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200 Independence Ave, S.W. Washington, D.C. 20201

Submitted electronically via www.regulations.gov

Re: Voluntary 2015 Edition EHR Certification Criteria - Proposed Rule

Dear Dr. DeSalvo:

athenahealth, Inc. ("athenahealth") appreciates the opportunity to provide comments on the proposed rule entitled "Proposed Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements".

We provide practice management, electronic health record, patient communication, care coordination, and related services to physician practices, working with a network of approximately 50,000 healthcare professionals nationwide. All of our providers access our services on the same instance of continuously- updated, cloud-based software. Our platform has enabled us to take an active role in assisting our clients in achieving Meaningful Use ("MU"), for example by aggregating MU data and working closely with our base of eligible professionals to monitor their progress against MU measures.

In these comments, we address the following topics, borrowing where possible the comment template provided by the Office of the National Coordinator ("ONC"):

- General Remarks
- Proposed Criteria for 2015 Edition Certification Criteria
- Provisions of the Proposed Rule Affecting the ONC HIT Certification Program
- Other Topics for Consideration for the 2017 Edition Certification Criteria Rulemaking

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General Remarks

athenahealth has long argued that in the second decade of the 21st century, the sole indispensable measure of "meaningful use" of any information technology is and should be actual interoperation between and among vendor platforms. Sadly, this continues to be a measure on which the health IT industry as a whole falls woefully short. We urge ONC to resist inevitable calls from vendors of non-interoperable technology platforms to lower interoperability standards and delay timelines. Previous repeated acquiescence to such demands, unfortunately, has significantly slowed progress toward true modernization of the nation's care delivery system.

athenahealth supports the advance notice that this NPRM provides, relative to the 2017 timeframe for Meaningful Use Stage 3 implementation. Though ours is an agile cloud-based EHR designed for iterative innovation and rapid evolution, the greater lead time will allow vendors to methodically prioritize and build new CEHRT functionality in alignment with client needs and concurrent development priorities.

We are also encouraged by the inclusion and expansion of standards related to the exchange of health information, patient engagement, quality reporting, and patient safety in the Proposed Rule. The increased focus on these critical areas will lay the foundation for providers to leverage health IT to achieve the Triple Aim of better patient care, better population health, and lower costs.

While we encourage ONC to continue furthering this cause, we caution that, while every new type of functionality is usually "good to have", it is not always the right trade-off to make relative to other, more valuable types of functionality that would serve the nation's care providers and patients more effectively. For example, this certification requires relatively little from the ability to Query & Retrieve clinical documents and even less from provider directories. These are two significant gaps in health IT today, and are far more impactful gaps than the need to continually re-visit the "code sets for Preferred Language" or the "Privacy & Security certification process". A sharpening of focus on high-value requirements would be far more effective than continued regulatory attention to requirements that provide relatively little benefit to most providers and patients.

In a related vein, readers and implementers of this regulation would be best served from an explicit reminder – or reset if necessary – of the policy goals of this regulation, especially as it is now decoupled from the Centers for Medicare and Medicaid Services ("CMS") Meaningful Use performance regulation. In particular, this NPRM seems, on occasion, to require or discuss functionality that goes beyond the Meaningful Use program goals of electronic data capture, interoperability, patient engagement, and improved outcomes. A number of the issues discussed are geared either to special interests (e.g., Military Service status) or gathering copious data from providers (QRDA I standard, Occupation codes) without a clear benefit. We recommend that more commentary, clarifications or even revisions should be included to align the purpose of this regulation with the core programmatic goals of Meaningful Use.

It is vitally important for both the ONC and CMS to maintain enough flexibility in the rules to foster continued innovation. Particularly in the case of health information exchange, we hope ONC will consider the certification criteria as minimum baseline standards, upon which both existing and innovative new means of electronic exchange can support providers in their achievement of Meaningful Use. We hope, in tandem, that CMS will aim for a Meaningful Use Stage 3 regulation that is closely aligned with these requirements, put in the context of the variety of real-world processes employed to provide effective care.

We strongly urge ONC and CMS to continue working together to enable providers to free themselves of the data silos and locked-in EHRs that encumber them today, and that work against the overriding policy goal of information fluidity and interoperation in health care. Stated simply: providers should be able to switch to technology solutions at any point in a MU reporting year. The current one-year reporting period expected applicable beginning in 2015 will prevent such

provider flexibility, stifling vendor competition and care innovation and effectively locking thousands of providers into their underperforming EHRs, or forcing them to forego attestation and incur penalties in order to make a switch. Greater attestation flexibility should be allowed to providers switching EHRs to enable and encourage technology upgrades. Further to this same end, ONC should strongly urge CMS to publish a list of vendors whose technologies have formed the basis for a "hardship exemption" from MU penalties, to enable care providers in the new or replacement EHR market to evaluate vendor promises against the reality of past MU performance.

We commend ONC's commitment to a transparent rule-making process, through public access to the Federal Advisory Committee meetings and recommendations, presence at industry events like HIMSS14, and participation opportunities in private-public collaborations such as the S&I Framework, and we appreciate this opportunity to comment.

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

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: We strongly support the proposal to split the CPOE certification criterion into three separate certification criteria focused on each of the three order types. As noted in the NPRM, such an approach enables innovative workflows that are more intuitive for the provider (e.g., mobile CPOE for medications) and does not constrain the future evolution of these workflows.	

§ 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*

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

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Public Comment Field:

As mentioned above, we strongly support the proposal to split the CPOE certification criterion into three separate certification criteria focused on each of the three order types. In addition, we agree that a certified EHR should have the ability to format lab orders as per the S&I Framework Lab Orders Interface (LOI) specification.

However, while we acknowledge that this S&CC rule does not set Meaningful Use thresholds for usage, we nonetheless caution to policymakers that, at this stage of the industry's development, the usage of this standard should be optional, due to two reasons:

(1) In the past, forward-looking organizations had already built the capability for exchange of electronic lab orders. Ripping and replacing this existing infrastructure will provide no additional value – it will simply contribute to overhead and cost on the part for vendors and ultimately providers.

(2) Today, clinical laboratories are not required to use the LOI standard, and much like the Lab Results Interface (LRI) standard introduced for the 2014 Edition, there is unlikely to be any pickup of the standard due to Meaningful Use. Instead, as for LRI, the EHR and/or provider will have to use a custom solution for every individual lab.

As such, we strongly endorse the capability of the EHR to be able to produce a LOI-formatted order, but not that providers are subsequently required to use it for a corresponding measure threshold. We note that, if forces like Clinical Laboratory Improvement Amendments (CLIA) and the American Clinical Laboratory Association (ACLA) are able to drive laboratory adoption of the standard – and hopefully automated/near-automatic interface validation options on top of this foundation - then we will have truly scalable closed-loop interoperability, and that is worth the early investment in building the capability. At that point, broad adoption and usage will inevitably follow.

§ 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:

As mentioned above, we strongly support the proposal to split the CPOE certification criterion into three separate certification criteria focused on each of the three order types.

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

MU Objective

Implement drug-drug and drug-allergy interaction checks.

