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May 7, 2012

Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: 2014 Edition EHR Standards and Certification Criteria Proposed Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave, S.W.
Washington, DC 20201
Via http://www.regulations.gov

Re: Document ID RIN 0991-AB82

Dear Dr. Mostashari:

Thank you for the opportunity to comment on the Notice of Proposed Rule-Making (NPRM) that proposes new and revised certification criteria that would establish the technical capabilities and specify the related standards and implementation specifications that Certified Electronic Health Record (EHR) Technology would need to include to, at a minimum, support the achievement of meaningful use.

The American College of Physicians, representing 132,000 internal medicine physicians and medical student members, believes that the focus on meaningful use is the right way to promote and assess adoption of EHRs. We offer the following comments and recommendations in the interest of improving the implementation of the 2009 HITECH legislation and ensuring that the goals set forth by the legislation are attained expediently without creating unintended consequences.

1. General Comments

Our primary concern is that the changes in requirements may be overwhelming for vendors and the resulting products may be unaffordable for providers. While we believe that most of the features and functions are desirable in the long term, the proposed changes are too ambitious for a single stage. We are worried that this is too much, too fast and will produce a backlash of failure and noncompliance.

The regulatory impact statement proposes that the changes would have less than a $100M/year impact, and therefore fails to qualify for "unfunded mandate" status. While the estimate for the impact on the vendors may be accurate, there is no estimate of the financial impact on providers. Given that vendors will not do anything that is unfunded, the cost, plus profit, will be passed on to providers and the impact for EPs and EHs will be significant.

Another potential impact is the possibility that an EHR vendor or product might be bought, or discontinued. This has happened already leading to additional costs for providers as they have to purchase another certified EHR to qualify for the EHR incentive. Further, there are hardware costs associated with CEHRT implementation and these lead to unpredictable expenses. One senior physician was informed that the server for his EHR was failing and needed to be replaced just 3-5 days after

receiving is incentive payment for Stage 1 Meaningful Use. Estimated cost: $10,200 – much of his incentive payment. There is no recognition or discussion of these financial factors affecting EPs and EHs who are trying to meet MU requirements.

Staging of requirements – The approach throughout Meaningful Use to-date has been for CMS to call for EPs to perform a new function at the same time as ONC is requiring EHR system vendors to add the new functionality to their systems. This commonly results in unanticipated negative consequences where the functionality is incompletely or poorly implemented, with usability challenges that make it difficult for EPs to incorporate the new functionality into existing workflows, or that forces modification of existing workflows to ones that are less efficient. As a general rule, we recommend that EPs should not be expected to demonstrate use of new functions until those functions have been implemented in systems and successfully tested in real-world settings. The current method of concurrent certification and implementation is like writing new software to control an airplane and communicate vital information about its status securely with air traffic control towers, using new standards that are not already broadly in use in the industry but "should be" by 2014, and then setting a deadline for use by hundreds of software vendors and hundreds of thousands of pilots flying a variety of planes with precious cargo on board without first proving the technology and workflows are feasible, broadly implementable and will work for virtually everyone who has reasonable competence and motivation to maintain and fly their aircraft. We do not believe this is reasonable or realistic; such expectations can be expected to result in stakeholder disengagement (lack of willingness to continue to engage in the Meaningful Use program), or inability to succeed even with their best efforts due to factors outside their control. We believe a much more sensible approach would be for ONC-Authorized Certification Bodies (ONC-ACBs) to certify functions as in place and usable for each certified EHR technology at least 2 years ahead of CMS incorporating them into "core" measures for Meaningful Use. Meaningful Use measures should never be based upon "should" statements regarding what will be available at a future date but is not broadly available today. It is difficult enough to adopt established, proven technologies and functions that are already in place, let alone tools and technologies that are not yet established or deployed but that "should" be by 2014.

Another problem caused by the current staging process is that vendors are placed in a position of having to implement functions in advance of fully balloted and tested standards. Just as demonstration of Meaningful Use must wait for mature functionality, mature functionality requires the availability of tested standards.

Care summaries - Each time a care summary is specified in this rule, it appears to be described slightly differently. These differences in requirements will cause unnecessary confusion and disruption throughout the care delivery process as well as risking unintentional failure to meet the "letter of the law" with regard to meeting the Meaningful Use measure. Also, none of the configurations mentioned precisely matches any existing balloted standard or implementation guide. CMS should not call for actions that are not based on approved standards/implementation guides. This will cause document processing to be unnecessarily difficult. In cases where information above and beyond a care summary is required, such as for a discharge summary, a separate document should contain the situation-specific content and an attached standard care summary should be referenced. While it would seem reasonable for problems, medications, and allergies/intolerances to be required in all cases, all other sections of clinical documents should be specified as optional and dependent on the clinical judgment of the sending clinician. Having said that, we agree that all specified sections should be required for certification. It is too early to mandate

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a single structure for a care plan that fits all patient conditions and circumstances. This is an area that needs to evolve slowly over time. Patient decision aids are also not defined adequately. Examples of qualified aids should be included.

Incorporate – We are concerned with the proposed definition of "incorporate." The automatic incorporation of discrete data into patient records presents unacceptable patient safety risks. Incorporation must always include manual oversight of the process.

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2. Specific comment table

§ 170.314(a)(9) - Electronic notes MU Objective **Record electronic notes in patient records.** ***(Not proposed by CMS)*** 2014 Edition EHR Certification Criterion **Electronic notes. Enable a user to electronically record, access, and search electronic notes.**	The limitation to physician, physician assistant or nurse practitioner is problematic. For CQMs much of the information required is present in nursing or medical assistant (MA) documentation (not at the level of Nurse Practitioner). The requirement is too limiting and creates a mismatch with CQM requirements and certification. The result will be either failure of the CQMs because of the excess requirements above and beyond certification, or unstated mandates to incorporate other practitioners. The lack of patient-generated data (verified by EPs or their delegates) is also problematic to represent patient reported outcomes, a key component of CQM expectations. The electronic search capability does not explicitly mention natural language processing (NLP). If that is intended, it should be so stated. To achieve the structured data required for CQMs, especially as designed from retooled measures, will require NLP. We would hope that scanned handwritten figures will be allowed as part of the EHR visit record as long as the most important parts of the visit notes – the problem list, allergies, orders, and medications – are entered as computer-searchable content, which would be the case because of other requirements of this rule. So, we would ask that the requirement for searchability be met by the aforementioned four parts of the visit note, and that care providers could still be allowed to record their narrative observations and their thinking about the patient as scanned handwriting.

