May 29, 2015

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

Attention: Minnesota e-Health Initiative Statewide Coordinated Response to the 2015 Edition Health IT Certification Criteria

The Minnesota e-Health Initiative is pleased to submit comments on the 2015 Edition Health IT Certification Criteria. We appreciate the work done to date by the ONC to listen to, identify, and propose next steps toward Health IT Interoperability through certification. Thank you for providing an opportunity to submit comments for your consideration. Should you have questions you may contact:

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Sincerely,

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- Greg Linden, Chief Information Officer, Stratis Health, Co-Chair, Standards and Interoperability Workgroup and Minnesota Coordinated Response
- Jonathan Shoemaker, IS Director of Clinical Applications, Allina Health System, Co-Chair, Standards and Interoperability Workgroup and Minnesota Coordinated Response
- Diane Rydrych, Director, Division of Health Policy, Minnesota Department of Health

The Minnesota e-Health Initiative Statewide Coordinated Response to the 2015 Edition Health IT Certification Criteria

Introduction and Approach

Minnesota e-Health Advisory Committee

The Minnesota e-Health Advisory Committee is a 25-member legislatively-authorized committee appointed by the Commissioner of Health to build consensus on important e-health issues and advise on policy and common action needed to advance the Minnesota e-Health vision (Figure 1). The Committee is comprised of a diverse set of key Minnesota stakeholders, including: consumers, providers, payers, public health professionals, vendors, informaticians, and researchers, among others.

Figure 1: The Minnesota e-Health Vision is to accelerate the adoption and effective use of electronic health record systems and other health information technology in order to improve health care quality, increase patient safety, reduce health care costs and improve public health. The vision's comprehensive scope includes four domains:

- Consumers
- Clinicians
- Policy/Research
- Public Health

For the past ten years the e-Health Initiative, led by the Minnesota e-Health Initiative Advisory Committee and the MDH Office of Health Information Technology (OHIT), has pushed for and supported e-health across the continuum of care; as a result, Minnesota is a national leader in implementation and collaboration. The committee is co-chaired by Bobbie McAdam, Senior Director, Medica, and Alan Abramson, Senior Vice President, HealthPartners. See Appendix A for a listing of current Advisory Committee Members.

Workgroups

Committee members participate in workgroups to dive into detailed topics such as privacy and security, health information exchange, and standards and interoperability. The workgroups are the primary vehicle for receiving public input and investigating specific e-health topics through discussion and consensus-building. Each workgroup has a charter declaring the purpose, schedule, deliverables, and co-chairs that guide the process. The co-chairs and workgroup participants contribute subject matter expertise in discussions, research, and analyses through hundreds of hours of volunteer time. OHIT staff facilitate, analyze and interpret data, and summarize findings that will contribute to e-health policy development. Workgroup participants are recruited statewide and are open to the public via in-person meetings and dial-in options.

Statewide Coordinated Response Approach

This statewide coordinated response to the request for public comment invited multiple stakeholders, including the Advisory Committee and workgroups, from the Minnesota health and healthcare system to

participate in two conference calls and submit written comments. Greg Linden, Stratis Health, and Jonathan Shoemaker, Allina Health System, provided leadership as co-chairs of the response and OHIT coordinated the work.

The Initiative recognizes the value in identifying best available standards and implementation specification for stakeholders that will advance the nation towards an interoperable HIT ecosystem, advance research, and achieve a learning health system. However, we identified areas needing more clarity or action in the comments and recommendations below. The Initiative is providing feedback through general comments and recommendations, and through comments and recommendations for each proposed certification criteria. We strongly encourage consideration of these comments and recommendations.

General Comments and Recommendations

1. We strongly support the development and use of the Health IT Certification Criteria and applaud the ONC for their effort.
2. To improve the use of this document, we strongly encourage the inclusion of examples for different provider types as to which certification criteria would apply to their practice.
3. We strongly support how this proposal encourages transparency among vendors, and between providers and vendors.
4. We recommend the collection and sharing of best practices on how states and organizations will use the Health IT Certification Criteria. For example, in Minnesota we will be determining how to best use the Health IT Certification Criteria in conjunction with the Minnesota e-Health Standards Guide.
5. We are encouraged of the potential for this proposal to promote interoperability and lead toward population health management once it is implemented. We encourage the use of this criteria toward the goal of accountable health communities.
6. Overall, we support consolidating Base EHR criteria to minimize the confusion among providers and streamline the certification process for vendors.
7. Within this criteria, we encourage the use of interactive patient portal technology to engage individuals and their caregivers in ownership of their health.
8. As vendors assume the challenge of creating interoperable systems, we encourage the criteria of user-ability and streamlining provider workflows whenever possible.

Proposed 2015 Edition Electronic Health Record (EHR) Certification Criteria, 2015 Edition Base EHR Definition, and ONC Health IT Certification Program Modifications

A. Provisions of the Proposed Rule affecting Standards, Implementation Specifications, Certification Criteria, and Definitions

§ 170.315(a)(1) Computerized provider order entry – medications
Included in 2015 Edition Base EHR Definition?
Yes, as an alternative to § 170.315(a)(2) or (3)

§ 170.315(a)(1) Computerized provider order entry – medications

Stage 3 MU Objective

Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

2015 Edition Health IT Certification Criterion

(1) Computerized provider order entry – medications. Technology must enable a user to record, change, and access medication orders.

Preamble FR Citation: 80 FR 16814 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support and currently encourage this criteria. We request clarification as to whether a Health IT Module should be able to include the primary diagnosis code. The NPRM requests comment as to the inclusion of the secondary diagnosis code, but we are unable to find reference to the inclusion of the primary diagnosis code. Exchange of indication and/or diagnosis information is necessary to ensure that all care providers, including pharmacists, have access to the necessary clinical information to appropriately treat the patient.

§ 170.315(a)(2) Computerized provider order entry – laboratory

Included in 2015 Edition Base EHR Definition?

Yes, as an alternative to § 170.315(a)(1) or (3)

Stage 3 MU Objective

Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

2015 Edition Health IT Certification Criterion

(2) Computerized provider order entry – laboratory.
- (i) Technology must enable a user to record, change, and access laboratory orders.
- (ii) Technology must be able to receive and incorporate a new or updated laboratory order compendium in accordance with the standard specified in § 170.205(l)(2) and, at a minimum, the version of the standard in § 170.207(c)(3).
- (iii) Ambulatory setting only. Technology must enable a user to create laboratory orders for electronic transmission in accordance with the standard specified in § 170.205(l)(1) and, at a minimum, the version of the standard in § 170.207(c)(3).

Preamble FR Citation: 80 FR 16814 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support and currently encourage this criteria.

§ 170.315(a)(3) Computerized provider order entry – diagnostic imaging

Included in 2015 Edition Base EHR Definition?

Yes, as an alternative to § 170.315(a)(1) or (2)

§ 170.315(a)(3) Computerized provider order entry – diagnostic imaging

Stage 3 MU Objective

Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

2015 Edition Health IT Certification Criterion

(3) Computerized provider order entry – diagnostic imaging. Technology must enable a user to record, change, and access diagnostic imaging orders.

Preamble FR Citation: 80 FR 16815 (also see 80 FR 16814) **Specific questions in preamble?** *Yes*

Public Comment Field:

We support and encourage the use of this criteria.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

2015 Edition Health IT Certification Criterion

(4) Drug-drug, drug-allergy interaction checks for CPOE.

(i) Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically 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.

(iii) Interaction check response documentation.

- (A) Technology must be able to record at least one action taken and by whom in response to drug-drug or drug-allergy interaction checks.
- (B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to drug-drug or drug-allergy interaction checks.

Preamble FR Citation: 80 FR 16815 **Specific questions in preamble?** *Yes*

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

Public Comment Field:

We support and encourage the use of this criteria. However, the functionality could be used outside of CPOE, for example during an initial assessment by nursing when meds are being taken down, or when meds are added in Public Health – especially non-prescriptive and herbal meds with drug interactions. We agree that this level of interaction checking should occur not only during the ordering process, but whenever the patient's history is updated, including their medication and medication allergy lists. Pharmacists are required under "OBRA 90" at https://www.govtrack.us/congress/bills/101/hr5835/text to perform drug utilization review, including interaction checks, and document the review; we are pleased to see that similar requirements are now being placed upon prescribers and feel that this will enhance the quality of patient care. Documentation of the review/intervention must be created, stored and produced upon request. We recommend the use of drug-drug, drug-allergy interactive checks when medications are reviewed, and not just during CPOE.

§ 170.315(a)(5) Demographics

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(5) Demographics.

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

(A) Race and ethnicity.

(1) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify race.

(2) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify ethnicity.

(3) Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(1) and (2) of this section to the categories in the standard specified in § 170.207(f)(1).

(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.

(C) Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1).

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

Preamble FR Citation: 80 FR 16816 **Specific questions in preamble?** *No*

§ 170.315(a)(5) Demographics

Public Comment Field:

We support including these criteria as Base EHR.

Race and Ethnicity:

We support the proposed granularity of race and ethnicity, and the proposed abilities to aggregate each one of the patient's races and ethnicities and map to the OMB minimum standard categories

Preferred Language:

We support the use of the RFC 5646 standard to identify preferred language. In addition, we recommend three questions on language:

1. How well do you speak and understand English?
   - ❒ Very well
   - ❒ Well
   - ❒ Not well
   - ❒ Not at all
2. In what language do you prefer to read about health information? (RFC 5646)
3. In what language do you prefer to hear about health information? (RFC 5646)

Sex:

The Unknown choice for Sex should be linked to a gender identity question, since it is meant to harmonize as a classification. In addition, the code for Unknown should be UN, not UNK, as it is in the HL7 Version3 Value Set for Administrative Gender codes.

Preliminary Cause of Death and Date of Death: We support the use of these demographics for inpatient settings.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

(6) Vital signs, body mass index, and growth charts.

(i) Vital signs. Enable a user to record, change, and access, at a minimum, a patient's height, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure in accordance with the following (The patient's height/length, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure must be recorded in numerical values only.):

(A) The standard specified in § 170.207(k)(1) and with the associated applicable unit of measure for the vital sign in the standard specified in § 170.207(m)(1);

(B) Metadata. For each vital sign in paragraph (a)(6)(i) of this section, the technology must also record the following:

(1) Date and time of vital sign measurement or end time of vital sign measurement;

(2) The measuring- or authoring-type source of the vital sign measurement; and

(3) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g); and

(C) Metadata for oxygen saturation in arterial blood by pulse oximetry. For the oxygen saturation in arterial blood by pulse oximetry, the technology must enable a user to record, change, and access the patient's inhaled oxygen concentration identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 8478-0.

