ONC Regulations FAQs

Question [9-10-001-1]: *What certification criteria will ONC-ATCBs 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regulations, as discussed in the Temporary Certification Program Final Rule (the Final Rule) (75 FR 36185) has been superseded or folded into the ONC-ATCB and ONC-ACB "authorization" processes.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 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 [9-10-002-1]: *If my EHR technology is capable of submitting batch files to an immunization registry using the adopted standards (HL7 2.3.1 or 2.5.1 and CVX), is that sufficient for demonstrating compliance with the certification criterion specified at 45 CFR 170.302(k)?*

Answer:
The certification criterion at 45 CFR 302(k) does not specify, and is 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 one or both of the adopted standards, is not prohibited by this certification criterion and would be acceptable.

Question [9-10-003-2]: *In the Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule published on July 28, 2010, the Secretary adopted the following implementation specifications at 45 CFR 170.205(d)(2) for the HL7 2.5.1 standard: Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and Errata and Clarifications National Notification Message Structural Specification. We believe that these implementation specifications may have been adopted in error because they only provide direction to public health agencies on how to report to the Centers for Disease Control and Prevention (CDC). Therefore, their adoption does not appear to either provide the appropriate or requisite implementation guidance for the adopted standard, HL7 2.5.1, or more importantly, to enable the user to "electronically record, modify, retrieve, and submit syndrome-based public health surveillance information…," as required by the adopted certification criterion, 45 CFR 170.302(l). Please clarify whether these implementation specifications are appropriate for the intended capability specified by the public health surveillance certification criterion at 45 CFR 170.302(l).*

Answer:
We have received numerous requests seeking clarification regarding these adopted implementation specifications. Based on additional discussions with various stakeholders, input from public health agencies, and the CDC, and after further review of the implementation specifications, we have determined that these implementation specifications were adopted in error. As some questioners correctly point out, the implementation specifications are not appropriate for the intended capability specified by the adopted certification criterion. They provide direction to public health agencies on the structure and methodology for using HL7 2.5.1 to report Nationally Notifiable Conditions to CDC and do not provide additional clarity for how EHR technology would need to be designed to implement the adopted standard or enable compliance with the capability identified in the certification criterion adopted at 45 CFR 170.302(l).

On October 13, 2010, we published an interim final rule in the Federal Register (75 FR 62686) with an immediate effective date to remove the implementation specifications adopted at 45 CFR 170.205(d)(2). The interim final rule also provides for a 30-day public comment period. Please refer to the instructions included at the beginning of the interim final rule if you are interested in submitting a comment.

Question [9-10-004-1]: *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 regulations do not specify who may ask an ONC-ATCB to test and certify 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 by an ONC-ATCB, 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 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 [9-10-005-1]: *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 definition of a Complete EHR, nor would it 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. Additionally, the separate component(s) would not satisfy the requirements of 45 CFR 170.450(c) related to the privacy and security testing and certification of EHR Modules.

This concept is similar to our treatment of integrated bundles of EHR Modules. We clarified in the Temporary Certification Program final rule (75 FR 36191) that EHR Modules, once certified as part of a bundle, would not each separately inherit a certification just because they were certified as part of a bundle.

Therefore, EHR technology developers must have the separate components of a certified Complete EHR tested and certified as EHR Modules before the components may be sold separately as certified EHR Modules. Because ONC-ATCBs that are authorized to test and certify Complete EHRs are also, by default, authorized to test and certify all types of EHR Modules, such ONC-ATCBs are not precluded from issuing separate certifications for the separate components of a Complete EHR as EHR Modules at the same time the Complete EHR is presented for testing and certification, provided that the ONC-ATCB satisfies its responsibilities under 45 CFR 170.450 as well as other such responsibilities related to EHR Modules (e.g., 45 CFR 170.423 the Principles of Proper Conduct for ONC-ATCBs).

