



## Pharmacy Health Information Technology Collaborative

**Via Electronic Submission to:**

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

April 28, 2014

Steve Posnack

Director, Federal Policy Division

Office of National Coordinator for Health Information Technology

Department of Health & Human Services

Hubert Humphrey Building, Suite 729D

200 Independence Ave., SW

Washington, DC 20201

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

Dear Mr. Posnack:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative, we are pleased to submit comments in response to *Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements*.

The Pharmacy HIT Collaborative (the Collaborative) and its member organizations are supportive of continued certification criteria and standards for health information technology (HIT) and EHR. The Collaborative has been involved with the Office of National Coordinator for Health Information Technology and the Center for Medicaid and Medicare Services since the early development of these standards and criteria as they apply to the Meaningful Use EHR Incentive Program and their affect on non-eligible pharmacist health care providers.

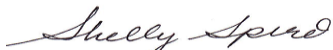
The Pharmacy HIT Collaborative's vision and mission are to assure the nation's healthcare system is supported by meaningful use of HIT, the integration of pharmacists for the provision of quality patient care, and to advocate and educate key stakeholders regarding the meaningful use of HIT and the inclusion of pharmacists within a technology-enabled integrated health care system. The Collaborative's goals seek to ensure HIT supports pharmacists in health care service delivery; achieve integration of pharmacists and pharmacies into HIEs, and advocates pharmacist recognition in HIT programs and policies. The Collaborative was formed in the fall of 2010 by nine pharmacy professional associations, representing 250,000 members, and also includes seven associate members from other pharmacy-related organizations. For additional information, visit [www.pharmacyhit.org](http://www.pharmacyhit.org).

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On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on *Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements*.

For more information, contact Shelly Spiro, Executive Director, Pharmacy HIT Collaborative, at [shelly@pharmacyhit.org](mailto:shelly@pharmacyhit.org).

Respectfully submitted,



Shelly Spiro

Executive Director, Pharmacy HIT Collaborative

Shelly Spiro, RPh, FASCP  
Executive Director  
Pharmacy HIT Collaborative  
[shelly@pharmacyhit.org](mailto:shelly@pharmacyhit.org)

Mary Jo Carden, RPh, JD  
Director, Regulatory Affairs  
Academy of Managed Care Pharmacy  
[mcarden@amcp.org](mailto:mcarden@amcp.org)

Peter H. Vlasses, PharmD, DSc (Hon), BCPS,  
FCCP  
Executive Director  
Accreditation Council for Pharmacy  
Education (ACPE)  
[pvllasses@acpe-accredit.org](mailto:pvllasses@acpe-accredit.org)

Thomas Felix, MD  
Director, Regulatory Affairs, R&D Policy, and  
Global Regulatory Affairs and Safety  
Amgen, Inc.  
[thfelix@amgen.com](mailto:thfelix@amgen.com)

William Lang, MPH  
VP Policy and Advocacy  
American Association of Colleges of Pharmacy  
[wlang@aacp.org](mailto:wlang@aacp.org)

C. Edwin Webb, Pharm.D., MPH  
Associate Executive Director  
American College of Clinical Pharmacy  
[ewebb@accp.com](mailto:ewebb@accp.com)

Stacie S. Maass, B S Pharm, JD  
Senior Vice President, Pharmacy Practice  
and Government Affairs  
American Pharmacists Association (APhA)  
[smaass@aphanet.org](mailto:smaass@aphanet.org)

Lynne Batshon  
Director, Policy & Advocacy  
American Society of Consultant Pharmacists  
[Lbatshon@ascp.com](mailto:Lbatshon@ascp.com)

Christopher J. Topoleski  
Director, Federal Regulatory Affairs  
American Society of Health-System Pharmacists  
[ctopoleski@ashp.org](mailto:ctopoleski@ashp.org)

Kim Swiger, RPh  
Vice President, Pharmacy Services  
Mirixa Corporation  
[kswiger@mirixa.com](mailto:kswiger@mirixa.com)

Rebecca Snead  
Executive Vice President and CEO  
National Alliance of State Pharmacy Associations  
[rsnead@nasp.us](mailto:rsnead@nasp.us)

Ronna B. Hauser, PharmD  
VP Policy and Regulatory Affairs  
National Community Pharmacists Association (NCPA)  
[ronna.hauser@ncpanet.org](mailto:ronna.hauser@ncpanet.org)

Roger Pinsonneault, R.Ph.  
Vice President, Business Development  
RelayHealth – Pharmacy  
[Roger.Pinsonneault@RelayHealth.com](mailto:Roger.Pinsonneault@RelayHealth.com)

Lynne Gilbertson  
VP Standards Development  
National Council for Prescription Drug Programs  
(NCPDP)  
[lgilbertson@ncpdp.org](mailto:lgilbertson@ncpdp.org)

Stephen Mullenix, RPh  
Sr VP, Communications & Industry Relations  
National Council for Prescription Drug Programs  
(NCPDP)  
[smullenix@ncpdp.org](mailto:smullenix@ncpdp.org)

Cynthia Kesteloot  
Vice President Technology  
OutcomesMTM  
[ckesteloot@outcomesmtm.com](mailto:ckesteloot@outcomesmtm.com)