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§ 170.315(a)(4) (Drug-drug, 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:

We support the adoption of a future certification criterion that would require EHR technology to be able to track health professionals' responses to the DDI/DAI checks that are performed. However, we think that the suggestion of tracking "viewed, accepted, declined, ignored, overrode" can actually be more detrimental than useful, for the following reasons:

(1) The terms are ill-defined: if a particular DDI rule triggers a recommendation and the provider dismisses it, would that be an instance of "decline" or "ignore"? If (s)he took some other step online or offline, would that mean (s)he overrode it, and to what degree would the EHR be responsible for tracking any step that was taken offline? In a similar vein, "view" is also ill-defined: does "view" mean that it was displayed on screen or that a button was clicked? Is such a distinction important for most DDI checks, or just the severe ones?

(2) Presenting this relatively large set of overlapping options can create confusion to the user. Even on the backend, tracking this seemingly precise data may provide false insights; for example, there may not be any real causality behind a series of EHR actions made by the provider and the inferred DDI/DAI paths for decline vs. ignore vs. override.

(3) The "commented on the product of the DDI/DAI check" is a needless addition. There are already natural, intuitive and non-invasive opportunities for capturing this data alongside the medications prescribed, and adding yet another data field contributes to further documentation work that the provider will need to do. This creates very little value and subtracts from the face-to-face time between providers and patients.

Instead, we suggest that the menu set of responses will be more helpful if limited as follows:

(1) For all DDI/DAI checks, it is reasonable for the EHR to track that the DDI/DAI check was "displayed", rather than "viewed". Putting the onus on the EHR to ensure that it is displayed - rather than on the provider to necessarily indicate (e.g., through a button-click) that it was viewed - will reduce the likelihood of alert fatigue.

(2) Only for "severe" DDI/DAI should more tracking options be enabled. We suggest two useful, clear-cut options: "Accepted" and "Declined", which the user must explicitly indicate. This will enable tracking of willful acceptance or rejection of the intervention, while maintaining a streamlined user experience, preventing pop-up fatigue, and enabling meaningful analytics. (Note that we believe that the term "severe" should also be defined, or if there is no industry standard then it should be determined by the EHR and/or its DDI/DAI content provider.)

In terms of the mechanism for reviewing tracked data, we suggest that responses to "severe" DDI/DAI checks should be accessed similarly to other data captured for auditing purposes, rather than contributing to on-screen clutter, as users will not engage with this functionality regularly. We believe that users should be able to configure their preferences for DDI/DAI checks based on personal preferences. As to "whether EHR technology should be able to track when an adverse event occurs", this suggestion is not practical because there is often no way to do so, particularly in the ambulatory setting, as adverse events largely occur outside of patient-provider experience.

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§ 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:

While we provide detailed comments and suggestions below, our overarching concern with this criterion is that it embodies a very poor trade-off in terms of the value of changing this standard at every Edition versus the time and effort spent on updating the EHR. Simply put, while we agree demographics are important to capture, there are more impactful and unsolved interoperability issues in which EHRs should be investing rather than continuously updating code sets for demographics.

Detailed comments:
We suggest that the full set of CDC Race and Ethnicity codes should be captured natively by the EHR. We caution that, for Race, OMB only supports 5 race codes and does not support the CDC R9 ("Other Race") code – a severe limitation on the semantic value of the code set, and cause for confusion for patients who obtain their health records. We suggest that OMB either expand their list of accepted codes, or that ONC update the Validator to allow R9 codes for certification/compliance.

For ethnicity, the CCDA specifies only two ethnicity values: 'hispanic or latino' or 'not hispanic or latino', so the EHR is forced to map down to these values even though providers can capture a richer set of ethnicities using the CDC codeset. We suggest that richer data be sent to enable stronger patient satisfaction and meet the needs of future data usage, and as such suggest that the CCDA support the CDC set rather than this binary option.

For preferred language, our analysis reveals that the 639-3 is far too granular – for example, it includes an overabundance of micro-dialects, as well as rarely-used historical languages – and so will result in a highly deteriorated provider performance and patient experience. On the other hand 639-1 excludes a number of active languages that are not uncommon across the US population. As such, our recommendation is to use the 639-2 standard, which is "just right" in terms of granularity and coverage. We also suggest that:
(1) An "Other " option should be available for the very small handful of meaningful languages excluded from this code set. For example, our experience has shown that "Hopi" and "American Sign Language" are popular enough to justify the need for an "Other" option, though these languages in particular would be even better served if there were given special exceptions as done for MU2014.
(2) An "Unknown" option should be available as it can be a legitimate response to the Preferred Language question.
(3) EHR certification should not prescribe how the language options are displayed, so that the EHR and providers can

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§ 170.315(a)(5) (Demographics)
determine how best to streamline the user experience for the patient population (e.g., which languages should be on a "Favorites" list vs. only available on the "Comprehensive" list).

§ 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:	
We support the usage of standardized code sets for all of the components mentioned in this NPRM, even more so if there were a single standard that would encompass all of the components. While we will refrain here from commenting on any one standard, we strongly encourage further research into the limitations of LOINC before any recommendation is made to use it. Our concern is that LOINC has been used more extensively in lab settings rather than other clinical settings, and vitals (e.g., head circumference) may not be as evenly covered by the code set as yet. In terms of approach, we strongly recommend "Option 2: require that EHR technology be able to represent such data … when such data would be exchanged" rather than requiring it to be captured natively. While it is possible that EHRs, over time, will natively store the data in standardized code sets, the value of implementing such standards is during interoperation with another system, and it is at that interface between the two systems that unambiguous specificity is most required. As such we think that Option 2 enables the EHR the flexibility to choose a conducive path towards interoperability. Note that when we refer to the "exchanged" language from the NPRM, we expect this to refer to both the import and the export of data, to enable true bi-directional semantic interoperation.	

§ 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).

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§ 170.315(a)(7) (Problem list)	
Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *No*
Public Comment Field: We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.	

§ 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: We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.	

§ 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: We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.	

§ 170.315(a)(10) (Clinical decision support)
MU Objective Use clinical decision support to improve performance on high-priority health conditions.

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§ 170.315(a)(10) (Clinical decision support)
2015 Edition EHR Certification Criteria (10) Clinical decision support. (i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) At least one demographic specified in paragraph (a)(5)(i) of this section; (E) Laboratory tests; and (F) Vital signs. (ii) Linked referential clinical decision support. (A) EHR technology must be able to: (1) Electronically identify for a user diagnostic and therapeutic reference information; or (2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (3). (B) For paragraph (a)(10)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(10)(i)(A), (B), and (D) of this section. (iii) Clinical decision support configuration. (A) Enable interventions and reference resources specified in paragraphs (a)(10)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role. (B) EHR technology must enable interventions to be electronically triggered: (1) Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section. (2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(i)(B) of this section. (3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4)(i)(A)(1) of this section. (iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(10)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology. (v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources: (A) For evidence-based decision support interventions under paragraph (a)(10)(i) of this section: (1) Bibliographic citation of the intervention (clinical research/guideline); (2) Developer of the intervention (translation from clinical research/guideline); (3) Funding source of the intervention development technical implementation; and (4) Release and, if applicable, revision date(s) of the intervention or reference source.
(B) For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline). (vi) Decision support – knowledge artifact. Electronically process clinical decision support knowledge artifacts in accordance with the standard specified at § 170.204(d). (vii) Decision support – service. Enable a user to electronically make an information request with patient data and receive in return electronic clinical guidance in accordance with the standard specified at § 170.204(e).