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§ 170.314(a)(12) - Imaging MU Objective **Imaging results and information are accessible through Certified EHR Technology.** 2014 Edition EHR Certification Criterion **Imaging. Electronically indicate to a user the availability of a patient's images and/or narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable immediate electronic access to such images and narrative interpretations.** We request public comment regarding whether there are appropriate and necessary standards and implementation specifications for this certification.	The ability to provide immediate electronic access is valuable. That structured results are not part of the certification suggests that: 1. CQMs requiring data from imaging procedures will require natural language processing (NLP) or structured reports. The result is a mismatch with certification requirements leading to concerns for implementation. If NLP is required or allowed [similar to §170.314(a)(9)] the issue may be addressed. 2. CQMs that require structured data from imaging procedures should be removed from the MU2 program. Though we support the use of DICOM for many purposes, we agree that the DICOM standards should not be required for displaying images and their associated narrative (read "text reports").
§ 170.314(a)(13) - Family health history MU Objective **Record patient family health history as structured data.** 2014 Edition EHR Certification Criterion **Family health history. Enable a user to electronically record, change, and access a patient's family health history.** We seek comments on the maturity and breadth of industry adoption of the HL7 Pedigree Standard format for export and import of family health history and the use of SNOMED-CT terms for familial conditions and their inclusion, where appropriate, on a patient's problem list. We also note that the Surgeon General has produced a tool that can capture, save, and mange family health histories using standard vocabularies and can export the data in eXtensible Markup Language (XML) format. We seek comments on the maturity and breadth of	We agree that the inclusion of family history as structured data is valuable for CQMs that require the concept to define data elements. The 090911 HITSC_CQMWG_VTF Transmittal Letter recommended LOINC for assessment instruments for family history and SNOMED-CT for appropriate responses (i.e., specific conditions for which there is a family history). The requirement for documentation should be consistent with this recommendation for CQMs to avoid confusion and separate requirements for CQMs vs. routine clinical care.

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adoption of this tool and its export format.	
§ 170.314(d)(4) – Amendments MU Objective **Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.** *2014 Edition EHR Certification Criterion* ***Amendments.*** **(i) Enable a user to electronically amend a patient's health record to:** **(A) Replace existing information in a way that preserves the original information; and** **(B) Append patient supplied information, in free text or scanned, directly to a patient's health record or by embedding an electronic link to the location of the content of the amendment.** **(ii) Enable a user to electronically append a response to patient supplied information in a patient's health record.** We specifically request comment on whether EHR technology should be required to be capable of appending patient supplied information in both free text and scanned format or only one or these methods to be certified to this proposed certification criteria.	The ability to append patient supplied information should be no different from the ability to append any other ancillary information (outside reports from other providers). Whether providers are required to do so is another matter. EPs could do it at their discretion and could pass excessive costs on to the patient. We can imagine scenarios where the inclusion of material supplied by a patient would be inappropriate. For the purposes of display of patient-entered data in an office note, only the information verified by the EP or other authorized healthcare professional should be visible in the note, although the patient-entered data should be preserved and retrievable from the database. We support a requirement for EHR technology to be capable of appending patient supplied information in both free text and scanned format.
§ 170.314(e)(1) - View, download, and transmit to 3rd party MU Objective **EPs** **Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.** **EHs and CAHs** **Provide patients the ability to view online, download, and transmit information**	We support the decision to specify a single standard (Consolidated CDA) for all clinical document content. We believe that this will greatly facilitate adoption and use throughout the healthcare system. See general comment on **Care summaries**. The 090911 HITSC_CQMWG_VTF Transmittal Letter listed preferred language for CQMs as: ISO 639-2 constrained to elements in ISO 639-1 for Patient's

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about a hospital admission. 2014 Edition EHR Certification Criterion **View, download, and transmit to 3rd party.** **(i) Enable a user to provide patients (and their authorized representatives) with online access to do all of the following:** **(A) View. Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data elements:** ***(1)* Patient name; gender; date of birth; race; ethnicity; preferred language; smoking status; problem list; medication list; medication allergy list; procedures; vital signs; laboratory tests and values/results; provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; and care plan, including goals and instructions.** ***(2)* Inpatient setting only. Admission and discharge dates and locations; reason(s) for hospitalization; names of providers of care during hospitalization; laboratory tests and values/results (available at time of discharge); and discharge instructions for patient.** **(B) Download. Electronically download:** ***(1)* A file in human readable format that includes, at a minimum:** ***(i)* Ambulatory setting only. All of the data elements specified in paragraph (e)(1)(i)(A)(1).** ***(ii)* Inpatient setting only. All of the data elements specified in paragraphs (e)(1)(i)(A)(1) and (e)(1)(i)(A)(2).** ***(2)* A summary care record formatted according to the standards adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):** ***(i)* Patient name; gender; date of birth; medication allergies; vital signs; the provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions;**	Preferred Language. This is a more specific constraint than listed in the NPRM. § 170.207(l) (smoking status types) should be aligned with CQM requirements. Note that the transmittal letter selected more expansive value set for race and for ethnicity than § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity) – this represents a mismatch in standards for CQMs and routine clinical care. The OMB set is a smaller set of codes already included in those CDC / HL7 sets recommended for CQMs. Therefore, a recommendation is important to indicate OMB code compliance will be sufficient for CQMs. However, if the larger set is required, a change to the OMB recommendation is in order. "For encounter diagnoses and procedures, we propose the use of ICD-10 (ICD-10-CM and ICD-10-PCS, respectively)." The Transmittal Letter referenced above was used by Measure Developers to define CQMs for Meaningful Use Stage 2 – Problems (diagnoses) were recommended in SNOMED-CT and Procedures in SNOMED-CT. The reason was to accommodate all encounters, not only those that generate a billing transaction (e.g., interactions by email, telephone, and other means). Similarly, procedures need to address counseling, education and specific interventions that are also not managed with billing vocabularies. This discrepancy is a significant mismatch of standard use by EHRs for routine interoperability and CQMs (as well as for clinical decision support which uses the same value sets as CQMs). The work performed under HHS contracts for CQMs for 2014 is nearly completed and the recommendations in the NPRM for certification are misaligned with that process. It is recommended that