Question [9-10-006-1]: *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 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 that is authorized to test and 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 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. Along those lines, if an ONC-ATCB permits a developer or presenter to request a different type of certification for the EHR technology it has submitted, the ONC-ATCB should be cognizant of other responsibilities it may need to satisfy for EHR Modules (e.g., 45 CFR 170.450).

Question [9-10-007-1]: *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. In relation to this question, we reiterate paragraph two of the definition of Certified EHR Technology at 45 CFR 170.102. "Certified EHR Technology means: … (2) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR." As we discussed in the Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" Final Rule (75 FR 44597), only proper combinations of EHR Modules would meet the definition of Certified EHR Technology. We encourage eligible health care providers who seek to implement certified EHR Modules to consider ahead of time the types of certified EHR Modules that may be needed to ensure that all applicable criteria will be met.

Question [9-10-008-1]: *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:
EHR Module means any service, component, or combination thereof that meets at least one certification criterion adopted by the Secretary. 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.

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 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)).

Question [9-10-009-1]: *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 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). 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 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) 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).

Additionally, an ONC-ATCB is responsible for reporting to ONC a current list of the EHR technology it has tested and certified. Only EHR technologies reported by ONC-ATCBs 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 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 is permitted to report information to ONC related to re-branded or renamed Complete EHRs that it has certified. We anticipate that 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 [9-10-010-1]: *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 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 testing and 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 306(f)(1)) and my EHR technology from EHR technology developer XYZ transmits summary records (45 CFR 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 [9-10-012-1]: *How many clinical quality measures must EHR technology be capable of calculating in order to get certified?*

Answer:
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 a specific certification criterion for each setting to correspond to the correlated meaningful use requirements for which eligible professionals and eligible hospitals and critical access hospitals must satisfy (45 CFR 170.304(j) and 45 CFR 170.306(i), respectively).

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 HIT Standards and Certification Criteria 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) 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.

Question [9-10-013-2]: *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 (45 CFR 170.304(j) or 45 CFR 170.306(i)) and for which you as an eligible health care provider have a correlated meaningful use requirement to satisfy.

Question [9-10-014-1]: *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 definition of Certified EHR Technology 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 all of the applicable certification criteria adopted by the Secretary have been met and 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.

Question [9-10-015-1]: *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 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:

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
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)).

Question [9-10-016-1]: *I'm in the process of implementing EHR technology developer XYZ's certified Complete EHR [or certified EHR Module] "E-HealthSystem2010."*

Scenario 1: *I have determined that E-HealthSystem2010 needs to be reconfigured in order to connect with one of my patient registration systems. Can I reconfigure E-HealthSystem2010 without compromising the certified status of my implementation of E-HeatlhSystem2010?*

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-HeatlhSystem2010's certification. 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-HeatlhSystem2010. Can I use SuperListGenerator 7.0 in lieu of PatientInfoTracker 2.0 without compromising the certified status of my implementation of E-HeatlhSystem2010?*

Answer:
With respect to Scenario 1, yes, you can reconfigure your implementation of E-HealthSystem2010 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 these modifications do not adversely affect the performance of E-HealthSystem2010 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-HealthSystem2010 that identifies SuperListGenerator 7.0 as a relied upon software program; or
- You seek certification for SuperListGenerator 7.0 as an EHR Module.

Question [9-10-017-2]: *I am an eligible health care provider seeking to achieve "meaningful use of Certified EHR Technology" under the Medicare and Medicaid EHR Incentive Programs. I understand that under the Medicare and Medicaid EHR Incentive Programs ("meaningful use") Final Rule, I am permitted to defer up to 5 meaningful use "menu set" objectives and associated measures for a given EHR reporting period. Do I need to possess EHR technology that has/have been tested and certified: A) to all of the applicable certification criteria adopted in ONC's Standards and Certification Criteria Final Rule; or B) only to those certification criteria that correlate with the Stage 1 core set objectives and associated measures and menu set objectives and associated measures I select to report on to CMS?*

Answer:
"A - to all of the applicable certification criteria adopted in ONC's Standards and Certification Criteria Final Rule."