Preamble FR Citation: 79 FR 10890	**Specific questions in preamble?** *Yes*

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§ 170.315(a)(10) (Clinical decision support)
Public Comment Field:
We support the proposal that EHR technology must demonstrate the capability to use at least one of the more specific data categories included in the "demographics" certification criterion. Further, we agree with the decision to drop the required adoption and use of Infobutton, particularly as it does not adequately support laboratory values/results. On the other hand, we suggest that while the standard should be left up to the EHR, it actually ***is*** exceedingly important and clinically sensible to enable CDS rules to be triggered by laboratory values/results, and advocate for retaining it in this criterion as an optional trigger. Athenahealth is a strong advocate for the power of open markets and open systems to dramatically improve the lives of patients and providers. As such, we applaud ONC's efforts to facilitate an open market for clinical decision support rules through the Health eDecisions (HeD) initiative. The caution we will add here is that the HeD set of standards have only recently been authored, and have not been adequately proven to work, e.g., through production-grade pilots. We urge that ONC not mandate the implementation of these standards into the EHR until there is proof of their viability. While we have not yet implemented the Decision Support Service IG for HeD, we also point out that requiring transactions with an external system during a medical encounter has the potential to create significant latency issues, thus damaging the provider experience and taking away from the time the provider may spend with the patient. Again we would suggest further real-world usage before this standard became a required component of the EHR.

§ 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*

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§ 170.315(a)(11) (Electronic notes)
Public Comment Field:
Although implementation of search across electronic notes will be non-trivial to many EHRs, providers deem this functionality highly useful. More specifically, we advocate for the ability to search across all closed encounters (sometimes referred to as "finalized notes") within a particular patient's record – this is the most powerful and commonplace use case that providers often struggle with today. Conversely, the capability to search across the whole patient population is both a burdensome investment by the EHR vendor as well as a potentially confusing user experience for the provider, especially given that it is a rarely-needed use case in comparison to the single-patient scenario. While we support the notion that metadata is extremely useful in improving search capability and efficiency, we fear that this proposed criterion is being too prescriptive. We do not see any value in mandating specific data to use for this purpose as it can hinder more innovative approaches beyond that which regulation can prescribe. Even more so, mandating the use of a particular implementation or specification is counter-productive given that there are no standards appropriate for this purpose. The NPRM suggests HL7 R2 as an example, but this is a standard meant specifically for document exchange rather than enhanced system functionality, and has a very high performance and memory overhead relative to the data it captures. As such we suggest that no requirement be imposed on metadata as it would need to be deliberately vague. Despite our support for the functionality as we have described above, this electronic notes criterion is particularly perplexing, as it is unclear why it would be included in regulation associated with Meaningful Use. The relationship between this functionality and the stated goals of Meaningful Use is not apparent. Even more worryingly, we fear that, 5-10 years from now, this criterion will be construed as an attempt to legislate a specific then-state-of-the-art innovation, which should have been left to evolve over time as technology itself rapidly evolves. In other words, policy should not directly legislate innovation; that should be left to innovators, in the context of policy geared towards making innovation possible.

§ 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*

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§ 170.315(a)(12) (Drug formulary checks)
Public Comment Field:
We support the proposal to use the NCPDP Formulary and Benefit Standard version 3.0, as version 4.0 is too unstable to be ready for mandated usage at this stage. We suggest that this certification criterion be left flexible as the market is likely to adopt it as de facto standard regardless. We also suggest that a formulary standard needs to be specified in the 2015/2017 criteria in addition to the NCPDP Telecommunications Standard ("Telecom"). While Telecom is a worthy standard whose benefits and usage in EHRs should continue to be explored, the current gaps in the standard for alternative medications will create new workflow issues for vendors and providers; as such, an alternative formulary standard should continue to be available.

§ 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:	
We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.	

§ 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:	
We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.	

§ 170.315(a)(15) (Family health history)
MU Objective
Record patient family health history as structured data.

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§ 170.315(a)(15) (Family health history)	
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:	
Similar to our comments on the demographics criterion and in our General Remarks, we urge ONC to not mandate change for the sake of change – the value to industry in repeatedly changing standards for a single type of content is progressively minimal. In the specific case of Family Health History, it would seem that the usage of a more broadly-adopted standard (SNOMED) would be the logical choice over the HL7 Pedigree standard; as such we implore ONC to further expound upon why they view the Pedigree standard as superior. It is our view that the age of a standard is not an indication of its usefulness: so while this NPRM is accurate in stating that the Pedigree standard was new in the 2014 Edition and requiring it as the only standard would not have been prudent at that time, it is unclear that the standard has demonstrated its superiority since that time. As such, we are not supportive of this change to the criterion.	

§ 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:	
We suggest that the available list of patient communication preferences be left up to the provider. Ultimately the provider will need to determine the best media for communication with his/her patients, responsive to both his/her patient population and the realities of his/her practice's capabilities. Mandates in this arena are destined to be quickly outdated as modes of communication rapidly evolve, and providers continuously respond to their patients' needs. We strongly oppose any criterion that requires EHR technology be able to provide patient reminders according to the patient-identified patient language, simply because there are just too many languages to support in practice. If the intent is to pick the most common subset set of languages (presumably English and Spanish), then this requirement is still problematic as it can quickly lead down a slippery slope as to which languages should be required and which should not.	

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§ 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:	
As with the electronic notes requirement, while we are supportive of the types of innovations being built into EHRs, it is unclear why they should be incorporated here in conjunction with Meaningful Use regulation. Specifying a standard for patient-specific educational resources seem overly prescriptive, without furthering the needs of interoperability and, even worse, potentially obstructing the opportunity to provide a much more innovative experience to providers and patients. Looking at this another way: we have been providing patient education resources since before the advent of Meaningful Use; to provide it in a "standard" format is simply additional work for no incremental value. Given the choices presented by the NPRM, we think that bare-minimum baseline standard such as Infobutton seems reasonable, and as such we advocate for "Option 3" of the choices provided: the ability to certify to Infobutton with the corollary ability to use other workflows as the product evolves without needing to certify every time. In terms of the language in which the patient-specific education is delivered, we do not support that this be required to be in the patient's preferred language, as the set of preferred languages is far greater than the number of languages supported by Patient Education vendors, and will be cost-prohibitive.	

§ 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:	
On the whole, we support the adoption of the capability to capture and share UDI information. We agree with the	

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

implicit assumption that the industry is reaching a sufficient state of maturity to enable capture and reporting of device information, albeit manually at first until specifications evolve. We also support sharing of this data through the CCDA. However, we do not think the industry has reached a point of maturity and adoption such that we can realistically expect device information to be electronically communicated between the device and the EHR. In addition, while we absolutely support the ability to trigger Clinical Decision Support rules off of this device information in the future, today there are a great many unknowns between this first step of capturing UDI information and the subsequent step of inferring and triggering relevant care information. The state of adoption is simply too nascent to build safe and vetted clinical rules, and so we suggest that CDS portion of this rule be shelved until adoption matures.

In terms of the device data suggested, we agree that the EHR should have the ability to capture all of the stated data elements; however we strongly oppose that the provider be required to capture this data every time, because there are likely to be a number of legitimate circumstances under which this information will simply not be available.