Michael E. Coughlin  
President, CEO and CFO  
ScriptPro  
[mike@scriptpro.com](mailto:mike@scriptpro.com)

Ken Whittemore, Jr., RPh, MBA  
Senior VP, Professional & Regulatory Affairs  
Surescripts  
[ken.whittemore@surescripts.com](mailto:ken.whittemore@surescripts.com)

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

***A. Proposed for 2015 Edition<sup>1</sup> Certification Criteria***

§ 170.315(a)(1) Computerized physician order entry - medications	
<b>MU Objective</b>	
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.	
<b>2015 Edition EHR Certification Criterion</b>	
(1) <u>Computerized provider order entry – medications</u> . Enable a user to electronically record, change, and access medication orders.	
<b>Preamble FR Citation:</b> 79 FR 10886	<b>Specific questions in preamble?</b> No
<b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.	

§ 170.315(a)(2) Computerized physician order entry - laboratory	
<b>MU Objective</b>	
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.	
<b>2015 Edition EHR Certification Criterion</b>	
(2) <u>Computerized provider order entry – laboratory</u> . (i) Enable a user to electronically record, change, and access laboratory orders. (ii) <u>Ambulatory setting only</u> . Enable a user to electronically create laboratory orders for electronic transmission: (A) With all the information for a test requisition as specified at 42 CFR 493.1241(c)(1) through (c)(8); and (B) In accordance with the standard specified at § 170.205(l)(1) and, at a minimum the version of the standard at § 170.207(c)(2).	
<b>Preamble FR Citation:</b> 79 FR 10887	<b>Specific questions in preamble?</b> No
<b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.	

§ 170.315(a)(3) (Computerized physician order entry – radiology/imaging)	
<b>MU Objective</b>	
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.	
<b>2015 Edition EHR Certification Criterion</b>	
(3) <u>Computerized provider order entry – radiology/imaging</u> . Enable a user to electronically record, change, and access radiology and imaging orders.	

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

<b>Preamble FR Citation:</b> 79 FR 10887	<b>Specific questions in preamble?</b> No
<b>Public Comment Field:</b> N/A.	

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

**MU Objective**

Implement drug-drug and drug-allergy interaction checks.

**2015 Edition EHR Certification Criterion**

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

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

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

**Preamble FR Citation:** 79 FR 10887

**Specific questions in preamble?** Yes

**Public Comment Field:** The Pharmacy HIT Collaborative supports certification requiring EHR technology to be able to track drug-drug and drug-allergy interaction (DDI/DAI) checks performed based on a patient's medication list and medication allergy list. The use of certified EHR technology for clinical decision support by pharmacists providing patient care, as well as other authorized health care professionals, could make patient care more effective.

The best medical outcomes happen with an integrated team approach of health care providers. Pharmacists' unique experiences, expertise, and access to medication information that others may not have bring enormous value to physicians in their prescribing decisions, particularly, with regard to checking DDI/DAIs. This is especially an important aspect in caring for patients after they are discharged from a hospital. Pharmacists also should be involved in helping to streamline drug-drug, drug-allergy interactions to prevent alert-fatigue.

To better incorporate the automated interaction check process, pharmacists in all practice settings should be permitted to review data collected by DDI/DAI, including prescriber overrides, and have the capability to configure certain areas/settings that could be used as alert triggers, as well as tailoring alerts to a patient-specific situation using patient information. Two examples of areas that pharmacists should have the ability to configure are drug groups (lists of individual medication products; generic or therapeutic groupings) and specific medication order information.

The Collaborative also recommends that EHR vendors be consistent and system designs follow established standards. EHR vendors should work collaboratively with pharmacy standard setting organizations, as well as the pharmacy profession, in this regard. It is recommended that industry standard vocabularies be used for exchanging drug-allergy information. We support NCPDP's position for standardizing the value sets for DDI/DAI terminology.

**§ 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.

### § 170.315(a)(5) (Demographics)

#### 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:** The Pharmacy HIT Collaborative supports following NCPDP's recommendation that standards used be based on previous regulatory guidance and that what is chosen support the code sets available for use in those standards. An entity can choose to use a subset if their language choices are narrower than the full set, but the base is the same set. If a code set is chosen, we request that it not be in conflict with the NCPDP standards.

- Languages - the ISO 639-3 Codes for the Representation of Names of Languages.
- Ethnicity – the Centers for Disease Control (CDC) PHIN Vocabulary Access and Distribution System (VADS) PHVS\_Race\_CDC <http://phinvads.cdc.gov/vads/ViewValueSet.action?id=66D34BBC-617F-DD11-B38D-00188B398520#>
- Race - Centers for Disease Control (CDC) PHIN Vocabulary Access and Distribution System (VADS) PHVS\_Race\_CDC <http://phinvads.cdc.gov/vads/ViewValueSet.action?id=66D34BBC-617F-DD11-B38D-00188B398520#>

### § 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:** The Pharmacy HIT Collaborative supports using standardized vocabularies for recording vital signs and the adoption of SNOMED CT and UCUM in this certification criterion for the 2017 edition. Pharmacists use this for documenting, collecting, and exchanging information for the patient-care services they provide.

