 for the same reasons expected in our comments on criterion 315.b.1.

§ 170.315(e)(3) (Ambulatory setting only – secure messaging)

MU Objective

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

2015 Edition EHR Certification Criterion

(3) 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 (or authorized representative) and EHR technology user are authenticated; and

(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

Preamble FR Citation: 79 FR 10908	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(f)(1) (Immunization information)

MU Objective

Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10908	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(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.

2015 Edition EHR Certification Criterion

(2) Transmission to immunization registries EHR technology must be able to electronically create immunization information for electronic transmission in accordance with:

(i) The standard and applicable implementation specifications specified in § 170.205(e)(4); and

(ii) At a minimum, the version of the standard specified in § 170.207(e)(2).

Preamble FR Citation: 79 FR 10908	**Specific questions in preamble?** *Yes*

Public Comment Field:

Others in the healthcare field are better prepared to comment on using NDC codes or other codes to replace CVX codes.

One additional comment we would make is that we have seen in our testing that the Immunization IG does not necessarily align with the other ONC criteria, such as using ICD-9 codes and also other races for demographics. If the IG can be better aligned with the ONC criteria, it will improve the overall CEHRT offering.

§ 170.314(f)(3) (Transmission to public health agencies – syndromic surveillance) and § 170.315(f)(3) (Transmission to public health agencies – syndromic surveillance)

MU Objective

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

Revised 2014 Edition EHR Certification Criterion

§ 170.314(f)(3) (Transmission to public health agencies – syndromic surveillance)

2015 Edition EHR Certification Criterion

§ 170.315(f)(3) (Transmission to public health agencies – syndromic surveillance)

(3) Transmission to public health agencies – syndromic surveillance. EHR technology must be able 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), (d)(5), or (k).

(B) Optional. The standard (and applicable implementation specifications) specified in § 170.205(d)(4).

(ii) Inpatient setting only. The standard (and applicable implementation specifications) specified in § 170.205(d)(4).

Preamble FR Citation: 79 FR 10909	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(f)(4) (Inpatient setting only – Transmission of reportable laboratory tests and values/results)	
MU Objective Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.	
2015 Edition EHR Certification Criterion (4) Inpatient setting only—transmission of reportable laboratory tests and values/results EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(g)(2); and (ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).	
Preamble FR Citation: 79 FR 10910	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

§ 170.315(f)(5) (Ambulatory setting only – cancer case information)	
MU Objective Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.	
2015 Edition EHR Certification Criterion (5) Ambulatory setting only—cancer case information. Enable a user to electronically record, change, and access cancer case information.	
Preamble FR Citation: 79 FR 10910	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

§ 170.315(f)(6) (Ambulatory setting only – transmission to cancer registries)	
MU Objective Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.	
2015 Edition EHR Certification Criterion (6) Ambulatory setting only—transmission to cancer registries. EHR technology must be able to electronically create cancer case information for electronic transmission in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2); and (ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).	
Preamble FR Citation: 79 FR 10910	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

§ 170.315(g)(1) (Automated numerator recording)

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10911	**Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(g)(2) (Automated measure calculation)

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10911	**Specific questions in preamble?** *No*

Public Comment Field:

We appreciate the work ONC put into this specific test procedure as the large amount of test data was beneficial in explaining how measures were to be implemented. We also want to share that this was an extremely challenging criteria, possibly the 2nd more difficult only behind CQMs (c.1-c.3).

As we continue with this percentage based measure testing, we actually need more detail to assist vendors is developing correct implementation. This type of work can be addressed outside the 2015 Edition regulation in the work of the supporting test procedures and test data. However, we want to use this opportunity to indicate further direction and guidance is needed to continue to improve this important criteria.

§ 170.315(g)(3) (Safety-Enhanced Design)

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

Preamble FR Citation: 79 FR 10911	**Specific questions in preamble?** *Yes*

Public Comment Field:

First, we should comment that from our experience that the usability test effort is not a small undertaking for EHR vendors. In fact, it was essentially one of the most difficult criteria to complete, although the vendor was not "judged" on the usability results. Privately, we had several vendors indicate they were glad they had to do this testing as it revealed key findings of their system which they were not aware.