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(ii) **Race and ethnicity. The standard specified in § 170.207(f);** ***(iii)*** **Preferred language. The standard specified in § 170.207(j);** ***(iv)*** **Smoking status. The standard specified in § 170.207(l);** ***(v)*** **Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);** ***(vi)*** **Encounter diagnoses. The standard specified in § 170.207(m);** ***(vii)*** **Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);** ***(viii)*** **Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);** ***(ix)*** **Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed;** ***(x)*** **Medications. At a minimum, the version of the standard specified in § 170.207(h); and** ***(xi)*** **Inpatient setting only. The data elements specified in paragraph (e)(1)(i)(A)(2).** ***(3)*** **Images formatted according to the standard adopted at § 170.205(j).** **(C) Transmit to third party. Electronically transmit the summary care record created in paragraph (e)(1)(i)(B)(2) or images available to download in paragraph (e)(1)(i)(B)(3) in accordance with:** ***(1)*** **The standard specified in § 170.202(a)(1); and** ***(2)*** **The standard specified in § 170.202(a)(2).** **(ii) Patient accessible 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)-(C), the following information must be recorded and made accessible to the patient:** ***(1)*** **The electronic health information affected by the action(s);** ***(2)*** **The date and time each action occurs in accordance with the standard specified at § 170.210(g);** ***(3)*** **The action(s) that occurred; and** ***(4)*** **User identification.** (B) **EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) if it is also certified to the certification criterion adopted at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.** Standard(s) and Implementation Specifications	management of encounter diagnoses and procedures be aligned in the Final Rule with the need for quality data for reporting, measurement and clinical decision support (including Info-Button access to information). The specified Web Content Accessibility Guidelines (WCAG) are too complex and expensive for a small practice to implement and support. This section requires "that the user's identification, the user's actions, and the health information viewed, downloaded or transmitted", be logged. The log itself is reasonable. Some clarification of the details would be helpful. Can anyone but the patient and the employees of the care organization use this delivery mechanism? It would be helpful to understand exactly who could be a "user". Is this logging intended to be applied to all users of the EHR or just users of this delivery system? How do you envision logging the users' identifier in a way that the patient would know who that user was? Would just an ID do? Or will it require a name? Or a role in the institution? At present this aspect is very unclear. When you describe the action, it is not clear what choices of action are possible. Just view, transmit, and download? If so, please make that explicit. When you say it should log the health information viewed, that gets tricky. When a user is viewing a web page, one can never be sure what he/she actually saw, but only what they might have seen. How detailed do you expect the recording of information (a description of what was queried e.g. "all labs for the last 2 years") or do you expect a copy of all of the data displayed in the web page to be copied into the log? The latter requirement could be very burdensome in terms of storage requirements. The XML Continuity of Care document can be

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§ 170.204(a) (Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance); § 170.205(a)(3) (Consolidated CDA); § 170.205(j) (DICOM PS 3—2011); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); § 170.202(a)(1) (Applicability Statement for Secure Health Transport) and § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.210(g) (synchronized clocks). For example, we welcome comment on, and will consider moving from, the use of object identifiers (OIDs) to uniform resource identifiers (URIs).	huge. Has the amount of storage needed been estimated? How long would organizations be expected to save the log information? We support the availability of DICOM capability but not to the exclusion of simpler mechanisms for delivering images e.g. images as JPEGs, as JPEGs or TIFFs within Word documents or PDFs, and the way they are often delivered to doctors at present. No one can disagree with the idea of giving every patient access to his/her data. And adherence to some of the WCAG 2.0 criteria -- including the ones mentioned in the NPRM (i.e. appropriate contrast ratios and ability to resize to 200%) is quite easy and should be required. But the requirements for interfacing to independent accessibility tools (also required by WCAG 2.0), such as those that read screen text aloud can be impossible to achieve for snappy and intelligent JavaScript-dependent applications. This is due to the lack of tight standards for the interaction between browsers and the accessibility tools as admitted in the NPRM ("We are interested in whether commenters believe additional standards are needed for certification to insure accessibility… such as UAAG which is …currently only in draft form"). We know of a developer who invested more than $150,000 and finally gave up trying to interface its sophisticated web page to a popular accessibility tool, because of conflicts that would cause the browser and/or the accessibility tool to crash or freeze. The only way at present to make sophisticated web browsers work well with screen readers is to write a completely separate and "dumbed-down" interface that does not use JavaScript -- this means duplicative and expensive work for EHR and website programmers and developers. Therefore, in response to the NPDM question, we do not think it is

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	reasonable to require support for screen readers and other accessibility tools until the specifications for the interaction between screen readers and browsers (UAAG) is completed and the screen readers and the browsers have adopted them successfully. Otherwise, such support requirements will either force large expenses on EHR developers that they will pass on to providers, and/or slow the progress toward fast and easy-to-use interfaces. So please delay the requirement for support of accessibility tools until the appropriate standards are in place and working. **Care summaries** - Each time a care summary is specified in this rule, it is described slightly differently. These differences in section requirements will cause unnecessary confusion and disruption throughout the care delivery process. Also, none of the configurations mentioned precisely matches any existing balloted standard or implementation guide. This will cause document processing to be unnecessarily difficult. In cases where information above and beyond a care summary is required, such as for a discharge summary, a separate document should contain the situation-specific content and an attached standard care summary should be referenced. While it would seem reasonable for problems, medications, and allergies/intolerances to be required in all cases, all other sections of clinical documents should be specified as optional and dependent on the clinical judgment of the sending clinician. All specified sections should be required for certification, however. It is too early to mandate a structure for a care plan. This is an area that needs to evolve slowly over time. Patient decision aids are not defined adequately.