### § 170.315(a)(7) (Problem list)

#### MU Objective

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

**§ 170.315(a)(7) (Problem list)**

**2015 Edition EHR Certification Criterion**

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

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

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

**Preamble FR Citation:** 79 FR 10890

**Specific questions in preamble?** *No*

**Public Comment Field:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for 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:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for 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:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.

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

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

**MU Objective**

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

2015 Edition EHR Certification Criteria

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

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

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

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

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

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

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

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

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

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

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

- (A) For evidence-based decision support interventions under paragraph (a)(10)(i) of this section:
  - (1) Bibliographic citation of the intervention (clinical research/guideline);
  - (2) Developer of the intervention (translation from clinical research/guideline);
  - (3) Funding source of the intervention development technical implementation; and
  - (4) Release and, if applicable, revision date(s) of the intervention or reference source.

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

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

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

**Preamble FR Citation:** 79 FR 10890

**Specific questions in preamble?** Yes

**Public Comment Field:** The Pharmacy HIT Collaborative supports the proposal to adopt the HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1 (January 2013) (HeD standard) as the standard for the 2015 Edition EHR Certification Criterion for this objective. Pharmacists use clinical decision support knowledge in the pharmacy services they provide to their patients, which includes DDI/DAI.



**§ 170.315(a)(11) (Electronic notes)**

**MU Objective**

Record electronic notes in patient records.

**2015 Edition EHR Certification Criterion**

- (11) Electronic notes. Enable a user to electronically:
- (i) Record, change, and access electronic notes; and
  - (ii) Search within and across electronic notes stored within EHR technology.

Preamble FR Citation: 79 FR 10891

Specific questions in preamble? Yes

**Public Comment Field:** The Pharmacy HIT Collaborative supports EHR technology having the capability to search for information across separate notes within the EHR technology rather than just within one particular note. The Collaborative recommends that vendors adopt the guidelines from the National Council for Prescription Drug Programs (NCPDP) for the use HL7 Consolidated CDA (C-CDA) for structured pharmacy/pharmacist care notes (PCN). Pharmacists provide clinical services daily. When these services are provided, it is necessary for pharmacists to record them in the PCN so that they may be shared with the patient's other health care providers. The PCN is a progress note that documents the care provided by a pharmacist. The PCN includes the reported and observed clinical status, problems and conditions of the patient, and the proposed plan of care. Prescribed medications, non prescribed (e.g. over the counter (OTC) medications), and supplements also are recorded.

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

**MU Objective**

Implement drug formulary checks.

**2015 Edition EHR Certification Criterion**

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

Preamble FR Citation: 79 FR 10892

Specific questions in preamble? Yes

**Public Comment Field:** The Pharmacy HIT Collaborative supports keeping the 2015 edition the same as the 2014 edition. The Collaborative also supports NCPDP's position and recommendation regarding the use of its Telecommunication Standard in conjunction with the NCPDP Formulary and Benefit Standard. As NCPDP notes, Formulary and Benefit Standard was created to inform providers of all elements of a drug's formulary status, patient copay, coverage restrictions, and relevant clinical messaging. It was not intended to be real time and patient specific because it describes all prescribable products, not just the drug that the provider selected. Some of the issues with the Formulary and Benefit Standard are the result of payer implementations (not full data, large files) versus an issue with the standard itself. Because the industry is in the early stages of exploring and developing alternative formulary solutions and transactions or piloting these solutions, we agree with NCPDP that it maybe premature for a real-time patient specific transaction to be adopted as an industry-wide standard at this time. We support NCPDP's recommend that the formulary check certification criterion should be left as-is (in its flexible form) as the industry works to determine the best solution for providing prescribers with accurate, patient-specific, drug-specific information at the point of prescribing.

**§ 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).

**§ 170.315(a)(13) (Smoking status)**

**Preamble FR Citation:** 79 FR 10892

**Specific questions in preamble?** *No*

**Public Comment Field:** N/A

**§ 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:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.

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

**MU Objective**

Record patient family health history as structured data.

**2015 Edition EHR Certification Criterion**

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

**Preamble FR Citation:** 79 FR 10893

**Specific questions in preamble?** *No*

**Public Comment Field:** Pharmacist collect family health history. In addition to supporting the adoption of family health history certification criterion according to the HL7 Pedigree standard and the HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1, the Pharmacy HIT Collaborative also recommends the use of SNOMED CT, even though it is omitted as an option.

**§ 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.

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

Preamble FR Citation: 79 FR 10893

Specific questions in preamble? *Yes*

**Public Comment Field:** With regard to the four issues for EHR technology certification that are raised, the Pharmacy HIT Collaborative supports the inclusion of all four aspects as a requirement for patient communication preferences. To provide robust communication with patients, particularly via electronic communication, patient communication preferences should be a requirement for inpatient and ambulatory settings. EHR technology should be capable of creating patient reminder lists based on a suggested minimum list of patient communication preferences, as well as allowing the patient to request a preference that may not appear on the minimum list. Because a patient may communicate primarily in a language other than English, EHR technology also should be able to use a patient's preferred language as a filter. Lastly, with regard to patient reminders as currently part of this MU objective, a certification criterion should be included that would require EHR technology to be able to provide patient reminders according to identified patient preferences and preferred language.

