American College of Physicians
Leading Internal Medicine, Improving Lives

April 28, 2014

Karen B. DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Office of the National Coordinator for Health
Information Technology
Attention: 2015 Edition EHR Standards and
Certification Criteria Proposed Rule
Hubert H. Humphrey Building
Suite 729D
200 Independence Ave, SW
Washington, DC 20201

Re: 45 CRF Part 170; Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements [RIN 0991-AB92]

Dear Dr. DeSalvo:

The American College of Physicians (ACP) appreciates this opportunity to comment on the above referenced Voluntary 2015 Edition EHR Certification Criteria proposed rule. ACP is the largest medical specialty organization and second-largest physician group in the United States, representing 137,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum, from health to complex illness.

ACP applauds the ONC for their diligence and hard work in developing proposed certification criteria, updates, and regulatory improvements for moving the country forward in the areas of interoperability and exchange of health information. Please consider this letter as you develop your final rule for moving forward in these critical areas.

Sincerely,

Peter Basch, MD, FACP
Chair, Medical Informatics Committee
American College of Physicians

ACP Comment Worksheet

ONC Proposed 2015 CEHRT Criteria	ACP Comments
Drug-Drug, Drug-Allergy Interaction Checks Given the positive impact we believe DDI/DAI checks can have on patient safety, we are considering whether a future certification criterion edition could require DDI/DAI capable EHR technology to track user responses to DDI/DAI notifications ("response tracking") and whether commenters believe this would be a positive potential step toward improving user experience with DDI/DAI checking. We therefore seek comment on whether we should consider adopting a certification criterion as part of a future edition of certification criteria that would require EHR technology to be able to track health professionals' responses to the DDI/DAI checks that are performed and whether such a capability should track if and when the health professional viewed, accepted, declined, ignored, overrode, or otherwise commented on the product of a DDI/DAI check. We also seek comment on who should be permitted to review the data collected by the DDI/DAI check tracking capability, who should be able to adjust its configuration settings, whether the data tracked should be limited in scope or specificity, and whether EHR technology should be able to track when an adverse event occurs for which a DDI/DAI check was missed or ignored. Last, we seek comment on whether a DDI/DAI tracking capability should only track inaction or responses related to certain drug-drug and drug-allergy reactions, such as only tracking DDI/DAI alerts that if missed or ignored would cause severe reactions in patients. We also seek comment on what factors, definitions, standards, or existing consensus should be considered in determining whether a likely DDI/DAI reaction should be considered severe	There is general consensus that most over-alerting occurs because of unnecessarily sensitive DDI/DAI. And where the literature supports the notion that most dismissals / overrides of DDI/DAI alerts are appropriate, the wrong solution is to add another layer of alerting / reporting as to why. This is likely to make EHRs less functional and may lead to downstream punitive actions based on appropriate clinical behavior. Work should be done first on making DDI/DAI alerts into alerts that matter, and thus should be attended to. At that point it might be appropriate to have system capabilities that track more dismissals / overrides of relevant DDI/DAI alerts. Further, producing another report, by itself, is not very useful. Generally, reports cause more work. They do not solve problems. DDI/DAI alerts are not consistent. They vary by setting, provider, tools used, and approach taken. Alerts and responses cannot be compared across systems and providers. Some EPs report using the alerts as shortcuts to changing medications. Others report alerts firing during medication changes that might be meaningful in other contexts, but which are useless when an anticipated change will invalidate the alert. Rather that calling for another report, ONC should focus on ways to minimize the improper alerting in today's systems.
Vital Signs, Body Mass Index, and Growth Charts We have continued to receive stakeholder feedback that we should consider adopting standardized vocabularies for recording vital signs (e.g., LOINC for observations). However, we have also received feedback that we should continue to allow flexibility in how vital signs are recorded. As a result, we solicit comment on whether we should	ONC is correct to focus on the need for getting context right when it comes to making vital signs interoperable. Current standards are insufficient for modeling context, and until we get the context right, there is little point in forcing standard coding. Coding an observation with an incomplete model does not make it more accurate. Blood pressure is a good example of a vital sign that is often miss-measured and inaccurate. A random blood pressure may be interesting, but it may be inappropriate for