Eligibility to receive a Medicare or Medicaid EHR incentive payment consists of two related, but distinct steps – the possession of Certified EHR Technology and subsequently demonstrating its meaningful use. In order to be able to attest to CMS or States at the end of your EHR reporting period that you possess EHR technology that meets the regulatory definition of Certified EHR Technology[1] adopted by HHS (45 CFR 170.102 and 42 CFR 495.4), the EHR technology in your possession must have been tested and certified to all applicable certification criteria adopted for the setting (ambulatory or inpatient) for which it was designed (see also CMS FAQ 10162). Please see the discussion below for more on the meaning of "applicable certification criteria" as well as what is required for the EHR technology in your possession to meet the definition of Certified EHR Technology.

Step 1: Possession of Certified EHR Technology

As discussed in more detail in FAQ 12-10-21, we consider "possessing" (or "having") Certified EHR Technology to include either the physical possession of medium on which a certified Complete EHR or combination of certified EHR Modules resides, or a legally enforceable right by an eligible health care provider to access and use, at its discretion, the capabilities a certified Complete EHR or combination of certified EHR Modules includes. 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 Certified EHR Technology.

Step 2: Demonstrating Meaningful Use of Certified EHR Technology

[1] Certified EHR Technology is defined at 45 CFR 170.102 to mean:

(1) A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary; or

(2) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

Generally stated, eligible health care providers, upon satisfying the core set objectives and measures, can choose 5 out of 10 menu set objectives and associated measures to satisfy the meaningful use requirements. Consequently, our general rule is that an eligible health care provider for meaningful use Stage 1 must attest to having satisfied the combined 19 (eligible hospital) or 20 (eligible professionals) core and selected menu set objectives and associated measures using capabilities and standards Certified EHR Technology includes to successfully demonstrate meaningful use of Certified EHR Technology. Stated another way, eligible health care providers will still be able to receive an incentive payment even if they are unable to demonstrate that they meet up to 5 of the meaningful use menu set objectives and associated measures.[2]

The definition of Certified EHR Technology does not vary based on the diverse combinations of menu set objectives and associated measures that each eligible health care provider could potentially select to satisfy the meaningful use requirements. Rather, it specifies the minimum set of adopted certification criteria to which the EHR technology in an eligible health care provider's possession must be tested and certified. Some of our reasons for this approach include, but are not limited to, the following:

- ONC and CMS have noted that in future rulemaking, the Department will consider making the optional Stage 1 meaningful use objectives mandatory for Stage 2 (see, for example, 75 FR 44322). Accordingly, the requirement that Certified EHR Technology support all Stage 1 objectives and associated measures creates a foundation eligible health care providers can build upon, without creating an obligation to meaningfully use each and every capability of Certified EHR Technology during Stage 1.
- We recognize that there will be a variety of circumstances and unanticipated implementation and workflow redesign challenges that will affect an eligible health care provider's ability to both prepare itself to participate in the EHR incentive programs and subsequently demonstrate meaningful use of Certified EHR Technology. By possessing Certified EHR Technology, eligible health care providers, especially those adopting EHR technology for the first time, will have the flexibility during an EHR reporting period to determine which menu set objectives and associated measures they will be capable of meeting or need to defer, in the event that one proves to be more difficult to meet than expected.
- We sought to accommodate the different legislative and programmatic requirements for the Medicare and Medicaid EHR Incentive Programs (e.g., Medicaid eligible health care providers are able to receive an incentive for adopting, upgrading, or implementing Certified EHR Technology in their first participation year and do not need to demonstrate meaningful use by satisfying the appropriate amount of core and menu set objectives and associated measures).

Meeting the Definition of Certified EHR Technology

[2] CMS regulations require that at least one of the menu set objectives chosen relate to public health. Also, CMS will need to review States' Medicaid Health Information Technology Plans to determine if States have requested to add to the core set of measures, per CMS's final regulations.