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§ 170.314(e)(3) - Secure messaging MU Objective **Use secure electronic messaging to communicate with patients on relevant health information.** 2014 Edition EHR Certification Criterion **Ambulatory setting only – secure messaging. Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:** **(i) Both the patient and EHR technology are authenticated; and** **(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).** Standard **§ 170.210(f) Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2.**	Some measures address communication from the provider to the patient (for purposes of education, care plan communication or other health record components). This mechanism might be best coordinated for CQMs as well. The 090911 HITSC_CQMWG_VTF Transmittal Letter recommended only SNOMED-CT.
§ 170.314(f)(7) - Cancer case information; and (f)(8) - Transmission to cancer registries MU Objective **Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice.**	The proposal for the criterion focused on the data capture is beneficial in that HL7 CDA, Release 2 can accommodate most of the data required for cancer registries, and also for other secondary uses, such as quality measurement and other types of reporting. SNOMED-CT and LOINC are also valuable for much of the required content, but the context of data is not necessarily included in these code systems. There are also data requirements (e.g., medications) which will require RxNorm, allergy data (medication in RxNorm, reaction in SNOMED-CT), procedures performed and

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2014 Edition EHR Certification Criteria (f)(7) **Ambulatory setting only – cancer case information. Enable a user to electronically record, change, and access cancer case information.** (f)(8) **(f)(8) Ambulatory setting only – transmission to cancer registries. Enable a user to electronically create cancer case information for electronic transmission in accordance with:** **(i) The standard (and applicable implementation specifications) specified in § 170.205(i); and** **(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and § 170.207(g).** Standards and Implementation Specifications **§ 170.205(i) (HL7 CDA, Release 2 and Implementation Guide for Healthcare Provider Reporting to Central Cancer Registries, Draft, February 2012); § 170.207(a)(3) (SNOMED CT® International Release January 2012); and § 170.207(g) (LOINC version 2.38).**	patient characteristics to which other sections of this report refer. CDA also limits the metadata about provenance. As cancer registries expand their data requirements with the new, potentially rich, source of electronic data from EHRs, there will be an increasingly significant requirement to know the source of each data element. For example, similar to measures of patient reported outcomes, the functional status captured directly from the patient or the patient's caregiver needs to maintain the patient as the source and recorder of the information. CDA limits provenance only to the individual sending the CDA document; it does not allow specification of provenance at the data level. Such provenance is also required for evaluating the relevance of each data element; e.g., is the pathology report from the Pathologist or subsequently entered by a different clinician?
§ 170.314(a)(2) (Drug-drug, drug-allergy interaction checks) [Ambulatory] MU Objective **Implement drug-drug and drug-allergy interaction checks.** 2014 Edition EHR Certification Criteria **Drug-drug, drug-allergy interaction checks.** **(i) Interventions. Before a medication order is placed during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user at the point of care of drug-drug and drug-allergy contraindications based on medication list and medication allergy list.** **(ii) Adjustments.** **(A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.** **(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.**	The objective is valuable. The certification should recommend specific code systems that should be used to accomplish such checking --- e.g., similar language to the final rule for MU Stage 1, a medication terminology that can be derived from RxNorm in the NLM UMLS – and for allergy, the same for the drug to which the patient is allergic, SNOMED-CT for the type of allergy. That would be consistent with requirements for secondary data use such as CQMs. See 090911 HITSC_CQMWG_VTF Transmittal Letter recommendations.

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Preamble FR Citation: **77 FR 13846**	**Specific questions in preamble?** *No*

§ 170.314(a)(3) - Demographics MU Objective **Record the following demographics: preferred language; gender; race; ethnicity; date of birth; and for the inpatient setting only, date and preliminary cause of death in the event of mortality in the EH or CAH.** 2014 Edition EHR Certification Criterion **Demographics.** **(i) Enable a user to electronically record, change, and access patient demographic data including preferred language, gender, race, ethnicity, and date of birth.** **(A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.** **(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(j) and whether a patient declines to specify a preferred language.** **(ii) Inpatient setting only. Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality in accordance with the standard specified in § 170.207(k).** Standards **§ 170.207(f)(OMB standards); § 170.207(j) (ISO 639-1:2002); and § 170.207(k) (ICD-10-CM).**	We urge ONC and CMS to select SNOMED for all relevant clinical data coding. For preferred language, the 090911 HITSC_CQMWG_VTF Transmittal Letter recommendations specifically noted ISO 639-2 constrained to elements in ISO 639-1 for Patient's Preferred Language. The reason is that 639-1 includes only active languages, 639-2 includes languages no longer in use. The statement in the NPRM seems contrary to the recommendation. For cause of death, the cause may be identified in clinical terms as the diagnosis active at the time of death that caused the death. From the 090911 HITSC_CQMWG_VTF Transmittal Letter recommendations, SNOMED-CT is specified for conditions, diagnoses and problems. As interim code systems, ICD-9 CM and ICD-10 CM were discussed during HITSC meetings with agreement by the Committee. Requiring different code systems for CQMs, other reporting requirements and routine clinical care will lead to confusion and excessive documentation efforts.

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§ 170.314(a)(5) - Problem list MU Objective **Maintain an up-to-date problem list of current and active diagnoses.** 2014 Edition EHR Certification Criterion **Problem list. Enable a user to electronically record, change, and access a patient's problem list for longitudinal care in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).** Standards **§ 170.207(a)(3)(SNOMED CT® International Release January 2012).** We welcome comments on our interpretation of longitudinal care. We also welcome comments on whether a term other than "longitudinal care" could and should be used to express the capability required by this certification criterion and the other referenced certification criterion ("medication list" and "medication allergy list").	We urge ONC and CMS to select SNOMED for all relevant clinical data coding. HHS should take responsibility for creating, maintaining, and publishing any cross-mappings with other vocabularies required for reporting purposes. We do not support requiring the use of an extra field for SNOMED-CT codes. For the purpose of this rule, Problem List management could be limited to a short period of time (multiple office visits, a single hospitalization), but that does not represent longitudinal care. A different term should be chosen to avoid confusing the industry. More importantly, there is limited value for a Problem List without management over a longer term. Actually, longitudinal care is the appropriate term – the definition should not be modified to accommodate a confusing standard. If necessary, an alternative is to specify that Problem Lists are maintained up-to-date within venues of care (e.g., Ambulatory care across visits, OR hospital inpatient care constrained within a single hospitalization). The issue of Problem List use across hospitalizations is noted. However, the Final Rule should require the reconciliation of Problem Lists as another relevant clinical component of updating clinical information. It is specifically left out of that recommendation. A requirement to reconcile Problem Lists at transitions of care will significantly improve care coordination and enable updated and more complete Problem Lists to be used for clinical care, clinical decision support, effective reporting to Public Health and other agencies and for CQMs. CQMs rely on an active list of medical and clinical problems for evaluation of criteria in measure denominators and numerators. A mismatch in

