ONC Regulations FAQs

Question [9-10-001-2]: *What certification criteria will ONC-ATCBs and ONC-ACBs use to certify EHR technology for purposes of the "deeming" provision of the Physician Self-Referral Prohibition and Anti-Kickback Electronic Health Record (EHR) Exception and Safe Harbor Final Rules?*

Answer:
Both the Physician Self-Referral Prohibition EHR Exception and the Anti-kickback EHR Safe Harbor regulations, at 42 CFR 411.357(w) and 42 CFR 1001.952(y), respectively, provide that software "is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the recipient." The "recognition" of certification bodies process referred to in these regulations, as discussed in the Temporary Certification Program Final Rule (the Final Rule) (75 FR 36185) has been superseded or folded into the ONC-ATCB and ONC-ACB "authorization" processes. Consequently, the ONC-ATCB and ONC-ACB "authorization" processes will constitute the Secretary's "recognition" of a certification body. With that said, as further explained in the Final Rule, ONC-ATCBs and ONC-ACBs are required to test and certify EHR technology to all applicable certification criteria adopted by the Secretary at 45 CFR part 170, subpart C. We believe that the certification criteria adopted by the Secretary specify essential interoperability requirements and build the foundation for more advanced interoperability in the future. Any questions regarding compliance with the exception or safe harbor should be directed to the Centers for Medicare & Medicaid Services (CMS) and the HHS Office of Inspector General (OIG), respectively.

Question [9-10-002-2]: *If my EHR technology is capable of submitting batch files to an immunization registry using the applicable adopted standards, is that sufficient for demonstrating compliance with the certification criterion specified at 45 CFR 170.302(k) or170.314(f)(2) (adopted as part of the 2011 and 2014 Edition EHR certification criteria, respectively)?*

Answer:
The certification criteria at 45 CFR 170.302(k) and 170.314(f)(2) do not specify, and are not intended to specify, when submissions should be made or the periodicity of the submissions. Consequently, submitting batch files to an immunization registry, provided that they are formatted according to the adopted standards referenced by the certification criteria at 45 CFR 170.302(k) and 170.314(f)(2), is not prohibited by these certification criteria and would be acceptable.

Question [9-10-003-2]: *This FAQ has been archived and can be found in the Archived FAQs.*

Question [9-10-004-2]: *I currently use EHR version 1.3 which I purchased from EHR technology developer XYZ. EHR technology developer XYZ has informed me that it is not going to seek certification for EHR version 1.3. Can I seek certification for EHR version 1.3 or can I partner with a group of other health care providers that also use version 1.3 to split the cost of certification? Additionally, if EHR version 1.3 becomes certified can anyone else using EHR version 1.3 rely on the certification issued to EHR version 1.3?*

Answer:
In response to your first question, yes, any individual health care provider, group of health care providers, other type of affiliation, or organization is permitted to seek to have EHR technology tested and certified. The Temporary Certification Program and ONC HIT Certification Program regulations do not specify who may seek testing and certification for EHR technology. However, we note that any party that seeks testing and certification for the EHR technology would typically assume the associated costs. We would also note that prior to presenting EHR technology for testing and certification, it may be prudent to conduct an analysis of the certification criteria with which, for example, EHR version 1.3 would be compliant (i.e., it may only be capable of meeting some, but not all, adopted certification criteria and could therefore only be certified as an EHR Module). Additionally, if the purchaser and EHR technology developer have entered into an agreement, the purchaser may want to review the terms and conditions of the agreement to see what, if any, restrictions have been placed on either of the parties in seeking certification of the EHR technology.

In response to the follow-up question, yes, regardless of who seeks (and/or incurs the costs) to have the EHR technology tested and certified, once the EHR technology is certified, the certification associated with that EHR technology is applicable to all identical copies (for example, all identical copies of EHR version 1.3). In addition, the ONC-ATCB or ONC-ACB would report to ONC that the particular EHR technology had been certified, and we would make this information available on our website through the Certified HIT Products List (CHPL).

Question [9-10-005-2]: *I am an EHR technology developer. I have sought and achieved certification for the Complete EHR that I sell. The Complete EHR, however, is also designed to be sold in separate components so that I can offer my customers different prices based on the capabilities they seek to implement. Is it possible for me to sell components of my certified Complete EHR separately as certified EHR Modules, or do I need to seek testing and certification for each of the separate components that I plan to sell as certified EHR Modules?*

Answer:
Stand-alone, separate components of a certified Complete EHR do not derive their own separate certified status based solely on the fact that they were included as part of the Complete EHR when it was tested and certified. The separate component(s) would no longer meet the Complete EHR definition, nor would the separate component have independently demonstrated that it can still properly perform capabilities for which certification is required in the absence of the capabilities with which it was previously certified as part of the Complete EHR. Therefore, EHR technology developers must have the separate components of a certified Complete EHR tested and certified as EHR Modules under the Temporary Certification Program or the ONC HIT Certification Program, as applicable, before the components may be sold separately as certified EHR Modules.

Similarly, components of a certified EHR Module do not derive their own certified status from being part of a certified EHR Module. Developers who seek to sell such components as certified EHR Modules must have them separately tested and certified under the Temporary Certification Program or the ONC HIT Certification Program, as applicable.

To read more about this policy, please see 77 FR 54266.

Question [9-10-006-2]: *I submitted a Complete EHR for certification, but it has not passed a test for one or more of the certification criteria. Can I request that the ONC-ATCB or ONC-ACB certify the EHR technology that I submitted as an EHR Module instead (i.e., certify only those capabilities that have been tested successfully)?*

Answer:
Yes, an ONC-ATCB or ONC-ACB that is authorized to certify Complete EHRs has the discretion to change the type of certification it would issue based on an EHR technology developer's request. Whether the ONC-ATCB or ONC-ACB would choose to honor a request for a change, as well as any costs associated with a change, would depend upon the arrangement between the EHR technology developer and the ONC-ATCB or ONC-ACB. Along those lines, if an ONC-ATCB or ONC-ACB permits a developer or presenter to request a different type of certification for the EHR technology it has submitted, the ONC-ATCB or ONC-ACB should be cognizant of other responsibilities it may need to satisfy for EHR Modules (e.g., 45 CFR 170.450 or 170.550).

Question [9-10-007-2]: *My hospital purchased a certified EHR Module that provides approximately 75% of the capabilities we need to meet the definition of Certified EHR Technology. The other 25% are provided by our own self-developed system(s). Can we have our self-developed system tested and certified as an EHR Module and then subsequently use the combination of our self-developed certified EHR Module with the certified EHR Module we purchased to meet the definition of Certified EHR Technology? As a follow up, do we need to have the combination of the purchased certified EHR Module and our self-developed certified EHR Module tested and certified together as a Complete EHR (above and beyond the certifications they have already been issued)?*

Answer:
Yes, you may seek testing and certification for only those systems that have not been certified as an EHR Module (in this case, the self-developed system), and no, you do not need to have the combination of certified EHR Modules certified again as a Complete EHR in order to meet the definition of Certified EHR Technology.