adopt standardized vocabularies for recording vital signs (specifically, whether we should adopt LOINC (for observations), SNOMED CT (for qualitative results), and UCUM (for units of measure)) in this certification criterion for the 2017 Edition. In addition to these vocabularies, we also solicit comment on whether other vocabularies would be better for recording vital signs. For recording vital signs, we are considering two different approaches: • Option 1 would be to require that EHR technology be able to record vital signs data natively using the aforementioned standards as part of the vital signs certification criterion. • Option 2 would be to require that EHR technology be able to represent such data in the aforementioned standards in any certification criterion that references vital signs when such data would be exchanged. For example, when exchanging a summary care record, the EHR technology would need to ensure blood pressure is represented in the CCDA formatted summary care record in the appropriate standard. Presumably, this option would be less burdensome on providers. It would also continue to allow them to collect vitals in local and non-standardized ways within their own EHR technology. However, it could also result in lost precision regarding the context associated with the vitals recorded. Last, additional feedback we have received from stakeholders indicated that if we were to pursue option 2, we would be best served to require EHR technology to record additional metadata related to the context around how the vital signs were collected. Stakeholders indicated that this additional information would provide context and comparability for the data if a standard vocabulary is not used when the data is recorded. For recording vitals, it is our understanding that unless particular contextual information associated with data collection is captured locally, data may be misinterpreted by a receiving party. Without certain kinds of contextual information, vitals data cannot be cross-walked or coded correctly. For example, a single blood pressure measurement may not represent a patient's true blood pressure. In older patients, the American Heart Association (AHA)[1] recommends taking the patient's blood pressure twice while standing, recording the average of the two, and then	determining blood pressure at goal (e.g., NQF 0018 relies on a single BP reading – the last in a measure period). Blood pressure control quality measures should not rely on it. We have noted that Meaningful Use has encouraged practices that do not regularly assess vital signs to start performing them regularly, although not with great accuracy. Patient records are filling with improperly performed vital sign measurements, and quoting Clem McDonald, we worry that CEHRT will "faithfully propagate" these erroneous data points. While Option 2 is less concerning than Option 1, neither should be implemented until we get accurate measurements and fully modeled context.

[1] New AHA Recommendations for Blood Pressure Measurement. *Am Fam Physician.* 2005 Oct 1;72(7):1391-1398.

taking the patient's blood pressure twice while sitting and using the sitting average as the final reading. The standing average is to be used as a reference point only. If this information (e.g., whether the patient was sitting or standing, if the measure is the first, second, or average) is not recorded in the EHR along with the blood pressure measurement itself, the readings may not be correctly understood by a receiving party, such as another provider or caregiver. Therefore, we are also soliciting comment on whether we should prioritize our attention toward making sure EHR technology can capture this kind of contextual information or other metadata and what kinds of data would be best or most helpful for EHR technology certification to require. Please note we are not proposing that blood pressure must be recorded according to the AHA's recommendations. Rather, we use their recommendations to illustrate how contextual information about vital signs may be important to prevent misinterpretation. Finally, we solicit comments on whether vocabularies (and other metadata) are sufficient for the reuse of more granular data elements and whether continued work through initiatives (e.g., the Clinical Information Modeling Initiative (CIMI), Fast Health Interoperable Resources (FHIR)) to support capturing clinical entity models or other approaches for representing more granular data elements is needed.	
Electronic Notes Specifically, for the 2015 Edition certification criterion, we propose that EHR technology have the capability to search for information across separate notes within the EHR technology rather than just within one particular note. While we propose to adopt the "search across notes" capability for the 2015 Edition, we request comment on the following: • Whether this functionality should extend to all patient electronic notes stored in the EHR or just to a specific patient's electronic notes or specific types of patient notes; • Whether we should require this functionality in the 2015 Edition or wait to include it in a potential 2017 Edition "electronic notes" certification criterion; and • Health care provider opinions on whether the availability of such functionality (either searching across a specific patient's electronic notes stored in the EHR or all patients' electronic notes stored in an EHR) is so widespread that it would be unnecessary to require it as a condition of certification. We note that the "electronic notes" objective and measure for MU Stage 2 requires that	We agree that an intelligent capability to search across the notes of a particular patient could be valuable. We worry that the devil will be in the implementation details. A straight text-string search, such as we can now do in a PDF document, where the return just takes us thru one instance of the text-string after another, one record at a time, would not be an acceptable way to implement this, for example. We would be able to provide more useful responses if more concrete use cases and examples were provided. Further, searching across notes of multiple patients raises HIPAA and ethical concerns that would have to be addressed thoroughly before such a function should be considered.

