AMIA

29 May 2015

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology (ONC)
Attention: 2015 Edition Health IT Certification Criteria Proposed Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave, S.W., Washington, D.C. 20201

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

On behalf of the American Medical Informatics Association (AMIA), I am pleased to submit
these comments in response to the above-referenced proposed rule. AMIA is the
professional home for biomedical and health informatics and is dedicated to the
development and application of informatics in support of patient care, public health,
teaching, research, administration and related policy. AMIA seeks to enhance health and
healthcare delivery through the transformative use of health information technology (health
IT).

AMIA's 5,000+ members advance the use of health information and communications
technology in clinical care and clinical research, personal health management, public and
population health, and translational science with the ultimate objective of improving health.
Our members work throughout the health system in various clinical care, research,
academic, government, and commercial organizations.

AMIA thanks the Department of Health and Human Services (the Department) and the
Office of the National Coordinator for Health Information Technology (ONC) for issuing this
proposed rule, which introduces a new edition of certification criteria (the 2015 Edition
health IT certification criteria or "2015 Edition"), proposes a new 2015 Edition Base EHR
definition, and proposes to modify the ONC Health IT Certification Program to make it open
and accessible to more types of health IT and health IT that supports various care and
practice settings. The 2015 Edition would also establish the capabilities and specify the
related standards and implementation specifications that Certified Electronic Health Record
(EHR) Technology (CEHRT) would need to include to, at a minimum, support the
achievement of meaningful use by eligible professionals (EPs), eligible hospitals, and
critical access hospitals (CAHs) under the Medicare and Medicaid EHR Incentive Programs
(EHR Incentive Programs) when such edition is required for use under these programs.
In providing input, we will provide general comments about ONC's approach to transitioning
the certification program from an EHR-centric program to a Health IT-centric program,
respond to certain requests for specific comment included in the Federal Register, and

discuss other selected provisions of the proposed rule. We will also discuss the relationship of this proposed rule with the CMS EHR Incentive Program--Stage 3 Proposed Rule.

General Comments

We support the design and implementation of a more accessible and modular Office of the National Coordinator (ONC) Health IT Certification Program as reflected in the 2015 Edition of Health IT Certification Criteria and directly support the full use of diverse health IT systems, including but not limited to, EHR technology ("Health IT Module" instead of "EHR Module"). Additionally, we strongly support the ONC Program's transition from the Meaningful Use EHR Incentive Programs toward broader alignment with HHS-wide goals to achieve better care, smarter spending, and healthier people as reflected through the proposed ten-year interoperability roadmap. We believe these changes will foster innovation, create new market opportunities, provide important choices for person-centered, lifelong health management, and support patients and providers within specific care episodes through new levels of electronic health information access and exchange.

We encourage the ONC to continue to pursue the thoughtful and incremental creation of a growing and dynamic certification program that supports Health IT across the care continuum ecosystem, including long-term and post acute care settings, chronic care management, behavioral health, community and public health, as well as other rapidly expanding settings including retail convenience and urgent care, employer-based clinics, and care at a distance augmented through telehealth capabilities. The ecosystem will continue to thrive as innovation supports adoption of Health IT, with shareable, comparable and exchangeable data all expanding shared decision-making by individuals and members of their families and support networks as they deem appropriate and in concert with nurses, physicians, interprofessional care team members and members of a wide community of care.

AMIA and our members advocate for using current and emerging health technologies (e.g., telehealth, mobile health, sensors/devices) and novel small, big and large data sources including person-generated health data and device/sensor-generated health data. This proposed approach offers a new opportunity to empower individuals and their self-identified family members to forge effective partnerships to guide effective lifetime health and healthcare management. As we develop and adopt a national digital health infrastructure that is person centric with capacity for personalized precision healthcare, the needs for the certification program will necessarily evolve. We also encourage ONC to align the Health IT Certification Program and discrete certification modules with the goals and vision of the 10-year interoperability roadmap to achieve a learning health system that recognizes the complementary needs of defined stakeholders.

With these general comments of support for the concept of certification expansion, we also express our strong concern that the totality of this expanded program as presented in this NPRM represents an overreach of the program. The transition of the program from one specifically tailored to support the CMS EHR Incentive Program to one that supports a broader set of programs -- both within and outside the federal government -- has the potential to create significant market confusion for vendors, providers and health care

consumers. We recommend that ONC consider introducing additional criteria (not associated with the current EHR Incentive Program) at a time when they can be directly connected to specific programs (whether federal or otherwise). It is exceedingly difficult for AMIA or other commenters to evaluate the overall fit of certification criteria outside of this context. Some of the concepts described for the design of ultra-large-scale systems can serve as a guide for ONC's thinking about how to expand the certification program to accommodate the ultimately unknowable and diverse requirements of our ever-evolving health care system.

The certification criteria proposed in this NPRM represent many important domains where standards for vocabulary, terminology, syntax and exchange can profoundly improve the way in which health care is delivered and better health outcomes are achieved when they are deployed thoughtfully into a marketplace that is ready and willing to receive them. Many AMIA members have dedicated their careers to advancing these ideas through research and practical implementations -- from basic terminology services to pharmacogenomics and advanced clinical decision support rules. We understand the value of moving forward and heartily support the goals.