Question [9-10-008-2]: *If an EHR Module addresses multiple certification criteria (thus providing multiple capabilities), does it need to be tested and certified to the applicable privacy and security certification criteria as a whole or for each capability?*

Answer:
An EHR Module could provide a single capability required by one certification criterion or it could provide all capabilities but one required by the certification criteria for a Complete EHR. In other words, for example, we would call HIT tested and certified to one certification criterion an "EHR Module" and HIT tested and certified to nine certification criteria an "EHR Module," where ten certification criteria are required for a Complete EHR.

We now provide two different answers to this question based on the Edition of EHR certification criteria in question.

<u>2011 Edition EHR Certification Criteria Answer:</u>
If an EHR Module addresses multiple certification criteria the EHR Module as a whole would be tested and certified to all privacy and security certification criteria unless the EHR Module is presented for testing and certification, and the presenter can demonstrate and provide documentation to the ONC–ATCB or ONC-ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be tested and certified in accordance with such certification criterion (see 45 CFR 170.450(c)(2) and 170.550(e)(2)).

<u>2014 Edition EHR Certification Criteria Answer:</u>
Pursuant to the changes made to the ONC HIT Certification Program rules at 45 CFR 170.550(e), ONC-ACBs are not required to assess the privacy and security criteria adopted at 45 CFR 170.314(d) when EHR technology is presented for certification to the 2014 Edition EHR certification criteria as an EHR Module. Under the ONC HIT Certification Program rules for EHR Module certification, an EHR technology developer has the choice whether to seek certification of its EHR Module to any of the privacy and security criteria adopted at 45 CFR 170.314(d).

Question [9-10-009-2]: *I'm an EHR technology developer and I've had my Complete EHR certified. I work with business partners/distributors and permit them to sell my (unmodified) certified Complete EHR under their own brand/name/label. Is this business practice permitted? Is there anything that I should do or be aware of?*

Answer:
Yes, this business practice is permitted. However, the ONC-ATCB or ONC-ACB that certified your Complete EHR is required to ensure that you adhere to the terms and conditions of the certification it issues, including communication of the information specified at 45 CFR 170.423(k) and 170.523(k), respectively. Thus, if you permit business partners/distributors to re-brand or rename your certified Complete EHR and represent that it has been certified, the ONC-ATCB or ONC-ACB that issued the certification for your Complete EHR may require you (consistent with Section 14 of Guide 65) to ensure that your business partners/distributors adhere to the requirements of 170.423(k) or 170.523(k) that apply to you. We encourage you to make arrangements with your business partners/distributors to ensure that they appropriately convey the information specified at 170.423(k) or 170.523(k), as applicable.

Additionally, ONC-ATCBs and ONC-ACBs are responsible for reporting to ONC a current list of the EHR technology that they have certified. Only EHR technologies reported by ONC-ATCBs and ONC-ACBs to ONC will appear on ONC's "Certified HIT Products List (CHPL)." Therefore, if you are an EHR technology developer that expects to work with business partners/distributors that will re-brand or rename your certified Complete EHR and represent that it has been certified, we encourage you to work with your ONC-ATCB or ONC-ACB to identify (up front, if possible, or on an ongoing basis) the different names under which your certified Complete EHR may be distributed. Otherwise, those re-branded or renamed Complete EHR(s) will not appear on the CHPL.

An ONC-ATCB or ONC-ACB is permitted to report information to ONC related to re-branded or renamed Complete EHRs that it has certified. We would list the re-branded or renamed Complete EHR(s) on the CHPL using the same unique certification identification that is assigned to your certified Complete EHR.

Question [9-10-010-2]: *My EHR technology is designed to receive demographic data from a registration system or a practice management system. The data from these other IT systems is then used by my EHR technology to demonstrate compliance with one or more certification criteria. Do these other IT systems that act as data sources to my EHR technology need to be certified?*

Answer:
No, other IT systems that act as data sources and are not intended to perform required capabilities in accordance with adopted certification criteria do not need to be certified simply because they supply data to a Complete EHR or EHR Module. Obviously, if the other IT systems have not been developed to, and cannot, perform required capabilities in accordance with adopted certification criteria then certification of those other IT systems would not be available. For the purposes of certification, an EHR technology developer must be able to demonstrate to an ONC-ATCB or ONC-ACB that its Complete EHR or EHR Module can perform the capabilities specified by all applicable certification criteria. Thus, in circumstances where the Complete EHR or EHR Module is designed to be implemented in multiple ways, including the ability to receive data from a different IT system, the EHR technology developer would need to demonstrate during testing that regardless of the source from which the Complete EHR or EHR Module receives data, it is compliant with all applicable certification criteria for which certification has been sought.

Question [9-10-011-1]: *I've identified that I am using two different EHR technologies to meet a single certification criterion (my document management system receives and displays summary records (45 CFR 170.306(f)(1)) and my EHR technology from EHR technology developer XYZ transmits summary records (45 CFR 170.306(f)(2)). Do both EHR technologies need to be certified?*

Answer:
Yes, in order to possess EHR technology that meets the definition of Certified EHR Technology, both the document management system and the EHR technology from EHR technology developer XYZ together need to meet this certification criterion in its entirety. As a result, (assuming you are not implementing a certified Complete EHR) you could elect to seek testing and certification yourself for these two systems as an EHR Module or implement a certified EHR Module that meets this certification criterion in its entirety.

Question [9-10-012-2]: *How many clinical quality measures (CQMs) must EHR technology be capable of calculating in order to get certified?*

Answer:
It depends.

First, it depends on whether the EHR technology is being certified to the 2011 or 2014 Edition EHR certification criteria. Second, it depends on whether the EHR technology is designed to be used in an ambulatory setting or in an inpatient setting as we have adopted specific requirements for each setting to correspond to the correlated meaningful use requirements that eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) must satisfy.

<u>2011 Edition EHR Certification Criteria Answer:</u>
For EHR technology designed for an ambulatory setting, it must be tested and certified as being compliant with all 6 of the core (3 core and 3 alternate core) clinical quality measures specified by CMS for eligible professionals as well as at a minimum 3 of the additional clinical quality measures CMS has identified for eligible professionals.

For EHR technology designed for an inpatient setting, it must be tested and certified as being compliant with all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals.

The Standards and Certification Criteria July 2010 final rule provides a more detailed discussion of this issue at 75 FR 44610. Additionally, eligible health care providers should be aware that ONC–Authorized Testing and Certification Bodies (ONC-ATCBs) and ONC-Authorized Certification Bodies (ONC-ACBs) are required to report to the National Coordinator (among other data) the clinical quality measures to which a Complete EHR or EHR Module has been tested and certified, and further, that the Complete EHR or EHR Module developer would need to make sure this information is available and communicated to prospective purchasers as part of the Complete EHR or EHR Module's certification.

<u>2014 Edition EHR Certification Criteria Answer:</u>
EHR technology may be separately tested and certified, according to applicable standards, to: (1) capture and export CQMs (45 CFR 170.314(c)(1)); (2) import and calculate CQMs (45 CFR 170.314(c)(2)); and (3) electronically submit CQMs to CMS (45 CFR 170.314(c)(3)).

EHR technology may be tested and certified to meet 45 CFR 170.314(c)(1) and/or (2) for only one CQM. However, to meet the <u>Base EHR definition</u>:

- EHR technology designed for an ambulatory setting must be tested and certified to 45 CFR 170.314(c)(1) and (2) for no fewer than 9 CQMs covering at least 3 domains from the set selected by CMS for EPs, including at least 6 CQMs from the recommended core set identified by CMS.