In the Standards and Certification Criteria Interim Final Rule (75 FR 2022), we explained what we meant by "applicable certification criteria" in the definition of Certified EHR Technology. We stated that Congress indicated in the HITECH Act its expectation that different types of HIT would be certified, and it referenced two examples in the statutory definition of Certified EHR Technology: "an ambulatory electronic health record for office-based physicians" and "an inpatient hospital electronic health record for hospitals." We noted that certain meaningful use Stage 1 objectives and associated measures only apply to an eligible professional or to an eligible hospital and that these two types of providers require different capabilities from Certified EHR Technology. Accordingly, we adopted specific certification criteria (at 45 CFR 170.304 and 45 CFR 170.306) that are only "applicable" to Complete EHRs or EHR Modules designed for use in an ambulatory setting (i.e., by eligible professionals) or an inpatient setting (i.e., by eligible hospitals). Consequently, the Certified EHR Technology an eligible professional must possess does not need to include, for example, the capabilities to create an electronic copy of discharge instructions and record advance directives (45 CFR 170.306(e) and 45 CFR 170.306(h), respectively) as those certification criteria are not "applicable" to that type of EHR technology

We explained in the Standards and Certification Criteria Interim Final Rule and Final Rule (75 FR 2023 and 75 FR 44597, respectively) that a certified Complete EHR or a combination of certified EHR Modules must include all of the capabilities required by all of the applicable certification criteria to meet the definition of Certified EHR Technology. In other words, for purposes of the definition of Certified EHR Technology, a certified Complete EHR and an equivalent combination of certified EHR Modules would have been tested and certified to the same applicable certification criteria. We noted that if a combination of certified EHR Modules <u>did not include all of the capabilities</u> required by all applicable certification criteria, such a combination <u>would not meet the definition of Certified EHR Technology</u>.

As an example (excluding the optional certification criterion at 45 CFR 170.302(w)), a Complete EHR designed for an ambulatory setting must be tested and certified to 32 certification criteria to meet the definition of Certified EHR Technology (i.e., the certification criteria adopted at 45 CFR 170.302(a)-(v) and 45 CFR 170.304(a)-(j)). Therefore, an equivalent combination of certified EHR Modules designed for an ambulatory setting would also need to include the capabilities required by those 32 certification criteria in order for the combination to meet the definition of Certified EHR Technology, regardless of the number of EHR Modules that make up the combination (*Note: Under the temporary certification program, EHR Modules are subject to certain certification requirements with respect to privacy and security, see 45 CFR 170.450(d)*).

****FAQ 9-10-017-1 is superseded by FAQ 9-10-017-2 and its companion FAQ 12-10-021-1****
****FAQ 9-10-017-1 is referenced below for informational purposes only****

Question [9-10-017-1]: *Under the Medicare and Medicaid EHR Incentive Programs Final Rule, eligible health care providers are permitted to defer certain meaningful use objectives and measures and still receive an EHR incentive payment. However, it is our understanding that in order for us to have our EHR technology certified, we must implement all of the applicable capabilities specified in the adopted certification criteria regardless of whether we intend to use all of those capabilities to qualify for our EHR incentive payment. Is our understanding correct?*

Answer:
Yes, this understanding is correct. The flexibility offered as part of the Medicare and Medicaid EHR Incentive Programs Final Rule is not mirrored in the Initial Set of Standards, Implementation Specifications, and Certification Criteria Final Rule because we believe that it is important to accommodate eligible health care providers' ability to achieve meaningful use. We recognize that in some circumstances an eligible health care provider may not know which meaningful use measures they will seek to defer until they begin implementation and in others an individual provider (even within a specialty) will want to choose different measures to defer based on their local situation and implementation experience. Thus, in order to possess EHR technology that meets the definition of Certified EHR Technology, it must be tested and certified by an ONC-ATCB to all applicable certification criteria adopted by the Secretary.

Question [9-10-018-1]: *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 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 in a standardized format (45 CFR 170.302(k)), it would need to be certified.

Question [9-10-019-1]: *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, there is more than one way to demonstrate compliance with this certification criterion. For this certification criterion, 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.