notes be text searchable, but does not require searching across electronic notes. Whether additional metadata should be required as part of electronic notes (such as the HL7 R2 header) to assist in both searching of notes, but also to make exporting electronic notes for patient data portability easier.	
Patient List Creation We propose to adopt a 2015 Edition "patient list creation" certification criterion that revises the 2014 Edition version to incorporate our guidance provided in FAQ 39.[2] Specifically, the text of the 2015 Edition "patient list creation" certification criterion provides that EHR technology must demonstrate its capability to use at least one of the more specific data categories included in the "demographics" certification criterion (45 CFR 170.315(a)(5)) (e.g., sex or date of birth). For a potential 2017 Edition "patient list creation" certification criterion, we request comment on four issues for EHR technology certification: (1) Whether patient communication preferences should be a requirement for the inpatient setting; (2) Whether a minimum list of patient communication preferences should be more specifically defined in order to require that EHR technology be capable of creating patient reminder lists based on a patient's preferred communication medium (e.g., electronically through secure email or a patient portal, paper/regular mail, or phone); (3) Whether EHR technology should be able to use a patient's preferred language as a filter; and (4) Because this certification criterion also supports the meaningful use objective and measure related to "patient reminders," whether we should include within this certification criterion or adopt a new certification criterion that would require EHR technology be able to provide patient reminders according to identified patient preferences and preferred language (for example, if the patient preference for a reminder was "email" and preferred language was English, the EHR technology would have to demonstrate that it could send reminders in English via email).	1. Not needed in the inpatient setting. 2. As with other proposed requirements involving the creation of lists and reports, creating this structured list may have some marginal value as a starting point. The real issue is whether the list is put to some useful purpose. Otherwise, it becomes another source of frustration for EPs. 3. The question, "What is your preferred language could result in an answer of "English" – whereas the correct question is, "In what language can you best understand health and wellness information?" And similar to #2 above – what would make this useful and not just annoying would be a companion requirement of a freeware health information translator. Thus, preferred language for healthcare information should result not in a list, but in reminders and educational material that are automatically available for the provider and patient. 4. This may be a good idea, but it should include freeware that does this work, as we are not aware of any vendor product that can create reminders and/or educational materials in anything other than English/Spanish.

[2] http://www.healthit.gov/policy-researchers-implementers/39-question-04-13-039

Implantable Device List We propose to adopt a new 2015 Edition certification criterion that would require EHR technology to be able to record and display a unique device identifier (UDI)[3] and other information about a patient's implantable devices. We propose to adopt a 2015 Edition certification criterion focused on EHR technology's ability to record UDI information about implantable devices. More specifically, EHR technology would have to enable a user to electronically record the UDI of an implantable device and other relevant information (such as a procedure note or additional information about the device) as part of a patient's "implantable device list." EHR technology would also be required to allow a user to electronically access and view a patient's list of UDIs and other relevant information associated with a patient's implantable devices. In addition, the EHR technology would need to be able to parse the UDI in order to extract and allow a user to view the "device identifier" and "production identifier" portions of the UDI. The purpose of this requirement is to ensure that a user will be able to use the device identifier to manually retrieve associated data elements from an authoritative source based on the GUDID, once available and, similarly, to ensure that a user will be able to manually use the production identifier in the event of a device recall. We expect that EHR technology would be able to automate these processes once appropriate standards and technical specifications are developed. As previously indicated, we believe EHR technology should also facilitate the UDI's exchange in order to increase the overall availability and reliability of information about patients' implants and other devices.	While this may sound like a good idea on the surface, depending on how policy ends up driving its use, it could become another burden on EPs. How will a PCP come to acquire these identifiers? Will this collection process become a requirement? We would be able to provide more useful comments if concrete use cases and examples were provided. Technical capabilities should not lead policy. There should be more thought put into this topic, including structured input from stakeholders. Producing another report or list, by itself is not very useful. Generally, reports cause more work. They do not solve problems. What is needed is functionality that will make good use of this new list.
Data Portability We also solicit public comment on the following: (1) Whether we should rename this certification criterion "data migration." Given that the "view, download, transmit to 3rd party" certification criterion addresses data availability from a patient's perspective, this certification criterion has always been more focused	We do not understand the implications of this set of questions. We would be able to provide more useful comments if concrete use cases and examples were provided. Technical capabilities should not lead policy. There should be more thought put into this topic, including structured input from stakeholders.