The EHR Incentive Program and the accompanying certification program have had a profound impact on the adoption and use of electronic health records. They have also dramatically shifted the development priorities of vendors as they focus first on certification, often at the cost of the priorities of their customers and users for mission-critical enhancements. We are concerned that the dramatic expansion of this program will further skew the development priorities toward compliance with the certification criteria over expressed customer needs. The overemphasis of certification can have deleterious effects such as the degradation of EHR usability. We believe that ONC must, along with CMS, be very mindful of allowing sufficient time for vendor development and provider implementation of new or revised functionality and recognize that scope along with time are critical factors in being able to complete and implement HIT functionality safely and with high quality.

A number of the standards proposed in this NPRM are still in pre-publication or are in draft standard for trial use (DSTU) form that have only been tested in limited environments. Publication alone is not sufficient to consider a standard mature for national deployment Especially as ONC considers expanding its purview to include certification criteria for Health IT Modules outside of the EHR Incentive Program, we implore ONC to carefully consider the stability and market readiness of each standard being named and specifically seek input from authoring SDOs and implementers about the relative maturity of each standard before requiring it as part of a certification criterion. Our comments on specific criteria below are all provided with the caveat that no certification criterion should be required for certification until it has been adequately field tested in multiple, representative settings to demonstrate its readiness to scale nationally.

We understand the challenges when naming standards in regulation -- that the timing of standards balloting is sometimes not in sync with the naming of the standard and that the overall process of going from standards development to balloting to naming in regulation to implementation can take years -- a timeframe that is not well-suited for rapid transformation and iterative advancement. Particularly with interoperability standards, as has been done

with vocabulary standards, ONC should consider adopting an approach of naming minimum standards versions and allowing for backwards compatible successors. The onus of responsibility for backwards compatibility would be on the organization adopting the successor versions to ensure that they can still maintain compatibility with the named version. This approach will allow vendors and implementers to adopt successor versions at a timing that is more suitable to their development and implementation schedules and allow for incremental improvements and corrections of the standards. We also encourage ONC to work with HL7 and other standards development organizations to ensure a transition path for addressing the "bilateral asynchronous cutover" issue so that successor versions of standards can be managed within the certification process.

We encourage HHS to make deeper investments in the total lifecycle of standards development -- giving special attention to real-world testing of these standards and proposed certification criteria through the development of an early adoption incentive program. While such a program would seem to slow the pace of our progress toward the shared goals of improved outcomes, lower costs and improved population health, we will ultimately be more successful as we thoughtfully and methodically make iterative and incremental progress through needs-based and patient-focused use case development and refinement, responsive standards development, rigorous testing and evaluation, market-directing certification, well-planned implementation, and post-deployment evaluation, resulting in continuous process improvement and a more functional health care system.

The change from the 2011 and 2014 editions -- including the unbundling of the ONC's role in defining the Certified EHR Technology (CEHRT) definition on behalf of CMS -- will require significant investments in the education of information technology industry leadership, healthcare delivery clinical and technology leaders, as well as eligible providers and hospital communities to prepare them for these significant changes. AMIA stands ready to assist in the education of our members and the broader community about the evolution of EHR and health IT certification.

With respect to the decoupling of the Health IT Module certification program and measures from the Medicare and Medicaid EHR Incentive Programs, we would like clarification from ONC if there will be opportunities for private sector entities to work with ACBs to establish additional certification criteria that are not required by any federal programs, but are useful adjuncts to the federally established certification criteria. For example, one could envision those interested in genomic data or other specialty-specific functions that aren't currently recognized by federal programs) to establish and fund certification criteria of their own. The market may be better off if these criteria were certified by the ONC-ACBs rather than separate certification entities. One could anticipate that these private certification criteria eventually make their way into federal programs as well. We would appreciate seeing ONC comment on their perspective on allowing ABCs to develop additional certification capabilities advanced in this manner.

In our comments on the CMS proposed rule for Stage 3 of the Medicare and Medicaid Incentive Programs, we have advocated for a postponement or outright cancellation of Stage 3 of Meaningful Use. As proposed, Stage 3 of MU will only exist as a stand-alone program for a single year before being consolidated into the MIPS program. Rather than

create all of the new requirements and program changes for a single year, it would be better for all if CMS simply extended its modified plan for 2015-2017 to cover 2018. This approach will save everyone from the heavy lift of a new program for 2018 and the expected heavy lift for a new program that will begin in 2019 to meet the requirements of the MIPS program. We emphasize that AMIA is strongly in favor of making progress and advancing greater interoperability and data flow -- especially for public health and for improving patient access to their own data. But we want these advances to be done in a thoughtful manner. We believe that ONC should take a similarly thoughtful approach to the structural changes and retooling of the certification program that have been proposed here.

On the same day these comments are due, AMIA has published a report that summarizes many months of work on recommendations for improving our collective experiences with electronic health records over the next five years. This report, called EHR 2020, has been published in *JAMIA*[1] and a summary is available on AMIA's blog.[2] We implore you to take advantage of the vision and priorities that have been presented in this work.

Below we have included the tables from ONC's response template only for the criteria where AMIA has specific comments. We ask that our general comments about the approach to certification ONC has proposed be considered when addressing the following comments.

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
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**.**
      a.   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.
      b.   Adjustments.
      i.   Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.
      ii.   Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.
 c.   Interaction check response documentation.