- EHR technology designed for an inpatient setting must be tested and certified to 45 CFR 170.314(c)(1) and (2) for no fewer than 16 CQMs covering at least 3 domains from the set selected by CMS for EHs and CAHs.

Question [9-10-013-3]: *I plan to use a "data warehouse" to calculate and submit meaningful use clinical quality measures. Does my data warehouse need to be certified for me to be able to use it to achieve meaningful use?*

Answer:
Yes, your data warehouse does need to be certified. However, only those capabilities that your data warehouse is intended to perform and for which certification is required would need to be tested and certified. Other capabilities that the data warehouse may also perform (e.g., benchmarking, research analytics) would not need to be tested and certified. Thus, if you plan to use a data warehouse to calculate and submit clinical quality measures to CMS or States for meaningful use, the data warehouse would be performing a capability for which the Secretary has adopted a certification criterion and for which you as an eligible health care provider have a correlated meaningful use requirement to satisfy.

Question [9-10-014-2]: *I've selected a certified Complete EHR [or certified EHR Module] from EHR technology developer XYZ. That being said, I prefer the certified CPOE EHR Module designed by EHR technology developer ABC over the CPOE capability included in EHR technology developer XYZ's Complete EHR. Can I use the certified CPOE EHR Module from EHR technology developer ABC instead of the CPOE capability included in EHR technology developer XYZ's certified Complete EHR? Alternatively, can I use both of the certified CPOE capabilities included in EHR technology developer XYZ and ABC's EHR technologies at the same time? In other words, can I use duplicative or overlapping certified capabilities of different certified EHR technologies without jeopardizing my ability to meaningfully use Certified EHR Technology?*

Answer:
Meeting the Certified EHR Technology definition can be achieved in numerous ways, including using EHR technologies that perform duplicative or overlapping capabilities (if that is what an eligible health care provider chooses to do) so long as those EHR technologies are certified. Consequently, an eligible health care provider could use both certified capabilities (e.g., CPOE) at the same time in two different sections/departments of its organization. The eligible health care provider would however be responsible for reconciling the data between those two certified capabilities for purposes of reporting to CMS or the States.

Eligible health care providers who take such an approach should use ONC's "Certified HIT Products List (CHPL)" webpage to generate a unique certification combination identification in order to accurately attest to CMS or the States the aggregate of certified EHR technologies used during the EHR reporting period.

We also refer readers to the Certified EHR Technology definition at 45 CFR 170.102 and FAQ 17 for further explanation of the Certified EHR Technology definition.

Question [9-10-015-2]: *I am an EHR technology developer preparing my EHR technology for certification. I am relying on a 3rd party software program to demonstrate my compliance with a specific certification criterion. Does this 3rd party software program need to be independently certified?*

Answer:
No, the 3rd party software program that your EHR technology relies upon does not need to be independently certified. In principle, when presenting your EHR technology to an ONC-ATCB or ONC-ACB you must be able to demonstrate that your EHR technology is in compliance with the certification criterion regardless of whether your EHR technology natively performs the specified capability or relies upon a 3rd party software program. Thus, in practice, if you rely upon a 3rd party software program to successfully demonstrate compliance with a certification criterion, the certification you are issued encompasses the 3rd party software program.
In the context of relied upon software, we require ONC-ATCBs and ONC-ACBs:

1. To include certain information about software that is relied upon when reporting your certification to the National Coordinator, which will result in your EHR technology's entry on the Certified HIT Products List (45 CFR 170.423(h)(6) and 170.523(f)(6), respectively); and

2. To ensure that you convey this information on your website and in all marketing materials, communications statements, and other assertions related to your EHR technology's certification (45 CFR 170.423(k)(1)(ii)) and 170.523(k)(1)(ii), respectively).

Question [9-10-016-2]: *I've implemented EHR technology developer XYZ's certified Complete EHR [or certified EHR Module] "E-HealthSystem" which has been certified to the 2011 Edition EHR certification criteria. The developer indicated that it's making the necessary development changes and will, in the next year, present "E-HealthSystem" for Complete EHR certification to the 2014 Edition EHR certification criteria.*

Scenario 1: *I determined that E-HealthSystem needed to be reconfigured in order to connect with one of my patient registration systems so I made the necessary adjustments. Is it okay to make adjustments? If necessary, can I also reconfigure, in a similar manner, the next version of E-HealthSystem that will be certified to the 2014 Edition EHR certification criteria without compromising the certified status of my implementation of E-HealthSystem?*

Scenario 2: *EHR technology developer XYZ communicated to my organization that they relied upon a 3rd party software program "PatientInfoTracker 2.0" for the purposes of demonstrating compliance with the "generate patient lists" certification criterion specified at 45 CFR 170.302(i) in achieving E-HealthSystem's certification. They've also informed me that they will rely on the same 3rd party program to meet the "create patient lists" certification criterion at 45 CFR 170.314(a)(14) as part of their Complete EHR certification to the 2014 Edition EHR certification criteria. I have already implemented, use, and would like to continue using "SuperListGenerator 7.0." I have determined that I can reconfigure SuperListGenerator 7.0 to work with E-HealthSystem. Can I use SuperListGenerator 7.0 in lieu of PatientInfoTracker 2.0 without compromising the certified status of my implementation of E-HealthSystem now and potentially with the 2014 Edition version?*

Answer:
With respect to Scenario 1, yes, you can reconfigure your implementation of E-HealthSystem without compromising its certified status, but you assume the risks associated with modifying a certified capability after it has been certified. You are also responsible for ensuring that the modifications do not adversely affect the performance of E-HealthSystem and, as a result, your ability to demonstrate meaningful use. We encourage eligible providers to use caution when modifying certified Complete EHRs or EHR Modules.

With respect to Scenario 2, no, you cannot use a different 3rd party program to perform a certified capability unless:

- EHR technology developer XYZ already has a separate certification for E-HealthSystem that identifies SuperListGenerator 7.0 as a relied upon software program; or

- You obtain certification for SuperListGenerator 7.0 as an EHR Module.

Question [9-10-017-3]: *As an eligible provider seeking to demonstrate meaningful use of Certified EHR Technology (CEHRT), what options do I have to meet the Certified EHR Technology definition before and after 2014?*

Answer:
The CEHRT definition can be found at 45 CFR 170.102 and applies to the calendar year (CY) for eligible professionals (EPs) and the fiscal year (FY) for eligible hospitals (EHs) and critical access hospitals (CAHs).

Before FY/CY 2014 (i.e., for the EHR reporting periods in 2011, 2012, and 2013)

<u>An eligible provider can satisfy the CEHRT definition in any one of the following three ways:</u>

1. The eligible provider possesses EHR technology certified to all of the mandatory 2011 Edition EHR certification criteria for the applicable setting.

2. The eligible provider possesses EHR technology certified to all of the mandatory 2011 Edition EHR certification criteria **<u>or equivalent</u>** 2014 Edition EHR certification criteria for the applicable setting. This option is similar to the first in that providers must possess EHR technology certified to all of the certification criteria for a setting (inpatient or ambulatory), but it can be a mix of technology certified to the 2011 and 2014 Editions of EHR certification criteria. For example, a provider who already has 2011 Edition EHR technology could purchase an EHR Module with CPOE functionality that is certified to the 2014 Edition CPOE certification criterion. A crosswalk of equivalent 2014 Edition EHR certification criteria can be found at http://www.healthit.gov/sites/default/files/pdf/EquivTable_8-18-12_Final.pdf.