In terms of Automatic ID and Data Capture (AIDC), while this idea is worthy of further piloting and demonstration, we believe this will be highly impractical requirement for certifying EHR technology. Devices are heterogeneous enough that a certification script oriented around this requirement will necessarily have to be device-specific, heavily contextualized, and essentially "staged" – and thus meaningless. These practical challenges aside, we believe that AIDC is a sensible path for the industry, and will be adopted through the power of market forces alone, as EHRs compete to improve the provider experience.

With respect to using the device identifier portion of the UDI to obtain and incorporate GUDID device identification attributes, it is clear that this process is simply not production-ready today. As an example, two weeks before the submission of these comments, the FDA GUDID system was down for a period of four days. Additionally, the FDA has communicated that they are currently working on this system and there is **draft** guidance available. We strongly advise more robust testing and broader usage before requiring such a capability to be built into the EHR.

We commend ONC for suggesting the use of UDI information to generate patient lists and for other reporting purposes, as we believe that this will create the greatest value from capturing UDI information in the near-term.

Finally, taking the further step of enabling exchange with procedure reporting systems makes tremendous sense in theory, but our experiences with similar requirements from earlier stages of Meaningful Use (such as Syndromic Surveillance requirement) should remind us to be wary of three important pragmatic constraints: (1) Not all providers will use any devices whatsoever; (2) there needs to be a single, unambiguous standard for exchange; (3) Receivers (procedure reporting systems, and the organizations who maintain them) need a very long lead time to be ready to receive data. So while we strongly advocate for the ability to capture this data and use it as per our suggestions above, we caution that it should not be a requirement for use in complementary Meaningful Use performance measures.

§ 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.

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§ 170.315(b)(1) (Transitions of care)

2015 Edition EHR Certification Criteria

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

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

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

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

(iii) Display.

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

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

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

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

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

(3) Cognitive status;

(4) Functional status;

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

(6) Inpatient setting only. Discharge instructions; and

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

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

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

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

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

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

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

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

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§ 170.315(b)(1) (Transitions of care)
(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:

We support the decoupling between the functional requirements of Transitions of Care and the HISP functionality to enable transactions. By "de-constraining" the solution while maintaining focus on the functional capability, this revamped measure enables far greater number of innovative workflows to be realized, and future-proofs it as well.

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§ 170.315(b)(1) (Transitions of care)

While we support the notion of implementing "at least one" of the Direct Edge protocols in the EHR, we point out that the HISP will need to support all of the protocols and thus the burden only shifts from one vendor to another (or one feature to another, for integrated EHRs/HISPs). Additionally, it is not clear why certification would be required for such universally-adopted and straight-forward "receiving" standards such as POP3 and IMAP; this seems akin to certifying that the provider's keyboard complies with ISO.

In terms of the "performance standard that would require EHR technology to successfully electronically process validly formatted Consolidated CDAs no less than 95% of the time", we are in favor of this direction, but additional clarification is required. Specifically, what does "process" imply? We agree with the 95% threshold if the requirement is that the EHR needs to be able to display valid inbound CCDAs. However, if "process" were to also include "incorporate/reconcile", then we suggest that a 95% threshold is far too high, due to legitimate reasons such as the prevalence of numerous templates, sections and even values (e.g., flavors of null) that are perfectly valid to include in a CCDA document but cannot be incorporated/reconciled by EHRs today.

We support the addition of the CCDA Clinical Notes template to the CCDA specification.

In terms of potential data to capture during the "Create" phase, so as to improve "Patient Matching Data Quality", our overarching comment is that this appears to be too onerous and not necessarily useful set of data to capture for this purpose. Specifically:

1. As we have in the past, we strongly recommend that a standard code set be used to represent gender.
2. We point out that "Place of Birth" is not an item typically recorded by providers – this is an additional documentation burden that providers will have to bear.
3. Similarly, asking providers to record historical data such as previous addresses and previous names is a massive patient data collection and data entry exercise. Not only will it substantially hamper the efficiency of the practice, but it will contribute to patient distrust and confusion as well, as such data is only tenuously connected to clinical intent. Instead, we suggest the use of strong, trusted identifiers (such as the driver's license) to identify and match patients unambiguously. For instance, providers whose EHRs implement the CommonWell Health Alliance specifications obtain explicit consent from their patients to use their strong identifier in order to query their health records across the care continuum; this reduces both the onerous task of data entry for the provider and the unclear usage of their identity from the perspective of the patient.
4. While we are strongly supportive of standardization of the address algorithm, it is clear that none should be specified until an unambiguous, unchanging, and production-ready source has been identified, as needing to re-work this requirement in the future will be a wasteful trade-off between effort and outcomes.

§ 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.

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§ 170.315(b)(2) (Clinical information reconciliation and incorporation)	
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: Clinical reconciliation is critical functionality that has specifically been enabled by EHR technology. We believe that reconciliation of additional data should be allowed – and in fact we do so in our EHR – but we caution that requiring additional elements can potentially lead down a slippery slope towards high burden for low value. That being said, the types of data which we believe should be reconciled are those common elements that can be received in standardized code sets, namely: Immunizations (in the CVX format); laboratory results (only if received in LOINC); and vitals (if these are conveyed in a single, broadly-adopted code set). These data elements can provide high value for clinical decision support and patient safety. It is important for the EHR to be able to capture and track the provenance of received data. As such, we agree that EHRs should store the original data in addition to reconciling it. However, we strongly discourage policymakers from regulating the user experience for discovering the original data, as this functionality would be used sparingly and can easily contribute to a confusing EHR experience if not carefully crafted for each EHR/user context.	

§ 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:	

We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.

§ 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:	
We agree with the recommendations made to update the 2015 Edition of this criterion.	

§ 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).

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§ 170.315(b)(6) (Data portability)	
Preamble FR Citation: 79 FR 10902	**Specific questions in preamble?** *Yes*

Public Comment Field:

If this criterion were left unchanged, then we support the name change to "Data Migration", which makes it clear that the purpose is to lower the switching cost for providers who want to migrate from one EHR to another. However, we also support the suggestion to change this certification criterion as part of a 2017 Edition proposal to promote a broader range of use cases. As such, for the sake of clarity, we suggest that these additional use cases be delineated as separate criteria, each with an unambiguous name.

In terms of the potential new use cases (namely: local access/query; targeted access/inter-organizational query; and distributed access/query) we strongly support the proposal that EHRs have these capabilities built-in. However, given the paucity of data to suggest how often these capabilities will be used, we strongly advocate against any specific thresholds on usage of these capabilities. Across all three use cases, we strongly suggest the usage of standards that have already been demonstrated in real-world usage. For the third use case in particular, we suggest monitoring the standards being developed and deployed by organizations such as CommonWell Health Alliance, which is currently using the IHE XCA specification as a starting point.

Clinical Quality Measures – Electronically Processing eMeasures	
Preamble FR Citation: 79 FR 10902	**Specific questions in preamble?** *Yes*

Public Comment Field:

We support the inclusion of standardized CDS and CQM formats for the 2017 Edition, in particular HQMF. We agree that broad adoption of such a standard will enable greater interoperability in the future. We believe that the ability to incorporate HQMF files should be built into CEHRT. But we do not advocate for active use of HQMF to be required in order to meet CMS Meaningful Use performance thresholds, as there are dozens of other programs that are using other (standard and non-standard) formats for CQMs, and the burden of building a translation engine between systems is substantial. If the goal is simply to ensure consistency across vendors, then we point out that the existing and more economical *Cypress* validation tool already contributes much in that regard.