[1] http://jamia.oxfordjournals.org/content/early/2015/05/22/jamia.ocv066
[2] http://fridsma.amia.org/ehr-2020-charting-the-course-to-a-better-future/

.   Technology must be able to record at least one action taken and by whom in response to drug-drug or drug-allergy interaction checks.

i.   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:

In this section, ONC stated, "we believe that there are instances when a user should be aware of a patient's DD/DAI when new medications or medication allergies are entered into the patient record." Informing a user when new or updated DD/DAI information is added to the CDS system is helpful, but what is "new" and what is "known" to an individual user is relative. Some providers may use a combination of medications with known interactions with valid clinical reasons. They do not want to be alerted to that particular contraindication because it is routinely countered. Having the ability to selectively manage the style of intervention of a CDS rule by the individual would be an overarching capability that would include new and updated information. A better approach may be to allow a user to indicate their interest in being alerted to any individual rule so that they are alerted about the ones with which they are less familiar and more passively reminded of an alert's availability for others that are routine. For example, a user could be given the option of being reminded of an alert again in one year. In the future, that alert might continue to prompt a flag (making it accessible with a click), but may not create a disruptive alert (e.g., a pop-up message). New and updated rules would, by design, be unfiltered on first use; then the user could set the future handling of the alert.

§ 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

2015 Edition Health IT Certification Criterion

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

a.   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.):

i.   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);

ii.   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

iii.   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.

    b.   <u>Optional – Body mass index percentile per age and sex.</u> 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.):

    .   <u>Identified</u>, 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

    i.   <u>Metadata.</u> 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. <u>Optional.</u> Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

    c.   <u>Optional – Weight for length per age and sex.</u> 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.):

    .   <u>Identified</u>, 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

    i.   <u>Metadata.</u> 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. <u>Optional.</u> Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

    d.   <u>Optional – Head occipital-frontal circumference.</u> 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.):

.   <u>Identified</u>, 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

i.   <u>Metadata.</u> The technology must also record the following:

1. Date and time of vital sign measurement or end time 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. <u>Optional.</u> Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

    e.   <u>Optional – Calculate body mass index.</u> Automatically calculate and display body mass index based on a patient's height and weight.

    f.   <u>Optional – Plot and display growth charts.</u> Plot and display, upon request, growth charts for patients.

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

Public Comment Field:

We agree that capturing data in a specific state is more valuable and provides the opportunity for greater accuracy in data collection and transmission. However, standards in §170.201 only specify the vocabulary standards, not the syntax. ONC would do better to adopt a consistent granular data standard first and then specify what metadata to put into that syntax. The work of the SDC initiative and the FHIR specification for CDEs would have been a better and more consistent approach to capturing granular data than relying only on vocabulary standards and creating inconsistencies in the metadata for granular data through a regulatory, rather than SDO, approach.

In addition, the question on where the value accrues should be considered. Capturing highly granular data can become a burden for capture, especially when the data must be specified

each time and the metadata is not consistent. Even if the metadata are set as defaults (e.g., blood pressure in the left arm, seated position, at rest, large adult cuff, manual sphygmomanometer, etc.), the accuracy of those metadata may decrease if the defaults are not diligently adjusted when deviations of data capture methods occur. As a result, highly specific but less accurate data may be transmitted, giving the false sense of validity as opposed to more ambiguous but accurate data being captured. These tradeoffs must be considered when making these determinations.

§ 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:
- a.　　Ambulatory setting**.** Over multiple encounters; or
- b.　　Inpatient setting**.** For the duration of an entire hospitalization.

Preamble FR Citation: 80 FR 16820　　　**Specific questions in preamble?** *No*

Public Comment Field:

No vocabulary standards are sufficient to accommodate all needs currently, so ONC is not establishing a code certification criterion. We suggest that ONC encourage the use of an Object Identifier (OID) registry approach (such as that used in the value set authority at the NLM) for identifying a standard vocabulary if one is used for the purpose of backward compatibility in the future.

§ 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.
a.　　Drug formulary checks.
i.　　Automatically check whether a drug formulary exists for a given patient and medication.
i.　　Indicate for a user the last update of the drug formulary; and
i.　　Receive and incorporate a formulary and benefit file in accordance with the standard specified in § 170.205(n)(1).
b.　　Preferred drug list checks.
.　　Automatically check whether a preferred drug list exists for a given patient and medication.
i.　　Indicate for a user the last update of the preferred drug list.

Preamble FR Citation: 80 FR 16821	Specific questions in preamble? *Yes*

Public Comment Field:

Providing information on when the formulary was last updated is only useful if you know that the last update is the most current one. Better to have a notice that an update is available, which means you need to know the timing of the last update and the date of issue of the most recently available update. A prerequisite for this capability is to require the "structured sig" components of the SCRIPT 10.6 standard, which are currently optional.

§ 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:
   a.   Identify, record, and access patient health information documents;
   b.   Reference and link to patient health information documents; and
   c.   Record and access information directly shared by a patient.

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

Public Comment Field:

Within the context of our general comments:

We concur with the language being used more consistently by the ONC for "person" as the center health, care and wellness, and encourage continued alignment and consistency from the 10-Year Interoperability Roadmap to the Health IT Certification Program language. Our language today remains disease centric and problem focused around episodes of illness; at best, health information is currently "person at the site-centered" rather than person-centered. As we continue to make advances in digitizing the care experience and creating conditions for real-time access to shareable, comparable, holistic, and longitudinal health data, we would expect the label for this criterion also to evolve. We strongly urge ONC to advance the notion that the 2015 Certification Program provides a pivot point to focus on the health of the nation and the opportunity for healthcare information systems to transform the health and well being of individuals, families and communities as we collectively make this shift.