[3] A UDI is a unique numeric or alphanumeric code that consists of two parts: (1) a device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and (2)
a production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device: the lot or batch number within which a device was manufactured; the serial number of a specific device; the expiration date of a specific device; the date a specific device was manufactured; the distinct identification code required by 21 CFR § 1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/.

on data availability from a health care provider's perspective. We believe that a more precise label for this certification criterion could prevent confusion as to its focus. (2) Whether we should consider adding more requirements for the 2017 Edition version of this certification criterion that we would propose in a future rulemaking and what those requirements should be. For example, should this criterion focus on an expanded time boundary to allow for more longitudinal data to be exported and should it reference more data? Can additional electronic notes be included in a data portability requirement with the addition of header metadata to support export/import functions? (3) Whether we should change this certification criterion as part of a 2017 Edition proposal to promote a broader range of use cases, including: 1) local access/query (i.e., a provider's ability to access their own data through, for example, an API); 2) targeted access/inter-organizational query (i.e., a provider's ability to query data from another provider or specific location, such as when one provider performs a "targeted query" to obtain a patient's information from another provider); and 3) distributed, multi-source access/query (i.e., a provider's ability to disseminate queries to multiple organizations). This change could result in multiple use case specific certification criteria if appropriate.	
E-Prescribing Controlled Substances Specifically, we seek comment on: (1) Whether we should adopt a general two-factor authentication capability requirement for certification. This requirement could complement e-prescribing of controlled substances requirements and more definitively support security requirements for remote access to EHR technology as well as any other EHR technology uses that may require two factor authentication. Note, given that DEA has its own 3rd-party assessors and available certification process for technology to demonstrate compliance with its rules, we have no intention nor do we believe that it would be prudent to duplicate DEA regulatory requirements in ours. In fact, two ONC-ACBs are also approved by DEA to perform its approved certification process.[4] Whether the HITPC's recommendations are appropriate	The DEA technology and workflow processes for EPCS was specifically designed to allow for ePrescribing of controlled substances. Its burdensome workflows were put in place to safeguard against unintended prescribing, and to prevent prescribers who inappropriately prescribed controlled substances from being able to claim that they simply clicked a button and were not aware of what they prescribed. Where two-factor authentication is needed *outside* of the EPCS program, we would support the effort to have EHR technology provide for it in a way that removes unnecessary burden, and supports better and safer care – which is not the rationale upon which the EPCS two-factor authentication program was built. However, at this point, this appears to be another example of technology driving policy. Without a demonstrated need or relevant use cases, we are concerned that there will be a push to use these new capabilities without a valid reason.

[4] http://www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm

and actionable and, if not, what level of assurance should be the minimum required for provider-users seeking remote access to EHR technology.	
Auditable Events and Tamper-Resistance Accordingly, we propose to adopt a 2015 Edition "auditable events and tamper-resistance" certification criterion that is similar to its 2014 Edition version, but that requires EHR technology to prevent all users from being able to disable the audit log through the EHR technology. The phrase "through the EHR technology" is meant to limit the scope of this capability to what is in the EHR technology's control and to be consistent with the same scope limitation expressed in the 2014 Edition version of this criterion that we placed on "audit log protection" at 170.314(d)(2)(iv) (77 FR 54235). In the past, we had heard from stakeholders that there were reasons (e.g., performance concerns) to allow for audit logs to be disabled. Given that the proposed 2015 Edition certification criterion would prohibit that type of action from being performed in order for the EHR technology to be certified, we seek public comment on the impact and potential unintended consequences of such a change and specific examples where disabling an EHR technology's audit log is warranted.	We agree that end-users should not have the ability to disable an auditable events log. This seems fundamental to any system that is part of a legal record. This does not mean that we would support expansion of the definition of auditable events to include keystroke or other similar fine-grained logging.
Activity History Log We propose to include two new data points in the 2015 Edition VDT criterion related to the activity history log. We propose that the addressee to whom an ambulatory summary or inpatient summary was transmitted and whether that transmission was successful (or failed) be recorded.	As with other proposals for new lists and reports, producing another report, by itself, is not very useful. Generally reports cause more work. They do not solve problems. What is needed in the certification criteria is functionality that will assist the EP in making good use of these data. Transmission failures should trigger actions, or at least alerts.
2017 Edition Issues for the VDT Certification Criterion under Consideration Images and Non-Text Data In the 2014 Edition NPRM we proposed to require EHR technology to be capable of enabling images formatted according to the Digital Imaging and Communications in Medicine (DICOM) standard to be downloaded and transmitted to a third party (77 FR 13840). We stated our belief that this specific capability has the potential to empower patients to play a greater role in their own care coordination and could help assist in reducing the amount of redundant and duplicative imaging-oriented tests performed. In response to public comment, however, we did not adopt this proposal. In considering improvements that could be made to the VDT certification criterion for the 2017 Edition, we request public comment on whether	This proposal appears to be a case where availability of technology is being allowed to drive policy for no particularly good reason. Physician practices are not imaging centers. There is not currently an expectation for practices to receive, store, manage, and transmit images. This is, correctly, the proper role of imaging centers. Practices typically do not even have access to diagnostic quality images. If patients are to have access to their images, they should get them from the imaging centers – not from their doctors.