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

2015 Edition Health IT Certification Criterion, 170.315(a)(6) Vital signs, body mass index, and growth charts, continued

(ii) Optional – Body mass index percentile per age and sex. Enable a user to record, change, and access a patient's body mass index [percentile] per age and sex for patients two to twenty years of age in accordance with the following (The patient's body mass index [percentile] per age and sex must be recorded in numerical values only.):

(A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 59576-9 and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and

(B) Metadata. The technology must also record the following:

(1) Date and time of vital sign measurement or end time of vital sign measurement;

(2) The measuring or authoring-type source of the vital sign measurement;

(3) The patient's date of birth;

(4) The patient's sex in accordance with the standard specified in § 170.207(n)(1); and

(5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

(iii) Optional – Weight for length per age and sex. Enable a user to record, change, and access a patient's weight for length per age and sex for patients less than three years of age in accordance with the following (The patient's weight for length per age and sex must be recorded in numerical values only.):

(A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with the LOINC® code and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and

(B) Metadata. The technology must record the following:

(1) Date and time of vital sign measurement or end time of vital sign measurement;

(2) The measuring- or authoring-type source of the vital sign measurement;

(3) The patient's date of birth;

(4) The patient's sex in accordance with the standard specified in § 170.207(n)(1); and

(5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

(iv) Optional – Head occipital-frontal circumference. Enable a user to record, change, and access a patient's head occipital-frontal circumference for patients less than three years of age in accordance with the following (The patient's head occipital-frontal circumference must be recorded in numerical values only.):

(A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 8287-5 and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and

(B) Metadata. The technology must also record the following:

(1) Date and time of vital sign measurement or end time of vital sign measurement;

(2) The measuring or authoring-type source of the vital sign measurement;

(3) The patient's date of birth;

(4) The patient's age in accordance with the standard specified in § 170.207(n)(1); and

(5) Optional. Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

(v) Optional – Calculate body mass index. Automatically calculate and display body mass index based on a patient's height and weight.

(vi) Optional – Plot and display growth charts. Plot and display, upon request, growth charts for patients.

Preamble FR Citation: 80 FR 16817 **Specific questions in preamble?** *Yes*

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

Public Comment Field:

We support the proposed specifications for Vital Signs, BMI, and growth charts with the exception of Body height. In addition to the use of LOINC standard 8302-2 for height, we would also recommend the use of 8306-3 for Height (Lying) based on the need of the patient. Clinicians do not want to use 8302-2 for a height (length) taken when the patient is lying down. We support this as an 'other' certification criteria option.

§ 170.315(a)(7) Problem list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(7) Problem list. Enable a user to 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)(4); 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)(4).

Preamble FR Citation: 80 FR 16819 **Specific questions in preamble?** *No*

Public Comment Field:

We support the use of September 2014 Release of SNOMED CT as the standard for the problem list, however we would like to have the issue of how to manage versions and allow to expand, to be addressed. While we recognize that the Standards Advisory will be published annually, we strongly recommend that additional fields/columns provide insight into a) an anticipated standard is likely to be sunset, and b) what standards are in the pipeline and will likely be approved (perhaps in the next year). This would improve the value and usefulness of the Advisory to Providers who are making implementation decisions. . We support the use of Problem List in the Base EHR.

§ 170.315(a)(8) Medication list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(8) Medication list. Enable a user to 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: 80 FR 16819 **Specific questions in preamble?** *No*

§ 170.315(a)(8) Medication list

We support the use of this criteria maintaining an active medication list as well as a medication history.

Although this criteria does not reference standards or implementation specifications, we are concerned about those standards. For example, does the term "medications" include OTC and herbal supplement? In addition, the definition needs to consider what the person/consumer considers medication. In Minnesota, medical cannabis will available July 1, 2015. How would this be in the medication list?

Recommendations

1. We recommend defining medications and working with consumer groups to make sure that all medications taken by patients can be included in the medication list.
2. We recommend the quick movement to add medical cannabis as a medication to RxNorm.

§ 170.315(a)(9) Medication allergy list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(9) Medication allergy list. Enable a user to 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: 80 FR 16820 **Specific questions in preamble?** *No*

Public Comment Field:

We are concerned about the lack of standards in coding allergies, and recommend the use of a standard medication allergy list which includes food and environmental allergies. We appreciate the work that is going into encompassing multiple standards for expressing the source of the allergen. We support the use of an active medication allergy list as criteria in the Base EHR.

§ 170.315(a)(10) Clinical decision support

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

§ 170.315(a)(10) Clinical decision support

2015 Edition Health IT Certification Criterion

(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) Technology must be able to identify for a user diagnostic and therapeutic reference information in accordance with the standard and implementation specifications at § 170.204(b)(3) or (4).
- (B) For paragraph (a)(10)(ii)(A) of this section, technology must be able to 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) Technology must enable interventions to be:
  - (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, problems, and laboratory tests and values/results are incorporated from a transition of care/referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.
  - (3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4) of this section.

(iv) CDS intervention interaction. Interventions provided to a user in paragraphs (a)(10)(i) through (iii) of this section must occur when a user is interacting with 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) Intervention response documentation.
- (A) Technology must be able to record at least one action taken and by whom in response to clinical decision support interventions.
- (B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to clinical decision support interventions.

Preamble FR Citation: 80 FR 16820 **Specific questions in preamble?** *Yes*

§ 170.315(a)(10) Clinical decision support
Public Comment Field:
Pharmacists are required under "OBRA 90" at https://www.govtrack.us/congress/bills/101/hr5835/text to perform drug utilization review, including interaction checks, and document the review; we are pleased to see that similar requirements are now being placed upon prescribers and feel that this will enhance the quality of patient care. Documentation of the review/intervention must be created, stored and produced upon request.

§ 170.315(a)(11) Drug-formulary and preferred drug list checks	
Included in 2015 Edition Base EHR Definition?	
No	
Stage 3 MU Objective	
EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).	
2015 Edition Health IT Certification Criterion	
(11) Drug-formulary and preferred drug list checks. Technology must either meet paragraph (a)(11)(i) or (ii) of this section. (i) Drug formulary checks. (A) Automatically check whether a drug formulary exists for a given patient and medication. (B) Indicate for a user the last update of the drug formulary; and (C) Receive and incorporate a formulary and benefit file in accordance with the standard specified in § 170.205(n)(1). (ii) Preferred drug list checks. (A) Automatically check whether a preferred drug list exists for a given patient and medication. (B) Indicate for a user the last update of the preferred drug list.	
Preamble FR Citation: 80 FR 16821	**Specific questions in preamble?** *Yes*

§ 170.315(a)(11) Drug-formulary and preferred drug list checks

Public Comment Field:

We appreciate the clarification between a drug formulary and a preferred drug list, and the recognition of the NCPDP Formulary and Benefit Standard. The Formulary and Benefit Standard includes the following dates: Transmission, Extract, and List Effective. We recommend that the "last update" presented to the user be the Extract Date. As defined in the NCPDP Data Dictionary: "This is the date the file was extracted from the internal source system. " Using this date will indicate to the user when the file was created by the source of the formulary data (usually the payer). The EHR vendor may choose to also present the "List Effective" date, as that indicates when the list (i.e. coverage, copay, alternatives) takes effect.

We also recommend the version number of the standard not be included here, but that the citation of the applicable regulation be included so that there is not a challenge in keeping regulatory documents and version reference information in sync.

The industry should continue to use Formulary and Benefit Standard version 3.0 while NCPDP reviews and approves industry-requested improvements. NCPDP will follow the appropriate regulatory process to request a new version of the Formulary and Benefit Standard be named and suggest the proposed timeline for adoption. Upon approval by the Secretary of Health and Human Services, it would be named under the Medicare Modernization Act and the entire industry will then move to that version. While having a version named under MMA technically only places requirements on providers who are part of Medicare, we have found that the commercial payers tend to follow Medicare when it comes to the use of standards. We do not support having one version named under Meaningful Use and another under MMA.

Pharmacists in Minnesota are involved with NCPDP, and have formed a task group that is analyzing use cases to support a real-time prescription benefit inquiry (RTBI). The task group is completing the business requirements and has begun compiling the necessary data elements to make the transaction successful. The task group anticipates completing the work by November 2015 and will present it to the NCPDP membership for review and direction on additional activity, i.e. creation/modification of new transactions/standards.

§ 170.315(a)(12) Smoking status

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(12) Smoking status. Enable a user to record, change, and access the smoking status of a patient in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

Preamble FR Citation: 80 FR 16822 **Specific questions in preamble?** *No*

§ 170.315(a)(12) Smoking status

Public Comment Field:

We support the use of this criteria in the Base EHR, however we recommend the use of 'Substance Use Status' so the smoking status is expanded to include other substances and routes of administration. "Smoking Status" does not accurately reflect a patient's use of chewing tobacco, or e-cigarettes. NCPDP is also moving towards a new version of the SCRIPT Standard that will support the concept of "Substance Use", which will include the product, route of administration and level of use. This will allow providers to track and share clinically relevant information.

The current use of Smoking Status with 8 SNOMED CT codes is ambiguous and not user friendly. How did the idea of 'at least 100 cigarettes during a lifetime' translate into a smoking status? Or that a 'light smoker' is interpreted to mean less than 10 cigarettes per day? We recommend the use of NCPDP new version for Substance Use for this criteria.

§ 170.315(a)(13) Image results

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(13) Image results. 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: 80 FR 16822 **Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(a)(14) Family health history

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(14) Family health history. Enable a user to record, change, and access a patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(4).

Preamble FR Citation: 80 FR 16822 **Specific questions in preamble?** *No*

§ 170.315(a)(14) Family health history

Public Comment Field:

We suggest ONC and partners work with the research community to get the appropriate feedback as to what family history knowledge leads to improved health outcomes.

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

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition as an alternative to § 170.315(a)(14).

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(15) Family health history – pedigree. Technology must be able to create and incorporate a patient's family health history in accordance with the standard and implementation specification specified in § 170.205(m)(1).

Preamble FR Citation: 80 FR 16822 **Specific questions in preamble?** *No*

Public Comment Field:

We support the availability of the family health history pedigree for certification as needed by specialty providers.

§ 170.315(a)(16) Patient list creation

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

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

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

Preamble FR Citation: 80 FR 16823 **Specific questions in preamble?** *No*

Public Comment Field:

We support the availability of this criteria as an option for provider organizations.

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

Included in 2015 Edition Base EHR Definition?