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	requirements between CQMs and routine clinical care will cause significant confusion. The code system required for CQMs by the 090911 HITSC_CQMWG_VTF Transmittal Letter recommendations is SNOMED-CT. Alternatively, ICD-9-CM or ICD-10-CM was allowed for the interim in subsequent HITSC meetings. It is reasonable to restrict to SNOMED-CT alone.
§ 170.314(a)(8) - Clinical decision support *MU Objective* **Use clinical decision support to improve performance on high-priority health conditions.** 2014 Edition EHR Certification Criterion **Clinical decision support.** **(i) Evidence-based decision support interventions. Enable a user to select (or activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in each one or any combination of the following:** **(A) Problem list;** **(B) Medication list;** **(C) Medication allergy list;** **(D) Demographics;** **(E) Laboratory tests and values/results; and** **(F) Vital signs.** **(ii) Linked referential clinical decision support.** **(A) Enable a user to retrieve diagnostic or therapeutic reference information in accordance with the standard specified at § 170.204(b)(1).** **(B) Enable a user to access the reference information specified in paragraph (ii)(A) relevant to patient context based on the data elements included in each one or any combination of the following:** **(*1*) Problem list;**	We support the specification of Infobutton for this purpose. However, the Context-Aware Knowledge Retrieval standard, Normative Edition, by itself, is not implementable. It can be implemented in conjunction with either of two available implementation guides – the URL-based Implementation guide, and/or the SOA-based Implementation Guide. We recommend that the certification criteria require EHRs to implement either of these implementation guides. The CDS criterion specifies decision support interventions, a valuable requirement. Specifically, a standard code system is required to implement the expected requirement, "that EHR technology enable interventions to be triggered when the specified data elements are incorporated into a summary care record pursuant to the capability specified at § 170.314(b)(1) (transitions of care – incorporate summary care record)." Value sets of information derived from or analogous to those in CQMs will be needed to implement this requirement. Thus, a standard code system to represent the data will be needed. The code systems should be specified for types of data as they are for CQMs. These should be aligned with the 090911 HITSC_CQMWG_VTF Transmittal Letter recommendations.

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(*2*) Medication list; **(*3*) Medication allergy list;** **(*4*) Demographics;** **(*5*) Laboratory tests and values/results; and** **(*6*) Vital signs.** **(iii) <u>Configure clinical decision support</u>.** **(A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) to be configured by an identified set of users (e.g., system administrator) based on each one of the following:** **(*1*) A user's role;** **(*2*) Clinical setting; and** **(*3*) Identified points in the clinical workflow.** **(B) Enable interventions to be triggered, based on the data elements specified in paragraph (a)(8)(i), when a summary record is incorporated pursuant to § 170.314(b)(1).** **(iv) <u>Automatically and electronically interact</u>. Interventions selected and configured in accordance with paragraphs (a)(8)(i)-(iii) must automatically and electronically occur when a user is interacting with EHR technology.** **(v) <u>Source attributes</u>. Enable a user to review the attributes for each intervention or reference source for all clinical decision support resources including:** **(A) Bibliographic citation (clinical research/guideline) including publication;** **(B) Developer of the intervention (translation from clinical research/guideline);** **(C) Funding source of the intervention development technical implementation; and** **(D) Release and, if applicable, revision date of the intervention.** Standards **§ 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval ("Infobutton")**	

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Standard, International Normative Edition 2010). We request comment on industry readiness to adopt this standard and on the benefits it could provide if required as a part of this certification criterion.	
§ 170.314(a)(16) - Patient-specific education resources MU Objective **Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.** 2014 Edition EHR Certification Criterion **Patient-specific education resources. Enable a user to electronically identify and provide patient-specific education resources according to:** **(i) At a minimum, each one of the data elements included in the patient's: problem list; medication list; and laboratory tests and values/results; and** **(ii) The standard specified at § 170.204(b)(1).** Standard **§ 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard, International Normative Edition 2010).**	This modification is valuable as it more clearly defines patient resources and that they should derive from reliable knowledge sources. Some issues should be identified: 1. The patient-specific resources must be in language that the patient can understand and be provided in the patient's preferred language when available. 2. The patient-specific resources can be construed to mean individualized educational resources. Determination of individualization will be too complex to define for the 2014 Rule and specific language should indicate that it is out of scope.

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§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record MU Objective **The EP, EH, or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.** 2014 Edition EHR Certification Criteria **(1) <u>Transitions of care – incorporate summary care record</u>. Upon receipt of a summary care record formatted according to the standard adopted at § 170.205(a)(3), electronically incorporate, at a minimum, the following data elements: Patient name; gender; race; ethnicity; preferred language; date of birth; smoking status; vital signs; medications; medication allergies; problems; procedures; laboratory tests and values/results; the referring or transitioning provider's name and contact information; hospital admission and discharge dates and locations; discharge instructions; reason(s) for hospitalization; care plan, including goals and instructions; names of providers of care during hospitalization; and names and contact information of any additional known care team members beyond the referring or transitioning provider and the receiving provider.** **(2)<u>Transitions of care – create and transmit summary care record</u>.** (i) **Enable a user to electronically create a summary care record formatted according to the standard adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):** **(A) Patient name; gender; date of birth; medication allergies; vital signs; laboratory tests and values/results; the referring or transitioning provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning**	We support the decision to specify a single standard (Consolidated CDA) for all clinical document content. We believe that this will greatly facilitate adoption and use throughout the healthcare system. See general comment on **Care summaries**. The 090911 HITSC_CQMWG_VTF Transmittal Letter listed preferred language for CQMs as: ISO 639-2 constrained to elements in ISO 639-1 for Patient's Preferred Language. This is a more specific constraint than listed in the NPRM. § 170.207(l) (smoking status types) should be aligned with CQM requirements. Note that the transmittal letter selected more expansive value set for race and for ethnicity than § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity) – this represents a mismatch in standards for CQMs and routine clinical care. The OMB set is a smaller set of codes already included in those CDC / HL7 sets recommended for CQMs. Therefore, a recommendation is important to indicate OMB code compliance will be sufficient for CQMs. However, if the larger set is required, a change to the OMB recommendation is in order.