**§ 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:** The Pharmacy HIT Collaborative supports the approach proposed for the 2015 edition, and possibly the 2017 edition, that will require EHR technology to demonstrate the capability to electronically identify for a user patient-specific education resources using Infobutton and an alternative method. We agree that EHR technology should be required to provide patient-specific education resources in a patient's preferred language. Providing these resources to a patient is important, especially, in regard to medication-related patient-specific education.

Information provided by providers electronically should be presented to patients in a way that would allow them to understand the information. Education level, age, literacy, language barriers, visual and hearing impairments, etc., need to be taken into consideration. Pharmacists are trained in and have knowledge of effective tools to communicate with patients about medication-related information that take into account those factors thus making medication information more understandable.

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

**MU Objective**

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

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

**2015 Edition EHR Certification Criterion**

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

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

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

**Preamble FR Citation:** 79 FR 10894

**Specific questions in preamble?** *No*

**Public Comment Field:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.

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

**MU Objective**

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

**2015 Edition EHR Certification Criteria**

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

**Preamble FR Citation:** 79 FR 10894

**Specific questions in preamble?** *No*

**Public Comment Field:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.

**§ 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:** N/A

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

**MU Objective**

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

**2015 Edition EHR Certification Criteria**

- (1) Transitions of care. (i) Send and receive via edge protocol. EHR technology must be able to electronically:
- (A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(e) and that leads to such summaries being processed by a service that has implemented the standard specified in §170.202(a); and
  - (B) Receive transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(e) from a service that has implemented the standard specified in §170.202(a).
- (ii) Receiving accuracy. EHR technology must meet or exceed the standard specified at §170.212(a)
- (iii) Display.
- (A) EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: §170.205(a)(1) through (4).
  - (B) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at §170.205(a)(3).
  - (iv) Create. (A) Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at §170.205(a)(4) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):
    - (1) Encounter diagnoses. The standard specified in §170.207(i) or, at a minimum, the version of the standard specified §170.207(a)(3);
    - (2) Immunizations. The standard specified in §170.207(e)(2);
    - (3) Cognitive status;
    - (4) Functional status;
    - (5) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information;
    - (6) Inpatient setting only. Discharge instructions; and
    - (7) Unique Device Identifier(s) for a patient's implantable device(s).
  - (B) Patient matching data quality. EHR technology must be capable of creating a transition of care/referral summary that includes the following data and, where applicable, represent such data according to the additional constraints specified below:
    - (1) Data. first name, last name, middle name (or middle initial in cases where only it exists/is used), suffix, date of birth, place of birth, maiden name, current address, historical address, phone number, and sex.
    - (2) Constraint. Represent last/family name according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0.
    - (3) Constraint. Represent suffix according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, PHD, ESQ). If no suffix exists, the field should be entered as null.
    - (4) Constraint. Represent the year, month and date of birth are required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in latter local time is assumed. If date of birth is unknown, the field should be marked as null.
    - (5) Constraint. Represent current and historical address information, including the street address, city, state, zip code, according to the United States Postal Service format;
    - (6) Constraint. Represent phone number (home, business, cell) in the ITU format specified in ITU-T E.123 and ITU-T E.164. If multiple phone numbers are present, all should be included.
    - (7) Constraint. Represent sex according to the HL7 Version 3 ValueSet for Administrative Gender.

**Preamble FR Citation:** 79 FR 10896

**Specific questions in preamble?** Yes

**Public Comment Field:** The Pharmacy HIT Collaborative supports the proposed standardized data to improve patient matching, including the use of NCPDP's guidelines for the use of HL7 Consolidated CDA (C-CDA) for pharmacy transition of care.

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

**Standardized patient identifying attributes should be required and captured by certified EHR technology for use in relevant exchange transactions. This would lead to increased match rates. Standardized data in patient matching is important to pharmacists providing services at transition of care.**

According to **ONC's February 2014, Patient Identification and Matching Final Report**, "even if similar data attributes are used across the continuum of care, often they are not stored in a standard format. " As an example, the report mentions that organizations noted that even a patient's name can become quite complicated, with variations in whether middle name or initial is used, how hyphens are handled, whether previously used names or nicknames are recognized, and how people of different ethnic backgrounds use their family names." Further, the report states, "Health systems frequently indicated that there needs to be a standardized way demographics such as name and date of birth are entered into systems and into electronic messaging formats." (Standardizations, pages 7-8.)

The **ONC report** also indicates that certification criteria should be introduced that require certified EHR technology (CEHRT) to capture the following list of data attributes not currently required in 2014 certification criteria (page 18):

- Previous last/family name
- Middle name or initial
- Suffix
- Current address
- Historical address(es)
- Phone (including home business, and cell)
- Historical phone(s)

The role of pharmacists needs to be recognized in this area, particularly, with regard to medication reconciliation at the transition of care. Pharmacists look at patients in a patient-centered way. That is pharmacists must follow their patients longitudinally through their care to increase medication-related patient safety. It is at these points of transition where pharmacists may see problems with the patients' medications that were prescribed.

Where patient demographic data elements are captured it should be in a structured consistent format. Historical information that is maintained should be in a structured consistent format. Linkage of the historical to current patient information is important. We support the linkage of historical patient information for the purposes of maintaining continuity of care over time, but separated from current patient information.