Clinical Quality Measures – Functions and Standards for CQM Certification	
Preamble FR Citation: 79 FR 10903	**Specific questions in preamble?** *Yes*

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Public Comment Field:

We do not support the requirements proposed by this revised criterion. Our overarching concern is that there is no clearly-articulated business goal for these suggestions, and consequently it is unclear what benefits will accrue and to whom.

Examining the requirements individually:

1. *"The need to create QRDA-I reports on a per encounter basis":* this seems to be a very hospital-centric issue that would create undue burden in the ambulatory practice. We estimate that it will create up to 10 times the number of QRDA files generated today, for little value. This is particularly problematic not just because of the volume of content created, but because currently there is no reliable, scalable, failure-resistant FTP automated data submission capability provided by the government agencies (or their vendors). This is a severe operational issue for health networks or cloud-based vendors who will need to submit such data at scale.

2. *"The EHR certification number must be assigned to each QRDA submission, an entirely new data element that would need to be added to databases and user interfaces in many cases. The new requirement to include the NPI/TIN for "associated providers" when the official Data Element Catalog referenced as a standard by ONC indicated that the NPI would only be required for EPs – again, a new data element with multiple implications for software development and provider usage.":* while we agree that there are differences between the QRDA submission requirements required by various agencies, we do not support reconciling these differences in the context of Meaningful Use as this generates additional work without any value. The reality is that (1) Not all vendors will be required to support all CMS programs/implementation guides, and (2) The perceived gains from reconciliation will be dwarfed by the substantial number of other programs that have differing QRDA requirements.

§ 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:

We do not recommend a requirement centered on QRDA II files, as the most granular level data and measurement data is already being submitted through QRDA I & III files. The additional file-generation and transmission effort seems wasteful given the ability to derive all other data from those two formats.

In addition, the generation of patient-level QRDA files (I or II) raises concerns that an over-abundance of patient information is being shared with government agencies. The concern on the part of patients is that there is no clear value proposition to justify why their confidential information should be shared at this level of detail with CMS, and that

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§ 170.315(c)(1) (Clinical quality measures – capture and export)
there is a lack of transparency as to the usage of the data. Further there is the always-present concern that a security breach of the data can severely compromise patients' privacy. These concerns are exasperated by the fact that CMS requires the data of all patients to be shared – even the data of patients not covered by CMS. As such we recommend only the submission of QRDA III files towards the explicit goal of clinical quality measurement.

§ 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:	
We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.	

§ 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:	
We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.	

§ 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

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

As with other new requirements and substantial changes specified in this NPRM, we urge ONC to more conscientiously articulate the business value created by the requirement. From our perspective, Population Health is increasingly critical to the achievement of the Triple Aim, and we encourage alignment between the various public agencies pursuing this venerable cause. In so far that certification to this requirement directly fulfills or at least creates a glide-path to other broadly-adopted programs such as GPRO, Pioneer ACO and PQRS, then it may have business value despite the substantial investment that this will require.

In terms of the patient population groupings and suggested data, while most seem reasonable, there are some open questions:

(1) It is unclear why grouping would be useful not just by a TIN/NPI combination, but by TIN and NPI separately as well.
(2) Within what limits are diagnoses codes required? How is this impacted if the patient is seen at different sites?

Again, understanding the business aim will help clarify the purpose of the data collected, and consequently what data and groupings will truly help to fulfill that purpose.

§ 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:

We are strongly supportive of the use of two-factor authentication for specific use cases, particularly Electronic Prescribing of Controlled Substances (EPCS). As noted in the NPRM, EPCS is being increasingly adopted and the need for a secure and appropriately stringent mechanism for access should be built into the EHR.

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§ 170.315(d)(1) (Authentication, access control, and authorization)
While the EPCS use case is clear and well-known, the "remote provider access" use case is far too vague and ambiguous. Specifically, what does “remote provider” mean in the context of a cloud-based EHR? What are the bounds beyond which a cloud-based provider is determined to be remote – and who determines them? – when the EHR is **designed** to enable secure, authenticated, *remote* accessibility? We suggest that the use case be clarified as applicable only to on-premise systems, which were not designed from ground-up for remote access and are thus far more susceptible to illegitimate usage.

§ 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 strongly support this requirement as a best practice. However, we recommend that ONC further clarify the term "through EHR technology" as it is still too vague and broad, given the real-world possibilities that are beyond the control of the EHR. We suggest that a more precise definition would be in line with the spirit of this requirement, e.g., “through the User Interface of the EHR technology”.	

§ 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*

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Public Comment Field:

In general we support this requirement, and offer the following suggestions in response to the questions posed:

(1) We do not believe that the ambiguous term "query" should be used in the context of audit reporting. Instead we suggest that the focus should be on database actions that can result in changes to the audit logs, that is: (a) additions, (b) deletions, and (c) changes.

(2) We do not recommend the application of "copy" and "print" actions, as there are so many different ways of performing these actions – directly through a menu command or more subversively through a screenshot or even photograph – that this capability will be necessarily deficient when implemented.

(3) We would be supportive of other actions that are worthy of auditing, such as "transmission" and "origination" actions on data – these are potentially useful attributes that can be clearly defined.

§ 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:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.

§ 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:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.

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§ 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:	
We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.	

§ 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:	
We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.	

§ 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.

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§ 170.315(d)(8) (Integrity)	
Preamble FR Citation: 79 FR 10905	**Specific questions in preamble?** *No*
Public Comment Field: We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.	

§ 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: We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition. Further, we agree that the "optional" designation of this criterion can be dropped.	

§ 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

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§ 170.315(e)(1) (View, download, and transmit to third party)	
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 (e)(1)(ii)(A) is accessible by the patient.	
Preamble FR Citation: 79 FR 10906	**Specific questions in preamble?** *Yes*
Public Comment Field: Overall, we support the continuing evolution of the VDT requirement. However, we advise ONC to be aware that patients will be far more likely to perform an action (e.g., obtaining their healthcare record) when they are not required to understand the technical plumbing underlying that functionality (e.g., Direct project protocols and addresses). This is akin to learning how to use an online banking website to pay a bill, versus being required to be aware of HTTPS/SSL. As such, we fear that inappropriate expansion of this requirement will have the unintentional effect of discouraging patient engagement for the vast majority of users. Specifically, while we agree that it is not a high technical investment to "…support at least the entry of any Direct	

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

address", we believe this emphasis is inappropriate and will do more harm than good. We expect that patients will rarely use this functionality over the next several years, as indicated by our long history of supporting the original Blue Button. In addition, because the overwhelming majority of patients do not know what Direct is, they will invariably try to enter URLs and email addresses, and then be frustrated when it does not work. To counter this, the EHR will have to build in workarounds, much error-checking, and probably patient education; even then, usage will likely be very low. If ONC insists that this functionality be available to patients, then we strongly advocate that it not be the **only** permissible way for patients to transmit their clinical records over Direct, as more human-friendly methods (e.g., "Click here to send your health record to Microsoft HealthVault") are likely to have greater traction in enabling real-world usage of Direct. In a similar vein, we support the notion that the ability to enter a Direct address be "accessible" to patients, but strongly advocate that regulation not be prescriptive about the User Interface, which should be left to innovators to design for maximum impact.