Therefore, we support expanding the scope of the "Safety-Enhanced Design" to include additional certification criteria, but we recommend focusing only those highly used/highly critical criteria, like problem list or those with a more open design aspect, like electronic notes. If the scope expanded to most or nearly all of the criteria, it would be an unnecessary burden.

We believe formative testing can be very valuable, but we do not believe it needs to be used as a substitute for the summative testing required in this criterion. The reality is vendors who have an established user base are not re-designing their system's layout/design very often, and the usability changes are more gradual. Thus, there will not be sufficient opportunities to do formative usability testing in a typical certification cycle.

We believe the current process of not requiring explicit usability tests has been acceptable, but we do think there is value in at least offering suggested usability tests to be performed, although stopping short of absolutely requiring them. Many vendors, especially smaller ones, are seeking guidance as how to best conduct viable usability testing.

Internally as on ACB and ATL, we decided to require a minimum of 5 clinical-type users (e.g. doing CPOE) and 2 administrative-type users (e.g. configuring CDS activation) for our vendor submitted usability reports although we were open to vendors using less than those numbers if they could clearly show why that was warranted. We believe establishing an general guideline for minimum number of participants would be of benefit, but we would caution flexibility should still be considered and also that the number needs to be relatively low for small vendors who would struggle with obtaining a large number of users given their lack of resources.

Finally, we do ask for guidance from ONC as to how much of the usability testing conducted for 2014 Edition can be inherited into 2015 Edition or if the entire usability tests must be re-administered. Basically, what is the "shelf life" of a usability test report.

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

MU Objective

N/A

2015 Edition EHR Certification Criterion

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

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

Preamble FR Citation: 79 FR 10911	**Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

§ 170.315(g)(5) (Non-percentage-based measures report)	
MU Objective N/A	
2015 Edition EHR Certification Criterion (5) Non-percentage-based measures use report (i) For each capability included in EHR technology that is also associated with a meaningful use objective and measure that is not percentage-based (except for the capabilities specified in § 170.315(a)(12), (b)(1), and (d)) electronically record evidence that a user used or interacted with the capability and the date and time that such use or interaction occurred, in accordance with the standard specified at § 170.210(g). (ii) Enable a user to electronically create a report of the information recorded as part of paragraph (g)(5)(i) of this section for the user's identified Medicare or Medicaid EHR reporting period.	
Preamble FR Citation: 79 FR 10911	**Specific questions in preamble?** *Yes*
Public Comment Field: We support the creation of this new criterion as we believe it will help providers and their vendors as well provide confidence in proper EHR functionality in efforts to achieve of MU compliance. We believe the word "evidence" should be changed as it implies to strong of a legal ramification. The EHR can only indicate when different features/options were "triggered" or "activated" within the EHR but not that a user did or did not properly act upon the MU related feature. This criterion should function as a very specific type of audit log showing when various MU related features were performed or recorded or enabled.	

§ 170.315(h)(1) (Transmit – Applicability Statement for Secure Health Transport)	
MU Objective N/A	
2015 Edition EHR Certification Criterion 1) Transmit – Applicability Statement for Secure Health Transport Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(a).	
Preamble FR Citation: 79 FR 10914	**Specific questions in preamble?** *No*
Public Comment Field: We support breaking out this functionality into its own criterion.	

§ 170.315(h)(2) (Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging)	
MU Objective N/A	
2015 Edition EHR Certification Criterion (2) Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(b).	
Preamble FR Citation: 79 FR 10914	**Specific questions in preamble?** *No*
Public Comment Field: We support breaking out this functionality into its own criterion. Regarding the Gap Certification eligibility status of this criterion, a challenge to consider in implementing this is that for both of the optional transport standards are not currently referenced on the ONC CHPL. Since the ONC-ACBs do not have a place to record the certification status of these transports on the CHPL, they are often not listed on the certification certificate either. There is a place for these in ONC Test Report Summary template to record if they were tested. For the Drummond Group ONC-ACB, we do review and certify these transports, but the ONC CHPL should be updated to allow their certification status in 2014 Edition certifications.	

§ 170.315(h)(3) (Transmit – SOAP Transport and Security Specification & XDR/XDM for Direct Messaging)	
MU Objective N/A	
2015 Edition EHR Certification Criterion (3) Transmit – SOAP Transport and Security Specification & XDR/XDM for Direct Messaging. Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(c).	
Preamble FR Citation: 79 FR 10914	**Specific questions in preamble?** *No*
Public Comment Field: We support breaking out this functionality into its own criterion. Also see comment above for criterion § 170.315(h)(2) regarding Gap eligibility.	