we should again propose to require that images be part of this criterion. More specifically, we seek comment on: 1) whether images for patients need to be of diagnostic quality; 2) whether they should be viewable and downloadable, but not required to be transmitted; and 3) whether cloud-based technology could allow for a link to the image to be made accessible. We also seek comment on other non-text data that we could require EHR technology to be able to make available to patients such as ECG waveforms.	
"OpenNotes" We also solicit public comment on whether a 2017 Edition VDT certification criterion should enable "OpenNotes"[5] functionality for EPs, EHs, and CAHs, to give patients the ability to gain access to their visit notes. The OpenNotes initiative was led by Beth Israel Deaconess Medical Center through a grant from the Robert Wood Johnson Foundation whereby "researchers undertook a year-long trial of OpenNotes in which 105 doctors shared their notes with more than 19,000 patients in Boston, rural Pennsylvania, and Seattle."[6] Additionally, in April 2013, the Department of Veterans Affairs announced that it had enabled OpenNotes through its My HealtheVet Blue Button.[7]	Based upon the research conducted thus far, we support the continued, voluntary expansion of note distribution / availability to patients. It would be helpful if CEHRT supported this, but there should not be any requirement to do so.
Non-Percentage-Based Measures Report The proposed certification criterion would require that an EHR technology presented for certification be capable of electronically generating a report that shows a user had used (or interacted with) the EHR technology capability associated with a non-percentage-based MU measure during an EHR reporting period. This means that, at a minimum, the EHR technology would need to be capable of determining an EHR reporting period (date range) and be able to record some evidence of use (e.g., transaction, user action, intervention/reminder) during the reporting period. We request public comment on whether we should make the regulatory text for this certification criterion more specific or if we should maintain the word "evidence" and use the final rule's preamble to provide more examples of what evidence would be acceptable (if we determine to adopt this criterion). If we were to make the regulatory text more specific, we propose these two options, but also solicit comment on other potential language that would make satisfying this criterion clearer.	This is clearly a case where the devil is in the details. We would be able to provide useful comments if concrete use cases and examples were provided. Both options are too broad and non-specific.

[5] http://www.myopennotes.org/what-is-opennotes-2/
[6] http://www.rwjf.org/en/grants/grantees/OpenNotes.html
[7] http://www.rwjf.org/en/blogs/pioneering-ideas/2013/04/why_the_va_embraces.html

• Option 1: Require the EHR technology to record evidence of use each time a particular capability was used during the reporting period. • Option 2: Require the EHR technology to record evidence of use at the beginning, during, and end of the reporting period.	
Complete EHR We propose to discontinue use of the Complete EHR definition as a regulatory concept beginning with the 2015 Edition EHR certification criteria. Currently, there are definitions for "Complete EHR, 2011 Edition" and "Complete EHR, 2014 Edition" under § 170.102. However, under our proposal, we would not add a new definition for "Complete EHR, 2015 Edition." As a result, ONC-ACBs would not be able to issue Complete EHR certifications to EHR technology certified to the 2015 Edition EHR certification criteria. As an alternative to the proposal, if we were to keep the Complete EHR concept and definition for the 2015 Edition, we propose and seek comment on the following two approaches: Continue the same policy of adopting an edition-specific Complete EHR (e.g., 2015 Edition Complete EHR). In addition to the significant drawbacks discussed above that come with keeping the Complete EHR definition, this approach would also be inefficient because it would continue the need for regular regulatory changes, including adopting new edition-specific Complete EHR definitions and making changes to the Base EHR definition to accommodate various editions of Complete EHRs. Define a Complete EHR as "EHR technology that has been developed to meet, at a minimum, all mandatory certification criteria of an edition of EHR certification criteria adopted by the Secretary for either an ambulatory setting or inpatient setting and meets the Base EHR definition." ONC-ACBs would be responsible for issuing Complete EHR certifications that specify the edition the Complete EHR was certified to. For example, EHR technology certified as a Complete EHR to the 2015 Edition would then be issued a certification that specifies that it is a 2015 Edition Complete EHR. This would also be evident through listing on the CHPL. This approach remains consistent with the policies we set forth in the 2014 Edition Final Rule that specify that a certification cannot be issued for a Complete EHR based on a combination of editions of EHR certification criteria and that certification	This is clearly a case where the devil is in the details. We would be able to provide useful comments if concrete use cases and examples were provided.