Note that, even if a patient is engaged and knows what Direct is, there is no guarantee that the EHR will be able to send the Direct message in practice, as there are several structural issues that need to be overcome. For one, the trust fabric for directed exchange is barely off the ground, which means that most EHRs (and HISPs) do not support the vast majority of other HISPs out there because there has been no trust relationship yet established. This will of course improve over time, but it is a slow process, despite the pressure of the Meaningful Use timetable on such adoption. Second, there is no publicly available provider directory from which a patient can obtain the Direct address of their provider, so (s)he will necessarily have to send it to one of the handful of systems that support patient-generated Direct messages. Third, the receipt of patient records can create a liability issue for providers; while we are in favor of the industry overcoming this issue since it pertains to a broad range of health information exchange, at this point of time it would make sense to allow CEHRT vendors to enable controls so that providers can choose whether or not to accept specific messages.

Taking a step back, we implore ONC to consider whether it would be more prudent for industry to reliably demonstrate provider-provider interoperability (including but not limited to Direct) before driving forward on the more complex patient-provider interoperability. We view this only as a pragmatic matter, to enable the technologies – and the ecosystem and behaviors that they engender – to mature somewhat, before increasing the level of complexity.

To summarize our point of view on this revised "Transmit" requirement, our message to ONC is clear: we support this policy direction and certainly see its long-term value, but it is manifestly clear from both the patient/provider perspective and the structural perspective, that the market is simply not yet ready to leverage this capability to any meaningful degree. We have full confidence that it will get there in time, however it is not likely to do so by the advent of the 2017 Edition.

In terms of accessibility, we note that this is not a request that users have asked for; as such, what is the business case for increasing the WCAG level? It seems to be a requirement for the sake of increasing a threshold on the standards, but in reality will generate much work for little value.

We fully support and encourage the adoption of the remaining 2015 Edition CERHT requirements for VDT, as we think this appropriately raises the bar on performance and the potential for meaningful patient engagement.

In terms of "2017 Edition Issues for the VDT Certification Criterion under Consideration":

(1) Images and Non-Text Data: We support this requirement and believe that it will help drive interoperability in a

§ 170.315(e)(1) (View, download, and transmit to third party)
meaningful way. Today, we do not think these images should be of diagnostic quality, as that will require a trade-off with download speed/patient portal performance that is likely to discourage patient engagement. As a result, while "View" and "Download" of this data is sensible at this time, "Transmit" of the data will be less valuable since it is not of diagnostic quality. From a performance perspective, if "Transmit" were required, it should refer to the transmission of either the image itself **or** a link to that image. In terms of whether cloud-based technology could allow for a link to the image to be made accessible, we agree that while this is technically possible, it is only true for a relatively small number of instances as the market has not quite figured out how to leverage this capability effectively as yet, and so this will create undue burden on providers. (2) OpenNotes: We do not support this potential requirement. Firstly, and most importantly, it is fallacy to believe that all documentation is for the benefit of the patient; in reality it can be very specifically for the provider's benefit, and in such circumstance there is a high likelihood that driving the use of the OpenNotes concept indiscriminately will confuse patients. Second, the early testimonials on Meaningful Use Stage 2 have clearly indicated that putting the EHR in the middle of the provider-patient interaction can be tremendous work. Indeed a lot of effort is already being spent by providers to redact data/sections so as to ensure patients are given the data that is actually necessary and/or appropriate for continued clinical care without creating patient safety risks or confusion; a requirement for OpenNotes will only exasperate this issue. Third, we contend that the OpenNotes functionality is actually redundant anyway, because access to this data is already available through other mechanisms such as VDT and the Clinical Summary requirements. Finally, OpenNotes particularly creates challenges in situations where patients and caregivers may rightfully have or deny access to the data, e.g., in a Pediatrics use case, it would have to be clear as to what data is visible to patients (e.g., teenagers) versus to their parents.

§ 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*

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Public Comment Field:

We agree with this proposed requirement. In response to the questions posed, we would add that LOINC has been well-demonstrated for use in laboratory tests and we fully support its usage for this purpose, but for other tests it is unproven and certainly not broadly adopted. As such it may significantly limit providers' ability to more specifically define diagnostic tests that are not LOINC-encodable today.

We have an overarching concern around this criterion that has been brought to us time and again by patients and providers: namely, that the criterion requires code sets to be included in this patient-facing document. Patients get confused by the seemingly-random codes attached to their document (even in the context of clarifying prose), and providers have reported much wasted time spent trying to lead the patient through this summary. As such, we recommend that the requirement be modified to exclude code-sets, as the Clinical Summary is almost exclusively used to support the layman patient rather than further the cause of computable semantic interoperability.

In contrast, we believe that it is fully appropriate that the VDT criterion's CCDA document leverages code sets for the purposes of patient-mediated data exchange – in fact we believe that that document can continue to become even more semantically interoperable as code sets evolve for as-yet-unsupported data such as gender identity, vitals, etc.

§ 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:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.

§ 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*

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Public Comment Field:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.

§ 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:

While we support the proposal to adopt the new IG, note that not every immunization registry will likely be ready for the new standard.

In terms of maturity of bi-directional exchange, the EHR side of this transaction will not be a substantial requirement presuming that some standard exists; but it is not clear that immunization registries will be ready to participate in such transactions in production by the 2017 timeframe. Furthermore, this idea is greatly hampered by the lack of an MPI so that a registry could safely and effectively send or request patient data. There is also the open question as to the standard and robustness of the matching algorithm to ensure data is routed to/from the right source at a high confidence level. As such we caution that the industry may not be ready for this requirement as yet.

In terms of vaccine coding, we strongly suggest that CVX codes should only be used to capture historical or manually entered vaccines. We also agree that newly entered vaccines should always be captured with NDC codes, while historical vaccinations may be available with either CVX and NDC codes. We prescribe this specific usage of the vaccine code sets in line with ONC's mantra of "send conservatively, receive liberally", and believe this will create the highest utility per unit effort.

To underscore our recommendation above, we argue against the other potential solution posited by the NPRM, in terms of substituting CVX codes with a new code set with the NDC format: not only does this create undue complexity that will be perpetuated by the healthcare system for a substantial period, but we question the completeness of the mapping itself, how the "generic NDC" code would work in practice, and whether we would have to revert to CVX anyway when the "generic NDC" is not known.

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§ 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: Several years of experience with public health agencies across the nation suggests that this entire criterion is not applicable to the ambulatory setting as the lion's share of public health agencies do not accept syndromic surveillance data from this setting. As such, we strongly recommend dropping this requirement altogether for the ambulatory setting, rather than searching for additional standards to meet a non-existent demand.	

§ 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: We agree with the removal of the "optional" designation on this criterion.	

§ 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.

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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:

We support the use of the updated Implementation Guide. We also point out that adoption of the existing version of the implementation guide has been poor, and it is very unlikely that a newer version of the standard will drive increased adoption.

§ 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:

We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition.

§ 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 support the proposal to revise this updated criterion.

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

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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:

Our overarching comment is that the design of the requirements specified in this criterion - and in all the other person-facing criteria - should apply more Human Factors expertise. Our experience in the 2014 Edition was that the prescribed details as to what needed to be captured and shared in patient- or provider-facing scenarios were often against the spirit of providing better, pertinent clinical care information. For example, for patient care and clinical summaries, the clinical value is realized only when patients and caregivers can easily consume the data that is most pertinent to that episode; the requirement to send broader sections of the chart (e.g., immunizations) has made it more difficult to feature the key information to be transmitted, and the volume of information actually lessens the likelihood that the information is read. Our Human Factors experts, and those from around the industry presumably, could be better leveraged by ONC to truly and successfully achieve the spirit of these types of person-facing regulations.