No

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

Stage 3 MU Objective

The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

2015 Edition Health IT Certification Criterion

(17) Patient-specific education resources. Technology must be able to:

(i) Identify patient-specific education resources based on data included in the patient's problem list and medication list in accordance with the standard (and implementation specifications) specified in § 170.204(b)(3) or (4); and

(ii) Request that patient-specific education resources be identified in accordance with the standard in § 170.207(g)(2).

Preamble FR Citation: 80 FR 16823 **Specific questions in preamble?** *No*

Public Comment Field:

We support the use of patient-specific education resources, however if the EHR has a way to offer this based on the patient specific needs (i.e. as an integrated solution without an 'infobutton'), this should be acceptable.

§ 170.315(a)(18) Electronic medication administration record

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(18) 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 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. 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: 80 FR 16823 **Specific questions in preamble?** *No*

Public Comment Field:

We support the use of this criteria for electronic medication administration record for inpatient settings to promote patient safety.

§ 170.315(a)(19) Patient health information capture
Included in 2015 Edition Base EHR Definition? No, but proposed for the EHR Incentive Programs CEHRT definition
Stage 3 MU Objective Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.
2015 Edition Health IT Certification Criterion (19) Patient health information capture. Technology must be able to enable a user to: (i) Identify, record, and access patient health information documents; (ii) Reference and link to patient health information documents; and (iii) Record and access information directly shared by a patient.
Preamble FR Citation: 80 FR 16823 **Specific questions in preamble?** *No*
Public Comment Field: We support the use of this criteria of Patient Health Information Capture, to be inclusive of Advanced Directives as well as other patient related health forms, however need more definitions and standards. For example standards for naming the documents. The linking feature implies an interactive nature. The patient should not only be able to link to an internet website document, but also download, change and/or delete the document. The system should capture the type of interaction with the patient (logged in user), and the date it was done.

§ 170.315(a)(20) Implantable device list
Included in 2015 Edition Base EHR Definition? Yes
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (20) Implantable device list. (i) Enable a user to record, change, and access, a list of Unique Device Identifiers associated with a patient's Implantable Device(s). (ii) Parse the following data elements from a Unique Device Identifier: (A) Device Identifier; (B) Batch/lot number; (C) Expiration date; (D) Production date; and (E) Serial number. (iii) Retrieve the "Device Description" attribute associated with a Unique Device Identifier in the Global Unique Device Identification Database. (iv) For each Unique Device Identifier in a patient's list of implantable devices, enable a user to access the following: (A) The parsed data elements specified under paragraph (a)(20)(ii) of this section that are associated with the UDI; and (B) The retrieved data element specified under paragraph (a)(20)(iii) of this section.
Preamble FR Citation: 80 FR 16824 **Specific questions in preamble?** *Yes*

§ 170.315(a)(20) Implantable device list

Public Comment Field:

We support the use of this criteria in the Base EHR for patient safety issues, better inventory and improved tracking of UDIs. We agree this should be included in the Common Clinical Data Set, and include the data elements of device identifier, device description, batch/lot#, expiration date, production date, and serial #. The criteria should also include dates the Implantable Device was removed or replaced. We look forward to the Global UDI Database (GUIDID) being available in September 2015. We also encourage that this list include all items not included in medication lists, for example Birth Control IUDs and other bio-similar meds.

§ 170.315(a)(21) Social, psychological, and behavioral data

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(21) Social, psychological, and behavioral data. Enable a user to record, change, and access, at a minimum, one of the following patient social, psychological, and behavioral data.

- (i) Sexual orientation. Enable sexual orientation to be recorded in accordance with the standard specified in § 170.207(o)(1) and whether a patient declines to specify sexual orientation.
- (ii) Gender identity. Enable gender identity to be recorded in accordance with the standard specified in § 170.207(o)(2) and whether a patient declines to specify gender identity.
- (iii) Financial resource strain. Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(o)(3) and whether a patient declines to specify financial resource strain.
- (iv) Education. Enable education to be recorded in accordance with the standard specified in § 170.207(o)(4) and whether a patient declines to specify education.
- (v) Stress. Enable stress to be recorded in accordance with the standard specified in § 170.207(o)(5) and whether a patient declines to specify stress.
- (vi) Depression. Enable depression to be recorded in accordance with the standard specified in § 170.207(o)(6) and whether a patient declines to specify stress.
- (vii) Physical activity. Enable physical activity to be recorded in accordance with the standard specified in § 170.207(o)(7) and whether a patient declines to specify physical activity.
- (viii) Alcohol use. Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(o)(8) and whether a patient declines to specify alcohol use.
- (ix) Social connection and isolation. Enable social connection and isolation to be recorded in accordance the standard specified in § 170.207(o)(9) and whether a patient declines to specify social connection and isolation.
- (x) Exposure to violence (intimate partner violence). Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in § 170.207(o)(10) and whether a patient declines to specify exposure to violence (intimate partner violence).

Preamble FR Citation: 80 FR 16826
Specific questions in preamble? *Yes, and also see requests for comment on work information (industry/occupation) data and U.S.uniformed/military service data*

Public Comment Field:

We support the use of Social Determinants of Health data as social, psychological, and behavioral certification criteria. It would be important to ask the questions the same way for consistency in responses.

Our preferred (updated) question for Sexual Orientation is:

Do you consider yourself to be:

- Lesbian, gay or homosexual
- Straight or heterosexual
- Bisexual
- Queer
- Decline to answer

The Minnesota Department of Health recommends collecting gender identity using:

What is your current gender identity?

- ❒ Male
- ❒ Female
- ❒ Transgender Man/Transgender Male/Female-to-Male (FTM)
- ❒ Transgender Woman/Transgender Female/Male-to-Female (MTF)
- ❒ Gender queer/Gender non-conforming
- ❒ Different identity, please specify
- ❒ Decline to answer

A SNOMED CT code for 'Decline to answer' is needed for these responses.

We support the use of all 10 data element standards and questions in this certification criteria, with the exception of:

- The Alcohol Use questions (AUDIT-C) needs the scoring listed.
- For consistency, a referral level suggestion or ranking should be given on many data elements – i.e. physical activity, alcohol use, and depression.
- HARK 4Q for Exposure to Violence: Intimate Partner Violence – consider a fifth question, or HARK-C about whether the children have seen any parent or adult violence. Some Local Public Health agencies noted this question will often get a parent to open up about partner violence. Because of different culture perspectives on this topic, they also recommend starting the questions with something like: "One in three women in the world are hurt in some way by someone. This is true all over the world, in all cultures, regardless of skin color or whether rich or poor." There needs to be a sensitivity around how the questions are asked for consistency in responses.

In addition, we agree the Industry/Occupation Data (I/O) should also be listed here under Social, psychological and Behavioral Data, and we would support the use of this criteria as optional and very helpful, but need to distinguish between current work, occupational history, and risk from length of

§ 170.315(a)(21) Social, psychological, and behavioral data
exposure. For example history and length of time of working in mine. Would there be specific occupations that could be listed as the risks to identify rather than listing all occupations regardless of risk?

§ 170.315(a)(22) Decision support – knowledge artifact	
Included in 2015 Edition Base EHR Definition?	
No	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(22) Decision support – knowledge artifact. Enable a user to send and receive clinical decision support knowledge artifacts in accordance with the standard specified in § 170.204(d)(1).	
Preamble FR Citation: 80 FR 16830	**Specific questions in preamble?** *Yes*
Public Comment Field:	
We support use of this criteria toward the use of forecasting, however the document is unclear as to how it will work. There is concern about alert overload and fatigue with this tool. We would support that all EMR users have the capability to set up preferences, and then only track those preferences which would be alerting.	

§ 170.315(a)(23) Decision support – service	
Included in 2015 Edition Base EHR Definition?	
No	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(23) Decision support – service. Enable a user to send and receive electronic clinical guidance in accordance with the standard specified in § 170.204(e)(1).	
Preamble FR Citation: 80 FR 16831	**Specific questions in preamble?** *Yes*
Public Comment Field:	
We support including this as an optional criteria, and could see an application in Immunization Forecasting, for example. By providing the immunization history and knowledge artifacts, a forecast would be returned. Need specific use cases and a way to standardize how this is done to be able to provide more feedback.	

§ 170.315(b)(1) Transitions of care
Included in 2015 Edition Base EHR Definition?
Yes

§ 170.315(b)(1) Transitions of care

Stage 3 MU Objective

The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.

2015 Edition Health IT Certification Criterion

(1) Transitions of care.

(i) Send and receive via edge protocol. Technology must be able to:

(A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d); and

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

(C) XDM processing. Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) if the technology is also being certified using an SMTP-based edge protocol.

(ii) Validate and display.

(A) Validate C-CDA conformance – system performance. Technology must demonstrate its ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with both of the standards specified in § 170.205(a)(3) and (4) This includes the ability to:

(1) Parse each of the document types formatted according to the following document templates: CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; Referral Note, and Discharge Summary.

(2) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified in either of the standards adopted in § 170.205(a)(3) and (4);

(3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from either of the standards adopted in § 170.205(a)(3) and (4);

(4) Correctly interpret empty sections and null combinations; and

(5) Record errors encountered and allow for a user to be notified of or review the errors produced.

(B) Technology must be able to display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(3) and (4).

(C) Section views. 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 either of the standards adopted in § 170.205(a)(3) and (4).

§ 170.315(b)(1) Transitions of care

2015 Edition Health IT Certification Criterion (b)(1) Transitions of care, continued

(iii) Create.

(A) Enable a user to create a transition of care/referral summary:

(1) Formatted according to the standards adopted in § 170.205(a)(3);

(2) Formatted according to the standards adopted in § 170.205(a)(4); and

(3) Includes, at a minimum, the Common Clinical 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 specified §170.207(a)(4);

(ii) Cognitive status;

(iii) Functional status;

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

(v) Inpatient setting only. Discharge instructions.

(B) Patient matching data quality. 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, maiden name, middle name (including middle initial), suffix, date of birth, place of birth, 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 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.

(6) Constraint. Represent sex in accordance with the standard adopted at § 170.207(n)(1).

Preamble FR Citation: 80 FR 16831 **Specific questions in preamble?** *Yes*

§ 170.315(b)(1) Transitions of care

Public Comment Field:

We support the Transition of Care criteria as part of the Base EHR.

We also promote the use of dual compliance when there are two HL7 releases available. One message should be able to meet both requirements.

We support the new structural elements, and recommend adding Social Determinants of Health for safety reasons. One safety issue for health care workers visiting a client in the home is if there are known violence issues. We recommend identifying how to capture and share safety issues on transitions of care.

We agree the creation of a transition of care/referral summary should be limited to C-CDA. At a minimum, the implementation and certification include the following optional C-CDA sections:

Family History Section
Encounters Section
Functional Status Section
Immunizations Section (entries required)
Medical Equipment Section
Mental Status Section
Nutrition Section
Plan of Treatment Section
Procedures Section

Without these sections, many sectors of healthcare would be unable to document or share their clinical information and patient focused robust longitudinal care plans across all applicable settings would not be possible.