§ 170.315(h)(4) (Transmit – Applicability Statement for Secure Health Transport & Delivery Notification in Direct)	
MU Objective N/A	
2015 Edition EHR Certification Criterion (4) Transmit – Applicability Statement for Secure Health Transport & Delivery Notification in Direct. Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(d).	
Preamble FR Citation: 79 FR 10914	**Specific questions in preamble?** *No*
Public Comment Field: We agree that the addition of this Direct MDN criterion will be valuable to further develop the EHR interoperability infrastructure.	

HIT Definitions

Public Comment Field:

We agree with the proposal to remove the Complete EHR definition. In our experience, we find many vendors still developing functionality which is typically not needed for their end users to support their MU attestation simply so they can claim the Complete EHR designation for marketing purposes. Going forward, we agree it will more difficult to maintain as we move to Stage 3 and beyond.

The biggest advantage to keeping the Complete EHR is it gives users full assurance that their EHR can meet MU objectives by just seeing the "Complete EHR" tag rather than looking at the list of individual certified criteria.

To that end, we encourage further development on the CHPL to help a user identify if their EHR in question will satisfy their intended MU objectives. One suggestion would be to allow a user to select the MU objectives which the provider/hospital is seeking to attest and utilize the CHPL entry to verify if the select CEHRT would in fact meet those measures.

If the Complete EHR designation remained, we would support the 2nd proposed option of defining a Complete EHR as "EHR technology that has been developed to meet, at a minimum, all mandatory certification criteria of an edition of EHR certification criteria adopted by the Secretary for either an ambulatory setting or inpatient setting and meets the Base EHR definition."

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

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

Applicability	
Preamble FR Citation: 79 FR 10918	**Specific questions in preamble?** *No*
Public Comment Field:	
We support the proposal to revise the "applicability" section (§ 170.501) for the ONC HIT Certification Program to clearly indicate that references to the term Complete EHR and Complete EHR certification do not apply to certification in accordance with the 2015 Edition EHR certification criteria and any subsequent edition of certification criteria adopted by the Secretary under subpart C.	

Non-MU EHR Technology Certification	
Preamble FR Citation: 79 FR 10918	**Specific questions in preamble?** *Yes*
Public Comment Field:	
We tentatively support the proposal for creating a "MU EHR Module" definition and a "non-MU EHR Module" non-MU certification and then allowing g.1/g.2 to be optional for "non-MU EHR Module" under a few conditions. First, we do see value in allow other communities to utilize the ONC certification program for compliance and verification of capabilities beyond MU so we do see the value in allowing this option. However, we do wonder currently how much demand there is for this. Hopefully you will hear from developers/users of non-MU settings. If there is not a significant demand, then it would not be worth doing this as it would just add unnecessary confusion. If it was adopted, we strongly recommend having distinct marks and certification language for both. The risk of confusing the healthcare community in the area is too greater if the certifications are easily confused. In that case, we would support revising § 170.523(k)(1)(i) to require a EHR Module developer to state whether its 2015 Edition EHR Module is "MU" or "non-MU" on its Web site nor in any marketing materials, communications statements, and other assertions related to the EHR Module's certification or at least to clearly mark if certified as non-MU. Using a separate mark/logo would be best. Again, we are just concerned about vendors skipping g.1/g.2 testing, which is extremely challenging, and then marketing themselves as ONC certified when the HIT community generally relates ONC certification to MU compliance. From our standpoint, we believe the best process for an EHR technology developers to inform ONC-ACBs as to the type of EHR Module certification would be to require the develop to explicitly notify the ONC-ACB in writing or some other special form of this request to NOT be certified for MU. Since the large majority of vendors will be pursuing certification for MU, it is better for that to be the "default" and not add confusion. Instead, it would be clear in our testing and certification guides that non-MU certification can be achieved and then lay the separate steps to achieve that. Thus, vendors who want this type of certification must explicitly seek it out so to reduce the risk of "accidentally" choosing non-MU when MU is the desired option, which it will be for nearly all EHR vendors. In terms distinguishing non-MU on CHPL, we would suggest a separate column indication or even coloring to identify the distinction. However, we suggest going slowly on this as it is not clear how big a need this will even be.	

