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Date May 29, 2015

Office of the National Coordinator
for Health Information Technology (ONC)
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; RIN 0991-AB93

Dear Sir or Madam:

The American Association for Homecare (AAHomecare) submits these comments in response to ONC's request for comments on the above captioned proposed rule. AAHomecare represents suppliers and manufacturers of durable medical equipment (DME), prosthetics, orthotics and supplies (collectively, DMEPOS) items which elderly and chronically ill patients use in their homes. We believe that the home is the fastest growing care setting. So AAHomecare strongly supports ONC's decision to expand the EHR standards so that they can encompass all care settings. AAHomecare believes that the failure to encompass standards for DMEPOS items used by patients in their homes has posed a significant hurdle to achieving full functionality for the EHR and permitting the health care system and patients to garner the benefits and efficiency of the EHR.

When referring to the "home" care setting, it is also necessary to distinguish among the health services and providers or suppliers that deliver those services in the home. It is especially important to distinguish home health services provided by home health agencies (HHAs) in a patient's home. Generally, HHAs furnish nursing, therapy and other medical services in the home. DMEPOS suppliers furnish medical technologies designed for patients to use in their homes. The processes for ordering, furnishing care and documenting home health and DMEPOS services and items are very different. Importantly, including an EHR standard for a plan of care does not eliminate the need to have Health IT certification standards specific to DMEPOS.

For DMEPOS items, AAHomecare also recommends that ONC develop specific templates or "knowledge artifacts" and that these templates be incorporated into the EHR certification standards. AAHomecare is available to work on developing these templates with the Centers for Medicare and Medicaid Services (CMS) and ONC. AAHomecare and

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the industry successfully developed the electronic template for PMD, however it has not been incorporated into existing EHRs.

AAHomecare requests the opportunity to meet with ONC to discuss issues pertaining to DMEPOS in more detail. We would like to work more closely with ONC to develop standards that are relevant to DMEPOS and that address our members' challenges in submitting EHR records to Medicare contractors to document medical necessity. Many of these challenges center on the ability of Medicare contractors to superimpose new or additional data elements that are not required under the Health IT certification criteria on the EHR generated order or other documentation and the ability of contractors to challenge the validity of a digital signature generated under an EHR that meets ONC certification criteria because the signature is in a format the contractor is not familiar with.

AAHomecare adopted the ONC comment template to submit its comments. To emphasize, the importance we place on ensuring that EHR certification standards adequately capture and address data elements necessary to support the home care setting, we reversed the order of the comment tables to make our comments below. The association's comments begin with the 2015 Health IT certification standards, specifically, all care settings. To facilitate your review of our comments, we also removed comment tables for topics that we did not address.

AAHomecare appreciates the opportunity to submit these comments. We look forward to meeting with you in person to discuss these issues in more detail. To that end, I will reach out post submission of comments to see what can be arranged. Until then, please feel free to contact me with any questions, or if I can be of assistance in any way.

Sincerely,

Kimberley S. Brummett, MBA
VP of Regulatory Affairs, AAHomecare

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A. Provisions of the Proposed Rule Affecting 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:

As noted, AAHomecare reversed the order of the comment tables because it believes that having an EHR that captures and address care that is delivered in every care setting must be ONC's primary goal from this point forward. The EHR has not been useful to providers, practitioners, or suppliers who prescribe or furnish durable medical equipment prosthetics, orthotics, and supplies (collectively, DMEPOS) in the past. ONC has omitted an important piece of the care continuum and perhaps the fastest growing venue for the delivery of care to the elderly and chronically ill.

AAHomecare recommends that § 170.315 (a) should add new subparagraphs to address computerized order entry for DMEPOS items. The EHR needs to include all of the elements for a valid DMEPOS order required under the CMS Program Integrity Manual (PIM) 100-8 § 5. Currently, the DME Medicare Administrative Contractors (DME MACs), do not accept many EHR generated orders for DMEPOS because the orders do not contain a separate data field to document the data the physician or other qualified practitioner signed the order (the Signature Date). Other aspects of the EHR that the DME MACs do not accept for validating the order are the date the DMEPOS supplier received the order. Even though an EHR generated order includes the date of transmission, the DME MACs require DMEPOS suppliers to print out a paper order, manually date stamp the order to confirm the date the supplier received the order for DMEPOS, then scan the order back into the supplier's electronic record.

The DME MACs require suppliers to circumvent the electronic work flow with intervening manual steps because they must "verify," via the manually applied date stamp, that the supplier received the order for the certain specified DMEPOS items before the delivery of the item to the beneficiary. For certain specified DME items, 42 CFR § 410.38, requires a supplier to have a written order from the prescribing physician before the supplier delivers the item to a beneficiary. An order rendered using an EHR that was certified compliant with ONC Health IT certification standards should be valid on its face for purposes of Medicare claims adjudication and medical review, notwithstanding the requirements of § 410.38, or any other applicable regulation. In addition we note that current EHR certification standards do not conflict with applicable DMEPOS regulations. We believe that despite what are *arguably* missing data elements like the Signature Date, the DME MACs *should* be required to accept an order generated by an EHR certified to the ONC standards. But, because the overwhelming majority of supplier's orders originate from EHRs, and because the MACs' rejection of these orders creates significant disruption to supplier's operations, increasing their costs, AAHomecare requests that computerized order entry include order entry specific to DMEPOS items and that the data fields for this section reflect the specific requirements imposed on DMEPOS orders by CMS and the DME MACs.