We support the use of valid/invalid C-CDA testing for system performance.

The Patient Matching Data Quality element of the Transition of Care document is a worthy concept. We need standards on how this metadata is presented in HTML format, and how we manage change between the data. Given standards for each data field, provider organizations should be allowed to send the data that is easiest for them to collect. The testing of this criteria also needs to show a confidence level back for the percent matching (e.g. 90+ %).

We support the use of Data Provenance in this criteria as a standard for harmonizing with other criteria to show what data came from where as it is integrated into an EHR. We encourage the use of vendor input on how to implement data provenance.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.

2015 Edition Health IT Certification Criterion

(2) Clinical information reconciliation and incorporation.

(i) General requirements. Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standard adopted in § 170.205(a)(3) as well as separately to the standard adopted in § 170.205(a)(4) using the Continuity of Care Document, Discharge Summary Document and Referral Summary document templates.

(ii) Correct patient. Upon receipt of a transition of care/referral summary formatted according to either of the standards adopted at § 170.205(a)(3) or (4), technology must be able to demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

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

(A) Simultaneously display (i.e., in a single view) the data from at least two 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 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)(3);

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

(3) Problems. At a minimum, the version of the standard specified in § 170.207(a)(4).

(iv) System verification. Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard adopted at § 170.205(a)(4) using the Continuity of Care Document document template.

Preamble FR Citation: 80 FR 16835 **Specific questions in preamble?** *No*

Public Comment Field:

We support the use of this criteria to encourage incorporating and updating C-CDA data elements into EHRs, and recommend obtaining feedback from vendors as to how this certification criteria could work with minimal workflow changes (or more streamlined workflow) for providers using the system.

§ 170.315(b)(3) Electronic prescribing

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

§ 170.315(b)(3) Electronic prescribing

2015 Edition Health IT Certification Criterion

(3) Electronic prescribing.

(i) Enable a user to prescribe, send, and respond to prescription-related transactions for electronic transmission in accordance with the standard specified at § 170.205(b)(2), and, at a minimum, the version of the standard specified in § 170.207(d)(3), as follows:
- (A) Create new prescriptions (NEWRX);
- (B) Change prescriptions (RXCHG, CHGRES);
- (C) Cancel prescriptions (CANRX, CANRES);
- (D) Refill prescriptions (REFREQ, REFRES);
- (E) Receive fill status notifications (RXFILL); and
- (F) Request and receive medication history information (RXHREQ, RXHRES).

(ii) Enable a user to enter, receive, and transmit structured and codified prescribing instructions for the transactions listed in paragraph (b)(3)(i) of this section for electronic transmission in accordance with the standard specified at § 170.205(b)(2) and, at a minimum, for at least the following component composites:
- (A) Repeating Sig;
- (B) Code System;
- (C) Sig Free Text String;
- (D) Dose;
- (E) Dose Calculation;
- (F) Vehicle;
- (G) Route of Administration;
- (H) Site of Administration;
- (I) Sig Timing;
- (J) Duration;
- (K) Maximum Dose Restriction;
- (L) Indication; and
- (M) Stop.

(iii) Technology must limit a user's ability to prescribe all medications in only the metric standard.

(iv) Technology must always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

Preamble FR Citation: 80 FR 16835 **Specific questions in preamble?** *Yes*

Public Comment Field:

Much of this criteria is currently required in Minnesota Statute §62J.497 ELECTRONIC PRESCRIPTION DRUG PROGRAM. Of the messages exchanged, the use of CHANGE and CANCEL prescription transactions are the most important in relationship to patient safety. The long term care industry uses the RxFill transaction today to notify a facility of a dispensing. A future version of the SCRIPT Standard contains enhancements to the RxFill transaction which will allow the prescriber to select to receive the transaction for a specific patient and medication. It is believed these enhancements will create better adoption of the RxFill transaction in other care settings. The pharmacy industry has adopted the Refill Request and Medication History transactions. In addition, Medication History is one of three transactions is being used in pilots under the S&I Framework PDMP initiative for the exchange of controlled substance prescription information from a State PDMP to a prescriber.

A factor that should be considered for end-to-end prescriber-to-receiver testing (and production) is if the pharmacy does not support a transaction, in most cases, the switch/intermediary will create a fail-over fax allowing the pharmacy to receive the information.

We support the baseline version of RxNorm, but since it is an ever changing code list, entities should support the most current version even if through trading partner agreements.

In Minnesota, we encourage standards and process to be developed to connect e-Prescribing with controlled substances, and recommend certification criteria to connect to controlled substance registries.

We also support the use of metrics whenever possible.

In addition, Minnesota Pharmacists support the following: We believe that additional guidance to the industry may be needed to further clarify requirements. Within the NCPDP SCRIPT Standard, use of the Structured and Codified Sig Segment is not required. When users choose to implement Structured and Codified Sig, there remains a fair amount of optionality. This was an intentional design decision, made before the CEHRT and MU programs existed, to encourage implementation. For example, in SCRIPT 10.6, Route of Administration is not required when the Structured and Codified Sig is used although it is required in future versions. Other fields are considered conditional and often are to be populated “when the prescriber specifies”. We recommend that CEHRT support the presentation of the structured fields so that prescribers can become accustomed to populating this data as part of the prescription creation and review process. NCPDP will provide additional comments specific to testing (via the request for comments on the test procedures), and suggest that it is appropriate to state that the CEHRT should be able to capture and send the information if it is available within the system, regardless of the optionality of the element.

The Structured and Codified Sig Format was designed to be comprehensive and applicable across a variety of care settings. It is clear to the NCPDP members engaged in the work related to Sig that implementation will be most successful if it is constrained initially. Therefore, NCPDP recommends that testing and certification should be limited to a subset of the Structured and Codified Sig format component composites as outlined in the NCPDP SCRIPT Implementation Recommendations Version 1.31. The subset supports very common ambulatory prescription instructions and includes the following segments: Dose, Sig Timing, Route of Administration, Indication, Code System, Sig Free Text

§ 170.315(b)(3) Electronic prescribing
String, Duration and Repeating. We further recommend that testing and certification of the Repeating Sig Segment be limited to what is presented in the Recommendations Document. Due to the constraints of the text field, more than two loops are likely to exceed the text field limitation. At this time, testing and certification for the Dose Calculation, Vehicle, Site of Administration, Maximum Dose Restriction and Stop are not recommended. We do note that as the NCPDP Sig Implementation Task Group continues to develop guidance, Site of Administration is included among the next set of common ambulatory prescription instructions and vendors may choose to include Site of Administration as part of their certification application process. We encourage the testing labs to develop test procedures that allow for vendors to test all of the segments of Sig, reiterating that only those that are represented in the Recommendations Document be required. Since the Recommendations Document is updated on a regular basis, we encourage ONC to specify the exact version implementers should reference, or include the subset in the final rule. We also encourage the testing labs to use the subset as a basis for creating their test procedures/scripts. As noted in our prior comment, NCPDP recommends only the following composites be required for certification: (A) Repeating Sig; (B) Code System; (C) Sig Free Text String; (D) Dose; (G) Route of Administration; (I) Sig Timing; (J) Duration; (L) Indication;

§ 170.315(b)(4) Incorporate laboratory tests and values/results
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objective N/A

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

2015 Edition Health IT Certification Criterion

(4) Incorporate laboratory tests and values/results.
(i) Receive results.
(A) Ambulatory setting only.
(1) 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)(3).
(2) Display the tests and values/results received in human readable format.
(B) Inpatient setting only. Receive clinical laboratory tests and values/results in a structured format and display such tests and values/results in human readable format.
(ii) Display the test report information:
(A) Specified in 42 CFR 493.1291(a)(1) through (3) and (c)(1) through (7);
(B) Related to reference intervals or normal 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) Attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

Preamble FR Citation: 80 FR 16837 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support the use of this criteria for lab tests and values – none of which are surprises to the Laboratory Industry.

Also noted is the Observation element in the NCPDP SCRIPT Standard v10.6, which may be used to communicate lab results to pharmacies.

§ 170.315(b)(5) Transmission of laboratory test reports

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(5) Transmission of laboratory test reports. Technology must be able to electronically create laboratory test reports for electronic transmission in accordance with the standard specified in in § 170.205(j)(2) and, at a minimum, the version of the standard specified in § 170.207(c)(3).

Preamble FR Citation: 80 FR 16838 **Specific questions in preamble?** *No*

Public Comment Field:

We support the use of this criteria for lab reports – none of which are surprises to the Laboratory Industry.

§ 170.315(b)(6) Data portability

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(6) Data portability.

(i) General requirements for export summary configuration. A user must be able to set the following configuration options when using technology to create an export summary or set of export summaries for patients whose information is stored in the technology. A user must be able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate.

(ii) Document creation configuration.

(A) Document-template types. A user must be able to configure the technology to create an export summary or export summaries formatted according to the standard adopted at § 170.205(a)(4) for any of the following document-template types.

(1) Generally applicable. CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.

(2) Inpatient setting only. Discharge Summary.

(B) For any document-template selected the technology must be able to include, at a minimum, the Common Clinical 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 at § 170.207(a)(4);

(2) Cognitive status;

(3) Functional status;

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

(5) Inpatient setting only. Discharge instructions.

(C) Use of the "unstructured document" document-level template is prohibited for compliance with the standard adopted at § 170.205(a)(4).

(iii) Timeframe configuration. A user must be able to configure the technology to set the time period within which data would be used to create the export summary or summaries. This must include the ability to enter in a start and end date range as well as the ability to set a date at least three years into the past from the current date.

(iv) Event configuration. A user must be able to configure the technology to create an export summary or summaries based on the following user selected events:

(A) A relative date or time (e.g., the first of every month);

(B) A specific date or time (e.g., on 10/24/2015); and

(C) When a user signs a note or an order.

(v) Location configuration. A user must be able to configure and set the storage location to which the export summary or export summaries are intended to be saved.

Preamble FR Citation: 80 FR 16839 **Specific questions in preamble?** *No*

Public Comment Field:

We support the use of this data portability criteria for Base EHRs and acknowledge the harmonization with other Transition of Care and Common Clinical Data Set criteria. We encourage the collaboration of vendors and provider organizations to implement this criteria with minimal (or reduced) workflow changes for clinicians.

