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Submitted Electronically

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, D.C. 20201

RE: AHIMA Comments on Proposed 2015 Edition Electronic Health Record (EHR) Certification Criteria, 2015 Edition Base EHR Definition, and ONC Health IT Certification Program Modifications (RIN 0991-AB93)

On behalf of the members of the American Health Information Management Association (AHIMA), we are pleased to submit comments related to the abovementioned proposed rule. AHIMA is a not-for-profit, membership-based healthcare association representing more than 101,000 health information management (HIM) and informatics professionals who work in more than 40 different types of entities related to our nation's healthcare and public health industry. Many of our members' daily work involves an ongoing commitment to ensuring the integrity of the data and information in EHRs to support patient safety and quality care as well as payment, legal, and regulatory purposes.

AHIMA understands that appropriate standards are critical for advancing the use of certified electronic health record technology (CEHRT) to achieve interoperability. In general, we believe these standards need to be reasonably mature and well tested prior to including them in the certification criteria. To the extent that standards proposed for inclusion in the 2015 edition have been balloted, tested and are out of trial phase, AHIMA supports their inclusion in the certification criteria.

Although the 2015 Edition proposed rule covers many important topics, our comments below are focused and limited to program modifications and new criteria that can impact the integrity of the electronic health record.

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

§ 170.315(a)(4) Drug-drug, drug-allergy interaction checks for CPOE
Included in 2015 Edition Base EHR Definition?
No

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

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

(1) 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*

Public Comment Field:

AHIMA recommends that drug-drug, drug-allergy (DD/DA) interventions are tracked when and if a user viewed, accepted, declined, ignored, overrode, or otherwise commented on the DD/DA intervention. This tracking is needed for record management and evidentiary support as well as the ability to review the effectiveness of the DD/DAI intervention.

§ 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

(2) 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:

AHIMA agrees that the technology must support the ability to capture all patient health information, not only advance directives. Health IT must be able to capture, label, link, and make the information easily accessible.

§ 170.315(a)(20) Implantable device list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

§ 170.315(a)(20) Implantable device list

2015 Edition Health IT Certification Criterion

(3) 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*

Public Comment Field:

AHIMA supports the ability a Health IT Module would have to enable a user to record, change, and access a patient's implantable device list, which would consist of one or more Unique Device Identifiers (UDIs). The Health IT Module should also have the ability to parse the following data elements from a UDI: device identifier; batch/lot number; expiration date; production date; and serial number.

§ 170.315(b)(1) Transitions of care

Included in 2015 Edition Base EHR Definition?

Yes

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,"

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

AHIMA agrees that there should be robust standards for patient data matching to accurately identify patients who are the subject of a transition of care/referral summary. Data collection and standards for the purpose of patient matching vary widely. This is an important issue in which patient safety is at stake and there should be broad engagement and acceptance by stakeholders of the data elements and sources listed above for patient matching data quality. It is not clear that the above list of data elements meets these criteria. We would encourage ONC to engage more broadly with stakeholders on these sources and data elements for patient matching before finalizing these criteria.

Some of our concerns about the way the patient matching data quality standard and constraints are described include:

- ***First Name, Last Name, Date of Birth and Gender are NOT sufficient to accurately match patient records. Any CEHRT that "auto-links" records (meaning no human intervention) based on these four data fields, even IF the four match exactly, will auto-link multiple birth records and records of persons with common names, e.g. a Jose Garcia in Dallas, TX with the same DOB and zip code. Also, when the four fields match exactly, and there is an error in one record's data field (say, the DOB year is off by one digit), but first name, last name, gender and zip all match, they get auto-linked – even though one the of patient's DOB is just off a bit.***
- ***While we applaud the inclusion of place of birth in matching criteria, there are no constraints on how this data is to be captured—city, state, country, etc. This will not help with patient matching if there are not constraints that help to ensure that this data is captured and expressed in a consistent manner.***
- ***We believe that it is critical to include the capture of full middle name (or null value) in CEHRT to address challenges with overlaying two records that don't belong to the same person (multiple birth records, patient's with common names living in a densely populated area being the most problematic, etc.)***

§ 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

(2) 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:

AHIMA supports the Data Segmentation for Privacy—send criterion. Though still not mature as a standard, it represents the best alternative currently available for protecting sensitive health data such as that related to behavioral health, substance abuse, etc. It is critical that providers of care have access to this information as the patient deems appropriate.

§ 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

(3) 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*

Public Comment Field:

AHIMA supports the Data Segmentation for Privacy—receive criterion. Though still not mature as a standard, it represents the best alternative currently available for protecting sensitive health data such as that related to behavioral health, substance abuse, etc. It is critical that providers of care have access to this information as the patient deems appropriate.

§ 170.315(d)(8) Integrity

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) 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:

AHIMA supports inclusion of the Integrity criterion that would be tested and certified to ensure the integrity of the information exchanged. This will be critical for patient safety and quality of care when the summary of care records as well as other types of information that are exchanged.

§ 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 (1) 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: ***AHIMA agrees with this proposal to revise the definition of the Common Clinical Data Set to account for new and updated standards and code sets***

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.

Types of Care and Practice Settings
Preamble FR Citation: 80 FR 16873 **Specific questions in preamble?** *Yes*
Public Comment Field: ***AHIMA agrees with the simplification and applying criteria to all health care settings to support health IT beyond the ambulatory and inpatient settings when the criteria is not specific to a particular setting.***

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

Referencing the ONC Health IT Certification Program
Public Comment Field:
AHIMA agrees with the proposed name change to include all of health IT that is beyond EHR technology. This is necessary to support health IT certification for other care and practice settings such as long-term post-acute care, behavioral health, and pediatrics. Further, the proposals in this rule would make it simpler for certification criteria and certified health IT to be referenced by other HHS programs (e.g., Medicaid and Medicare payment programs and various grant programs), other public programs, and private entities and associations.

AHIMA appreciates the opportunity to comment on the NPRM for the 2015 Edition of the CEHRT Criteria and thanks you for consideration of our comments. Should ONC have questions about these comments, please contact me at Lynne.thomasgordon@ahima.org or (312) 233-1165.

Sincerely,

Lynne Thomas Gordon, MBA, RHIA, CAE, FACHE, FAHIMA
Chief Executive Officer