The Collaborative supports NCPDP's request to consider up- and down-stream impacts to these possible rules and data values. If these possible rules are specific to the CDA, they can be supported. The reason for this request is that these possible rules may impact the transactions that are being exchanged today using NCPDP standards. Analysis must be performed to determine if these rules are necessary for these data exchanges, and if so, the impact. It is suggested that part of the testing should include interoperability with pharmacy systems.

### § 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.

**§ 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:** The Pharmacy HIT Collaborative supports including clinical information reconciliation and incorporation into the 2015 and 2017 editions. The Collaborative agrees that it is important to reconcile medications and other areas by pharmacists providing patient care. Pharmacists currently provide medication reconciliations for their patients.

**§ 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:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition. The Collaborative supports the bidirectional exchange of e-prescribing.

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

**MU Objective**

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

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

**2015 Edition EHR Certification Criteria**

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

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

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

(ii) Electronically display the test report information:

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

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

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

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

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

Preamble FR Citation: 79 FR 10901

Specific questions in preamble? No

**Public Comment Field: The Pharmacy HIT Collaborative supports including the HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Laboratory Results Interface, Release 1 (US Realm) (S&I Framework LRI) with Errata60 in the 2015 Edition “transmission of electronic laboratory tests and values/results to ambulatory providers” certification criterion.**

**Pharmacists providing patient care need to have access to laboratory tests and values/results for exchanging medication-related information. Additionally, it should be noted that pharmacists providing patient care have the ability to order, receive, and have access to laboratory tests and values/results.**

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

**MU Objective**

Provide structured electronic laboratory results to eligible professionals.

**2015 Edition EHR Certification Criteria**

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

(i) That includes the information:

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

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

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

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

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

Preamble FR Citation: 79 FR 10901

Specific questions in preamble? No

**Public Comment Field: The Pharmacy HIT Collaborative supports including the HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Laboratory Results Interface, Release 1 (US Realm) (S&I Framework LRI) with Errata60 in the 2015 Edition “transmission of electronic laboratory tests and values/results to ambulatory providers” certification criterion.**

**Pharmacists are ambulatory providers, many of whom provide CLIA information (e.g., hyperlipidemia, bone scans, etc.). Additionally, pharmacists providing patient care need to have access to laboratory tests and values/results for exchanging medication-related information.**



**§ 170.315(b)(6) (Data portability)**

**MU Objective**

N/A

**2015 Edition EHR Certification Criterion**

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

- (i) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);
- (ii) Immunizations. The standard specified in § 170.207(e)(2);
- (iii) Cognitive status;
- (iv) Functional status;
- (v) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information;
- (vi) Inpatient setting only. Discharge instructions; and
- (vii) Unique Device Identifier(s) for a patient's Implantable Device(s).

**Preamble FR Citation:** 79 FR 10902

**Specific questions in preamble?** Yes

**Public Comment Field:** The Pharmacy HIT Collaborative strongly supports the use of consolidated CDA; particularly, for comprehensive medication review. Concerning the three questions raised, we agree that 1) renaming this certification data migration could prevent confusion with a more precise label; 2) adding more requirements for the 2017 edition to allow for more longitudinal data to be exported would be beneficial; and 3) expanding this certification for the 2017 edition for a broader range of uses (e.g., local access/query, targeted access/inter-organizational query, and distributed multi-source access/query) is appropriate.

The Collaborative is working toward electronically processing of clinical quality measures for pharmacists providing patient care. We support the use of HL7 Health Quality Measures Format (HQMF) standard for representing a clinical quality measure as an electronic document for the 2017 edition. Additionally, we support the HQMF R2 standard within EHR technology (including medications, laboratory, allergies information) for future use by pharmacists.

**Clinical Quality Measures – Electronically Processing eMeasures**

**Preamble FR Citation:** 79 FR 10902

**Specific questions in preamble?** Yes

**Public Comment Field:** The Pharmacy HIT Collaborative supports unified, modularized CDS and CQM standards for the 2017 edition.

**Clinical Quality Measures – Functions and Standards for CQM Certification**

**Preamble FR Citation:** 79 FR 10903

**Specific questions in preamble?** Yes

**Public Comment Field:** N/A.

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

**§ 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:** The Pharmacy HIT Collaborative supports the current requirement to export a CQM data file formatted in accordance with the QRDA Category I standard and would be supportive of broadening the export requirement to include reference to QRDA Category II formatted data file. Although pharmacists are not currently using these measurements the Pharmacy Quality Alliance (PQA) is developing a framework for these measurements. The Collaborative is working with PQA regarding these.

**§ 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:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for 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.

<b>Preamble FR Citation:</b> 79 FR 10903	<b>Specific questions in preamble?</b> No
<b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.	

§ 170.315(c)(4) (Clinical quality measures – patient population filtering)	
<b>MU Objective</b>	
N/A	
<b>2015 Edition EHR Certification Criterion</b>	
(4) <u>Clinical quality measures – patient population filtering</u> . EHR technology must be able to record structured data for the purposes of being able to filter CQM results to create different patient population grouping by one or a combination of the following patient characteristics: <ul style="list-style-type: none"> <li>(i) Practice site and address;</li> <li>(ii) Tax Identification Number (TIN), National Provider Identifier (NPI), and TIN/PIN combination;</li> <li>(iii) Diagnosis;</li> <li>(iv) Primary and secondary health insurance, including identification of Medicare and Medicaid dual eligibles; and</li> <li>(v) Demographics including age, sex, preferred language, education level, and socioeconomic status.</li> </ul>	
<b>Preamble FR Citation:</b> 79 FR 10903	<b>Specific questions in preamble?</b> Yes
<b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports patient population filtered data for collecting metadata. Because of the role pharmacists' play, especially with regard to immunizations, this is important.	