§ 170.315(b)(7) Data segmentation for privacy – send	
Included in 2015 Edition Base EHR Definition?	
No	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(7) Data segmentation for privacy – send. Technology must enable a user to create a summary record formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).	
Preamble FR Citation: 80 FR 16841 (also see 80 FR 16840)	**Specific questions in preamble?** *No*
Public Comment Field:	
We support the availability of this criteria as added security and limiting access to sensitive client information, but with a need to share it for improved health care outcomes. We agree that the 'The sending system must: 1. Identify information that requires enhanced protection or is subject to further restrictions; 2. Verify that the patient's privacy consent decision allows for the disclosure of health information; and 3. Add privacy metadata to the health information being disclosed. In turn, the receiving system must: 1. Be able to process the privacy metadata associated with the received health information; and 2. Verify the patient's consent before re-disclosure, if the receiving system has a need to re-disclose the information.'	

§ 170.315(b)(8) Data segmentation for privacy – receive	
Included in 2015 Edition Base EHR Definition?	
No	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(8) Data segmentation for privacy – receive. Technology must enable a user to: (i) Receive a summary record that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1); (ii) Apply document-level tagging and sequester the document from other documents received; and (iii) View the restricted document (or data), without incorporating the document (or data).	
Preamble FR Citation: 80 FR 16842 (also see 80 FR 16840)	**Specific questions in preamble?** *No*

§ 170.315(b)(8) Data segmentation for privacy – receive

Public Comment Field:

Again, we agree with the use of this criteria, and would encourage the combination of the send and receive criteria into one certification requirement. Both need to be required of a vendor system to work correctly.

§ 170.315(b)(9) Care plan

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(9) Care plan. Technology must enable a user to record, change, access, create, and receive care plan information in accordance with the Care Plan document template in the standard adopted in § 170.205(a)(4).

Preamble FR Citation: 80 FR 16842 **Specific questions in preamble?** *Yes*

Public Comment Field:

We are surprised this criteria is not part of the Base EHR, or included in the Transition of Care criteria as we expect to share data elements that are outcome based. The care plan has outcome based assessment fields and should include the action plan (also called Plan of Treatment for some providers). The Minnesota Beacon Asthma Care Plan is one example of a use case with an action plan that is shared for improved outcomes. It would be helpful to utilize the C-CDA standards and incorporate different clinical care plans in this format. The patient matching data quality and data provenance are also important issues for this criteria element, and are already included in the Transition of Care criteria.

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

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

(1) Clinical quality measures – record and export.

(i) Record. For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data 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. A user must be able to export a data file formatted in accordance with the standard specified at § 170.205(h) for one or multiple patients that includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

Preamble FR Citation: 80 FR 16842 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support the use of this criteria in the Base EHR, and encourage vendor input as to how this could be incorporated and utilized for providers who do not currently have meaningful use components in their EHRs (e.g. local public health departments have not been collecting meaningful use items, but recognize the benefit of record and export functions).

Additionally, providers have noted that current HL7 versions have not met the chart extractions needed for this criteria, so need to harmonize the versions with these criteria. We recommend for 2015 to use the most recent HL7 standard with September update, with an ONC annual Standard Advisory update – to keep stakeholders on the latest version. We also recommend vendors move forward toward the use of FHIR with direction by the ONC.

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

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(2) Clinical quality measures – import and calculate.

(i) Import. Enable a user to import a data file in accordance with the standard specified at § 170.205(h) for one or multiple patients and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

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

Preamble FR Citation: 80 FR 16843 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support the concept of import and calculate, but question to what extent the calculations are wanted. With Clinical Quality Measurement, the challenge has been in the denominator. These characteristics need to be defined, and the systems needs to allow for flexibility in how the user wants to calculate, or vary, the measurements for comparison purposes.

Reserved for § 170.315(c)(3) Clinical quality measures – report	
Included in 2015 Edition Base EHR Definition? No, but proposed for the EHR Incentive Programs CEHRT definition	
Stage 3 MU Objective N/A	
2015 Edition Health IT Certification Criterion (3) [Reserved]	
Preamble FR Citation: 80 FR 16844	**Specific questions in preamble?** *No*
Public Comment Field: No additional comments	

§ 170.315(c)(4) Clinical quality measures – filter	
Included in 2015 Edition Base EHR Definition? No	
Stage 3 MU Objective N/A	
2015 Edition Health IT Certification Criterion (4) Clinical quality measures – filter. (i) Technology must be able to record the data listed in paragraph (c)(4)(iii) of this section in accordance with the identified standards, where specified. (ii) Technology must be able to filter CQM results at the patient and aggregate levels by each one and any combination of the data listed in paragraph (c)(4)(iii) of this section. (iii) Data. (A) TIN; (B) NPI; (C) Provider type; (D) Patient insurance; (E) Patient age; (F) Patient sex in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(1); (G) Patient race and ethnicity in accordance with, at a minimum, the version of the standard specified in § 170.207(f)(2); (H) Patient problem list data in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4); and (I) Practice site address.	
Preamble FR Citation: 80 FR 16844	**Specific questions in preamble?** *Yes*

§ 170.315(c)(4) Clinical quality measures – filter

Public Comment Field:

We support the use of this criteria as an additional option for vendors and organizations to compare individual and aggregate data. Those organizations who are engaged in monitoring cohorts of attributed populations or managing population health, in particular, will need this capability. We consider the data element list to be standard, and are concerned that the definitions are adequate enough to understand how the value is represented and used. In particular, the Patient Insurance data element requires further defining for harmonizing between systems, and may require multiple fields of data to have the granularity needed for comparisons. These defining values need to be part of the standards advisory.

We further recommend that systems be flexible enough for the user to select any of these data elements, singly or in combination, with up to an additional 5 selected data elements for comparison.

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

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(1) Authentication, access control, and authorization.

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

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

Preamble FR Citation: 80 FR 16846 **Specific questions in preamble?** *No*

Public Comment Field:

We acknowledge that the vendors recognize this need and have developed systems to meet the need for authentication, access control and authorization. The question remains 'whose responsibility is it – the provider or the vendor?'

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

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

(2) Auditable events and tamper-resistance.

(i) Record actions. Technology must be able to:

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

(B) Record the audit log status (enabled or disabled) in accordance with the standard specified in § 170.210(e)(2) unless it cannot be disabled by any user; and

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

(ii) Default setting. 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) or (C) of this section, or both paragraphs (d)(2)(i)(B) and (C).

(iii) When disabling the audit log is permitted. For each capability specified in paragraphs (d)(2)(i)(A) through (C) of this section that technology permits to be disabled, the ability to do so must be restricted to a limited set of users.

(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 technology.

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

Preamble FR Citation: 80 FR 16846 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support the use of auditing and logging criteria, however need further definition on the retention of this data. In many systems, the user has the ability to control the logging and auditing function. Other systems have chosen to only turn this functionality on when needed, so data is not captured proactively. There are many interpretations of the HIPAA rules and how to implement them. With the use of technology for health information exchange, these HIPAA rules need further clarity to harmonize the implementation of this conditional criteria.

§ 170.315(d)(3) Audit report(s)

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT 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: 80 FR 16847 **Specific questions in preamble?** *No*

Public Comment Field:

No additional comments

§ 170.315(d)(4) Amendments	
Included in 2015 Edition Base EHR Definition?	
No, but a conditional certification requirement	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(4) Amendments. Enable a user to select the record affected by a patient's request for amendment and perform the capabilities specified in paragraph (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: 80 FR 16847	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment.	

§ 170.315(d)(5) Automatic access time-out	
Included in 2015 Edition Base EHR Definition?	
No, but a conditional certification requirement	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(5) Automatic access time-out. (i) Automatically stop user access to health information after a predetermined period of inactivity. (ii) Require user authentication in order to resume or regain the access that was stopped.	
Preamble FR Citation: 80 FR 16847	**Specific questions in preamble?** *Yes*
Public Comment Field:	
We support the use of the term Automatic access time-out, and the eligibility as a gap certification.	

§ 170.315(d)(6) Emergency access	
Included in 2015 Edition Base EHR Definition?	
No, but a conditional certification requirement	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(6) Emergency Access. Permit an identified set of users to access electronic health information during an emergency.	
Preamble FR Citation: 80 FR 16847	**Specific questions in preamble?** *No*

§ 170.315(d)(6) Emergency access

Public Comment Field:

We support the use of this 'break the glass' type of capability, but need more explanation as to why it would be a separate certification criteria.

§ 170.315(d)(7) End-user device encryption

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT 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) 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 the 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)(3);

(B) Default setting. 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) Technology is designed to prevent electronic health information from being locally stored on end-user devices after use of the technology on those devices stops.

Preamble FR Citation: 80 FR 16847 **Specific questions in preamble?** *Yes*

Public Comment Field:

This certification criteria needs further explanation – is it referring to Patient Health Information (PHI) in transit or at rest?

If the intent of this criteria is to protect PHI on a mobile device, please explain the intent in the criteria. This criteria is justified if a vendor provides not only the software solution, but also the devices for the software to run on. Typically, the vendor is only supplying the software, and in which case the organization would need to prove that the device is working in concert with the EHR. This requirement could be met through a security risk assessment rather than certification.

If the intent is to protect PHI in a cloud-based system, then need to explain the requirements of the vendor (EHR) in tracking this encryption.

§ 170.315(d)(8) Integrity

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

§ 170.315(d)(8) Integrity	
2015 Edition Health IT 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: 80 FR 16847	**Specific questions in preamble?** *Yes*
Public Comment Field: We support this as an underlying expectation and part of testing for every other certification. Therefore, we question why this is a separate criteria for certification.	

§ 170.315(d)(9) Accounting of disclosures	
Included in 2015 Edition Base EHR Definition? No	
Stage 3 MU Objective N/A	
2015 Edition Health IT 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: 80 FR 16848	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

§ 170.315(e)(1) View, download, and transmit to a third party
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objectives The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability. Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

2015 Edition Health IT Certification Criterion

(1) View, download, and transmit to 3rd party.

(i) Patients (and their authorized representatives) must be able to use 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 health IT to view in accordance with the standard adopted at § 170.204(a)(1), at a minimum, the following data:

(1) The Common Clinical 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.

(4) Laboratory test report(s). Laboratory test report(s), including:

(i) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(i) through (7);

(ii) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and

(iii) The information for corrected reports as specified in 42 CFR 493.1291(k)(2)

(5) Diagnostic image report(s).

(B) Download.

(1) Patients (and their authorized representatives) must be able to use EHR technology to download an ambulatory summary or inpatient summary (as applicable to the health IT 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. The use of the "unstructured document" document-level template is prohibited for compliance with the standard adopted at § 170.205(a)(4).

(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), (2), (4), and (5) of this section.

(ii) Inpatient setting only. All of the data specified in paragraphs (e)(1)(i)(A)(1), and (3) through (5) of this section.