ONC Regulations FAQ 28	
Preamble FR Citation: 79 FR 10920	**Specific questions in preamble?** *No*
Public Comment Field:	
We support this proposal to revise § 170.314(g)(1) to be an optional certification criterion as a means of providing regulatory clarity for the certification of Complete EHRs to the 2014 Edition.	

Patient List Creation Certification Criteria	
Preamble FR Citation: 79 FR 10920	**Specific questions in preamble?** *No*

Public Comment Field:

We support the proposal to allow EHR technology presented for certification to a "patient list creation" certification criterion (2014 or 2015 Edition) but does not include a capability to support "patient reminders," to NOT be certified to the "automated numerator recording" certification criterion (§§ 170.314(g)(1) for the 2014 Edition and 170.315(g)(1) for the 2015 Edition) nor the "automated measure calculation" certification criterion (§§ 170.314(g)(2) for the 2014 Edition and 170.315(g)(2) for the 2015 Edition) for "patient reminders" percentage-based measure capabilities. In our experience, there are only a handful of systems which this is applicable so it will not be widespread situation but more of very niche focused market.

ISO/IEC 17065 (§ 170.503(b)(1))	
Preamble FR Citation: 79 FR 10920	**Specific questions in preamble?** *No*

Public Comment Field:

We support the proposal to revise our references to ISO/IEC standards 17011, 17065 and Guide 65 in § 170.503 by removing or not including the date reference for each standard.

ONC Certification Mark (§ 170.523(k)(1))	
Preamble FR Citation: 79 FR 10921	**Specific questions in preamble?** *No*

Public Comment Field:

In general, we support the use of the "ONC Certified HIT" certification and design mark (the "Mark") for certifications of the ONC program. However, we would like some further guidance how options to include the ONC-ACBs personal mark alongside with the ONC mark. We believe these details can be worked out in discussions with ONC and the ONC-ACBs to ensure the singular identifying mark from the ONC and company marks as well.

Certification Packages for EHR Modules	
Preamble FR Citation: 79 FR 10921	**Specific questions in preamble?** *Yes*

Public Comment Field:

As a testing and certification body, it is difficult to assess the value in these certification packages for the user community because we are so "deep" into the testing and certification that we consider the EHRs at the most granular level, down to what optional standards they implement, so a package designation it rather moot to us. Of course, we are not the target audience of this packaging.

For any new designation to be of value, it has to provide special meaning and represent something beyond the ordinary. To put it another way, if most everyone can display it, it probably does not mean much. Therefore, we would encourage ONC to make the packaging represent specific turnkey functionality that goes beyond the ordinary.

For Care Coordination Package, we would suggest adding 170.315(h)(1) (Transmit – Applicability Statement for Secure Health Transport) since we expect most EHR Module which certify to 315.b.1 would also certify to 315.b.2 and therefore it would not reveal much. Adding the 315.h.1 would represent a full support of TOC measure.

For Patient Engagement Package, we suggest NOT adding the 170.315(a)(16) (Patient list creation) or § 170.315(a)(17) (Patient-specific education resources) criteria as those features are almost always very distinct from the e.1 and e.3 criteria. Frankly, it would be a stretch for most portal systems to attempt to add those two criteria and often rather useless for a provider, who will need the functionality for those two criteria in "main" EHR. Many vendors of portal systems initially express interest in Patient Education criterion. However, after they realize that criteria is more about the selection of education materials rather than the storage/delivery of education material then they decide against pursuing it. Same with the Patient List creation which actually does not cover the actual creation of patient reminders themselves.

One packaging we would suggest ONC consider is a Public Health Package which covers § 170.315(f)(2) (Transmission to immunization registries), § 170.315(f)(3) (Transmission to public health agencies – syndromic surveillance, § 170.315(f)(4) (Inpatient setting only – Transmission of reportable laboratory tests and values/results) and § 170.315(f)(6) (Ambulatory setting only – transmission to cancer registries). A package like this would indicate quick assurance that the EHR can support the provider or hospital in any of the public health related transmission options and present something of an achievement since many ambulatory EHRs elected to not do the optional Cancer Case submission criteria.