3. The eligible provider possesses EHR technology that meets the CEHRT definition established for FY/CY 2014 and subsequent years at 45 CFR 170.102. By selecting this option, an eligible provider may be able to satisfy the CEHRT definition without necessarily having to possess EHR technology certified as having all of the capabilities as they would in options 1 and 2. Specifically, this means the provider would, at a minimum, only need to have or possess EHR technology certified to the 2014 Edition EHR certification criteria that meets the Base EHR definition and supports the objectives, measures, and their ability to successfully report the clinical quality measures (CQMs), for the meaningful use (MU) stage that they seek to achieve.

For FY/CY 2014 and Subsequent Years

An eligible provider must possess EHR technology that satisfies the CEHRT definition for FY/CY 2014 and subsequent years at 45 CFR 170.102. Again, this means, at a minimum, possessing EHR technology certified to the 2014 Edition EHR certification criteria that meets the Base EHR definition and supports the objectives, measures, and their ability to successfully report the CQMs, for the MU stage that they seek to achieve.

FY/CY 2014 CEHRT Definition Flexibility as it Pertains to Meaningful Use

Menu Objectives and Core/Menu Exclusions
For Stages 1 and 2, in cases where the EP, EH, or CAH could defer a menu objective or (in most cases) meet an exclusion for a core or menu objective, the EP, EH, or CAH would not necessarily need to have EHR technology certified that supports the objective and associated measure in order to have EHR technology that satisfies the CEHRT definition.

Provider Responsibility
EPs, EHs, and CAHs will be responsible for ensuring that they have the necessary EHR technology to meet the FY/CY 2014 CEHRT definition. This means that EPs, EHs, and CAHs could run the risk of not having sufficient CEHRT to support their achievement of MU if, for example, they turn out not to be able to exclude a MU objective and measure as anticipated or they end up needing to satisfy a menu objective and measure that they originally expected to defer.

Question [9-10-018-2]: *I use or would like to use an "interface" to submit data to a public health agency/registry. Does this interface need to be certified?*

Answer:
It depends. We recognize that the term "interface" has several different meanings depending on the context in which it is used, the IT infrastructure of which it is a part, and the capability it performs. Consequently, depending on various factors, an interface may or may not need to be certified.

"NO"

- The answer to your question would be "no," if the interface provided a user with the ability to directly enter data to the public health agency/registry. In that scenario, the interface would **not** be providing a capability for which the Secretary has adopted a certification criterion and that Certified EHR Technology must include.
- Similarly, if the interface would solely be serving as a conduit between your EHR technology and the public health agency/registry and providing the underlying communication protocol to transport data from point A to point B, it would not need to be certified. In this case, the interface would simply be providing the connection between you and the public health agency/registry and the means for the submission to occur. The interface would **not** be providing the capability specified in the certification criterion adopted by Secretary, which Certified EHR Technology must include.

"YES"

- If, however, the interface were to perform a capability specified in an adopted certification criterion and the interface was intended to satisfy a correlated meaningful use requirement, it would need to be certified. Why? Because you are required to use Certified EHR Technology to demonstrate meaningful use and qualify for your respective EHR incentive program. As an example, if the interface was intended to provide the capability of electronically recording, modifying, retrieving and submitting immunization information according to the standards required by 45 CFR 170.302(k) or the capability to create immunization information for transmission according to the standards required by 45 CFR 170.314(f)(2), it would need to be certified.

Question [9-10-019-2]: *The "electronic copy of health information" certification criteria (45 CFR 170.304(f) and 45 CFR 170.306(d)) each require that Certified EHR Technology "enable a user to create an electronic copy of a patient's clinical information… in: (1) Human readable format; and (2) On electronic media or through some other electronic means…." Is there more than one way to demonstrate compliance with these certification criteria?*

Answer:
Yes, as discussed in the Initial Set of Standards, Implementation Specifications, and Certification Criteria Final Rule published in July 2010 (75 FR 44630), there is more than one way to demonstrate compliance with these certification criteria. For these certification criteria, Certified EHR Technology must be capable of generating two outputs to produce an electronic copy (i.e., a copy in human readable format and a copy as a CCD or CCR). If the Certified EHR Technology is capable of generating one copy that could meet both of these requirements, we would also consider that to be a compliant implementation of this capability.

Note: This answer is only relevant to 2011 Edition EHR certification as the "electronic copy of health information" certification criteria were revised and merged into the "view, download, and transmit to a 3rd party" certification criterion as part of the 2014 Edition EHR certification criteria.

Question [9-10-020-2]: *The certification criterion at 45 CFR 170.302(n) specifies (and similarly specified in 45 CFR 170.314(g)(2)) that "[f]or each meaningful use objective with a percentage-based measure, electronically record the numerator and denominator and generate a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure." Is it possible for the action of "record" in the certification criterion to be implemented in different ways and still remain in compliance with the certification criterion? For example, could "record" comprise the ability of a centralized analytics EHR Module to accept or retrieve raw data from another EHR Module or EHR Modules, and upon receipt of this raw data, the centralized analytics EHR Module would calculate the numerator, denominator, and the resulting percentage as specified by 45 CFR 170.302(n) and 170.314(g)(2)?*

Answer:
Yes, it is possible for the action of "record" in this certification criterion to be implemented in different ways. The example in this question appears to be one possible way to demonstrate compliance with this certification criterion. Other possible methods could include a Complete EHR that accepts or retrieves raw data, analyzes the data, and then generates a report based on the analysis; a Complete EHR that separately tracks each capability with a percentage-based meaningful use measure and later aggregates the numbers and generates a report; or an integrated bundle of EHR Modules in which each of the EHR Modules that is part of the bundle categorizes relevant data, identifies the numerator and denominator and calculates, when requested, the percentage associated with the applicable meaningful use measure. In each of these examples, the action of "record" means to obtain the information necessary to generate the relevant numerator and denominator.

Question [12-10-021-2]: *What does it mean to "possess" EHR technology as mentioned in FAQ 9-10-017?*

Answer:
We consider "possession" of EHR technology certified to an edition of EHR certification criteria to be either the physical possession of the medium on which a certified Complete EHR, or certified EHR Module resides, or a legally enforceable right by an eligible health care provider to access and use, at its discretion, the capabilities of a certified Complete EHR or certified EHR Module. An eligible health care provider may determine the extent to which it will implement or use these capabilities, which will not affect the provider's "possession" of the certified Complete EHR or certified EHR Module.

An EP, EH, or CAH must possess all of a certified Complete EHR or certified EHR Module (i.e., the capabilities for which certification is required) in order to receive the benefit of such certification. An EP, EH, or CAH cannot purchase or possess only "components" of a certified Complete EHR or certified EHR Module for the purposes of meeting the CEHRT definition. That is, unless independently certified, those "components" could not be used to meet the CEHRT definition. We further explain this policy in FAQ 5 and in the 2014 Edition EHR certification criteria final rule (77 FR 54266). In the final rule, we also note that the possession policy does not apply to those capabilities that an EHR technology developer may include with those that constitute a certified Complete EHR or certified EHR Module but for which certification is not required. In those instances, because these other included capabilities are not required for certification, an EP, EH, or CAH, would not necessarily need to possess them if the EHR technology developer would separately sell them.