(3) Inpatient setting only. Patients (and their authorized representatives) must be able to 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) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(2) of this section in accordance with at least one of the following.

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

(ii) Through a method that conforms to the standard specified at § 170.202(d) and leads to such summary being processed by a service that has implemented the standard specified in § 170.202(a).

(2) Inpatient setting only. 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 at least one of the following:

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

(i) The standard specified in § 170.202(a).
(ii) Through a method that conforms to the standard specified at § 170.202(d) and 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 or when an application requests electronic health information using the capability specified at paragraph (e)(1)(iii) of this section, the following information must be recorded and made accessible to the patient:
(1) The action(s) (i.e., view, download, transmission, API response) 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) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

(B) 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.

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

2015 Edition Health IT Certification Criterion, §170.315(e)(1) View, download, and transmit to 3rd party, continued

(i) Application access. Patients (and their authorized representatives) must be able to use an application that can interact with the following capabilities. Additionally, the following technical outcomes and conditions must be met through the demonstration of an application programming interface (API) that can respond to requests from other applications for data specified within the Common Clinical Data Set.

(A) Security. The API must include a means to establish a trusted connection with the application requesting patient data, including a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.

(B) Patient selection. The API must include a means for the application to query for an ID or other token of a patient's record in order to subsequently execute data requests for that record in accordance with (e)(1)(iii)(C) of this section.

(C) Data requests, response scope, and return format. The API must enable and support both of the following data request interactions:

(1) Data-category request. The API must support syntax that allows it to respond to requests for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in either XML or JSON.

(2) All-request. The API must support syntax that allows it to respond to a request for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted at § 170.205(a)(4).

(D) Documentation. The API must include accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(E) Terms of use. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

Preamble FR Citation: 80 FR 16848 **Specific questions in preamble?** *Yes*

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

Public Comment Field:

Vendors who have been supporting meaningful use have been working the VDT process for some time. This criteria seems to only address structured data elements, however subscribers want the unstructured data as well. The standard for this criteria needs to address how unstructured content is formatted in a structured way. An example of unstructured content would be the provider notes in an EHR – should the provider want to include his/her Notes, there should be a structured way to include unstructured notes.

There is also a question as to whether this criteria regulates the output data types. We recommend that the system have the capability of specifying which data types are output depending on which provider type is seen by the consumer.

In a patient-centered, consumer-engaged health care environment, we acknowledge the VDT criteria as the first steps toward an interactive portal for individuals to record, change and update their personal health data. This would also be a repository for receiving data from person health tools such as Fit Bits or home glucose monitoring. As with all other shared clinical data, data provenance would need to be included in the use. We recommend the ONC to encourage the next steps of this certification toward the infrastructure capacity for interactive consumer engagement of personal health data.

§ 170.315(e)(2) Secure messaging

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

2015 Edition Health IT Certification Criterion

(2) Secure messaging. Enable a user to send messages to, and receive messages from, a patient in a manner that ensures:

(i) Both the patient (or authorized representative) and 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: 80 FR 16850 **Specific questions in preamble?** *No*

Public Comment Field:

No comment.

§ 170.315(f)(1) Transmission to immunization registries

Included in 2015 Edition Base EHR Definition?

No

§ 170.315(f)(1) Transmission to immunization registries

Stage 3 MU Objective

The EP, eligible hospital, or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

2015 Edition Health IT Certification Criterion

(1) Transmission to immunization registries.

(i) Technology must be able to create immunization information for electronic transmission in accordance with:

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

(B) At a minimum, the version of the standard specified in § 170.207(e)(3) for historical vaccines; and

(C) At a minimum, the version of the standard specified in § 170.207(e)(4) for administered vaccines.

(ii) Technology must enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4).

Preamble FR Citation: 80 FR 16850 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support the use of this criteria, but we currently are challenged by which code set to use. Historically, CVX has been used, and moving toward NDC provides better tracking of antigens, is more complex, and yet adds granularity and better standards. However, the mapping of the current data is restricted. While we agree that NDC codes could add value to the interfaces we are dealing with, we are concerned about the amount of maintenance that will need to be done to keep that code set up to date. We would like for CVX/MVX to still be allowable for administered vaccinations and that CVX/MVX(where available) remain the code set for historical immunizations.

We believe mapping NDC to CVX may, in fact, be a more challenging effort in a dynamic environment. Given that new NDCs can be created at the discretion of vaccine manufacturers, it may be more challenging to be timely in maintaining a complex mapping table that can then be leveraged by all EHRs (and their providers) as well as IIS. New NDCs (and their associated mapping) would need to be recognized and added to all systems prior to a vaccine becoming available and needing to be messaged to ensure uninterrupted data exchange. Similarly, maintenance would also be required to retire frequently changing NDC codes as well.

In addition, we strongly support the inclusion of bi-directional exchange as part of this certification, and this data should be available for local public health and other health care providers for individual and aggregate forecasting of immunization needs.

We support the proposal to adopt the latest IG for immunizations (HL7 2.5.1 r1.5).

§ 170.315(f)(2) Transmission to public health agencies – syndromic surveillance

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

2015 Edition Health IT Certification Criterion

(2) Transmission to public health agencies—syndromic surveillance.
- (i) Ambulatory setting only.
  - (A) Technology must be able to create syndrome-based public health surveillance information for electronic transmission.
  - (B) Optional. Technology must be able to create syndrome-based public health surveillance information for electronic transmission that contains the following data:
    - (1) Patient demographics;
    - (2) Provider specialty;
    - (3) Provider address;
    - (4) Problem list;
    - (5) Vital signs;
    - (6) Laboratory test values/results;
    - (7) Procedures;
    - (8) Medication list; and
    - (9) Insurance.
- (ii) Inpatient setting only. Technology must be able to create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(4).

Preamble FR Citation: 80 FR 16853 **Specific questions in preamble?** *No*

Public Comment Field:

We acknowledge the need and use for this certification criteria in population health management, however Minnesota does not support syndromic surveillance.

§ 170.314(f)(3) Transmission to public health agencies – reportable laboratory tests and values/results

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

2015 Edition Health IT Certification Criterion

(3) Transmission to public health agencies – reportable laboratory tests and values/results. Technology must be able to 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)(4) and (c)(3).

§ 170.314(f)(3) Transmission to public health agencies – reportable laboratory tests and values/results	
Preamble FR Citation: 80 FR 16853	**Specific questions in preamble?** *No*
Public Comment Field: We support the use of the latest release of SNOMED CT and LOINC for this criteria, and are in the planning process for beginning this transaction within Minnesota. Although vendors have had the capability to transmit laboratory tests and values, state agencies have not had the capacity to receive and use them electronically. We look for improved standards and guidelines as more state agencies are engaged in using these transactions for population health management.	

§ 170.315(f)(4) Transmission to cancer registries	
Included in 2015 Edition Base EHR Definition? No	
Stage 3 MU Objective The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.	
2015 Edition Health IT Certification Criterion (4) Transmission to cancer registries. Technology must be able to 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)(4) and (c)(3).	
Preamble FR Citation: 80 FR 16854	**Specific questions in preamble?** *Yes*
Public Comment Field: We support the use of this criteria to set up standards for the reporting of cancer cases and transmission to cancer registries, and are interested in the use of ICD-10 mentioned in the transmission guidelines for this criteria. Is there potential for improved risk stratification if ICD-10 data is included for other populations?	

§ 170.315(f)(5) Transmission to public health agencies – case reporting	
Included in 2015 Edition Base EHR Definition? No	
Stage 3 MU Objective The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.	
2015 Edition Health IT Certification Criterion (5) Transmission to public health agencies – case reporting. Technology must be able to create case reporting information for electronic transmission in accordance with the standard specified in § 170.205(q)(1).	
Preamble FR Citation: 80 FR 16855	**Specific questions in preamble?** *Yes*

§ 170.315(f)(5) Transmission to public health agencies – case reporting
Public Comment Field:
Minnesota is currently not transmitting case reports electronically. We recommend more resources and support for public health agencies to implement and use the standards and implementation specifications.

§ 170.315(f)(6) Transmission to public health agencies – antimicrobial use and resistance reporting	
Included in 2015 Edition Base EHR Definition?	
No	
Stage 3 MU Objective	
The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.	
2015 Edition Health IT Certification Criterion	
(6) Transmission to public health agencies – antimicrobial use and resistance reporting. Technology must be able to create antimicrobial use and resistance reporting information for electronic transmission in accordance with the standard specified in § 170.205(r)(1).	
Preamble FR Citation: 80 FR 16855	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment	

§ 170.315(f)(7) Transmission to public health agencies – health care surveys	
Included in 2015 Edition Base EHR Definition?	
No	
Stage 3 MU Objective	
The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.	
2015 Edition Health IT Certification Criterion	
(7) Transmission to public health agencies – health care surveys. Technology must be able to create health care survey information for electronic transmission in accordance with the standard specified in § 170.205(s)(1).	
Preamble FR Citation: 80 FR 16856	**Specific questions in preamble?** *No*
Public Comment Field:	
We support and encourage the use of National reporting and repository for this data.	

§ 170.315(g)(1) Automated numerator recording
Included in 2015 Edition Base EHR Definition?
No, but proposed for the EHR Incentive Programs CEHRT definition

§ 170.315(g)(1) Automated numerator recording
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (1) Automated numerator recording. For each meaningful use objective with a percentage-based measure, 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: 80 FR 16856 **Specific questions in preamble?** *No*
Public Comment Field: This is currently provided by those vendors involved in meaningful use. No additional comments.

§ 170.315(g)(2) Automated measure calculation
Included in 2015 Edition Base EHR Definition? No, but proposed for the EHR Incentive Programs CEHRT definition
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (2) Automated measure calculation. For each meaningful use objective with a percentage-based measure that is supported by a capability included in a technology, 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: 80 FR 16856 **Specific questions in preamble?** *No*
Public Comment Field: This is currently provided by those vendors involved in meaningful use. No comments.

§ 170.315(g)(3) Safety-enhanced design
Included in 2015 Edition Base EHR Definition? No, but a conditional certification requirement
Stage 3 MU Objective N/A

§ 170.315(g)(3) Safety-enhanced design

2015 Edition Health IT Certification Criterion

(3) Safety-enhanced design.

(i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs (a)(1) through (10) and (18), (20), (22), (23), and (b)(2) through (4) of this section.

(ii) The following information must be submitted on the user-centered design processed used:

(A) Name, description and citation (URL and/or publication citation) for an industry or federal government standard; or

(B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.