We support new certification criteria for Health IT Modules to have functionality to be able to accept patient health information, including documents such as advance directives and birth plans, which have been generated by the patient or on behalf of the patient and their authorized representatives. These two use cases, with a focus on functionality for identifying health information documents with labels, enabling a user to 1) record (capture and store); 2) access (ability to examine or review) health information documents; 3) access narrative information related to a document's location; and 4) link to external sites via the internet have application across the continuum of care, including LTPAC, in emergency and

first responder settings and among interprofessional care team members -- all with the person at the center. We encourage the ONC to consider how these types of patient health information documents are dynamic and may change over time. How will the functionality of the Health IT Model certification program encourage periodic checks with consumers about the content and location of information, annotate updates, and, over time, support wide-spread adoption of OpenNotes such that each person and associated family system members play an active role to create, modify, and guide the distribution and sharing of their own health record?

We also support new certification criteria for Health IT Modules to have functionality for accepting inbound patient generated health information via a wide range of data sources, including directly from a mobile device. Patient (Person) Generated Health Information (PGHI) is a broad category of health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices and other information—that is created, recorded, gathered or inferred by or from patients or their designees (i.e., care partners or those who assist them). PGHI is distinct from data generated in clinical settings and through encounters with providers, in several ways, including 1) Patients, not providers, are primarily responsible for capturing or recording these data in paper and/or electronic forms; 2) Patients direct the sharing or distributing of these data to recipients of the individual's choosing, which range from caregivers to health care providers and other stakeholders; 3) The data may or may not be integrated into EHRs, PHRs, HIEs, patient portals.

Ongoing consideration by the ONC should acknowledge the rapid growth and expected massive size of this type of health data, through smart phones, remote monitoring devices, apps, sensors, and ubiquitous networks, and the bidirectional nature of data flow for care coordination and shared decision making.

While the ONC has not proposed any standards for these criteria, we acknowledge agreement with the ONC's Interoperability Roadmap statement: "*no widely established policies and practices (for engagement, privacy, security and appropriate use) exist today to define the optimal use of patient generated health data, much less support it.*" We recognize that clinicians in the field are challenged with developing best practices for with incorporating PGHI into daily practice, and time will be needed for pilots and research to develop best practices into clinical workflow and engaging patients with meaningful decision support.

We encourage the ONC to devote additional time to establishing policies, practices and standards for PGHI, in particular how it relates to transitions of care, care planning, shared decision making and social and behavioral determinants of health.

§ 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. <u>Implantable device list.</u>

    a.   Enable a user to record, change, and access, a list of Unique Device Identifiers associated with a patient's Implantable Device(s).

    b.   Parse the following data elements from a Unique Device Identifier:

     i.   Device Identifier;

     ii.   Batch/lot number;

     iii.   Expiration date;

     iv.   Production date; and

     v.   Serial number.

c.   Retrieve the "Device Description" attribute associated with a Unique Device Identifier in the Global Unique Device Identification Database.

d.   For each Unique Device Identifier in a patient's list of implantable devices, enable a user to access the following:

.   The parsed data elements specified under paragraph (a)(20)(ii) of this section that are associated with the UDI; and

i.   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:

Within the context of our general comments above:

We concur with the proposed new 2015 Edition certification criterion focused on the ability of a Health IT Module to record, change, and access a list of unique device identifiers (UDIs) corresponding to a patient's implantable devices ("implantable device list"), parse certain data from a UDI, retrieve the "Device Description" attribute associated with a UDI in the Global Unique Device Identification Database (GUDID), and make accessible to a user both the parsed and retrieved data.

We recognize that the proposed criterion represent a first step towards enabling health IT to facilitate the widespread availability and use of unique device identifiers. It will take additional steps and criteria to prevent device related adverse events, enhance clinical decision-making related to devices, improve the ability of clinicians and patients to respond to device recalls and device-related safety information, and achieve other important benefits consistent with the fundamental aims of the HITECH Act and the HHS Health IT Patient Safety Action and Surveillance Plan.

We encourage the ONC to continue to think broadly about Health IT certification needs for implantable medical devices from the perspectives of the person at the center, the team of care providers accessing and exchanging information across the continuum, and the broader ecosystem. While it is vital for patient safety to able to record, change and access a list of UDIs associated with a patient's Implantable Devices(s), the parsed data relative to the UDI, and the device description attribute associated with the UDI – the more significant and longer-term value relates to integrating other device and patient-generated data -- captured by a provider and/or a patient -- and linking this information to clinical decision support to making adjustments in device settings, symptom control and management, device recalls, and other safety measures.

As other devices (class 2 devices, medical apps, sensors, etc) become more ubiquitous in healthcare, the requirements to both access UDI information and transmit UDI information

with device data will be critical. Without including UDI as part of the network and transmission requirements, it will be challenging to be able to interpret the context of the data, follow the provenance, or support device interoperability.

Implantable medical devices and other new wearable devices and sensors, like traditional clinical medical devices in care settings, will need predictable and reliable functional device interoperability allowing for the exchange of and interaction with data from patient data sources and repositories including EHRs and personal health information tools (e.g., patient portals).