must specify what edition an EHR technology is compliant with.	
Disability Information and Accommodation Requests 1. Are you deaf or do you have difficulty hearing? If so, what special assistance may you need? 2. Are you blind or do you have difficulty seeing, even when wearing glasses? If so, what assistance may you need? 3. Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions? (patients 5 years old or older)[8]. If so, what assistance may you need? 4. Do you have difficulty walking or climbing stairs? (patients 5 years old or older) If so, what assistance may you need? 5. Do you have difficulty dressing or bathing? (patients 5 years old or older). If so, what assistance may you need?[9] 6. Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping? (patients 15 years old or older). If so, what assistance may you need? 7. Do you have difficulty communicating, reading, or do you have limited proficiency in English? If so, what assistance may you need? We request comment on whether: • These questions are the right questions to ask (with yes/no responses and a field for additional explanation); • These questions and answers can be accurately and efficiently recorded in an EHR; • There are alternative questions that could be asked related to disability status and additional assistance requests;	1. It is another uncompensated burden on the office staff or provider. This will lead to an expectation that this collection process will be added to the inelastic patient encounter time slot and would be a distraction from the primary goal of care provision. 2. This would typically be data collection for research or population management. The primary purpose of clinical documentation should be to support patient care and improve outcomes. 3. Even if the patient were to complete the questions they will be asking the staff for clarifications. 4. Collection of the data might also put the practice at risk of failing to provide accommodation. If the patient states they have limited proficiency in English are we now obligated to get a translator for every encounter? 5. We are concerned that data errors could result in improper labeling of patients.

[8] The specified age designations mean that the questions that include these designations only apply to patients older that the specified age. The underlying assumption is that patients younger than the specified age would inherently have the difficulties inquired about. This is consistent with the American Community Survey methodology.

[9] For the purposes of this question, dressing and bathing are considered functionally similar (strength, range of motion, transferring and supporting abilities) as the question seeks to generally determine the patient's functional ability and not attribute a "yes" to either ability or to be used for research purposes. This question will allow individuals recovering from long illnesses, paralysis, or post-surgery limitations to choose "yes," and then identify issues they may need assistance with.

• There are other ways for capturing patients' needs in EHR technology and patients' needs related to interacting with EHR technology; and • There are any available standards that could be used to capture in an EHR the listed questions (and answers) or <u>any</u> disability information and accommodation requests in a structured way. For example, would the following standards be appropriate for the associated information or suffice to code the listed questions and answers: o ICF (International Classification of Functioning, Disability and Health) for categories of function; o LOINC® for assessment instruments; and o SNOMED CT® for appropriate responses.	
<u>U.S. Military Service</u> In terms of electronically capturing U.S. Military service, we request comment on the following: • Use of the following concepts for coding U.S. Military service in EHR technology: History of Employment in U.S. Military; No History of Employment in U.S. Military; and Currently Employed by U.S. Military. • Whether it would be appropriate to capture the actual start date and date of separation from service. • Whether EHR technology should be able to record the foreign locales in which the service member had recently served. • Whether there are better concepts/values that could capture information related to U.S. Military status or uniformed service status, including through capturing occupational status and use of occupational code sets.	1. It is another uncompensated burden on the office staff or provider. This will lead to an expectation that this collection process will be added to the inelastic patient encounter time slot and would be a distraction from the primary goal of care provision. 2. This would typically be data collection for research or population management. The primary purpose of clinical documentation should be to support patient care and improve outcomes. 3. Even if the patient were to complete the questions they will be asking the staff for clarifications. 4. Collection of the data might also put the practice at risk of failing to provide accommodation. If the patient states they have limited proficiency in English are we now obligated to get a translator for every encounter?
<u>Work Information – Industry/Occupation</u> Widely used code sets are available for converting narrative I/O text into structured data. The combination of Bureau of Census (BOC) I/O codes[10] and NIOSH-added codes (e.g., for unpaid workers) – identified as the CDC_Census system in the Public Health Information Network Vocabulary Assignment and Distribution System (PHIN VADS)[11] – can be used to code patient I/O in EHR technology. The CDC_Census code sets are already used to classify the I/O information provided by respondents in most major U.S. health surveys. Given all of the effort by NIOSH and other stakeholders to advance this important	1. It is another uncompensated burden on the office staff or provider. This will lead to an expectation that this collection process will be added to the inelastic patient encounter time slot and would be a distraction from the primary goal of care provision. 2. This would typically be data collection for research or population management. The primary purpose of clinical documentation should be to support patient care and improve outcomes. 3. Even if the patient were to complete the questions they will be asking the staff for clarifications.