(iii) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:

(A) Name and version of the product; date and location of the test; test environment; description of the intended users; and total number of participants;

(B) Description of participants, including: sex; age; education; occupation/role; professional experience; computer experience; and product experience;

(C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;

(D) List of the specific metrics captured during the testing, including; task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy);

(E) Test results for each task using metrics listed above in paragraphs (g)(3)(ii)(A) through (D) of this section;

(F) Results and data analysis narrative, including: major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.

(iv) Submit test scenarios used in summative usability testing.

Preamble FR Citation: 80 FR 16856 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support the use of this criteria as error prevention for EHRs.

§ 170.315(g)(4) Quality management system

Included in 2015 Edition Base EHR Definition?

No, but a mandatory certification requirement

Stage 3 MU Objective

N/A

§ 170.315(g)(4) Quality management system

2015 Edition Health IT Certification Criterion

(4) Quality management system.
- (i) For each capability that a 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 that is:
  - (A) Compliant with a QMS established by the Federal government or a standards developing organization; or
  - (B) Mapped to one or more QMS established by the Federal government or standards developing organization(s).
- (ii) If a single QMS was used for applicable capabilities, it would only need to be identified once.
- (iii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified.

Preamble FR Citation: 80 FR 16858 **Specific questions in preamble?** *No*

Public Comment Field:

We support this criteria.

§ 170.315(g)(5) Accessibility technology compatibility

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(5) Accessibility technology compatibility. For each capability technology includes that is specified in the certification criteria at paragraphs (a), (b), and (e) of this section, the capability must be compatible with at least one accessibility technology that includes text-to-speech functionality.

Preamble FR Citation: 80 FR 16858 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support the use of this criteria, and that the vendor would demonstrate that the capability is compatible with at least one accessibility technology to meet this criteria.

§ 170.315(g)(6) Consolidated CDA creation performance

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

§ 170.315(g)(6) Consolidated CDA creation performance

2015 Edition Health IT Certification Criterion

(6) Consolidated CDA creation performance. The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iii) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially.

(i) Reference C-CDA match. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that matches a gold-standard, reference data file.

(ii) Document-template conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates a valid implementation of each of the following document templates (as applicable to the adopted standard):

(A) Generally applicable. CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.

(B) Inpatient setting only. Discharge Summary.

(iii) Vocabulary conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates the required vocabulary standards (and value sets) are properly implemented.

Preamble FR Citation: 80 FR 16859 **Specific questions in preamble**? *Yes*

Public Comment Field:

We support the use of this criteria as a conditional requirement when a Health IT Module includes C-CDAs, so that verifications can be made for reference C-CDA match, document template conformance, and vocabulary conformance within the C-CDA. Currently, there are insufficient constraints for the implementation of C-CDAs, and we support criteria to make this tighter.

§ 170.315(g)(7) Application access to Common Clinical Data Set

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objectives

The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

§ 170.315(g)(7) Application access to Common Clinical Data Set

2015 Edition Health IT Certification Criterion

(7) Application access to Common Clinical Data Set. The following technical outcomes and conditions must be met through the demonstration of an application programming interface (API) that can respond to requests from other applications for data specified within the Common Clinical Data Set.

(i) Security. The API must include a means to establish a trusted connection with the application requesting patient data, including a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.

(ii) Patient selection. The API must include a means for the application to query for an ID or other token of a patient's record in order to subsequently execute data requests for that record in accordance with paragraph (g)(7)(iii) of this section.

(iii) Data requests, response scope, and return format. The API must enable and support both of the following data request interactions:

(A) Data-category request. The API must support syntax that allows it to respond to requests for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in either XML or JSON.

(B) All-request. The API must support syntax that allows it to respond to a request for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted at § 170.205(a)(4).

(iv) Documentation. The API must include accompanying documentation that contains, at a minimum:

(A) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(B) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(v) Terms of use. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

Preamble FR Citation: 80 FR 16860 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support this criteria to test the capability of Health IT to respond to requests for patient data from other applications. This provides new opportunities for providers to obtain clinical patient data, however vendors want to know how to implement this capability.

§ 170.315(g)(8) Accessibility - centered design

Included in 2015 Edition Base EHR Definition?

No, but a mandatory certification requirement

Stage 3 MU Objective

N/A

§ 170.315(g)(8) Accessibility - centered design

2015 Edition Health IT Certification Criterion

(8) Accessibility-centered design. For each capability that a Health IT Module includes and for which that capability's certification is sought, the use of a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of that capability must be identified.

(i) If a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.

(ii) If different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.

(iii) If no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Preamble FR Citation: 80 FR 16861 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support accessibility design for PHI, however are unclear how this criteria is different than the Accessibility Technology Compatibility in g(5).

§ 170.315(h)(1) Direct Project

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(1) Direct Project.

(i) Applicability Statement for Secure Health Transport. Technology must be able to send and receive health information in accordance with the standards specified in § 170.202(a).

(ii) Optional – Applicability Statement for Secure Health Transport and Delivery Notification in Direct. Technology must be able to send and receive health information in accordance with the standard specified in § 170.202(e)(1).

Preamble FR Citation: 80 FR 16862 **Specific questions in preamble?** *No*

Public Comment Field:

We support the use of Direct in the Base EHR, however suggest the request that the delivery notification be required, and recommend that further clarification and education is provided on when custodianship of a message is changed.

§ 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM

Included in 2015 Edition Base EHR Definition?

Yes, as an alternative to § 170.315(h)(1)

Stage 3 MU Objective

N/A

§ 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM	
2015 Edition Health IT Certification Criterion (2) Direct Project, Edge Protocol, and XDR/XDM. Technology must be able to send and receive health information in accordance with: (i) The standards specified in § 170.202(a); (ii) The standard specified in § 170.202(b); and (iii) Both edge protocol methods specified by the standard in § 170.202(d).	
Preamble FR Citation: 80 FR 16863 (also see 80 FR 16862)	**Specific questions in preamble?** *No*
Public Comment Field: We support the use of this criteria – encouraging three distinct capabilities for Direct messaging to ensure exchange with a variety of other systems. However, some systems are still using SMTP and I-map – are these still supported? Please clarify in the criteria.	

§ 170.315(h)(3) SOAP Transport and Security Specification and XDR/XDM for Direct Messaging	
Included in 2015 Edition Base EHR Definition? No	
Stage 3 MU Objective N/A	
2015 Edition Health IT Certification Criterion (3) SOAP Transport and Security Specification and XDR/XDM for Direct Messaging. Technology must be able to send and receive health information in accordance with the standards specified in § 170.202(b) and (c).	
Preamble FR Citation: 80 FR 16863	**Specific questions in preamble?** *No*
Public Comment Field: We would like to acknowledge that the selected transport standard in the IIS community is SOAP/Web Services, leveraging a common WSDL to support the standard interface. Although the majority of IIS have embraced this transport mechanism, and we believe more will continue to do so, we would like to confirm that transport will continue to be allowed to be specified at the state level in accordance with local law and policy.	

§ 170.315(h)(4) Healthcare Provider Directory – query request
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objective N/A

§ 170.315(h)(4) Healthcare Provider Directory – query request

2015 Edition Health IT Certification Criterion

(4) Healthcare provider directory – query request. In accordance with the standard specified in § 170.202(f)(1), technology must be able to make, at a minimum, the following queries to a directory and subsequently process the response returned:
- (i) Query for an individual provider;
- (ii) Query for an organizational provider;
- (iii) Query for both individual and organizational providers in a single query; and
- (iv) Query for relationships between individual and organizational providers.
- (v) Optional - federation. In accordance with the standard specified in § 170.202(f)(1), technology must be able to process federated responses.

Preamble FR Citation: 80 FR 16863 **Specific questions in preamble?** *No*

Public Comment Field:

We support this as a non-Base EHR criteria for use by HISPs, and implemented by providers who have EHRs without this capability. The criteria should identify this as a use case to clarify confusion from vendors and provider organizations.

Related to a provider directory, we have struggled in Minnesota to set up the infrastructure for an accessible provider directory throughout the state, and would support the creation and use of a national provider directory instead. We applaud the efforts of the EHR/HIE Interoperability Workgroup, and encourage movement toward the national provider directory, while defining the mechanisms, in order to avoid duplication of efforts. In the absence of a national provider directory, we recommend incentives for state entities, or state approved entities to maintain a provider directory within each state.

§ 170.315(h)(5) Healthcare Provider Directory – query response

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(5) Healthcare provider directory – query response. In accordance with the standard specified in § 170.202(f)(1), technology must be able to, at a minimum, respond to the following queries to a directory:
- (i) Query for an individual provider;
- (ii) Query for an organizational provider;
- (iii) Query for both individual and organizational providers in a single query; and
- (iv) Query for relationships between individual and organizational providers.
- (v) Optional - federation. In accordance with the standard specified in § 170.202(f)(1), technology must be able to federate queries to other directories.

Preamble FR Citation: 80 FR 16864 **Specific questions in preamble?** *No*

§ 170.315(h)(5) Healthcare Provider Directory – query response
Public Comment Field:
We support the use of the query response criteria, and request further definition of which type of organizations are encouraged to provide the query response. In Minnesota we primarily see this as a function of the Health Information Organizations (HIOs). Although Minnesota has a law requiring entities who govern data to become state-certified, those organizations lack an incentive to step up for interoperability and take on the burden for their surrounding communities. Currently, provider organizations are trying to make decisions as to which entities, and how many entities, they should spend the resources to exchange with. An infrastructure that allows them to exchange through one HIO to obtain data from multiple locations would streamline their processes and limit health care expenses for all entities. We recommend the ONC identify incentives for organizations to become a part of this base health care exchange infrastructure as an HIO with more secure sustainability. Querying could also include C-CDAs and population health analysis.

§ 170.315(i)(1) Electronic submission of medical documentation
Included in 2015 Edition Base EHR Definition?
No
Stage 3 MU Objective
N/A

§ 170.315(i)(1) Electronic submission of medical documentation

2015 Edition Health IT Certification Criterion

(1) Electronic submission of medical documentation.

(i) Document templates. Health IT must be able to create electronic documents for transmission formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i). With respect to § 170.205(a)(5)(i):

(A) Health IT must be able to create the following document types regardless of the setting for which it is designed: Diagnostic Imaging Report; Unstructured Document; Enhanced Operative Note Document; Enhanced Procedure Note Document; and Interval Document.

(B) Ambulatory setting only. Health IT must be able to create an Enhanced Encounter Document.

(C) Inpatient setting only. Health IT must be able to create an Enhanced Hospitalization Document.

(ii) Digital signature.

(A) Applying a digital signature. Technology must be able to apply a digital signature in accordance with the implementation specification adopted at § 170.205(a)(5)(ii) to a document formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i). It must also be able to demonstrate that it can support the method for delegation of right assertions.