§ 170.315(d)(1) (Authentication, access control, and authorization)	
<b>MU Objective</b>	
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	
<b>2015 Edition EHR Certification Criterion</b>	
(1) <u>Authentication, access control, and authorization</u> . (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 <ul style="list-style-type: none"> <li>(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.</li> </ul>	
<b>Preamble FR Citation:</b> 79 FR 10904	<b>Specific questions in preamble?</b> Yes
<b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports e-prescribing of controlled substances. A hindrance to allowing this still remains. Although the DEA now permits controlled substance e-prescribing, not all of the states allow this. For this to work efficiently, e-prescribing needs to be allowed in all 50 states and be done with uniform standards. This would need to be done through the states' legislative and regulatory processes.	
The Collaborative also support the NCPDP's recommendation to analyze before requiring two-factor authentication for remote access to EHR technology, as there are situations where this may be onerous for e-prescribing functions (e.g. emergency prescriptions).	

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

**§ 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:** The Pharmacy HIT Collaborative supports the 2015 edition proposal that would prohibit an EHR technology's audit log from being disabled by a user.

**§ 170.315(d)(3) (Audit report(s))**

**MU Objective**

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

**2015 Edition EHR Certification Criterion**

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

**Preamble FR Citation:** 79 FR 10905

**Specific questions in preamble?** Yes

**Public Comment Field:** The Pharmacist HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition. The Collaborative also believes EHR technology should always be capable of being audited no matter what standard is being used.

**§ 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.

**§ 170.315(d)(4) (Amendments)**

**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:** *N/A.*

**§ 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:** *The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.*

**§ 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:** *The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for 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.

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

**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:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for 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.

**Preamble FR Citation:** 79 FR 10905

**Specific questions in preamble?** *No*

**Public Comment Field:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for 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:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.

**§ 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.

EHRs and CAHs

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

**2015 Edition EHR Certification Criterion**

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

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

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

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

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

(B) Download.

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

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

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

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

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

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

(1) Enter a 3<sup>rd</sup> 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).

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

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

**Preamble FR Citation:** 79 FR 10906

**Specific questions in preamble?** Yes

**Public Comment Field:** The Pharmacy HIT Collaborative supports view/download and transmit to third party and the use of consolidated CDA for the certification criterion for the 2015 edition; however, we recommend real time transmission following the protocol established by NCPDP be used.

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

**MU Objective**

Provide clinical summaries for patients for each office visit.

**2015 Edition EHR Certification Criterion**

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

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

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

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

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

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

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

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

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

**Preamble FR Citation:** 79 FR 10907

**Specific questions in preamble?** Yes

**Public Comment Field:** The Pharmacy HIT Collaborative supports and promotes the use of consolidated CDA, CVX, and LOINC for clinical summaries; medications administered, including immunizations; and diagnostic tests for the 2015 edition.

**§ 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: The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for 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*

**Public Comment Field: The Pharmacy HIT Collaborative supports NCPDP comments related to the inclusion of bidirectional immunization data exchange as part of the 2015 and 2017 editions. NCPDP supports the use of CVX for reporting of immunizations to registries.**

**§ 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: The Pharmacy HIT Collaborative supports inclusion of bidirectional immunization data exchange as part of the 2015 and 2017 editions.**

**§ 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:** The Pharmacy HIT Collaborative supports the revisions to include HL7 CDA and QRDA III standards for 2014 and 2015 editions. The Collaborative is supportive of standards used by public health agencies.

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

**MU Objective**

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

**2015 Edition EHR Certification Criterion**

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

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

**Preamble FR Citation:** 79 FR 10910

**Specific questions in preamble?** No

**Public Comment Field:** The Pharmacy HIT Collaborative supports adopting the technical revision for transmission of reportable laboratory tests and values/results for 2014 edition to have it continue to point to HL7 2.5.1 and HL7 Version 2.5.1 : Implementation Guide: Electronic Laboratory Reporting to Public Health, et al) and keeping these revisions for the 2015 edition.

**§ 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:** The Pharmacy HIT Collaborative supports the proposed removal of “optional” designation for cancer case information from this certification as part of the 2015 edition and agrees that designation would no longer be necessary.

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

**MU Objective**

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

**2015 Edition EHR Certification Criterion**

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

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

**Preamble FR Citation:** 79 FR 10910

**Specific questions in preamble?** *No*

**Public Comment Field:** The Pharmacy HIT Collaborative supports the proposed removal of “optional” designation for transmission to cancer registries from this certification as part of the 2015 edition and agrees that designation would no longer be necessary.

**§ 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:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for 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:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.

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

**MU Objective**

N/A

**2015 Edition EHR Certification Criterion**

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

**Preamble FR Citation:** 79 FR 10911

**Specific questions in preamble?** Yes

**Public Comment Field:** The Pharmacy HIT Collaborative supports adoption of the same 2014 edition requirements for the 2015 edition. The Collaborative would support additional safety-enhanced certification criteria for medication-related services provided by pharmacists.