§ 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.

a.	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.

b.	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.

c.	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.

d.	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.

e.	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.

f.	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.

g.	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.

h.	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.

i.	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.

j.	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:

Within the context of our general comments above:

We support the addition of a new 2015 Edition "social, psychological, and behavioral data" certification criterion that would require a Health IT Module to be capable of enabling a user to record, change, and access a patient's social, psychological, and behavioral data based on SNOMED CT® and LOINC® codes. We also support the functionality requirement that would include the ability to record a patient's decision not to provide the information. We concur that this new set of health data and related functionality will assist a wide array of stakeholders (e.g., providers, consumers, payers, community-based organizations, and state and local governments) in better understanding how these data may adversely affect health and also support the person at the center to optimize their capacity for self care, chronic care and healing. We also recognize the collateral benefit the self-reporting of information by individuals in response to the questions included in these social, psychological, and behavioral measures could be utilized for the EHR Incentive Programs Stage 3 objective on patient engagement, including patient-generated health data.
AMIA members have been a part of the recent Institute of Medicine's Committee on Recommended Social and Behavioral Domains and Measures for EHRs, directed by a collection of federal and private sponsors, resulting in Phase 1 and Phase 2 reports by the National Academies Press (2014). Additionally, we call your attention the Advanced Access article published on April 24, 2015 in the Journal of the American Medical Informatics Association, Hripcsak G., et. al., "Informatics to support the IOM Social and Behavioral Domains and Measures," J AM Med Inform Assoc 2015; 0:1-4. The article outlines the informatics research opportunities to incorporate the panel of domains and measures into practice, including: standardization, efficient collection and review, storage, interpretation and reuse, decision support and support for research. While the article and initial body of work focuses on the incorporation of the data into the EHR, direct patient use of the information may be the most important outcome of the initiatives. AMIA's research, policy, clinical practice and translational science interests align well to support the ONC in further developing this body of work. In particular, there is a strong Nursing Informatics Working Group (NIWG) that holds expertise in care planning, coordination and management across the continuum and into community settings, with an interest in furthering this work. In addition to these criterion for certification, there are many implications, uses cases, new workflows, data visualization and clinical decision support tools needed for interprofessional colleagues, patients and families, public health and community organization partners to incorporate this panel of health data and improve a patient's and family's capacity for self-care.
We have one major concern about the approach outlined in the certification criterion. While you acknowledge that the certification criteria are not meant to be comprehensive, the criteria requires the Health IT Module to enable a user to record, change, and access, at a minimum, <u>one</u> of the following patient social, psychological, and behavioral data. The recent work convened by the IOM created a concise, comprehensive and coordinated evidence-based panel of Social and Behavioral Determinants of Health (SBDH) domains and a set of scientifically validated operational measures for each domain. A set of domains, measures

and standardized question and answer sets were created, based on a conceptual framework of inter-related levels of SBDH, rather than individual elements. There is no single element that is more important than the other; it is the interrelationship of the elements, variable over time, that will create the context of longitudinal health for the individual, family and neighborhood. With the goal of consistent collection and use, standardizing this information will improve individual clinical care, prevention, quality improvement, research, public and population health efforts. The set needs to stay as a set, rather than broken apart. "Other than social history that is irregularly and idiosyncratically collected as part of clinical practice, information about these determinants remains largely untapped," (Hripcsak et. al. 2015).

Responses to specific questions:
The appropriate measures have been included for the listed social, psychological, and behavioral data. We agree with the prioritized set of domains and questions, and recognize that for those question-answer sets for specific domains that currently do not have a LOINC® code in place; it is expected that LOINC® codes will be established in a newer version of LOINC® prior to the publication of a subsequent final rule.
There should be standardized questions associated with the collection of sexual orientation and gender identity data (and if so, **what vocabulary standard would be best suited for coded these standardized questions):** We encourage ONC to align with national standards that are emerging and evolving based on ACA, HHS actions, Office of Civil Rights. As we understand, collecting information about Sexual Orientation and Gender Identify (SO-GI) continues to be optional although highly encouraged by HHS, Healthy People 2020 goals, and CDC. HHS has recently tested gender identity demographic questions for the Behavior Risk Factor Surveillance System (BRFSS) Survey in 2013. We also concur with ONC's expressed concern that current privacy and data security standards may not be adequately protective of SO-GI information in electronic records. We do not see this as a valid reason to avoid collecting this data altogether, but rather encourage ONC to develop consumer privacy and online security measures hand-in-hand with the adoption of SO-GI measures in Health IT. We also understand that HRSA has recently commissioned Fenway Health through a cooperative agreement to serve as a National Training and Technical Assistance Center, to support all of HRSA's community health centers on the needs of LGBT persons and populations Education will be needed to support clinicians to understand that Gender Identity and Sexual Orientation are two separate yet related concepts to biologic sex
We should set a minimum number of data measures for certification (e.g., at a minimum: one, 3, or all); and should these measures should be part of one certification criterion or separate certification criteria. We recommend keeping the full set together (all) as one criterion for certification, and set data measures as a minimum for certification. We encourage the ONC to allowing flexibility for local providers to determine how they will integrate the collection and use of the data in their clinical practice, while continue to look for ONC's guidance on policy, privacy and data security standards.

§ 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.
    a. Send and receive via edge protocol. Technology must be able to:
    i. Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d); and
    ii. 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).
    iii. 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.
    b. Validate and display.
        . 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.
        i. 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).
        ii. 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)
    c. Create.
        . 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):
                a. Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified §170.207(a)(4);
                b. Cognitive status;
                c. Functional status;
                d. Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information; and

     e.   <u>Inpatient setting only</u>. Discharge instructions.

    i.   <u>Patient matching data quality</u>. 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. <u>Data.</u> 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. <u>Constraint.</u> 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. <u>Constraint.</u> 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. <u>Constraint.</u> 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. <u>Constraint.</u> 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. <u>Constraint.</u> Represent sex in accordance with the standard adopted at § 170.207(n)(1).

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

Public Comment Field:

Please see our comments on bilateral asynchronous cutover in the general comments section.