[10] Census (1) (United States Census Bureau). 2012. Industry and Occupation. Available at: http://www.census.gov/people/io/methodology/indexes.html

[11] PHIN Vocabulary Access and Distribution System. 2012. Available at: http://www.cdc.gov/phin/tools/PHINvads/

work, we request comments on whether we should propose as part of the 2017 Edition that EHR technology be capable of enabling a user to electronically record, change, and access the following data elements for certification: • Narrative text for both current and usual industry and occupation (I/O), with industry and occupation for each position linked and retained in perpetuity and time stamped. • CDC_Census codes for both current and usual I/O, with industry and occupation for each position linked and retained in perpetuity and time stamped.	4. Collection of the data might also put the practice at risk of failing to provide accommodation. If the patient states they have limited proficiency in English are we now obligated to get a translator for every encounter? 5. EPs take a history sufficient to determine if the patient's occupation puts them at risk for disease. But to require staff or the provider to look up a code does not enhance patient care but is a burden on the office to generate data for third party entities.
Provider Directories We have received feedback from many different stakeholder groups that a single standard for "provider directories" is needed. The impetus for this feedback appears to be MU Stage 2's added exchange requirements and a general industry need to find providers electronic service information. At a minimum, EHR technology would need to be able to query provider directories for the following information and electronically process the response returned in accordance with the MSPD IG requirements (which are expected to be adopted by IHE USA as an IHE USA profile): • Query for an individual provider; • Query for an organizational provider; • Query for relationships between individual providers and organizational providers.	This is a good idea, but what is needed first is more study of what a useful and usable model should contain. Premature specification may result in a directory structure that does not permit accurate identification of providers (e.g., Dr. John Smith, cardiology, NYC).
Oral Liquid Medication Dosing Given the clinical need and stakeholder support for reducing preventable adverse events resulting from dosing errors in e-prescribing, we solicit comment on whether we should adopt a certification criterion (or establish a requirement within a certification criterion) for EHR technology to use the metric standard for prescribing oral liquid medications or to solve the problem more generally using a structured Sig[12] standard. Potential (non-mutually exclusive) options for certification include, but are not	Trying to dictate data models and user interfaces at the federal government level is inappropriate and invasive. Is this really the best way to try to solve the problem at hand? The final option, requiring EHR technology to be able to accurately a liquid dose to the metric standard, is preferable to the other options.

[12] A prescription contains a number of different elements. In addition to the patient and prescriber information, it must state the name, dosage form and strength of the medication; the dose; the amount to be dispensed; the number of refills; and the directions for use, or Sig. "Sig" is an abbreviation for "signatura," Latin for "Mark thou". The Sig contains the instructions explaining how the patient is to take the medication. http://www.ncpdp.org/pdf/Sig_standard_imp_guide_2006-06.pdf