Question [9-10-020-1]: *The certification criterion at 45 CFR 170.302(n) specifies 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)?*

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 [12-10-021-1]: *What does it mean to "possess" Certified EHR Technology as discussed in FAQ 9-10-017 and can I still possess Certified EHR Technology without implementing or using a capability it includes?*

Answer:
In the first version of FAQ 9-10-017, the "question" asked whether eligible health care providers needed to "implement all of the applicable capabilities specified in the adopted certification criteria regardless of whether [they] intend to use all of those capabilities to qualify for [an] EHR incentive payment." We did not directly address the term "implement" in our "answer" to the first version of this question. Rather, we stated at the end of our "answer," consistent with our usage throughout our regulations, that in order to possess EHR technology that meets the definition of Certified EHR Technology, it must be tested and certified by an ONC-ATCB to all applicable certification criteria adopted by the Secretary. Since the publication of our "answer" to the first version of this question, we received more questions expressing confusion about what is required to meet the definition of Certified EHR Technology and whether the certified EHR technology in an eligible health care provider's possession must be implemented or used in order for the definition to be met.

We consider "possession" of Certified EHR Technology to be either the physical possession of medium on which a certified Complete EHR or combination of certified EHR Modules resides, or a legally enforceable right by an eligible health care provider to access and use, at its discretion, the capabilities a certified Complete EHR or combination of certified EHR Modules includes. 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 Certified EHR Technology. While we recognize that eligible health care providers may enter into various business arrangements depending on their particular needs and circumstances, we would expect that such arrangements could potentially include agreements with EHR technology developer(s) to access and use the capabilities included in Certified EHR Technology. Further, that these business arrangements could make an eligible health care provider's payment for a particular capability contingent on its use or implementation of that capability in a production environment or the provider's request for maintenance or technical support. If an eligible health care provider has sought testing and certification for its own "self-developed" EHR technology, we would presume that such EHR technology would be in the provider's possession because it would possess the physical medium on which a certified Complete EHR or combination of certified EHR Modules resides.

We offer the following scenarios to further explain the above points.

Scenario 1: Dr. Joe, an eligible professional, has acquired a license to use EHR Technology Developer A's certified Complete EHR. In order to meet the "timely access" meaningful use objective and associated measure (42 CFR 495.6(e)(5)), he would prefer to use EHR Technology Developer B's certified EHR Module to provide his patients' online access (45 CFR 170.304(g)) because he considers it "best in class." In this circumstance, Dr. Joe and EHR Technology Developer A could, for example, structure the terms of his license agreement such that he would not have to pay for the online access capability that is included with EHR Technology Developer A's certified Complete EHR.

Scenario 2: Hospital ABC, an eligible hospital, has sought testing and certification for its own "self-developed" EHR technology as an EHR Module that performs computerized provider order entry (CPOE) (45 CFR 170.306(a)), in order to meet the "CPOE" meaningful use objective and associated measure (42 CFR 495.6(f)(1)). Hospital ABC would prefer to acquire a license to use EHR Technology Developer C's certified Complete EHR in order to possess Certified EHR Technology and subsequently satisfy the remaining meaningful use objectives and associated measures it will need to meet in order to receive an incentive payment. In this circumstance, Hospital ABC and EHR Technology Developer C could, for example, structure the terms of the license agreement such that Hospital ABC would not have to pay for the CPOE capability that is included with EHR Technology Developer C's certified Complete EHR.

With respect to both of these scenarios, please see ONC FAQ 14 regarding the permitted use of a duplicative or overlapping certified capability and meeting the definition of Certified EHR Technology.