§ 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.   <u>Clinical information reconciliation and incorporation.</u>

i.   <u>General requirements.</u> 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.

i.   <u>Correct patient.</u> 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.

i.   <u>Reconciliation.</u> 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:

There are significant constraints and limitations in some current EHR medication reconciliation systems: for medications requiring reconciliation that are complex (e.g., steroid tapers, TPN, patient-controlled analgesia), the source and last modification date of the medication are not adequate for safely and completely reconciling medications during a transition in care. Fully leveraging the information in the SCRIPT 10.6 standard, including structured sig information, would improve the ability reconcile prescriptions that have different dosing frequencies or potencies, (10mg 1 pill twice a day versus 5mg, 2 pills twice a day).

§ 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).

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:
   . Repeating Sig;
   A. Code System;
   B. Sig Free Text String;
   C. Dose;

D.	Dose Calculation;
E.	Vehicle;
F.	Route of Administration;
G.	Site of Administration;
H.	Sig Timing;
I.	Duration;
J.	Maximum Dose Restriction;
K.	Indication; and
L.	Stop.

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

v.   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:

We would recommend including additional transactions to support prior-authorization transactions. Current prior-authorization standards are being establish at a state-by-state level and a national standard would simplify this transaction for prescribers and pharmacists.

§ 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).

ii.   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 relative date or time (e.g., the first of every month);
- A.   A specific date or time (e.g., on 10/24/2015); and
- B.   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:

AMIA agrees that the data portability function should be user-driven and user-friendly and configurable without developer intervention. The ability to export a summary document is a necessary first step, but it is insufficient to support the HIPAA regulations that grant a patient the rights to a copy of their full medical record. We would support the ability of an EHR to export ALL of the patient information under HIPAA in an electronic format. For information that is structured, (i.e., CCDA) that information should be included in a fully structured format. For information that is free-text but unstructured, the data should remain in a computable format, but the CCDA standard for unstructured data. The information should not, however, be converted into PDFs or non-computable formats.

Patients should have the right to their full medical record in a computable format that includes both structured and unstructured data. The CCDA contains templates that include operative notes, H&P, and other document formats found in the electronic record. At not point should information be converted into non-computable formats, but the entire record, not just the care summary record should be available electronically.

§ 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. <u>Data segmentation for privacy – send.</u> 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:

Incomplete information is, indeed, not a new concept within health care. We should not put

the expectation that electronic data are somehow more complete within the certification program for Health IT Modules. We suggest including an indicator when sharing data in instances where a data sharing request is only partially filled because of data sharing restrictions. While this indication that something has been left behind in itself is a form of disclosure, it can then be the provider's opportunity to evaluate where the information shared is sufficient for managing the encounter or condition being addressed or whether they want to enter a dialogue with the patient/caregiver about expanding disclosure for clinical purposes.

§ 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:

Within the context of our general comments:

We concur with ONC's proposed adoption of a new 2015 Edition certification criterion that would reflect a Health IT Module's ability to enable a user to record, change, access, create and receive care plan information in accordance with the "Care Plan document template" in the C-CDA Release 2.0 standard. We recognize the movement forward in calling out that the sharable and exchangeable Care Plan document template is distinct from the "Plan of Care Section" in previous versions of the CCDA. The Care Plan document template represents the synthesis of multiple plans of care (for treatment) for a patient, whereas the Plan of Care Section represented one provider's plan of care (for treatment). To make this distinction clear, the C-CDA Release 2.0 has renamed the previous "Plan of Care Section" as the "Plan of Treatment Section (V2)."

We ask the ONC to be more specific in defining "users" of the care plan, including how patients and authorized family caregivers are included. Care planning is a dynamic and cyclical process of development with patients/family caregivers, establishing mutual goals, identifying interventions that are specific to the patient/family caregiver and professional providers, and establishing targets to evaluate outcome and adherence. The word "update" should be added to the list of verbs the technology should enable, (e.g., the technology must enable a user to record, change, access, create and receive and **update** care plan information…" Patients and authorized agents also should have capacity to designate their sharing preferences with the ability to easily modify these consent preferences over time.

We recognize that moving from one provider's care plan to a synthesis of multiple plans of care will require collaboration, clinical workflow changes, and new decision support tools that scale across the care continuum, including into patient's homes. We encourage the ONC to continue to build on this body of work, including the recent listening session conducted on e-care planning. Novel innovations are needed from Health IT vendors to

support the portability, mobility and continuity of these processes. Like the related body of work with social and behavioral determinants of health, AMIA NIWG members have expertise in care planning, with strong interest in incorporating new models of care planning, patient and family engagement into research and practice. There are linkages between a patient's SBDH profile and their capacity for care plan adherence and achievement of outcomes.

Responses to specific requests for comments:

Whether we should require certain "Sections" that are currently deemed optional as part of the Care Plan document template for certification to this criterion. For example, we invite comment on whether we should require the optional "Health Status Evaluations and Outcomes Section" and "Interventions Section (V2)" as part of certification to this criterion, and if so, for what value/use case. We recommend that these sections are required for Health IT Module certification and optional as implemented in practice settings to meet the needs of diverse care providers, settings and patient needs. Tracking patient adherence to care plans is beneficial and distinct from evaluating outcomes and changes in health status over time. Many groups will benefit from these requirements, including providing flexibility for providers, patient/family caregivers, population health efforts to access and track this kind of feedback information over time.

§ 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
ii.   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):

. Ambulatory setting only. All of the data specified in paragraph (e)(1)(i)(A)(1), (2), (4), and (5) of this section.

i. 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.