Question [12-10-022-2]: *Do the 2011 Edition and 2014 Edition certification criteria pertaining to electronic prescribing, which reference certain content exchange standards (e.g., NCPDP SCRIPT 10.6), require that a Complete EHR or EHR Module be capable of electronically exchanging information with only external recipients (i.e., recipients that are not part of that legal entity) according to the appropriate standard (and implementation specifications) or do they apply more broadly?*

Answer:
The 2011 Edition and 2014 Edition certification criteria pertaining to electronic prescribing refer to the capability of electronically exchanging information only with external recipients. The certification criteria adopted at (45 CFR 170.304(b) and 170.314(b)(3)) for electronic prescribing reference content exchange and vocabulary standards that were adopted for the purpose of enabling a user of Certified EHR Technology to electronically "exchange" certain health information with different legal entities. As we explained in the proposed and final rules for the 2014 Edition EHR certification criteria (77 FR 13845 and 77 FR 54198), this position is consistent with and supports the meaningful use policy for the electronic prescribing MU objective as described in the Stage 2 proposed and final rules (77 FR 13710 and 77 FR 53989).

Question [12-10-023-2]: *Could an interface that transmits lab results in HL7 message format between a hospital laboratory system and a physician's EHR (presuming that the transmissions were occurring between two different legal entities) satisfy the certification criteria related to the exchange of key clinical information in 45 CFR 170.304(i) and 45 CFR 170.306(f)? If not, please specify the required data types and exchange characteristics that must be part of the required clinical information exchange.*

Answer:
As implied in the question, for certification a Complete EHR or an EHR Module must have the capability to electronically receive and display, and transmit certain key clinical information in accordance with one of two separate certification criteria (45 CFR 170.304(i) or 45 CFR 170.306(f)), depending on the setting for which the EHR technology is designed (ambulatory or inpatient, respectively). Generally speaking, these certification criteria require two types of information exchange capabilities – the capability to:

1. Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list in accordance with the continuity of care document (CCD) standard (and the HITSP/C32[1] implementation specifications) or the continuity of care record (CCR) standard and that upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format.

2. Electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list using the CCD standard (and the HITSP/C32 implementation specifications) or the CCR standard while also representing specific named data elements (problems, laboratory test results, and medications) according to adopted standards.

Note: The above uses language from 45 CFR 170.304(i). The certification criterion adopted at 45 CFR 170.306(f) also includes "procedures" as a required, standardized data element within these exchange capabilities.

Therefore, an interface that transmits lab results in HL7 message format between a hospital laboratory system and a physician's EHR (where the transmission is occurring between two different legal entities) would not qualify as an exchange of key clinical information that complies with the requirements of either of these two certification criteria. The interface would not satisfy the required capabilities included within the adopted certification criteria, and more specifically, the ability to transmit a patient summary record in accordance with the CCD standard (and the HITSP/C32 implementation specifications) or the CCR standard.

Note: This answer is only relevant to 2011 Edition EHR certification as the "exchange clinical information and patient summary record" certification criteria were revised and included in the

[1] HITSP Summary Documents Using HL7 Continuity of Care Document (CCD)

"transition of care" certification criteria at 45 CFR 170.314(b)(1) and (2) as part of the 2014 Edition EHR certification criteria.

Question [3-11-024-1]: *For the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, is an eligible professional or eligible hospital limited to demonstrating meaningful use in the exact way that EHR technology was tested and certified? For example, if a Complete EHR has been tested and certified using a specific workflow, is an eligible professional or eligible hospital required to use that specific workflow when it demonstrates meaningful use? Similarly, if the EHR technology was tested and certified with certain clinical decision support rules, are those the only clinical decision support rules an eligible health care provider is permitted to use when demonstrating meaningful use?*

Answer:
This FAQ has been jointly posted by ONC as FAQ24 and by CMS as FAQ 10473.
In most cases, an eligible professional or eligible hospital is not limited to demonstrating meaningful use to the exact way in which the Complete EHR or EHR Module was tested and certified. As long as an eligible professional or eligible hospital uses the certified Complete EHR or certified EHR Module's capabilities and, where applicable, the associated standard(s) and implementation specifications that correlate with the respective meaningful use objective and measure, they can successfully demonstrate meaningful use even if their exact method differs from the way in which the Complete EHR or EHR Module was tested and certified.

It is important to remember the purpose of certification. Certification is intended to provide assurance that a Complete EHR or EHR Module will properly perform a capability or capabilities according to the adopted certification criterion or criteria to which it was tested and certified (and according to the applicable adopted standard(s) and implementation specifications, if any). The Temporary Certification Program and Permanent Certification Program Final Rules (75 FR 36188 and 76 FR 1301, respectively), published by the Office of the National Coordinator for Health IT (ONC), acknowledged that eligible professionals and eligible hospitals could, where appropriate, modify their certified Complete EHR or certified EHR Module to meet local health care delivery needs and to take full advantage of the capabilities that the certified Complete EHR or certified EHR Module includes.

These rules also cautioned that modifications made to a Complete EHR or EHR Module post-certification have the potential to adversely affect the technology's capabilities such that it no longer performs as it did when it was tested and certified, which could ultimately compromise an eligible professional or eligible hospital's ability to successfully demonstrate meaningful use.

In instances where a certification criterion expresses a capability which could potentially be added to or enhanced by an eligible professional or eligible hospital, the way in which EHR technology was tested and certified generally would not limit a provider's ability to modify the EHR technology in an effort to maximize the utility of that capability. Examples of this could include adding clinical decision support rules, adjusting or adding drug-drug notifications, or generating patient lists or patient reminders based on additional data elements beyond those that were initially required for certification. Modifications that adversely affect the EHR technology's capability to perform in accordance with the relevant certification criterion could, however, ultimately compromise an eligible professional or eligible hospital's ability to successfully demonstrate meaningful use.

In instances where the EHR technology was tested and certified using a sample workflow and/or generic forms/templates, an eligible professional or eligible hospital generally is not limited to using that sample workflow and/or those generic forms/templates. In this context, the "workflow" would constitute the specific steps, methods, processes, or tasks an eligible professional or eligible hospital would follow when using one or more capabilities of the certified Complete EHR or certified EHR Module to meet meaningful use objectives and associated measures. An eligible health care provider could use a different workflow and/or substitute different forms/templates for those that are included in the certified Compete EHR or certified EHR Module. Again, care should be taken to ensure that such actions do not adversely affect the Complete EHR's or EHR Module's performance of the capabilities for which it was tested and certified, which could ultimately compromise an eligible professional or eligible hospital's ability to successfully demonstrate meaningful use.