**§ 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:** The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.

**§ 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? <i>Yes</i>
<p><b>Public Comment Field:</b> The Pharmacy HIT Collaborative agrees that the specific certification requirement for MU Stage 1 objective “Implement drug-formulary checks” and the associated non-percentage-based measure should not be included the 2015 edition, as it was merged into the new MU Stage 2 objectives with new percentage-based measures. Because pharmacists are ineligible providers under the EHR incentive program, the Collaborative supports voluntary “meaningful use” of EHR technology for pharmacists. As ONC acknowledges in its <i>Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments</i>, “these ‘ineligible’ types of providers routinely interact with health care providers who are eligible for EHR incentive payments and face policy and technology challenges unique to their settings.” In moving forward to 2015 and 2017, to achieve interoperable electronic health information exchange, we agree with ONC that EHR technology developers serving ineligible health care providers need to seek certifications to these criteria.</p>	

§ 170.315(h)(1) (Transmit – Applicability Statement for Secure Health Transport)	
<p><b>MU Objective</b> N/A</p>	
<p><b>2015 Edition EHR Certification Criterion</b> 1) <u>Transmit – Applicability Statement for Secure Health Transport</u> Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(a).</p>	
Preamble FR Citation: 79 FR 10914	Specific questions in preamble? <i>No</i>
<p><b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the proposal for the 2015 edition that would enable EHR technology to be tested and certified solely to perform transmission with the Applicability Statement for Secure Health Transport.</p>	

§ 170.315(h)(2) (Transmit – Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging)	
<p><b>MU Objective</b> N/A</p>	
<p><b>2015 Edition EHR Certification Criterion</b> (2) <u>Transmit – Applicability Statement for Secure Health Transport &amp; XDR/XDM for Direct Messaging</u> Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(b).</p>	
Preamble FR Citation: 79 FR 10914	Specific questions in preamble? <i>No</i>
<p><b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the proposal for the 2015 edition that would enable EHR technology to be tested and certified solely to perform transmission with the Applicability Statement for Secure Health Transport.</p>	

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

<b>MU Objective</b>	
N/A	
<b>2015 Edition EHR Certification Criterion</b>	
(3) <u>Transmit – SOAP Transport and Security Specification &amp; XDR/XDM for Direct Messaging</u> Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(c).	
<b>Preamble FR Citation:</b> 79 FR 10914	<b>Specific questions in preamble?</b> No
<b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the proposal for the 2015 edition that would enable EHR technology to be tested and certified solely to perform transmission with the Applicability Statement for Secure Health Transport.	

<b>§ 170.315(h)(4) (Transmit – Applicability Statement for Secure Health Transport &amp; Delivery Notification in Direct)</b>	
<b>MU Objective</b>	
N/A	
<b>2015 Edition EHR Certification Criterion</b>	
(4) <u>Transmit – Applicability Statement for Secure Health Transport &amp; Delivery Notification in Direct</u> Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(d).	
<b>Preamble FR Citation:</b> 79 FR 10914	<b>Specific questions in preamble?</b> No
<b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the proposed adoption that would enable EHR technology to be tested and certified solely to perform transmissions in accordance with the Applicability Statement for Secure Health Transport, as support for this objective in general. The Collaborative also supports the use of voluntary guidelines for non-MU EHR users.	
With regard to Section G, Certification Packages for EHR Modules, pharmacists providing patient care services are not eligible for EHR incentives, and as noted previously in Section 170.315(g)(5) Nonpercentage-Based Measures, the Collaborative supports <i>ONC's Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments</i> document. Pharmacists are an integral part of a patient's health care team and have access to engage the patient.	

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

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

<b>Non-MU EHR Technology Certification</b>	
<b>Preamble FR Citation:</b> 79 FR 10918	<b>Specific questions in preamble?</b> Yes
<b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the proposed revisions for the 2015 edition and establishing a definition for non-MU EHR Module. As noted previously, pharmacists providing patient care services are not eligible for EHR incentives. Pharmacists are an integral part of a patient's health care team and have access to engage the patient.	

<b>Preamble FR Citation:</b> 79 FR 10920	<b>Specific questions in preamble?</b> No
<b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.	

<b>Patient List Creation Certification Criteria</b>	
<b>Preamble FR Citation:</b> 79 FR 10920	<b>Specific questions in preamble?</b> No
<b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.	

<b>ISO/IEC 17065 (§ 170.503(b)(1))</b>	
<b>Preamble FR Citation:</b> 79 FR 10920	<b>Specific questions in preamble?</b> No
<b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the proposal to keep the 2014 edition certification criterion for the 2015 edition.	

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

<b>Certification Packages for EHR Modules</b>	
<b>Preamble FR Citation:</b> 79 FR 10921	<b>Specific questions in preamble?</b> Yes
<b>Public Comment Field:</b> As noted above in Section 170.315(g)(5) Nonpercentage-Based Measures, the Collaborative supports <i>ONC's Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments</i> document. Pharmacists are an integral part of a patient's health care team and have access to engage the patient; however, pharmacists providing patient care services are not eligible for EHR incentives.	