. The standard specified in § 170.202(a).

i. 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:

. The standard specified in § 170.202(a).

i. 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.

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

iii. 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. <u>All-request</u>. 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.   <u>Documentation</u>. 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.   <u>Terms of use</u>. 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*

Public Comment Field:

We are encouraged that ONC is giving serious attention to the role of patients and caregivers in accessing their own health information and increasing their engagement in their health. The "view, download and transmit" provisions in the proposed rule provide an essential but not sufficient component for realizing this goal.

As ONC moves into certification for Health IT Modules, a critical component of patient engagement will be the management of the data that patients receive. Though we have seen a strong movement of engaged patients and caregivers and support this movement, relatively few individuals with complex medical conditions that span time or multiple health care delivery settings will be able to successfully consolidate and organize on their own the information that would be delivered through a VDT paradigm as envisioned in this proposed rule. It will be insufficient to establish a marketplace for apps to receive this information; at some level, "view, download and transmit" will need to be expanded to "view, download, transmit, transfer, and manage."

As we indicated in § 170.315(b)(6) Data portability, the patient should have access to their entire medical record, both structured information and unstructured information. While APIs will be helpful in system-to-system connections, APIs often focus only on structured data, and patient will need the capability to move their entire medical record in a computable format from one HIT ecosystem to another. This is not unlike the ability of a person to move a document from the Microsoft Office environment to the Google docs environment (and back again) by downloading the document, and transferring it to another program. For patients who switch providers, this capability is critical to patient safety and quality so that their information is not reduced to scanned images of paper documents.

We believe it will be important that both certified EHRs and more patient-centric, person-controlled personal health record systems that include person-generated health information (PGHI) will ultimately be certified with these capabilities and that certified EHRs will need to be able to receive consolidated data from these data aggregators just as they will be able to receive transition of care summary records. We also anticipate that many patients will choose to have these services performed by their primary care providers or other health

care providers, who will serve as consolidators of their longitudinal health records.

We acknowledge that this view represents a next step in the evolution of health information management and interoperability and will be out of scope for the 2015 Edition. We encourage HHS to invest in standards development and piloting to support the deeper inclusion of patients and caregivers in their own health information.

§ 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*

Public Comment Field:

Within the context of our general comments:

There are positive components of the 2015 Edition proposed rule for certification criteria and we applaud ONC's effort to support this new criteria in the CMS proposed rule. We know that there are pressures on ONC to minimize the addition of new standards and that the rule can be modified in that context.

We believe that case reporting needs can be addressed with standards for which EHRs are already being certified. Most importantly, it is critical that MU advance a case reporting criterion now, whether it does so with the new standards that ONC has proposed or not. The most important needs for case reporting are the orchestration of the steps with EHRs and clinical care and the Meaningful Use incentives that are essential to making that happen. Standards and certification criteria needed for case reporting fall into three general areas of need.

The first component of electronic public health case reporting is the automated initiation of an initial case report from EHRs when an indication of a reportable condition is recorded there. Initial case report data can be sent to public health directly, via health information exchanges and HISPs, and via Electronic Laboratory Reporting (ELR) as the starting point for the case reporting process.

We applaud the references to a C-CDA Transition of Care message as this closely matches the needs for core data required for an initial case report. We believe that an HL7 refinement of C- CDA for this purpose can meet these initial needs and that existing transport mechanisms can be used for conveyance of this initial information to the health

department. All of this, including the use of "trigger codes" for indicating the diagnoses for which a message should be sent, is being currently done for other purposes for certified EHRs.

The use of already available transport modalities for the conveyance of this initial reporting information will ensure that extant capabilities, security, and workflows can be used at a nationwide scale.

The second component of case reporting is for public health to inform clinical care "reporters" that a reportable condition may be present, to share other relevant public health information about that condition and that patient, and when needed, to request the additional information needed to confirm the case and facilitate a complete report. We believe that the same initial case C-CDA can be used, this time being sent from public health to clinical care, with the addition of the reportability status and links to additional information and supplemental data reporting. We note that including a "notice of reportability" that will facilitate supplemental data reporting is an important need for other use cases as well. In particular, when Electronic Laboratory Results (ELR) are received directly by health departments, they usually lack certain critical clinical data, patient demographic information, and even at times the identity of the clinician of record. Making this second step electronic will also serve ELR and other situations and will reduce health department and clinical care reporting burden represented currently by multiple phone calls. Furthermore, by using the C-CDA to communicate from public health to clinical care, public health lab results and other information not previously communicated to clinicians can be shared by health departments.

Importantly, while the notice of reportability will go to the provider of record, the supplemental requests for data will also go to the "reporter" role identified for the clinical care organization. Frequently, an infection control practitioner or other staff person will actually communicate public health reports. By identifying the reporting role, it will act to further reduce clinician burden and manage continuity of reporting when clinicians change coverage.

Over time, when RESTful, FHIR-based approaches are available, tested, and refined, when an approach to securing and encrypting RESTful approaches is widely achieved, and when system-to-system RESTful transactions are supportable by EHRs and public health alike, this too can be an approach for supporting the first two case reporting transactions. Also, over time, there will be alternate ways to ask for supplemental data. Already some will use Health Information Exchange queries as a substitute for this step. Similarly, over time, direct electronic queries can further minimize reporting burden. The third component of case reporting is having a supportable approach for the entry of supplemental case data and emergency data queries. This step should also address for clinical care reporters the issues of when, where, and how to report in order to have the data end up in the appropriate public health surveillance / outbreak management system. The ONC certification NRPM proposes a new, not currently certified, standard they have been working on; Structured Data Capture (SDC), for public health case reporting. The IHE balloted, and the proposed, to be balloted, HL7 FHIR SDC guides both include three different approaches. The "XML" and "HTML" versions are not mature and do not address

all public health needs. The ONC has indicated as much by suggesting only the use of a "URL" approach which we believe to be a reference to the SDC "URI" version and we will reference as "SDC-URI" here.