Another packaging we suggest is a Transmit package covering § 170.315(h)(1) (Transmit – Applicability Statement for Secure Health Transport), § 170.315(h)(2) (Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging), § 170.315(h)(3) (Transmit – SOAP Transport and Security Specification & XDR/XDM for Direct Messaging) and § 170.315(h)(4) (Transmit – Applicability Statement for Secure Health Transport & Delivery Notification in Direct). This would quickly indicate to a user that the EHR module is capable of supporting any of transmission method defined in the ONC program.

From a surveillance standpoint, there would be some extra time needed to verify vendor accuracy in their representation of certification packages on their marketing. However, it would probably not be too significant of a burden as long as the packaging options did not overall or too numerous.

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

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

Additional Patient Data Collection	
Preamble FR Citation: 79 FR 10922	**Specific questions in preamble?** *Yes*
Public Comment Field:	
Others in the healthcare field can better comment on the value of implementing this certification criterion this in terms of impact of patient care. However, given that this type of information is what a healthcare provider would need to know and computer systems are well designed for data recording, it would make sense to expand patient data collection beyond the core demographics currently captured. It would also not necessarily be challenging to verify through testing activities. We would add that given that most of the information in this section is information only the patient would know that it would make sense for EHR systems to allow this information to be record in a patient portal or kiosk which is then synced to the patient records in the main EHR system. This type of architecture is out of the scope of ONC rule making, but it would be worth confirming that EHRs may collect and record this type of information through various means as long as it is securely handled and unambiguously explained.	

Medication Allergy Coding	
Preamble FR Citation: 79 FR 10925	**Specific questions in preamble?** *Yes*
Public Comment Field:	
The explanation in the NPRM makes a compelling case to add better allergy coding, especially given the importance of patient safety and correctly identifying allergies. As a testing body, this would not necessarily be difficult to test as long as vocabularies/requirements are well defined. From our experience, we have seen that EHR systems often do not have sufficient granularity to identify ingredients apart from individual drugs. However, our concern is the complexity for the vendors in implementing all of these areas. Adopting of additional vocabularies to code medication allergies to drug ingredients would not necessarily be an easy task for vendors as it would require changes in several areas of the EHR (medication allergy list, DDI, clinical information reconciliation, CQMs, etc.). Using NDF-RT seems like the best option given its mapping with RxNorm which is already used in medication allergies now.	

Certification Policy for EHR Modules and Privacy and Security Certification Criteria	
Preamble FR Citation: 79 FR 10925	**Specific questions in preamble?** *Yes*

Public Comment Field:

We were a part of the 2011 Edition program which required vendors submit a Privacy and Security attestation document for review and approval in order NOT to test the eight required privacy and security criteria. It was not used very often as most vendors did support all eight, but when it was invoked, the process worked well and it was fairly easy to evaluate. Not having it in 2014 Edition has been easier from a man-power perspective, but it was not a significant change.

As noted in the NPRM, relaxing the requirements of minimum certification of privacy and security has not caused a wide change in the choices of most vendors. In our experiences, vendors who choose not to pursue certification of privacy and security criteria do so because their EHR is a more niche-focused EHR which is utilized in conjunction with another main EHR system, for example patient portal or clinical quality measure system. In most of those situations, we expect the vendors could have certified some privacy and security criteria but simply choose not to because of the permission in the ruling. However, we also do not think their users were "surprised" at this as they presumed the main privacy and security components would be supplied by their main EHR system.

Of the options put forward, we believe the other options besides Option #3 (the HITSC) would be fine, but we do not believe the HITSC option is a good choice. It adds unnecessary compilation. Option #1 (2011 Edition method) or Option #2 (2014 Edition method) are equally as good, with each have strengths and weakness but overall balancing each other out. Option #4 has merit, but we would recommend that if selected it would be slightly modified so that each ONC criteria had its own list of minimum criteria based on the functionality. Making a universal minimum list is not appropriate. For example, the authentication, access control, and authorization certification criterion would probably be required for most criteria as most criteria require some type of user interface to perform the requirements of the criteria. However, some criteria which can be handled through an interface system may not need authentication, access control, and authorization certification criterion. For example, a CQM analytics system may just be a software service that is configured by data files without needing a user interface. However, an EHR certifying in Drug-Drug/Drug-Allergy Checking would have to have authentication, access control, and authorization because the criteria requires only certain users have access to intervention setting (thus needing authorization controls).