Question [6-12-025-2]: *For an eligible professional using EHR technology certified to the 2011 Edition, can the definition of Certified EHR Technology be met by combining EHR technology certified for an inpatient setting with EHR technology certified for an ambulatory setting?*

Answer:
Yes. For all of the certification criteria that apply to Complete EHRs or EHR Modules designed for use in an ambulatory setting for which there is an equivalent or more comprehensive certification criterion that applies to Complete EHRs or EHR Modules designed for use in an inpatient setting, the EP may include the EHR technology tested and certified to the inpatient certification criteria as part of the EHR technology the EP possesses. For example, the "electronic copy of the health information" certification criterion adopted for the inpatient setting at 45 CFR 170.306(d) is more comprehensive (i.e., requires more data but not less) than the certification criterion adopted at 45 CFR 170.304(f) for the ambulatory setting. As discussed in the Standards and Certification Criteria interim final rule and the July 2010 final rule, we believe that the clinical setting should determine the applicable certification criteria. The following five certification criteria fall within this flexibility:

- 170.304(a) which is the same as 170.306(a);
- 170.304(e) which is the same as 170.306(c);
- 170.306(b) which is more comprehensive than 170.304(c);
- 170.306(d) which is more comprehensive than 170.304(f); and
- 170.306(f) which is more comprehensive than 170.304(i).

However, in order for an EP to possess EHR technology that meets the definition of Certified EHR Technology, the EP will also need to possess EHR technology with capabilities that are unique to the ambulatory setting and for which certification is required (e.g., electronic prescribing (170.304(b)); patient reminders (170.304(d); timely access; (170.304(g)); clinical summaries (170.304(h)); clinical quality measures (170.304(j))).

EPs that pursue this approach should use ONC's "Certified HIT Products List (CHPL)" webpage to generate a "CMS EHR ID #" to accurately attest to CMS or States the combination of certified EHR technologies used during the EHR reporting period. Further instruction on this approach is provided on the CHPL.

Question [10-12-026-1]: *Will ONC immediately enforce the new provisions in the Principles of Proper Conduct for ONC-ACBs (45 C.F.R. § 170.523) that require ONC-ACBs to report test results hyperlinks to ONC as well as ensure that EHR technology developers follow "price transparency" requirements?*

Answer:
No.

Reporting of Test Results Hyperlinks to ONC
In the September 4, 2012 standards and certification criteria final rule (77 FR 54163), section 170.523(f) was revised to require an ONC-ACB to provide ONC a hyperlink that enables the public to access the test results used by the ONC-ACB to certify each Complete EHR and EHR Module.

We will only enforce this provision against ONC-ACBs for certifications that are issued:

1. After ONC specifies that the CHPL is capable of posting test results hyperlinks; and
2. For a Complete EHR or EHR Module certified to the 2014 Edition EHR certification criteria.

We anticipate that the posting of test results hyperlinks on the CPHL will be available sometime after testing and certification to the 2014 Edition EHR certification criteria begins. We believe enforcing this provision only for certifications that are issued based on the 2014 Edition EHR certification criteria may reduce potential confusion on the part of health care providers and other consumers of EHR technology. If we were to enforce this provision for certifications issued based on the 2011 Edition EHR certification criteria, the test results used to certify EHR technology under the ONC HIT Certification Program would be publicly available, whereas the test results used under the Temporary Certification Program would not. This could lead to potential confusion for purchasers as to why some 2011 Edition EHR technology has test results available for review but most do not.

Ensuring that EHR Technology Developers Follow "Price Transparency" Requirements
In the September 4, 2012 standards and certification criteria final rule (77 FR 54163), section 170.523(k)(1) was revised to require an ONC-ACB to ensure that a Complete EHR or EHR Module developer discloses any additional types of costs that an EP, EH, or CAH would pay to implement the capabilities a certified Complete EHR or certified EHR Module includes in order to attempt to meet MU objectives and measures. As noted in the final rule, these types of costs are in addition to those costs that an EP, EH, or CAH would pay to purchase (or upgrade to) the EHR technology capabilities for which certification is required. These may be one-time or recurring costs, or both. ONC-ACBs will only be required to ensure that EHR technology developers disclose the types of additional costs – not the actual dollar amounts of such costs.

We will only enforce this provision for certifications issued by ONC-ACBs for EHR technology certified to the 2014 Edition EHR certification criteria. As with the reporting of test results hyperlinks, if we were to enforce this provision with regard to certifications issued based on the 2011 Edition EHR certification criteria, EHR technology certified under the Temporary Certification Program would not be affected. For that reason, we believe this policy may help to reduce potential confusion by consumers of EHR technology.

Question [10-12-027-1]: *The 2014 Edition preferred language standard (45 CFR 170.207(g)) requires EHR technology to be capable of representing a patient's preferred language in accordance with ISO 639-2 "limited" by ISO 639-1. What does "limited" or "constrained" by ISO-639-1 mean? Additionally, in some instances, there are ISO 639-2 languages that have both a (B) bibliographic code and (T) terminology code. In these instances, what code must be used?*

Answer:
"Limited" or "constrained" by ISO 639-1 means that the languages in ISO 639-2 that an EHR technology must be capable of representing are limited or constrained to those languages that have a corresponding alpha-2 code in ISO 639-1. EHR technology must be capable of representing these languages in the alpha-3 codes of ISO 639-2 for the purposes of certification. In instances where both a bibliographic code and terminology code are present for a required ISO 639-2 language, EHR technology is expected to be capable of representing the language in accordance with the (T) terminology codes (ISO 639-2/T) for the purposes of certification. For example, Albanian is the first language in ISO 639-2 where two codes [alb (B), sqi (T)] are present and, thus, "sqi" should be used to represent this language for certification. The bibliographic codes are for bibliographic applications and exist for historical reasons.

For further discussion of the differences between the bibliographic and terminology codes within ISO 639-2, please see the frequently asked question published by the Library of Congress at http://www.loc.gov/standards/iso639-2/faq.html#3.

Question [11-12-028-1]: *Are ONC-ACBs required to certify 2014 Edition Complete EHRs to both of the mandatory certification criteria at 45 CFR 170.314(g)(1) and (g)(2)? Similarly, if EHR technology presented for certification as an EHR Module has been tested to satisfy a combination of the capabilities specified in 45 CFR 170.314(g)(1) or (g)(2),what certification criterion must an ONC-ACB indicate as the one to which the EHR technology is certified when the ONC-ACB submits its weekly certification data to ONC?*

Answer:

Complete EHRs

EHR technology issued a 2014 Edition Complete EHR certification must be certified to § 170.314(g)(2) ("automated measure calculation") as it is a mandatory certification criterion consistent with the 2014 Edition Complete EHR definition requiring certification to all mandatory certification criteria for a particular setting (ambulatory or inpatient). While § 170.314(g)(1) ("automated numerator recording") is also designated as a mandatory certification criterion, a 2014 Edition Complete EHR is not required to be certified to the certification criterion (and therefore tested to the associated test procedure) because a 2014 Edition Complete EHR would have demonstrated capabilities beyond those included in § 170.314(g)(1) by being certified to (g)(2).

EHR Modules

Section 170.550(f)(1) requires ONC-ACBs to certify all EHR technology presented for certification as an EHR Module to be certified to § 170.314(g)(1) ("automated numerator calculation") for each capability (for which certification is sought) that would support a meaningful use objective with a percentage-based measure. Additionally, as we indicated in the 2014 Edition EHR certification criteria final rule (77 FR 54186), ONC-ACBs can certify an EHR Module to either § 170.314(g)(1) or (g)(2). In issuing a certification to an EHR Module for either of these certification criteria, we wish to further explain the testing process and subsequent certification issued to an EHR Module because the preamble expressed in the final rule did not include this level of specificity.