Question [12-10-022-1]: *Does the certification criterion pertaining to electronic prescribing, which references certain content exchange standards (i.e., NCPDP SCRIPT 8.1 and 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 does it apply more broadly?*

Answer:
For the certification criterion pertaining to electronic prescribing (45 CFR 170.304(b)), which references those two content exchange standards adopted at 45 CFR 170.205(b) and the vocabulary standard 170.207(d) (i.e., any source vocabulary that is included in RxNorm), a Complete EHR or EHR Module must be certified as being capable of electronically generating and transmitting prescriptions and prescription-related information to external recipients in accordance with the appropriate adopted standard(s) (and implementation specifications). These standards were adopted for the purpose of enabling a user of Certified EHR Technology to "exchange" electronically certain health information, as indicated in the first sentence of the regulatory section and the section title, and as alluded to in various other parts of the Standards and Certification Criteria Interim Final and Final Rules.

We intended the capability required by this certification criterion and the referenced standards and implementation specifications to apply to the electronic exchange of prescription information between different legal entities (e.g., from an eligible professional's Certified EHR Technology to a pharmacy that is not part of the eligible professional's legal entity), to complement how CMS has generally described "exchange" in the context of meaningful use as information "sent between different legal entities with distinct certified EHR technology or other system that can accept the information…." (75 FR 44361-62). In the Standards and Certification Criteria Interim Final Rule and in the Standards and Certification Criteria final rule, we discussed current Medicare Part D electronic prescribing regulatory requirements for using NCPDP SCRIPT 8.1, and the anticipated use of NCPDP SCRIPT 10.6. (75 FR 2031-32, 75 FR 44625-26). In both rules, we also had explained that the purpose of the adopted standards and certification criteria was not to specify how or when Certified EHR Technology must be used, but only what capabilities Certified EHR Technology must include. (75 FR 2022-23, 75 FR 44592-93). We sought to align the adopted standards, implementation specifications, and certification criteria with certain already established regulatory requirements to ensure that Certified EHR Technology would provide a base-level of capabilities to assist users in meeting those other regulatory requirements. (See, for example, 75 FR 44591, and 75 FR 44598.) Then, when discussing electronic prescribing, we referred to the adopted NCPDP SCRIPT standard as a standard required under the Medicare Part D e-prescribing regulations when "an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy)…." (75 FR 2031-32, 75 FR 44592). Consequently, with respect to the capability a Complete EHR or EHR Module must demonstrate in order to be certified to the certification criterion adopted at 170.304(b), a Complete EHR or EHR Module must be capable of electronically transmitting prescriptions and prescription-related information to external recipients according to NCPDP SCRIPT 8.1 or 10.6 in addition to the adopted vocabulary standard for medications at 45 CFR 170.207(d).

This approach is consistent with a principle we established in the Standards and Certification Criteria Interim Final Rule where we sought to ensure that eligible health care providers seeking to meaningfully use Certified EHR Technology and engaging in electronic exchange would be able to do so in a manner that would be compliant with other applicable law. Thus, with respect to electronic prescribing, we adopted NCPDP SCRIPT 8.1 and 10.6 to ensure that when an eligible professional electronically transmits a prescription or prescription-related information for Medicare Part D covered drugs for

Medicare Part D eligible individuals to, for example, a pharmacy that is not part of the legal entity of the eligible professional, the eligible professional would be able to do so using Certified EHR Technology and also comply with the Medicare Part D e-prescribing rules.

See CMS FAQ 10284 for information about how these transmissions should be counted.

Question [12-10-023-1]: *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[3] 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.

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

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 [6-12-025-1]: *For an eligible professional, 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 and final rules, 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.

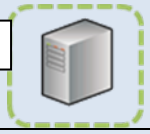
Question [11-12-030-1]: *What certification approaches would satisfy the 2014 Edition transitions of care certification criteria adopted at 45 CFR 170.314(b)(1) and (b)(2) as well as permit an eligible provider to have EHR technology that meets the Certified EHR Technology (CEHRT) definition? Please 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)[4] and eHealth Exchange[5] 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.

[4] http://www.ihe.net/technical_framework/upload/ihe_iti_tf_rev7-0_vol3_ft_2010-08-10.pdf

[5] http://www.healthit.gov/policy-researchers-implementers/nationwide-health-information-network-exchange