## ***C. Other Topics for Consideration for the 2017 Edition Certification Criteria***

### ***Rulemaking***

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

Additional Patient Data Collection	
Preamble FR Citation: 79 FR 10922	Specific questions in preamble? <i>Yes</i>
<p><b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the inclusion of data elements and standards for demographics certification criterion (allowing the functionality to enable a user to electronically record, changes, an access patient data on preferred language, sex, race, ethnicity, and date of birth); new standalone certification criteria for each data element; and new certification together (e.g., disability, sexual orientation and gender identity in one certification criterion with veterans status and occupation status in a separate criterion) for the 2017 edition.</p> <p>With regard to sections V1-4, the Collaborative also supports the proposed additions, as well as the use of LOINC and SNOMED CT as standards to capture these data elements in an EHR, including disability information and accommodation requests, sexual orientation and gender identity, and U.S. military service.</p> <p>Regarding Gender Identity, it is recommended that impacts to clinical decision support, i.e. related to medication dosing/administration, be examined before modifications are made or new gender identity codes are implemented.</p>	

Medication Allergy Coding	
Preamble FR Citation: 79 FR 10925	Specific questions in preamble? <i>Yes</i>
<p><b>Public Comment Field:</b> The Pharmacy HIT Collaborative supports the use of SNOMED CT vocabulary for coding DDIs. The Collaborative also proposes working with the National Library of Medicines and other terminology organizations to develop a more comprehensive coding vocabulary and value set for coding food-drug interactions and allergies.</p> <p>With regard adoption of additional vocabularies to code medication allergies, the Collaborative also will be working with the National Library of Medicines for vaccine reaction and adverse events to develop a more comprehensive coding vocabulary in this area.</p>	

Certification Policy for EHR Modules and Privacy and Security Certification Criteria	
Preamble FR Citation: 79 FR 10925	Specific questions in preamble? <i>Yes</i>
<p><b>Public Comment Field:</b> N/A.</p>	

Provider Directories	
Preamble FR Citation: 79 FR 10926	Specific questions in preamble? <i>No</i>
<p><b>Public Comment Field:</b> N/A.</p>	

Oral Liquid Medication Dosing	
Preamble FR Citation: 79 FR 10926	Specific questions in preamble? <i>Yes</i>



**Public Comment Field:** The Pharmacy HIT Collaborative supports following NCPDP's recommendations to implement the structured Sig in the NCPDP SCRIPT Standard Version 10.6, especially for pediatric prescriptions, to facilitate the exchanges in electronic prescribing of liquid oral medications as it addresses the concerns outlined above. Dose limit and dose calculation checks should be performed in the EHR. The structured Sig supports the exchange of the data components, which allow the pharmacist to validate the calculation for patient safety. At the present time, certain complex dosing regimens may not be supported by the current structured Sig in the NCPDP SCRIPT Standard Version 10.6 but are supported in published future versions of the NCPDP SCRIPT Standard Version 2012 and above.

We agree that the harmonizing prescribing, transcribing, labeling, dispensing, and administering oral liquid medications in the community setting with standards used in hospital and other healthcare settings, recommendations for non-prescription (e.g. over-the-counter (OTC) medications), and international standards of expressing volumetric measurement can reduce errors and improve patient safety.

### Medication History

Preamble FR Citation: 79 FR 10927

Specific questions in preamble? Yes

**Public Comment Field:** The Pharmacy HIT Collaborative supports the proposal to add medication history capabilities to the 2017 Edition certification criterion using the Medication History transactions in the appropriate NCPDP SCRIPT Standard. The measure should be the attempt to query an external history source, receive data, and take appropriate action. When it comes to the certification criteria, it is suggested this be placed under the Medication List criteria. The Collaborative supports NCPDP's recommendation to make external medication history sources data available to EHR systems. Medication history can be used to support medication reconciliation for a system to compare to external sources, as well to update a medication list, both of which are important functions for patient care.

### Blue Button +

Preamble FR Citation: 79 FR 10927

Specific questions in preamble? Yes

**Public Comment Field:** The Pharmacy HIT Collaborative is a committed member of the Blue Button Initiative. The Collaborative not only supports the standard/inoperability of Blue Button + but is also a supporter of educating patients about access to their medical records through the Blue Button connector.

### 2D Barcoding

Preamble FR Citation: 79 FR 10928

Specific questions in preamble? Yes

**Public Comment Field:** N/A

### Duplicate Patient Records

Preamble FR Citation: 79 FR 10928

Specific questions in preamble? Yes

**Public Comment Field:** The Pharmacy HIT Collaborative supports improved patient matching for the 2017 edition, as well as supports ONC's guidance for patient identification. We agree with ONC that identifying duplicate patient records within EHR systems is important for matching patients to their records and that certification criteria should require CEHRT that performs patient record matching to demonstrate the ability to generate and provide to the end users reports that detail potential duplicate records as a potential means to improve patient matching data quality.

#### Disaster Preparedness

**Preamble FR Citation:** 79 FR 10928

**Specific questions in preamble?** *Yes*

**Public Comment Field:** N/A.

#### 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:** The Pharmacy HIT Collaborative supports voluntary certification, particularly for non-MU EHR Modules. The Collaborative also recommends adding to the examples of Specific Types of Health Care Settings pharmacist providing patient care outside the dispensing function.