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provider and the receiving provider; care plan, including goals and instructions;

(B) Race and ethnicity. The standard specified in § 170.207(f);

(C) Preferred language. The standard specified in § 170.207(j);

(D) Smoking status. The standard specified in § 170.207(1);

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

(F) Encounter diagnoses. The standard specified in § 170.207(m);

(G) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);

(H) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);

(I) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed;

(J) Medications. At a minimum, the version of the standard specified in § 170.207(h); and

(K) Inpatient setting only. Hospital admission and discharge dates and location; names of providers of care during hospitalizations; discharge instructions; and reason(s) for hospitalization.

(ii) **Transmit. Enable a user to electronically transmit the summary care record created in paragraph (i) in accordance with:**

(A) The standards specified in § 170.202(a)(1) and (2).

(B) Optional. The standard specified in § 170.202(a)(3).

Standards

§ 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); and § 170.202(a)(1) (Applicability Statement for Secure Health Transport); § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.202(a)(3) (SOAP-Based Secure Transport RTM version 1.0).

We request public comment on whether in the final rule we should create separate

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<table>
<tr><td>certification criteria for all of these data elements.</td><td></td></tr>
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<tr><td>§ 170.314(b)(4) - Clinical information reconciliation</td></tr>
<tr><td>MU Objective
The EP, EH, or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.</td></tr>
<tr><td>2014 Edition EHR Certification Criterion
<u>Clinical information reconciliation</u>. Enable a user to electronically reconcile the data elements that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:
(i) Electronically display the data elements from two or more sources in a manner that allows a user to view the data elements and their attributes, which must include, at a minimum, the source and last modification date.
(ii) Enable a user to merge and remove individual data elements.
(iii) Enable a user to review and validate the accuracy of a final set of data elements and, upon a user's confirmation, automatically update the list.</td></tr>
</table>
Finally, we request public comment on whether as part of this certification criterion we should require EHR technology to perform some type of demographic matching or verification between the data sources used. This would help prevent two different patients' clinical information from being reconciled. We propose to adopt this revised criteria.
</td><td>In general, reconciliation of clinical information, including patient demographics, is essential to care coordination. The addition of allergy lists and problem lists to the previously indicated medication list is applauded ("We now propose to revise this certification criterion and adopt as part of the 2014 Edition EHR certification criteria an expanded version that focuses on the reconciliation of data elements in each of a patient's medication, problem, and medication allergy lists.") A comment that reconciliation of other clinical information, including patient demographics, would be helpful.

However, as we have also noted in our comments to the CMS Proposed Rule for Stage 2 Meaningful Use, there are challenges to Problem List and Allergy List reconciliation that are at least as great as those for medication reconciliation. We are concerned that the definition of the active medication list as "a list of medications that a given patient is currently taking" and reconciling to only that definition could yield a medication list that is inaccurate and hide noncompliance that should be addressed. Patients frequently do not remember the names of medications they are taking, an issue contributed to by complex and counterintuitive medication names that are frequently advertised as brand names but prescribed as generics. If a medication list must be reconciled to a list of medications that a patient is currently taking, there are challenges to knowing what to do if a patient isn't sure about a specific medication, if they take it as needed are not taking it currently, or know they should be taking it but are currently noncompliant. In busy offices (particularly</td></tr>
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	subspecialty offices based on our reports), staff who room patients either compare the existing list with a list the patient brings in (which may or may not be accurate) and reconciles to that list. Alternatively they may had the patient the list of what the office currently has recorded and asks the patient to make any corrections (which certainly not all patients can do accurately), and then summarily deletes those the patient indicates he/she is not taking without further inquiry. Removing a medication that a patient reports he/she is not taking may not only be inaccurate but also ill-advised, with the appropriate action not being to remove the medication from the list but rather to note that the patient is not taking the medication and to communicate this information to the prescribing physician so appropriate action can be taken. Our members report important errors affecting patient safety resulting from the assumption that the list must exactly match what 1) the patient reports he/she is taking, 2) appears in a discharge summary, 3) what is listed on a clinical summary from a different office or 4) is listed on a well-worn piece of paper the patient keeps in his/her wallet or purse. We are also concerned that the definition of an up-to-date problem list as "a list populated with the most recent diagnoses known by the EP or hospital" as risking the removal of problems that are current and important but do not meet an EP's intuitive definition of "most recent known by the EP" such that a 20-year history of diabetes is removed because it is not recent enough and a diagnosis of asthma is removed because the EP caring for them today doesn't see any evidence of it. There is also less agreement about what belongs on a problem list, such as "History of Breast Cancer" or "Status post cholecystectomy" or "Family History of Prostate Cancer" that raise further questions about what constitutes a "problem" vs. a family history element or past medical/surgery

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	item. Reasonable physicians disagree on this issue and without clarification about what can be included we risk inaccuracies and documenting at crossed purposes. Finally, allergy lists are often used by EHR vendors and EPs to record intolerances that are not true allergies and patients often have very vague and inaccurate recollections of what they are "allergic" to, making it harder to reconcile to the point where there is a clear sense that the list is accurate, complete and up-to-date. The standards and certification criteria need to account for all of these issues.
§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting MU Objective **N/A** 2014 Edition EHR Certification Criteria **(1) Clinical quality measures – capture and export.** **(i) Capture. Electronically record all of the data elements that are represented in the standard specified in § 170.204(c).** **(ii) Export. Electronically export a data file that includes all of the data elements that are represented in the standard specified in § 170.204(c).** **(2) Clinical quality measures – incorporate and calculate.** **(i) Incorporate. Electronically incorporate all of the data elements necessary to calculate each of the clinical quality measures included in the EHR technology.** **(ii) Calculate. Electronically calculate each clinical quality measure that is included in the EHR technology.** **(3) Clinical quality measures – reporting. Enable a user to electronically create for transmission clinical quality measurement results in a data file defined by CMS.**	Alternative Data Capture Certification Options Considered There are several options that are workable. We would discourage two of these - Explicit Certification Criteria and Explicit Data Capture List. These options will lead to "building to the regulations" rather than building to what is right for patient care. The 090911 HITSC_CQMWG_VTF Transmittal Letter recommended code systems (vocabularies) to represent categories of information in CQMs as defined by the Quality Data model (QDM). The rest of the requirements for vocabularies are not consistent with those recommendations. Inconsistent requirement will generate confusion and extra work effort for implementations and increased clinical workflow unnecessarily. Many of the requirements for certification ignore the needs for a data-driven approach to meaningful use. True meaning is achieved by defining the data standards and using them consistently for routine care, interoperability, clinical decision support, public health reporting, and CQMs. The data are the common elements for all of these uses. In this and prior rules, CQMs are addressed as separate entities with separate workflows. It is not the QDM that