#	If EHR technology presented as an EHR Module is tested to:	Then an ONC-ACB, when issuing an EHR Module certification, should report in its weekly certification data to ONC that:
1	170.314(g)(1) only	170.314(g)(1) only was certified
2	170.314(g)(2) only	170.314(g)(2) only was certified
3	A combination of 170.314(g)(1) & (g)(2)	170.314(g)(1) only was certified

For scenario #3, when an EHR Module is tested to some combination of 170.314(g)(1) and (g)(2), an ONC-ACB can only attribute to that EHR technology's certification the fact that it had met 170.314(g)(1). This is so because, as we stated in the preamble, satisfying (g)(2) requires that an EHR Module presented for certification be capable of calculating all of the percentage-based MU measures for all of the capabilities it includes and that correlate to such percentage-based MU measures.

Question [11-12-029-1]: *How many clinical quality measures (CQMs) must EHR technology be certified to in order to be issued a 2014 Edition Complete EHR certification?*

Answer:
A 2014 Edition Complete EHR is defined as EHR technology that meets the Base EHR definition and has been developed to meet, at a minimum, all mandatory 2014 Edition EHR certification criteria for either an ambulatory setting or inpatient setting. The Base EHR definition specifies how many CQMs EHR technology must be certified to for the inpatient and ambulatory setting and, thus, how many CQMs EHR technology must be certified to in order to be issued a 2014 Edition Complete EHR certification.

For the ambulatory setting, in order for EHR technology to be issued a 2014 Edition Complete EHR certification it would need to be certified to § 170.314(c)(1) and (2) for no fewer than 9 CQMs covering at least 3 domains from the set selected by CMS for eligible professionals, including at least 6 CQMs from the recommended core set identified by CMS. For more information about the CQMs selected by CMS for eligible professionals beginning in CY 2014, please see Table 8 of CMS's EHR Incentive Program – Stage 2 final rule (77 FR 54069-54075) and subsequent notice correcting errors in Table 8 (77 FR 64755).

For the inpatient setting, in order for EHR technology to be issued a 2014 Edition Complete EHR certification it would need to be certified to § 170.314(c)(1) and (2) for no fewer than 16 CQMs covering at least 3 domains from the set selected by CMS for eligible hospitals and critical access hospitals (CAHs). For more information about the CQMs selected by CMS for eligible hospitals and CAHs beginning in FY 2014, please see Table 10 of CMS's EHR Incentive Program – Stage 2 final rule (77 FR 54083-54087).

To note, for 2014 Edition Complete EHR certification, EHR technology would also need to be certified to the mandatory certification criterion for electronic submission of CQMs at § 170.314(c)(3). This certification criterion includes the capability to electronically create a data file for transmission of clinical quality measurement data in accordance with QRDA Category I and III and that can be accepted by CMS.

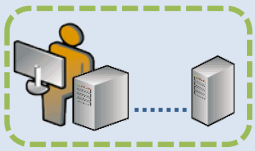
Question [11-12-030-1]: *What certification approaches would satisfy the 2014 Edition transitions of care certification criteria adopted at 45 CFR 170.314(b)(1) and (b)(2) as well as permit an eligible provider to have EHR technology that meets the Certified EHR Technology (CEHRT) definition? Please emphasize how the adopted transport standards fit in.*

Answer:
In general, EHR technology developers can take the three approaches outlined in the table below to meet the transitions of care certification criteria and their included transport standard(s). EHR technology certified according to any one of these three approaches could then be used by eligible providers to meet the CEHRT definition.

As additional context, it is important to keep in mind the "scope of a certification criterion" in the 2014 Edition EHR certification criteria (see 77 FR 54168). In the final rule, we describe that in order for a certification criterion to be met, all specific capabilities expressed under the second regulation text paragraph (e.g., everything under 170.314(b)(1)) would need to be demonstrated for certification. In other words, if EHR technology was presented for certification and could only perform the specific "create a CCDA" capability expressed in 170.314(b)(2)(i), that EHR technology would **not** meet this certification criterion.

With respect to transport standards, both certification criteria at 170.314(b)(1) and (b)(2) follow the same framework. At a minimum, EHR technology presented for certification must be able to electronically receive and transmit (in the respective certification criteria) transitions of care/referral summaries according to the Applicability Statement for Secure Health Transport. EHR technology developers are also able to seek certification to two optional transport standards:

- The Applicability Statement for Secure Health Transport specification and the XDR and XDM for Direct Messaging specification; and
- The Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 standard and the XDR and XDM for Direct Messaging specification.

Approach	Description
#1 Or #3	The EHR technology presented for certification can perform all of the specific capabilities expressed by the certification criterion, including the required capabilities for content and transport standard (and any optional transport standards) (e.g., for 170.314(b)(1), receipt according to transport standards, display of CCD/C32, CCR, and CCDA, and incorporation of CCDA sections). To the left, the images are meant to illustrate that the EHR technology presented for certification could be from an EHR technology developer that likely includes other clinical capabilities (top image) or from an EHR technology developer (e.g., HIE/HISP) that focuses on transition of care/transmission related capabilities (bottom image).
#2 	The EHR technology presented for certification can perform most of the capabilities expressed by the certification criterion (e.g., CCDA creation for 170.314(b)(2)), but also relies on a health information exchange (HIE) organization, health information service provider (HISP), or other 3rd party's technology to perform the required transport standard capability (and any optional transport standards). Under this approach and to meet the certification criterion: 1. The EHR technology must be presented for certification together with the technology supplied by the other entity to perform the transport capability (this other technology would be treated as "relied upon" software under ONC's certification rules (see FAQ 16)).

	2. The certification issued would represent the unique pairing of the EHR technology and the other entity's transport technology.

Finally, we note that these certification approaches could also be pursued in combination so long as the full scope of the certification criterion is met. For example, in order for an EHR technology developer to get its EHR technology certified to meet the required transport standard capability it could pursue the second approach and also seek certification for its EHR technology's native capability to perform to the second optional transport requirement (i.e., the SOAP-based RTM + XDR/XDM), which would enable its customers to have additional transport capabilities as part of their CEHRT.

Question [11-12-031-1]: *The XDR/XDM for Direct Messaging v1.0 adopted at 45 CFR 170.202(b) specifies that the value of three attributes (i.e., DocumentEntry.uniqueId, SubmissionSet.sourceId, and SubmissionSet.uniqueId) should be a UUID URN (Universally Unique Identifier Uniform Resource Name). This part of the XDR/XDM specification appears to be inconsistent with how both Integrating the Healthcare Enterprise (IHE)[2] and eHealth Exchange[3] specifications represent those same attributes (i.e., in the form of OIDs). Shouldn't these attributes all be represented the same way to be consistent across all three sets of specifications?*

Answer:
Yes, there should be consistency across these specifications. Thus, for these three attributes, EHR technology developers implementing the XDR/XDM for Direct Messaging specification should use UUID URNs formatted as OIDs. We expect testing to this specification to reflect this clarification.