If we had to make our choices, our order of preference would be:

1. Option #2 (2014 Edition approach)
2. Option #1 (2011 Edition approach)
3. Option #4-Modified) (Adopt a limited applicability but per criteria or still allow exception requests to be processed)
4. Option #4 (Adopt a limited applicability approach)
5. Option #3 (HITSC approach)

Provider Directories	
Preamble FR Citation: 79 FR 10926	**Specific questions in preamble?** *No*

Public Comment Field:

We agree that provider directories query should be strongly considered for 2017 Edition as this is the obviously next step in summary care interoperability after addressing the transport layer via Direct. While these standards are still somewhat new at this point, they are near the point where vendors can begin implementation if there is sufficient market demand. The EHR | HIE Interoperability Workgroup has worked on this, but so far there has not been widespread adoption among EHR vendors. It will likely require ONC direction and/or requirements to push this forward. However, it should be considered the fact that Direct was a significant challenge to implement, and this will be as well, if not more so. The requirement level bar should be set so that it is high enough to be of use but no so high that it proves too difficult for widespread vendor implementation.

Oral Liquid Medication Dosing	
Preamble FR Citation: 79 FR 10926	**Specific questions in preamble?** *Yes*

Public Comment Field:

Others in the healthcare field can better comment on the value of implementing this certification criterion this in terms of impact of patient care. One related comment to add is that we have seen vendors struggle to properly codify medication dosing information within the CCDA in terms of consistency across all EHR system. This is an area where further guidance (and examples) would be useful, although this may need to come from HL7 rather than ONC.

Medication History	
Preamble FR Citation: 79 FR 10927	**Specific questions in preamble?** *Yes*

Public Comment Field:

Others in the healthcare field can better comment on the value of implementing this certification criterion this in terms of impact of patient care. In our experience, many EHR systems do obtain medication history information from RxHub/Surescripts.

Blue Button +	
Preamble FR Citation: 79 FR 10927	**Specific questions in preamble?** *Yes*

Public Comment Field:

We have discussed internally how testing for BB+ would work, and we believe there is a market for this, or at least there soon will be after more portals are deployed in Stage 2. In our experience, several EHR systems still need to manually upload/sync patient data to the portal, and the use of BB+ with automation/triggers would be of value. The testing and certifying BB+ would be a natural extension of the current testing and certification already done by the ONC.

2D Barcoding	
Preamble FR Citation: 79 FR 10928	**Specific questions in preamble?** *Yes*

Public Comment Field:

We do test 2D barcoding for the eMAR criteria (314.a.16). While it is not explicitly required, every EHR system we have certified in eMAR has used barcoding. Expanding the 2D barcoding capture would be a natural fit for most systems, at least Inpatient. Others in the healthcare field can better comment on the value of expanding this in terms of impact of patient care.

Duplicate Patient Records	
Preamble FR Citation: 79 FR 10928	**Specific questions in preamble?** *Yes*

Public Comment Field:

From our testing experience, we would agree with your statement that patient matching capabilities vary and are inconsistently applied in EHR technology today. Additional guidance and direction is needed.

Disaster Preparedness	
Preamble FR Citation: 79 FR 10928	**Specific questions in preamble?** *Yes*

Public Comment Field:

Others in the healthcare field are better prepared to comment on the specifics of EHR support for disaster preparedness than we are. However, we would encourage ONC to consider how they could at least support the efforts to create guidelines/best practices on these areas of standardized naming convention for EHR technology to use for temporarily naming unidentified patients and these other areas. Even without a specific certification requirement behind it, this work could help align the industry and encourage those have not adopted this capability a starting point for doing so.

Certification of Other Types of HIT and for Other Health Care Settings	
Preamble FR Citation: 79 FR 10929	**Specific questions in preamble?** *No*

Public Comment Field:

Our only comment is that we do get requests from other healthcare groups for specialty specific types of certification. We have not followed through with this effort as we did not want to attempt to define any requirements apart from the work the ONC is doing. If the HIT community believes certifications requirements for other types of HIT would be of benefit, then ONC is the best place to define and implement these requirements.