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Standard **§ 170.204(c) (NQF Quality Data Model).** ***Alternative Data Capture Certification Options Considered*** We recognize that the gap between the data defined by the QDM and the data traditionally captured in EHR technology is, in some areas, broad and we request comments regarding (1) Industry readiness for the expansion of EHR technology data capture; (2) how this would impact system quality, usability, safety, and workflow; and (3) how long the industry believes it would take to close this gap."	generates disconnects with data capture and analysis, it is the lack of a data-driven approach to information in the EHRs. Where standards are not ready or standards requirements are overly burdensome, it is reasonable to limit the information sought for calculating quality measures and implementing clinical decision support. That decision, however, is not an inherent data (or QDM) issue, it is one of practicality and feasibility given the existing or expected state of the market. Retooling measures implies that the content and intent of the measures as written is appropriate for any data platform. In many cases, the measures being retooled were written for different data platforms and different implementation workflows. The experience to-date confirms that data platform issues must be addressed in the development and testing of measures. As an example, many hospital measures require that the defining diagnosis for the denominator must be the principal diagnosis resulting in hospitalization. Principal diagnosis uses a concept "ordinality" to define principal vs. secondary, etc. It is defined by payment definitions but it is not necessarily a clinical concept used today by EHRs. Similarly, information available to highly trained clinicians who abstract hospital records cannot be clearly defined within EHRs without significant complex logic and requirements for structured data. This is especially true for information gleaned from progress notes and other clinical unstructured text. In the ambulatory environment, measures designed for reporting by physicians at the time of a bill using specifically defined codes (usually CPT-II codes) do not translate easily. A CPT-II code can be analogous to the inpatient abstraction process since the physician decides the patients to report and whether an intervention (e.g., counseling) is performed. There is no analogous standard structured method for defining such concepts in EHRs as routine documentation. Therefore, the measures for MU Stage 2 should be defined specifically for EHRs

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	as they are expected to function in 2014, and not retooled measures designed for other platforms. The QDM was designed to address information required for measures. It provides a generally comprehensive method to describe information that may be needed for quality measures. Similar to a dictionary that can be used to find words and synonyms to write a Pulitzer Prize winning novel or one that is poorly written, using the QDM requires education. Measure developers are new to the EHR specification process and most are grounded in the abstraction or claims-based world of data. Measures for MU Stage II should be developed using the QDM to help with consistency of data expression. However, those measures chosen should address only the information that is structured in EHRs in a standard manner consistent with the MU Stage 2 Rule certification. Thus, certification needs to address the issues required for the measures desired. **Examples:** 1. The vocabularies should align with what measures developers have been provided to express their measures. The current NPRM took a different approach and addressed vocabularies only for the interoperability use case. CQMs were considered separate entities. Such a path leads to confusion and complaints. 2. Requirements for certification may be limited due to market readiness, e.g., the requirement to incorporate image viewing via EHRs using DICOM does not include the use of structured results. Thus, CQMs for MU Stage 2 should not address structured image results. If the CQM cannot be expressed using alternate data, it should be removed from the program. That does not make the CQM unusable; it will, however, require a

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	hybrid methodology to implement it. 3. Some CQMs require the source and recorder of the data elements. If provenance of data elements is not addressed in the Final Rule for Certification, it will create an undue burden to expect implementation of such measures. Such provenance is required for some patient-centered outcome measures as well as some behavioral health measures now being evaluated for MU Stage 2. 4. Procedures and interactions (encounters) with providers that are not billable are often used in CQMs. The NPRM for certification should address such procedures and interactions (encounters), including the vocabularies used for them, to avoid excess effort to implement the measures. This issue is not a QDM issue, it is a programmatic one. 5. Including problem list, allergy list and medication list reconciliation will significantly help CQM implementation since if correctly defined, implemented and reconciled in EHR systems the data will be more reliable and can be trusted to manage the content required for CQMs. However, the patient's experience with problems (i.e., inactive or resolved ones, or even ones like Depression or Erectile Dysfunction that they disagree with or do not want "published" to their Problem List for all to see), medications (i.e., prior medications) and allergies (i.e., type of allergy) is not consistently managed; the CQM value is significantly decreased. That is because the detail required to define a specific element does not have the filter of a human brain to evaluate if criteria are met. Only the EHR representation of the data element can be relied upon in an eMeasure to determine its value.

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	Omissions: 1) A key component of many CQMs is the ability to display and capture data in a smart format, storing the data as a calculated observation (e.g., PHQ-9 or SF-36 score). That function is essential for functional status and risk assessments. The Transmittal Letter mentioned in the document addressed such function, allowing for LOINC for the forms and their questions, SNOMED-CT for the answers unless they are numerical. And as with other data, provenance at the data level is important. 2) Many measures look for a care plan, i.e., linked conditions, interventions and GOALS and outcomes. If these aren't required many measures will fail. That is not a QDM question. It is a timing issue when ONC believes it can deliver on the requirement. 3) It is critical that EHR systems support the automated collection of data from all sources, including from patients, nurses, other care providers, and other systems. Quality measurement should not be dependent on the direct entry of data by EPs. At the same time, building such functionality into CEHRT that currently lacks it could be prohibitively expensive for EPs, EHs or CAHs to implement. **Recommendation:** The NPRM lists the QDM and its calculations as the issue to be considered and, perhaps, tested for certification. It is recommended that, instead, the essential requirements for certification listed in the final rule include all of the expected data requirements for the CQMs included in the Final Rule from CMS. And secondly, that those requirements are consistent with data requirements for certification for the interoperability and clinical decision support use case. Constraining the QDM is not the issue. It is