(1) The cryptographic module used as part of the technology must: be validated to meet or exceed FIPS 140-2 Level 1; include a digital signature system and hashing that are compliant with FIPS 186-2 and FIPS 180-2; and store the private key in a FIPS-140-2 Level 1 validated cryptographic module using a FIPS-approved encryption algorithm. This requirement may be satisfied through documentation only.

(2) Technology must support multi-factor authentication that meets or exceeds Level 3 assurance as defined in NIST Special Publication 800-63-2.

(3) After ten minutes of inactivity, technology must require the certificate holder to re-authenticate to access the private key.

(4) If implemented as a software function, the system must clear the plain text private key from the system memory to prevent the unauthorized access to, or use of, the private key when the signing module is deactivated.

(5) Technology must record time and date consistent with the standard adopted at § 170.210(g).

(B) Validating a digital signature. Technology must be able validate a digital signature that has been applied to a document according to the implementation specification adopted at § 170.205(a)(5)(ii).

(iii) Author of record level 1. Using the same system capabilities expressed in paragraph (i)(1)(ii), technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iii) to sign single or bundles of documents a document formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i).

(iv) Transactions. Using the same system capabilities expressed in paragraph (i)(1)(ii) of this section, technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iv) to a transaction and include the signature as accompanying metadata in the signed transaction.

Preamble FR Citation: 80 FR 16864 **Specific questions in preamble?** *No*

§ 170.315(i)(1) Electronic submission of medical documentation
Public Comment Field:
We support the use of this criteria to encourage national efforts underway for the development and implementation of a standard for the exchange of supporting information for health care claims ("claims attachments"). The Administrative Simplification provisions of the ACA (section 1104) include mandates to develop a national claims attachment standard for use by Jan. 1, 2016. The status of this effort is summarized in a September 2014 letter from NCVHS to HHS, which clarifies the complexity and difficulty of setting the standard (and implicitly makes clear that the Jan. 1, 2016 implementation date cannot be met). A larger overarching question is: CMS' Medical Documentation (esMD) program is obviously being well planned and lessons are no doubt being learned. How is the planning and the corresponding lessons of esMD being integrated with the claims attachments standards development mandated under the ACA (to apply to all HIPAA covered entities, not just Medicare services)? We support the use of this criteria for health care providers to communicate encounter documentation to a payer, not only to satisfy Medicare FFS coverage, but for other third party payers as well.

Gap Certification Eligibility Table for 2015 Edition Health IT Certification Criteria	
Preamble FR Citation: 80 FR 16867	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment	

Pharmacogenomics Data – Request for Comment	
Preamble FR Citation: 80 FR 16869	**Specific questions in preamble?** *Yes*
Public Comment Field:	
No comment	

Base EHR Definitions	
Preamble FR Citation: 80 FR 16870	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment	

Certified EHR Technology Definition	
Preamble FR Citation: 80 FR 16871	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment	

Common Clinical Data Set Definition	
Preamble FR Citation: 80 FR 16871	**Specific questions in preamble?** *No*
Public Comment Field: No comment	

Cross Referenced FDA Definitions	
Preamble FR Citation: 80 FR 16872	**Specific questions in preamble?** *No*
Public Comment Field: No comment	

B. Provisions of the Proposed Rule Affecting the ONC Health IT Certification Program

The following comment tables are meant to capture proposals relevant to the ONC Health IT Certification Program.

Subpart E – ONC Health IT Certification Program	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *No*
Public Comment Field: We support this robust proposal to improve interoperability across all health care providers and across the continuum of care. One missing component is the 'user-ability' of the EHR and of the health information exchange. With the addition of more and more functionality, electronic health systems can become non-user abled - to the point of being dysfunctional for the user. For this reason, we need a standard for efficient and effective use of the system. This could be reflected in either a separate required certification criteria of user-ability, or each criteria would be tested with a component of user efficiency. The Pharmacists in Minnesota request that for any code set named in other regulation, i.e. RxNorm in MMA, a version not be specified here, but that the other regulation is cited as reference. We also request that rather than naming a specific version, the reference be to "the most recently published version" of the code set, thereby ensuring that the industry continues to use the most current information available.	

Health IT Modules	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *No*

Health IT Modules
Public Comment Field:
We understand and appreciate the use of different Health IT Modules for adaptability based on need of various providers. However, this document needs to provide examples for different types of providers as to what certification criteria they would need (collectively) to be able to exchange health information to improve outcomes as appropriate for their specialty.

"Removal" of Meaningful Use Measurement Certification Requirements	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment	

Types of Care and Practice Settings	
Preamble FR Citation: 80 FR 16873	**Specific questions in preamble?** *Yes*
Public Comment Field:	
No comment	

Referencing the ONC Health IT Certification Program	
Preamble FR Citation: 80 FR 16874	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment	

Privacy and Security	
Preamble FR Citation: 80 FR 16875	**Specific questions in preamble?** *Yes*
Public Comment Field:	
No comment	

Design and Performance (§ 170.315(g))	
Preamble FR Citation: 80 FR 16876	**Specific questions in preamble?** *No*
Public Comment Field:	
No Comment	

"In-the-Field" Surveillance and Maintenance of Certification	
Preamble FR Citation: 80 FR 16876	**Specific questions in preamble?** *Yes*
Public Comment Field:	
No comment	

Transparency and Disclosure Requirements	
Preamble FR Citation: 80 FR 16880	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment	

Open Data Certified Health IT Product List (CHPL)	
Preamble FR Citation: 80 FR 16883	**Specific questions in preamble?** *Yes*
Public Comment Field:	
We support the development and use of the CHPL.	

Records Retention	
Preamble FR Citation: 80 FR 16885	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment	

Complaints Reporting	
Preamble FR Citation: 80 FR 16885	**Specific questions in preamble?** *No*
Public Comment Field:	
No comment	

Adaptations and Updates of Certified Health IT	
Preamble FR Citation: 80 FR 16885	**Specific questions in preamble?** *Yes*
Public Comment Field:	
No comment	

"Decertification" of Health IT – Request for Comment	
Preamble FR Citation: 80 FR 16886	**Specific questions in preamble?** *Yes*
Public Comment Field:	
No comment	

Collections of Information – Paperwork Reduction Act	
Preamble FR Citation: 80 FR 16893	**Specific questions in preamble?** No

Collections of Information – Paperwork Reduction Act
Public Comment Field:
No comment

Regulatory Impact Statement	
Preamble FR Citation: 80 FR 16895	**Specific questions in preamble?** No
Public Comment Field:	
No comment	

Appendix A: Minnesota e-Health Advisory Committee Members, 2014-15

Alan Abramson, PhD
Advisory Committee Co-Chair
Senior Vice President, IS&T and CIO
HealthPartners
Representing: Health System CIOs

Daniel Abdul
Chief Information Officer
UCare
Representing: Health Plans

Wendy Bauman, MPH
Deputy Director
Dakota County Public Health
Representing: Local Public Health Departments

Laurie Beyer-Kropuenske, JD
Director
Community Services Divisions
Representing: Minnesota Department of Administration

Lynn Choromanski, PhD, RN-BC
Nursing Informatics Specialist
Gillette Children's
Representing: Experts in Health IT

Susan Heichert
Senior Vice President, Chief Information Officer
Allina Health
Representing: Large Hospitals

Maureen Ideker, MBA, RN
Director of Telehealth
Essentia Health
Representing: Small and Critical Access Hospitals

Mark Jurkovich, DDS, MBA
Dentist
Gateway North Family Dental
Representing: Dentists

Paul Kleeberg, MD
Clinical Director
Regional Extension Assistance Center for HIT
Representing: Physicians

Ruth Knapp
Manager, Health Data Quality
Minnesota Department of Human Services
Representing: Minnesota Department of Human Services

Marty LaVenture, PhD, MPH, FACMI
Director, Office of Health IT and e-Health
Minnesota Department of Health
Representing: Minnesota Department of Health

Jennifer Lundblad, PhD
President and Chief Executive Officer
Stratis Health
Representing: Quality Improvement

Bobbie McAdam
Advisory Committee Co-Chair
Senior Director, Business Integration
Medica
Representing: Health Plans

Charlie Montreuil
VP, Enterprise Rewards & Corporate Human Resources
Best Buy Co., Inc.
Representing: Health Care Purchasers

Kevin Peterson, MD
Family Physician
Phalen Village Clinic
Representing: Community Clinics and FQHCs

Steve Simenson, BPharm, FAPhA
President and Managing Partner
Goodrich Pharmacy
Representing: Pharmacists

Peter Schuna
Director of Strategic Initiatives
Pathway Health Services
Representing: Long Term Care

Cheryl M. Stephens, MBA, PhD
Executive Director
Community Health Information Collaborative
Representing: Health IT Vendors

Donna Watz, JD
Deputy General Counsel
Minnesota Department of Commerce
Representing: MN Department of Commerce

Marty Witrak, PhD, RN
Professor, Dean
School of Nursing, College of St. Scholastica
Representing: Academics and Research

Cally Vinz, RN
Vice President, Health Care Improvement
Institute for Clinical Systems Improvement
Representing: Clinical Guideline Development

Bonnie Westra, PhD, RN, FAAN, FACMI
Associate Professor
University of Minnesota, School of Nursing
Representing: Nurses

Ken Zaiken
Consumer Advocate
Representing: Consumers

Kathy Zweig
Associate Publisher & Editor-in-Chief
Inside Dental Assisting Magazine
Representing: Clinic Managers

Designated Alternates

Sunny Ainley
Associate Dean, Center for Applied Learning
Normandale Community College
Alternate Representing: HIT Education and Training

Jeff Benning, MBA
President and CEO
Lab Interoperability Collaborative
Alternate Representing: Expert in HIT

Barb Daiker, RN, PhD
Manager of Quality Improvement
Minnesota Medical Association
Alternate Representing: Physicians

Cathy Gagne, RN, BSN, PHN
St. Paul-Ramsey Department of Public Health
Alternate Representing: Local Public Health

Nancy Garrett, PhD
Chief Analytics Officer
Hennepin County Medical Center
Alternate Representing: Large Hospitals

Susan Severson
Director, Health IT Services
Stratis Health
Alternate Representing: Quality Improvement

Mark Sonneborn
Vice President, Information Services
Minnesota Hospital Association
Alternate Representing: Hospitals

Trisha Stark, PhD, LP, MPA
Licensed Psychologist
Alternate Representing: Behavioral Health

Meyrick Vaz
Vice President - Healthcare Solutions
Optum Global Solutions
Alternate Representing Vendors