In terms of summative testing, we were largely disappointed by the lack of vigor and standardization across ONC-ATBs. EHR vendors committed to User Centered Design invested heavily in rigorous summative testing to achieve certification, while other vendors were certified without evidence of any commitment to effective user experience. In effect, vendors who were meeting the intent of the Safety Enhanced Design criterion were inadvertently penalized for "doing the right thing".

With respect to the specific questions posed by this NPRM:

(1) We strongly oppose any expansion of the summative testing requirements - or the battery of usability tests overall - until a baseline level of clarity, consistency and stringency is in place, so that poor studies (e.g., those with less than 15 users, or those that use employees of the EHR vendor to attest to the quality of the user experience) will not be allowed to pass.

(2) If summative testing will continue to be used, then we strongly encourage certification based on stricter adherence to standard summative testing procedure, especially with regard to recruiting. We do support a minimum number of 15 test participants, along with a requirement that participants be representative of the EHR Usability Test intended users (e.g., no participants who work for the company), etc.

(3) We oppose requiring formative testing, as it is very context-specific and would be difficult to prescribe in a meaningful way. We are especially opposed to requiring publication of formative findings. Formative testing is designed to reveal problems with the system, and requiring publication of results intrinsically would encourage system vendors to subvert an authentic study, once again penalizing the systems that "do it right". As an alternative, we recommend that this criterion require the CEHRT vendor to delineate the User-Centered Design process that was used, and if/how techniques such as formative testing were included. In other words, we suggest that ONC not be prescriptive about the processes used, but rather enable transparency about the processes that were used by the vendor.

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§ 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: We support the retention of this criterion, as well as the intention of leaving it unchanged from the 2014 Edition to the 2015 Edition. See our further comments in the previous section titled §170.315(g)(3) (Safety-Enhanced Design)	

§ 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 agree that this requirement will be beneficial to the aims of measure reporting. Additionally, we suggest that it be left to the EHR/provider as to what constitutes "evidence" for non-percentage based measure. We oppose both of the proposed options as we believe that a one-size-fits-all approach will compromise the quality of sensible implementations. We encourage the use of examples to demonstrate acceptable forms of "evidence", but strongly discourage a prescriptive implementation.	

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§ 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 strongly support the inclusion of this standard, and strongly support the approach proposed to decouple the transport mechanism from the functional requirements of the EHR.	

§ 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 the inclusion of this standard, and strongly support the approach proposed to decouple the transport mechanism from the functional requirements of the EHR.	

§ 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 the inclusion of this standard, and strongly support the approach proposed to decouple the transport mechanism from the functional requirements of the EHR.	

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§ 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: While this requirement will create additional effort on all EHRs, we strongly support this criterion as it paves the way for more robust interoperability as the Direct ecosystem matures and expands to enable valuable use cases such as sending/receiving laboratory orders and results. We point out that this criterion as written seems duplicative of the existing SMTP/SMIME standard specified in a previous criterion by referring to the Direct Project implementation guide ("Applicability Statement") each time, and suggest that only one criterion is needed to satisfy both.	

Provisions of the Proposed Rule Affecting the ONC HIT Certification Program

We are deeply concerned about the proposed changes to the ONC HIT Certification Program. While the "Complete EHR" concept might have disadvantaged individual module developers, we fear that the pendulum has now swung to the other extreme, to the detriment of EHR vendors who intend to sell integrated systems.

It is presumptuous to say that the primary reason that providers choose Complete EHRs was because of "confusion". Based on our previous experience selling modular HIT services and subsequent experience selling Complete EHRs, we contend that providers often look for a "complete" solution so that they can meet their needs without incurring unnecessary complexities. Practical operational issues such as quality of the provider workflow, simplicity in contracting, ease of troubleshooting, and so on, all play a significant part when providers choose to meet their needs. The "Module"-centric approach conveyed by this NPRM implies that a single EHR platform is completely equivalent to a handful of "Modules" or "packages" stitched together, and that is simply not going to be the case. Providers should be given meaningful and transparent choice.

As a concrete example, consider that the NPRM proposes that CEHRT will be listed on the CHPL according to the Modules/Certification Packages that it complies with. However, just because an EHR meets the requirements of a certain Certification Package or set of requirements that qualify it as a Module, that does not mean that the vendor intends to sell that component separately, and this should be made clear. In the case of this specific proposal, we suggest that every Module or package is available as "stand-alone" or "integrated" or both. Such balance is critical across the implementation approach for certification.

Another concrete example where the implementation of this approach may create unintended affects: the ongoing re-certification of updated products. We note that some EHRs – particularly cloud-based EHRs – often have multiple software updates per year, distributed immediately to a broad number of clients. If the functionality changes are either aligned with (or non-material to) Meaningful Use requirements, then such releases usually amount to a seamless update of the version number for that EHR displayed on the CHPL. We strongly advocate that, given the deprecation of the "Complete EHR" concept, there should still be a seamless process to update the multiple Module entries now associated with that single integrated EHR.

Looking back at the evolution from the 2011 Edition to the 2014 Edition, we applaud ONC and the National Institute of Science and Technology (NIST) for significantly increasing the rigor of the certification process, particularly the thorough test scripts and the consistent use of sufficient "real-world-like" data. This greatly improved the likelihood that real-world systems would truly interoperate, and we encourage that this rigorous approach be continued for the 2015 and 2017 Editions.

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Other Topics for Consideration for the 2017 Edition Certification Criteria Rulemaking

Additional Patient Data Collection	
Preamble FR Citation: 79 FR 10922	**Specific questions in preamble?** *Yes*

Public Comment Field:

Given the minimal differences in implementation effort and value regardless of the regulatory layout of data elements, we refrain from commenting how any potential criteria should be grouped. Instead we focus on each data element piecewise:

1. Disability Information and Accommodation Requests: we agree that EHRs should be able to capture this information. However, we strongly oppose any mandatory requirement that providers be required to capture this data for every patient, because this data is applicable to a limited set of circumstances in ambulatory and specialty settings, e.g., it would be rarely (if ever) applicable in a dermatology setting.

2. Sexual Orientation and Gender Identity: we are supportive of being able to capture this information, as clinicians and patients ask for such data to be captured.

3. U.S. Military Service: we have not seen a market need for this this type of data today. This seems to be data being collected for data collection's sake, and is of very little value to providers and most patients. We can see how this might apply to a VA and DoD Hospital use case, but otherwise the applicability of this data is relatively infrequent.

4. Work Information – Industry/Occupation: we strongly oppose the collection of this data as it severely impacts the efficiency and efficacy for the clinical encounter. Experience shows that these code sets are significantly overcomplicated for general medical staff use, and are far more appropriate for the "general census" use cases for which they were developed.

Medication Allergy Coding	
Preamble FR Citation: 79 FR 10925	**Specific questions in preamble?** *Yes*

Public Comment Field:

We strongly support the adoption of additional vocabularies to enable unambiguous coding, in particular the use of UNII codes for non-drug allergies, as this enables more robust semantic interoperability. We also support the adoption of the CDC Vaccine Reaction and Adverse Event value set. We agree that there is greater value in using specific reaction value sets rather than general problem value sets.