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	recommended that testing of measures is needed and also that education of measures developers is needed to appropriately constrain eMeasures in concert with the parsimonious and more expanded certification requirements.
§ 170.314(b)(3) - Electronic prescribing [Note: this is a revised certification criterion for the ambulatory setting and why this table appears twice, see page 7] MU Objective **Generate and transmit permissible prescriptions electronically (eRx).** 2014 Edition EHR Certification Criterion **Electronic prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:** **(i) The standard specified in § 170.205(b)(2); and** **(ii) At a minimum, the version of the standard specified in § 170.207(h).** Standards **§ 170.205(b)(2) (NCPDP SCRIPT version 10.6) and § 170.207(h)(RxNorm February 6, 2012 Release)**	The ability to generate and transmit prescriptions for EHs and CAHs should be the same as for EPs. The consistency is appreciated. A requirement to accept received and dispensed information in return is significant for care coordination and medication safety. While the ability to receive dispensed medication information is still limited (in part due to the requirement by PBMs, SureScripts, or EHR vendors that a current signed consent form be on file before a medication fill history can be obtained despite the established relationship between the patient and provider) , an expectation in the ambulatory setting for incorporation of dispensing information where available will significantly increase the attention and help resolve some of the conflicts for decrementing prescriptions and enabling care coordination based on medication adherence. Expanding fill history information to all medications dispensed by a pharmacy rather than only those that are tied to a pharmacy benefits payer would also facilitate quality and safety.
§ 170.314(e)(2) - Clinical summaries MU Objective **Provide clinical summaries for patients for each office visit.** 2014 Edition EHR Certification Criterion **Ambulatory setting only – clinical summaries. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, the following data elements: provider's name and office contact information; date and location**	We support the decision to specify a single standard (Consolidated CDA) for all clinical document content. We believe that this will greatly facilitate adoption and use throughout the healthcare system. See general comment on **Care summaries**.

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of visit; reason for visit; patient's name; gender; race; ethnicity; date of birth; preferred language; smoking status; vital signs and any updates; problem list and any updates; medication list and any updates; medication allergy list and any updates; immunizations and/or medications administered during the visit; procedures performed during the visit; laboratory tests and values/results, including any tests and values/results pending; clinical instructions; care plan, including goals and instructions; recommended patient decision aids (if applicable to the visit); future scheduled tests; future appointments; and referrals to other providers. If the clinical summary is provided electronically, it must be:

(i) Provided in human readable format; and

(ii) Provided in a summary care record formatted according to the standard adopted at § 170.205(a)(3) with the following data elements expressed, where applicable, according to the specified standard(s):

(A) Race and ethnicity. The standard specified in § 170.207(f);

(B) Preferred language. The standard specified in § 170.207(j);

(C) Smoking status. The standard specified in § 170.207(l);

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

(E) Encounter diagnoses. The standard specified in § 170.207(m);

(F) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);

(G) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);

(H) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed; and

(I) Medications. At a minimum, the version of the standard specified in § 170.207(h).

Standards

§ 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release).

We welcome public comment on whether we should adopt separate certification criteria for these data elements. For certain other data elements in §

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170.314(e)(2), we propose to require that the capability to provide the information be demonstrated in accordance with the specified vocabulary standard."	
Page 34 ""US Realm Header" (section 2.1 of the Consolidated CDA), which includes the metadata elements we were considering for patient identity and provenance, we do not believe that it would be necessary or prudent to propose separate metadata standards at this time."	Provenance of data elements is essential for evaluation of patient-reported outcomes and to determine the value and reliability of individual data elements. If elements captured by different means and from different sources are mixed in the CDA, the header information provides only the identity of the source of the CDA document, and not the individual data within it. Therefore, the value is lost. It is recommended that the decision to ignore data provenance be reconsidered especially if there is a desire to compute CQMs which require sources as they are being tooled now for MU Stage 2. It would also help if designation of care team members and attribution of responsibility (sole or shared) and accountability for problems/diagnoses, tests and treatment was established to improve the ability to determine and influence accountability for performance against quality measures for those who are (or should reasonably be) held accountable for quality in that domain (e.g., PCP and cardiologist for CAD or CHF; PCP and endocrinologist for DM management).
IV. Provisions of the Proposed Rule Affecting the Permanent Certification Program for HIT ("ONC HIT Certification Program") *E. Continuation and Representation of Certified Status* 2011 or 2014 Edition EHR Certification Criteria Compliant We request public comment on our approach and any other approach that would present the least burden for EHR technology developers and the least confusion for the market." (pg. 13870)	Making the certification test results transparent will likely lead to problems related to malpractice suits. Places where certification is not given will look like system failures rather than lack of system function and will be used against the providers in ways that go beyond reimbursement incentives.

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Conclusion

Despite the concerns identified in this document, ACP wishes to reaffirm its strong support of CMS and the Office of the National Coordinator for Health IT in the effort to transition the healthcare delivery system from paper to connected, robust, health information technology. We believe that well designed health IT is critically important to improving the quality of healthcare and will likely contribute to reducing the cost of evidence-based care. However, in general, we feel that the NPRM underestimates the challenges to EPs, EHs and CAHs of such a transition, even for those doing well with Stage 1. We believe that substantive changes will be needed in the Final Rule to keep EPs and EHs engaged, able and willing to continue striving to achieve and advance Meaningful Use of CEHRT in Stage 2.

ONC needs to be aware that the Proposed Rule in its current form includes core measures that even our most experienced and advanced EHR users are not confident they will be able to meet, in part because standards are not sufficiently in place and determined to sufficiently broadly implementable to predict the ability of EPs, EHs and CAHs to use them by 2014. We look forward to Final Rules that are significantly responsive to these concerns and inspire greater confidence among our members that the measures are reasonable, feasible, and achievable by all those willing to strive to achieve them.

Sincerely yours,

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Chair, Medical Informatics Committee
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