For your reference, we have included a number of specific examples of EHR orders that the DME MACs have concluded are unacceptable because they are missing data elements like a Signature Date.

AAHomecare also recommends that 170. § 315 (a) include a subparagraph for computerized order entry of diagnostic tests other than imaging. Specifically, polysomnography is a diagnostic test that is to confirm a diagnosis of obstructive sleep apnea (OSA) and other respiratory conditions. These studies, also known as sleep studies can be performed in a patient's home, and institution like a hospital sleep lab, or a free standing clinic. An oximetry test is required to diagnosis hypoxemia. These tests can be performed by a physician or an independent diagnostic testing facility (IDTF). OSA and hypoxemia are treated with respiratory equipment like PAP or RAD devices and oxygen respectively.

Currently many Medicare required tests are manually annotated or generated by an EHR and do not meet DME MAC requirements to be considered valid tests. This results in Medicare beneficiaries being required to be retested at the expense of the Medicare program.

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B. 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)	
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: **The medication list should include oxygen which is a legend drug.**	

§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

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

2015 Edition Health IT Certification Criterion

(2) 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.

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§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*

Public Comment Field:

Vital signs need to include oximetry. The EHR should identify the conditions under which the test was performed, including the following data elements: at rest, on room air, on oxygen; during exercise: at rest on room air, six minute walk on room air, six minute walk on oxygen and specify the liters per minute of oxygen use.

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§ 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 (3) 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*
Public Comment Field: **AAHomecare supports the inclusion of this standard. This standard is an important reference for the prescription of oxygen therapy and for the safe delivery and use of oxygen by an individual in his or her home.**

§ 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 (4) 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: **Consistent with the comments above, AAHomecare believes that the diagnostic test standard should be broader in order to capture the tests used to prescribe DME items like oxygen and other respiratory equipment like respiratory assist devices (RAD or positive airway pressure (PAP) devices that are used in the home. At a minimum these diagnostic tests include sleep studies and oximetry tests. The data fields need to capture the name and Medicare enrollment status of the entity performing the test and the specific conditions under which the test occurred. Test outcomes could be referenced under the decision support standard to link the authorized user to the applicable decision tree for the prescription of the device. Documentation under the decision tree can be in the form of opened questions following the outline of the applicable Medicare local coverage determination. AAHomecare recommends that the decision tree reference the Medicare LCDs because the LCD criteria are often followed by other payers in making coverage determinations for respiratory equipment.**

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§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:

As noted, DME MACs often reject EHR documentation because they question the authentication of the digital signature. EHR records that are transmitted to other providers should be self-authenticating. We recommend that each EHR document contain a legend that identifies the EHR's authentication procedure. This legend should be in a form that is readable by the human eye. AAHomecare recommends that ONC prioritize the order for displaying the legend.

§ 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

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*

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

Public Comment Field:

The audit log and event tracking speaks to the integrity of the information in the EHR and the authentication of the records. Audit trails should be reasonably accessible so that they can be made available to entities like the DME MACs in the event questions arise about the authenticity of records or entries in an EHR.

§ 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:

See AAHomecare comment above.

§ 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*

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§ 170.315(d)(4) Amendments
Public Comment Field:
Accepted and denied amendments to an EHR must be identifiable and they must be able of being transmitted to other providers and suppliers caring for a patient. All amendments must meet ALL Medicare criteria to be considered valid. The CMS must have a standard for valid amendments and all Medicare contractors must follow which is built into the EHR standard.

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

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§ 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*

Public Comment Field:

An authenticated EHR record must be capable of being transmitted to providers and suppliers involved in a patient's care regardless of the care setting. These records must be capable of also being transmitted by recipients for purposes of documenting the need for care at the request of a payer. We understand the emphasis on the esMD process, however, from a DMEPOS supplier's perspective there are some significant hurdles to the adoption of this technology: it is expensive for suppliers to use and the system is not readily accessible because there are limited numbers of options for esMds. DME MAC contractors compete with esMds by establishing their own portals and prefer suppliers use the contractor's portal. AAHomecare supports having one platform like the esMD. The platform should be free for all providers and suppliers. MAC contractors should be precluded from establishing competing systems. Finally ONC should encourage and foster the development of more esMds, using these principles.

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Records Retention	
Preamble FR Citation: 80 FR 16885	**Specific questions in preamble?** *No*

Public Comment Field:

EHR systems should be designed to retain records for a minimum of ten years from the date of service plus whatever additional time is required under state law to preserve the rights of minors.

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