limited to: • Require EHR technology to use a structure Sig with explicit dosing units, frequency, and number of units; • Require EHR technology to provide the metric standard as one option to record liquid medication doses; • Require EHR technology to record liquid medication doses in the metric standard only; and • Require EHR technology to be able to accurately convert a liquid dose to the metric standard. For this last option, we are also soliciting comment on minimum/maximum dosing checks for dose conversion. We also solicit comment on EHR readiness to implement the metric standard for prescribing oral liquid medications, the effect on existing vocabulary standards for units of measurement (e.g., UCUM), and implications on the structured Sig format for e-prescribing.	
Duplicate Patient Records In September 2013, in response to the 2011 HITPC and HITSC recommendations and stakeholder feedback, ONC formally undertook an initiative to improve patient matching.[13] Due to our experience with this initiative, we are considering a 2017 Edition certification criterion that would require EHR technology to be capable of generating and providing to end users reports that detail potential duplicate patient records as a potential means to improve patient matching data quality. We anticipate that this certification criterion could also include functionality for end users to correct duplicate records, which typically requires the merging of records and unmerging incorrectly merged records. We believe a certification criterion including these capabilities, in addition to the patient matching capabilities proposed for inclusion in the 2015 Edition "transitions of care" certification criterion, would significantly improve a provider's ability to properly match patients to their health information. While many EHR systems today with built-in matching functionality and processes offer reports that identify potential duplicate records, not all EHR systems offer such a capability. Additionally, some EHR systems have the capability, but do not make the reports accessible to users. As for merging and unmerging, we understand these capabilities vary and are inconsistently applied in EHR technology today. While some EHR technology may	Producing yet another report is, by itself, not very useful. Generally, reports cause more work. They do not solve problems. What is needed is functionality that will assist in resolving the discrepancies. Having such functionality in CEHRT is critical to interoperability.

[13] http://www.healthit.gov/buzz-blog/health-innovation/onc-launches-patient-matching-initiative/

enable users to merge and unmerge back to a specific point in time, others do not unmerge and instead delete the entire record and create two new ones. We seek comment on provider demand for/interest in these types of capabilities in addition to any capabilities that should be included or excluded from this potential certification criterion.	
Disaster Preparedness Given these issues, we solicit comments on: (1) Whether there could be a standardized naming convention for EHR technology to use for temporarily naming unidentified patients during disaster and emergency events? (2) Whether we should consider adopting a certification criterion that would be available for certification for EHR technology developers to show that their EHR technology can batch print face sheets or patient snapshots in bulk (by floor or unit, or by facility) to support movement/evacuation of large numbers of patients? (3) Whether there are particular capabilities or standards we should consider as part of EHR certification that would better assist providers track and identify patients and victims and share basic clinical information quickly across the full continuum of care during everyday emergencies, disasters, and public health emergencies? (4) Whether EHR technology should be able to denote care provided during disasters or public health emergencies and allow for designation of care provided under situations which demand contingency or crisis standards of care? (5) Whether there are any EHR capabilities and certification criteria that we should consider for certification that could improve/expedite how EHR technology is used to report standardized and de-identified patient data to public health and emergency management authorities, in a manner that would allow such authorities the ability to measure, track and trend health system resiliency, stress, preparedness, and recovery?	Of all of the topics presented in this NPRM, this one is the farthest from being ready for regulation. Years of study, evaluation, and discussion will be required before we are ready to specify requirements that will truly improve disaster preparedness. However, we are in favor of the concept that the EHR should provide for a new documentation model that is available for emergency care during disasters and public health emergencies. This model should remove documentation frameworks based on E&M coding, and unless non-emergency care was also provided to these patients during an applicable measure period, also EXCLUDE these patients from all quality and other measurement programs (a virtual good Samaritan).
Other Types of HIT This proposed rule takes a step towards the expansion of the ONC HIT Certification Program to accommodate other types of HIT. By proposing changes to the ONC HIT	This may be a good idea, but it should be left to the marketplace – module makers and module buyers to innovate without adding regulatory burden for all EHRs.

Certification Program to recognize the certification of MU and non-MU EHR Modules, EHR technology designed for other settings and purposes could be certified under the ONC HIT Certification Program to the 2015 Edition without having to meet certification criteria designed specifically for MU (see section IV.B for further discussion). With additional changes to the ONC HIT Certification Program, we could provide the proper visibility and attribution for these technologies by permitting them to be certified as "HIT Modules." "HIT Modules" would be distinct from EHR Modules in that they would represent technologies that stakeholders recognize as distinct from EHR software and services. Certification for "HIT Modules" could also have long-term practicality as the ONC HIT Certification Program evolves. We welcome comments on this potential change to the ONC HIT Certification Program as we are considering moving in this direction as part of our 2017 Edition rulemaking.	