We enthusiastically support the notion that EHR Clinical Decision Support interventions should include alerts/guidance based on drug-drug interactions (DDIs). Drug-drug interaction checking is a critical input into physician prescribing decisions, as demonstrated both by market demand for such functionality and as per vendor-agnostic/FDA reports.

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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 strongly suggest that requirements such as this one should not be repeatedly updated – it creates needless work and very low value, and represents effort spent by both regulators and implementers on the tougher problems of the day. As such, we recommend Option 2 (maintain the 2014 Edition approach), or alternatively Option 1 (re-adopt the 2011 Edition approach).

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

Public Comment Field:

We strongly advocate for the inclusion of a provider directory requirement in the 2017 Edition. We strongly advocate for constraints and expectations be placed on the API/access to the provider directory, specifically that CEHRT be required to respond to a provider directory query from trusted third parties, when such data is available to the EHR (whether internally or through its HISP/service provider). We discourage any limitations be placed on the internal/backend storage of the directory, as this does not meaningfully impact interoperability.

From a standards point of view, we are supportive of the federated HPD approach being undertaken by the ONC Mod Spec effort today. However, we note as per the NwHIN Power Team discussion on April 17, 2014, that this specification is lacking a discovery mechanism such that provider directory nodes can automatically "find each other" much as Direct addresses do (through DNS) today. We agree with the Power Team that such functionality is highly desirable and should be included in the future, and it is possible that it might even be ready by the time of the 2017 Edition. But regardless, our view is that this missing discovery functionality should not preclude the inclusion of a real-world-tested federated directory solution in the 2017 Edition, as today there is no other viable alternative and the operational impact of Direct has been severe industry-wide.

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

Public Comment Field:

We support the requirement that the EHR should use a structured Sig with the explicit data suggested, and that the EHR should be able to accurately convert between a liquid dose and the metric standard.

We strongly oppose any requirements to govern how to store the data. We note that, in practice, the standards captured by the EHR are limited by commercially available drug directories. We posit that the decision to store the data in a particular unit is therefore being discussed in the wrong forum; if these storage standards are of concern, then the FDA should guide those drug directories towards using metric units instead. As such we suggest that the requirement only be imposed on the ability to convert between units rather than the ability to store in a specific standard.

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

Public Comment Field:

We are largely in support of this requirement. It seems clinically useful, while not being a burden on the provider, to be able to: receive the medication history from a third party; capture it from a patient; generate a medication list; and be able to prescribe electronically. However requiring reconciliation of the medical history will burden the provider disproportionately to the value that it will create.

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

Public Comment Field:

While we avidly support the BlueButton+ project and are incorporating the recommendations into the CEHRT, we do not believe that it is necessary to require a specific certification criterion for this, as it is incremental to the VDT criterion. In addition, while it is noble and increasingly critical to enable patients to be proactive when they choose to do so, past and current experience continues to demonstrate that provider-provider interaction is both more common and more efficient as we continue on the path of interoperability industry-wide. As such, while we absolutely support the proposed functionality, we do not advocate for increased performance thresholds on such patient-centered requirements because it actually compromises real-world interoperation.

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

Public Comment Field:

We support the 2D barcoding requirement, and suggest that it be used for vaccines. However, if the state of the art matures such that medications can also be represented by such codes, then we strongly suggest that both vaccines and medications utilize the same standard.

Although not indicated by the NPRM, in the past the movement to 2D barcodes has been concomitant with the expectation that EHRs perform the functionalities of inventory systems, which we strongly oppose: this type of functionality is required by only a subset of practices, and will detract from the EHR user experience.

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

Public Comment Field:

We support the notion that patient records should be de-duplicated. But rather than addressing the de-duplication problem *a posteriori* as implied by the NPRM, we suggest that the EHR mitigate the need for de-duplication upfront, by being required to do more robust patient matching when a patient is first created in the system.

Given that de-duplication will likely always be an imperfect process, a consequent action that is logical to include is a "merge" action, which is a straightforward action to employ. A corresponding "unmerge" action is considerably less trivial, however, without substantial bloat of the patient data repository, to keep track of where every field came from; as such we strongly suggest that such an action not required, or if so, then not be prescriptive since the EHR may have more than one effective way to address a patient that has been incorrectly merged, e.g., through a clone-and-prune process.

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

Public Comment Field:

We generally oppose this type of criterion as it really seems geared towards hospital emergency room settings only, and attempts to shoehorn process safeguards into technology solutions. This is a dangerous approach that will provide a false sense of security, and undermining the flexibility of providers to respond expediently when there is a true unforeseen emergency. Specifically:

(1) *Standardized naming convention for temporarily naming unidentified patients during disaster and emergency events:* while we agree that this is certainly feasible, we do not recommend any particular convention here, largely as we believe that this functionality is more applicable to EHRs in the emergency room rather than in the ambulatory setting.

(2) *Batch printing of print face sheets or patient snapshots in bulk:* we strongly oppose this potential criterion, as it is usually inapplicable to a cloud-based vendor, as demonstrated by athenahealth's EHR during the Hurricane Sandy tragedy in Louisiana. In addition, thanks to the Meaningful Use Stage 2 criterion on Data Portability, EHRs can already bulk-export CCDAs. Our observation is that disaster recovery processes and capabilities are very specific to the type and context of the EHR installation, and suggest that it will be more appropriate for each hospital to make appropriate disaster recovery plans in its context.

(3) *Capabilities or standards to better assist providers during everyday emergencies, disasters, and public health emergencies:* again, we believe that mandating any functionality will be too prescriptive and ultimately provide a false sense of security, when disaster-preparedness should instead be a function led by the provider's leadership. However, we support the reuse of existing standards and technology built into the EHR to be available as tools in disaster preparedness planning; in particular the Direct Project for directed push, CommonWell/Query standards for pulling data across the care continuum, and Data Portability for bulk export.

(4) *Ability to denote care provided during disasters or public health emergencies:* this is clearly a process issue being shoehorned into a technology solution. It is also primarily applicable only to the hospital setting. Our view is that it is not realistic to prescribe the right course of action when hospital settings are so variable and hence context-sensitive, given a rich and flexible set of tools already supported by the EHR.

(5) *Improve/expedite how EHR technology is used to report standardized and de-identified patient data to public health and emergency management authorities:* this seems like functionality that belongs specifically in the Emergency Room health IT system, rather than in the generalized EHR.

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:

While we agree that the new approach enables ecosystem partners and other types of technology systems to innovate and improve the functionality available to the provider, the preamble in this section appears to be "reaching" for regulatory oversight over a greater scope of technology beyond the initial stated scope of Meaningful Use. While we do not oppose ONC guidance in a broader array of regulatory issues, we do caution that other agencies (e.g., the FDA) are also in the process of doing so, and not all regulation (and certainly not overlapping regulation) leads to better innovation or outcomes. As such, we recommend coordinated regulation where it is required to drive meaningful outcomes, and coordinated abstinence when it is not.

Conclusion

In conclusion, we appreciate ONC's engagement of the public to inform the direction of the 2015 Edition Standards and Certification criteria. athenahealth continues to welcome the opportunity to provide feedback and participate in the transformation of health care.

Sincerely,

Dan Haley
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Assistant General Counsel
athenahealth, Inc.