We applaud the ONC for trying to advance a standard for form entry of data that are needed by others outside of the direct provision of care. The IHE balloted, SDC-URI standard is almost exactly the IHE RFD standard which has been demonstrated in multiple public health contexts and situations. IHE RFD adds capabilities to a simple web URL and would be nice to have for this third step of supplemental data entry in public health case reporting. But we believe that another approach for this step is for direct data entry into public health web systems. As such, the new standard that ONC proposes, SDC-URI, is desirable but not critical.

As in other areas of technology there are different possible implementation approaches. We believe that the loose coupling of three steps mentioned above offer the opportunity to provide the most public health and clinical care flexibility for the variety of different nationwide environments, while minimizing the EHR vendor integration needs. Sending a C-CDA is already a certified EHR activity. The C-CDA core, initial, message will be fixed and invariant across all jurisdictions. Receiving a C-CDA is already a certified EHR activity. And presenting a URL to a clinical care reporter (not usually the clinician of record) is a low burden integration that can work well in the reporter's workflow.
Most importantly, it is critical that case reporting be advanced in Meaningful Use Stage III, whether it is done through existing, or the addition of new, standards.

Pharmacogenomics Data – Request for Comment	
Preamble FR Citation: 80 FR 16869	Specific questions in preamble? *Yes*

Public Comment Field:

AMIA is actively involved in advancing the use of genomic and other "omic" data in care delivery and clinical decision support. There are an increasing number of examples where pharmacogenomic data can be very useful in clinical decision support (CYP2D6 and codeine; TMPT variants and thiopurines; and certain HLA variants for SJS in certain populations are just a few examples). In the absence of reliable drug-genotype interaction information standards for articulating these associations, we believe it would be premature to attempt to set this as a certification criterion. Right now, for most patients, and most hospitals, genomic data does not exist (and if it does, it does not live in the EMR natively).

We believe this is an area where further coordinated federal investment in standards for data documentation and sharing for known genotype-related drug effects would be of value. As discussed in the NPRM, the management of these data will be further enhanced by the development of effective methods for data segmentation.

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:
Please see our general comments above.

Health IT Modules
Preamble FR Citation: 80 FR 16873 **Specific questions in preamble?** *No*
Public Comment Field:
Please see our general comments above.

"Removal" of Meaningful Use Measurement Certification Requirements
Preamble FR Citation: 80 FR 16873 **Specific questions in preamble?** *No*
Public Comment Field:
Please see our general comments above.

Referencing the ONC Health IT Certification Program
Preamble FR Citation: 80 FR 16874 **Specific questions in preamble?** *No*
Public Comment Field:
Please see our general comments above.

"In-the-Field" Surveillance and Maintenance of Certification
Preamble FR Citation: 80 FR 16876 **Specific questions in preamble?** *Yes*
Public Comment Field:
As some have called for, certification should ultimately be on systems "as implemented" rather than "as designed" (at the vendor level). While this is not practical for the initial testing and certification of Health IT Modules and Complete EHRs, "in-the-field" testing of the sort outlined in the proposed rule would help to create a shared responsibility between vendors and implementers to get things right. AMIA encourages ONC to consider applying the Safety Assurance Factors for EHR Resilience (SAFER)[3] guides as foundational tools for evaluating the effectiveness of EHRs as implemented.
ONC will need to provide greater specificity about what the objectives of this surveillance program will be and how testing will be conducted. The program will require specific testing scripts and usability assessments. If not well designed with a meaningful feedback process, this program will be a very expensive exercise that yields little benefit.
As the ONC-Authorized Certification Bodies develop this aspect of their surveillance

[3] http://www.healthit.gov/safer/safer-guides

program, ONC should consider requiring that these evaluations be unannounced (similar to Joint Commission visits).

Complaints Reporting
Preamble FR Citation: 80 FR 16885 **Specific questions in preamble?** *No*

Public Comment Field:

ONC should consider including a certification requirement that Health IT Modules facilitate reporting (perhaps via screen capture and metadata about events) at the time an error is identified by a user. Moreover, systems need better self-monitoring capabilities to detect and allow reporting of problems and variances that might not be recognized by the clinician user, but might be clinically consequential (e.g., a major change in the heparin dose facilitated via a clinical decision support tool or, alternatively, the lack of a major change in the heparin dose if a patient's weight had changed significantly since the last time heparin was dosed). ONC should explore how Health IT Modules could help automate/facilitate completion of AHRQ common format reporting elements.

AMIA appreciates the opportunity to submit these comments. Again, we thank the ONC for issuing this proposed rule, which we anticipate will be revised in timely fashion so that eligible providers and hospitals and technology vendors can prepare their systems to demonstrate meaningful use of EHRs and continue to participate in the Medicare and Medicaid EHR Incentive Program and other programs as they develop. Please feel free to contact me or Dr. Ross Martin, AMIA's Vice President of Policy and Development at ross@amia.org at any time for further discussion of the issues raised here.

Sincerely,

Blackford Middleton, MD, MPH, MSc, FACMI
Chair, AMIA, Board of Directors