[2] http://www.ihe.net/technical_framework/upload/ihe_iti_tf_rev7-0_vol3_ft_2010-08-10.pdf
[3] http://www.healthit.gov/policy-researchers-implementers/nationwide-health-information-network-nwhin

Question [11-12-032-2]: *CMS allows EPs, eligible hospitals, and CAHs flexibility in the ways they can calculate certain percentage-based meaningful use measures for attestation. As an EHR technology developer seeking certification to the 2014 Edition "automated measure calculation" certification criterion (45 CFR 170.314(g)(2)), must the EHR technology I present for certification be able to support every possible method of calculation that an EP, eligible hospital, or CAH could choose for a percentage-based measure?*

Answer:
For the 2014 Edition "automated measure calculation" certification criterion, we explained in the final rule that "for MU objectives which CMS has provided flexibility in its final rule for EPs, EHs, and CAHs to pursue alternative approaches to measuring a numerator and denominator, the EHR technology must be able to support all CMS-acceptable approaches in order to meet this certification criterion" (77 FR 54244 – 54245). This FAQ clarifies that statement in order to provide EHR technology developers with a more precise understanding of this certification criterion's scope.

What is required for certification depends on the type of flexibility identified by CMS. In some cases, CMS identifies certain measurement flexibilities that are limited to "either/or" options. In these cases, (specifically: 1) calculating hospital admissions based on the observation services method or the all ED method; 2) recording all three vital signs or just height/weight or just blood pressure; 3) including controlled substances in the eRx measure or not; and 4) for the hospital labs send structured electronic clinical lab results objective, counting electronic lab orders received or lab orders received) EHR technology presented for certification must be able to calculate the percentage based on both identified options. The one exception to this rule is if EHR technology presented for certification for e-prescribing does not include the capability to e-prescribe controlled substances, the EHR technology developer will not need to support that alternative measure calculation.

In cases where CMS has identified measurement flexibilities that are open-ended and dependent on a unique decision by an EP, eligible hospital, or CAH at the practice/organization-level for a given EHR reporting period (such as: including more than the minimum set of encounters as relevant for medication reconciliation, or excluding certain orders from the CPOE measure because they are protocol/standing orders), then the EHR technology presented for certification is not required to support every possible method of calculation in order to meet this certification criterion. Rather, the EHR technology must support at least one calculation method for this certification criterion. We strongly encourage EHR technology developers to work with their clients and to incorporate as many of these practice/organization-level open-ended flexibilities in the EHR technology as appropriate to make the meaningful use measures as relevant as possible to their clients' scopes of practice.

Question [12-12-033-1]: *Certain data found in paragraphs 45 CFR 170.314 (e)(2)(iii)(A) and (B), appear duplicative in the listing of the required data for the EHR technology clinical summary certification criterion. For that data and also for "immunizations" as part of the clinical summary certification criterion, how will these be tested and certified where vocabulary standards have been adopted?*

Answer:
In subparagraphs 45 CFR 170.314 (e)(2)(iii)(A) and (B), we list the minimum data EHR technology must permit a user to select when creating a clinical summary. However, upon further analysis, we have identified inadvertent redundancies between subparagraphs (A) and (B) that we now seek to clarify.

As identified in the table below, certain data specified in subparagraph (B)are duplicative or are generally redundant of those listed in subparagraph (A) as part of the Common MU Data Set. For those data where duplication exists, we have clarified whether testing and certification will require an adopted vocabulary standard. For testing and certification of "immunizations" in clinical summary data, we also provide such clarification:

Data specified in subparagraph (B)	Specified in subparagraph (A) as part of the Common MU Data Set?	Will testing and certification require the use of the adopted vocabulary standard?
Medications	Yes, as Medications	Yes; RxNorm.
"Diagnostic tests pending" and "Future scheduled tests"	Yes, as Lab Tests	Yes; to the degree that such "tests" could be coded in LOINC.
Immunizations	No	No; however, we encourage EHR technology developers to use the CVX code set similar to how it is required in other adopted certification criteria.

Question [12-12-034-1]: *Will the demonstration/use of vital signs and/or medication allergies data be individually required for testing and certification of the linked referential clinical decision support (CDS) capability specified in the certification criterion adopted at 45 CFR 170.314(a)(8)?*

Answer:
The specific capability for linked referential CDS is found at 45 CFR 170.314 (a)(8)(ii)(A), which states:

> *"(A) EHR technology must be able to:*
>
> > *(1) Electronically identify for a user diagnostic and therapeutic reference information; or*
> >
> > *(2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (2).*

and, further 45 CFR 170.314 (a)(8)(ii)(B) states:

> *(B) For paragraph (a)(8)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section."*

Based on analysis and stakeholder feedback (with which we agree), we clarify that testing for the linked referential CDS capability will not require the individual demonstration/use (i.e, the "each one" requirement) of vital signs or medication allergies data.

We understand that for the Infobutton-enabled capability at (a)(8)(ii)(A)(2), the implementation guides do not support either of these two data. Thus, we do not intend for testing or compliance with this specific capability within the certification criterion to be based on the individual assessment of vital signs or medication allergies data (i.e., the "each one" requirement) to meet the capability specified at (a)(8)(ii)(A)(1) or (a)(8)(ii)(A)(2).

We also understand and clarify that with respect to demographics data that certain demographic data (e.g., age) can and should be used as a modifier. We intend for testing and certification to evaluate this specific capability in that way. Similar to the prior clarification we do not intend for demographic data to be individually tested or required for certification as part of the "each one" requirement of this specific capability.
In summary, for the purposes of testing and compliance with the capability specified at (a)(8)(ii)(A)(1) or (a)(8)(ii)(A)(2) in the CDS certification criterion, demographics, vital signs, and medication allergies data are not expected to be individually tested or required for certification as part of the "each one" requirement of this specific capability.

Question [12-12-035-1]: *Are "coded entries" required for data referenced by 2014 Edition EHR certification criteria that specify the use of the Consolidated CDA standard even when the standard allows for narrative?*

Answer:
Yes, in all instances where we have adopted a vocabulary standard in § 170.207 the accompanying Consolidated CDA section-template implemented must be done so using the section-template with required structured data, coded entries required. Additionally, where a section-template with coded entries required is unavailable, we expect that testing and certification will still assess that data for which a vocabulary standard is adopted is represented in an appropriate coded entry structure within that section-template. Please see 77 FR 54180 (right column) for a more detailed explanation.

Question [12-12-036-1]: *Are ONC-Authorized Certification Bodies (ONC-ACBs) required to perform gap certification under the ONC HIT Certification Program?*

Answer:
No. We stated in the Permanent Certification Program final rule (76 FR 1291) that gap certification would be an option for ONC-ACBs and that it would be left to the discretion of each ONC-ACB as to whether to offer gap certification. We emphasize, however, that if an ONC-ACB decides to offer gap certification, it must conduct gap certification according to regulatory requirements and should be aware of ONC guidance under the ONC HIT Certification Program. ONC-ACBs should also offer gap certification according to procedures that are available to any EHR technology developer that would seek certification from the ONC-ACB and provide clear and equitable treatment of EHR technology developers' requests for gap certification.

Question [12-12-037-1]: *In the 2014 Edition Standards and Certification Criteria Final Rule, ONC clarified that the two new SNOMED CT codes for smoking status "light tobacco smoker" and "heavy tobacco smoker" meant, respectively, fewer than 10 cigarettes per day and greater than 10 cigarettes per day. To which code should exactly 10 cigarettes per day be attributed?*

Answer:
The "heavy tobacco smoker" code.