

NPRM Requests for Public Comment—Temporary Certification

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We request public comment on whether ONC–ATCBs should also be required to test and certify that any EHR Module presented by one EHR Module developer for testing and certification would properly work (*i.e.*, integrate) with another EHR Module presented by a different EHR Module developer (this request for public comment would also apply to ONC–ACBs under the permanent certification program).

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Additionally, we request public comment on whether the National Coordinator should permit applicants to seek authorization to test and certify only Complete EHRs designed for an ambulatory setting or, alternatively, Complete EHRs designed for an inpatient setting.

Under our current proposal, an applicant seeking authorization to perform Complete HER testing and certification would be required to test and certify Complete EHRs designed for both ambulatory and inpatient settings. However, if we were to separately authorize Complete HER testing and certification, we see certain benefits for the temporary certification program as well as some negative effects. Among the benefits, this approach could create the potential that more organizations would apply for ONC–ATCB status because fewer resources may be needed and could be focused on one type of testing and certification. Among the negative effects, this approach could result in a situation in which no ONC–ATCB exists to certify one or another type of Complete EHR. This would prevent the testing and certification of Complete EHRs designed for either an ambulatory or inpatient setting from being able to be tested and certified.

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3. Authorized Testing and Certification Methods

We propose that in being authorized to test and certify Complete EHRs and or EHR Modules, ONC–ATCBs must have the capacity to test and certify Complete EHRs and/or EHR Modules at their facility. We propose further that an ONC–ATCB must also have the capacity to test and certify Complete EHRs and or EHR Modules through some secondary means or at a secondary location. Such secondary methods would include testing and certification: (1) At the site (*i.e.*, physical location) where a Complete EHR or EHR Module has been developed (*e.g.*, at a Complete EHR developer’s facility); or (2) at the site (*i.e.*, physical location) where the Complete EHR or EHR Module resides (*e.g.*, at a hospital where the HIT has been installed); or (3) remotely (*i.e.*, through other means, such as through secure electronic transmissions and automated Web-based tools, or at a location other than the ONC–ATCB’s facilities). We believe that these secondary testing and certification methods will better accommodate self developed Complete EHRs and EHR Modules. For example, a Complete EHR developer may submit a Complete EHR to an ONC–ATCB to be tested and certified at the ONC–ATCB’s facility. In other cases, it may not be practicable for a hospital with a self-developed Complete EHR to submit its Complete EHR to an ONC–ATCB for testing and certification at the ONC–ATCBs facility and, in these cases, we expect that ONC–ATCBs would either test and certify the hospital’s Complete EHR at the hospital where the Complete EHR resides or remotely through other means that do not require the ONC–ATCB to be physically present at the hospital. We expect that the most common form of remote testing and certification will employ the use of automated programs that can be accessed by the hospital via the Internet to demonstrate to the ONC–ATCB that its Complete EHR meets all applicable certification criteria adopted by the Secretary. Other forms of remote testing and certification may include an employee of the ONC–ATCB walking through a particular scripted scenario with predefined data that the hospital would have to “plug-in” to their Complete EHR and then convey the result (*e.g.*, the hospital would be asked to enter fabricated information on a group of “test” patients into its Complete EHR and provide responses to specific questions asked by the ONC–ATCB employee). We request public comment on whether an ONC–ATCB should be required to perform any of the secondary methods discussed above in addition to testing and certifying Complete EHRs and/or EHR Modules at its facility.

4. The Testing and Certification of “Minimum Standards”

In the HIT Standards and Certification Criteria interim final rule (75 FR 2014), we explained how we would approach the testing and certification of Complete EHRs and EHR Modules for certain vocabulary code set standards. Our

approach included the establishment of these standards as “minimum standards.” Adopting a particular version of the code set as a “minimum” permits a Complete EHR and/or HER Module to be tested and certified to a permitted newer version of an adopted code set without the need for additional rulemaking on the part of the Secretary. For example, on the day the HIT Standards and Certification Criteria interim final rule was put on display by the **Federal Register** for public inspection a new version (version 2.29) of Logical Observation Identifiers Names and Codes (LOINC) was released. In that regard, we stated the following in the HIT Standards and Certification Criteria interim final rule:

[W]e understand that certain types of standards, specifically code sets, must be maintained and frequently updated to serve their intended purpose effectively * * * To address this need and accommodate industry practice, we have in this interim final rule indicated that certain types of standards will be considered a floor for certification. We have implemented this approach by preceding references to specific adopted standards with the phrase, “at a minimum.” In those instances, the certification criterion requires compliance with the version of the code set that has been adopted through incorporation by reference, or any subsequently released version of the code set. This approach will permit Complete EHRs and EHR Modules to be tested and certified, to, “at a minimum,” the version of the standard that has been adopted or a more current or subsequently released version. This will also enable Certified HER Technology to be updated from an older, “minimum,” adopted version of a code set to a more current version without adversely affecting Certified EHR Technology’s “certified status.” We intend to elaborate in the upcoming HIT Certification Programs proposed rule on how testing and certification would be conducted using standards we have adopted and designated as “minimums” in certain certification criteria. That being said, we understand that this approach has certain limitations. In some cases, for instance, rather than simply maintaining, correcting, or slightly revising a code set, a code set maintaining organization will modify the structure or framework of a code set to meet developing industry needs. We would consider this type of significant revision to a code set to be a “modification,” rather than maintenance or a minor update of the code set. An example of a code set “modification” would be if a hypothetical XYZ code set version 1 were to use 7-digit numeric codes to represent health information while XYZ code set version 2 used 9-digit alphanumeric codes to represent health information. In such cases, interoperability would likely be reduced among Complete EHRs and EHR Modules that have adopted different versions of the structurally divergent code sets. If a code set that we have adopted through incorporation by reference is modified significantly, we will update the incorporation by reference of the adopted version with the more recent version of the code set prior to requiring or permitting certification according to the newer version.

At the end of this discussion we provided examples of when a standard would be considered a “minimum standard” and the limitation to our approach. To address the identified limitation, we propose to clarify when a newer version of an adopted “minimum standard” code set would be permitted for use in testing and certification and when it would not. We believe that there are two prevailing methods the Secretary could use to determine whether a significant revision to a code set represents a “modification, rather than maintenance or a minor update of the code set” and, consequently, when a code set version should not be permitted for testing and certification above the minimum adopted by the Secretary until additional public comment can be obtained.

The first method would allow for any member of the general public to notify the National Coordinator about a new version of an identified “minimum standard” code set. For this method, we would encourage the person or entity who submits a notification to the National Coordinator to include any relevant information the National Coordinator would need to correctly identify the “minimum standard” code set (*e.g.*, name and version) and any additional information that the National Coordinator could use to determine whether the new version constitutes general maintenance or minor updates, or a significant revision or modification. Upon receipt of these notifications and a determination by the National Coordinator that the new version of the code set did not represent a significant revision or modification, the National Coordinator would request the Secretary to permit the use of the identified new version for testing and certification purposes. The second method we considered, and solicit public comment on, would be for the Secretary to proactively identify newly published versions of adopted minimum standard code sets and issue determinations as to whether they reflect maintenance efforts or minor updates of the adopted code set and would be permitted for testing and certification. For either method above, we propose that once the Secretary has granted permission for a new version of an adopted minimum standard code to be used: (1) Any ONC–ATCB may test and certify Complete EHRs and/or EHR Modules according to the new version; (2) Certified EHR Technology may be upgraded to comply with the new version of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified HER Technology; and (3) ONC–ATCBs would not be required to test and certify Complete EHRs and/or EHR Modules according to the new version until we updated the incorporation by reference of the adopted version to a newer version. For either method, we also propose to regularly publish (on quarterly basis) either by presenting to the HIT Standards Committee or by posting a notification on our Web site, any Secretarial determinations that have been made with respect to “minimum standard” code sets. We request public comment on whether a quarterly publication is an appropriate notification interval. We also seek public comment on other methods we might take to identify acceptable newer versions of minimum standard code sets in addition to the two methods we have discussed. Please note that the two methods we have proposed are not mutually exclusive and we request public comment on whether it would be advantageous to pursue both methods.

We request public comment on whether the National Coordinator should also consider proposing the revocation of an ONC-ATCB's status for repeatedly committing Type-2 violations even if the ONC-ATCB has adequately corrected the violations each time. We further request comment on how many corrected Type-2 violations would be sufficient for proposing revocation of an ONC-ATCB and to what extent the frequency of these violations should be a consideration.

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Consequently, if an eligible professional or eligible hospital were seeking to obtain a certified Complete EHR or certified EHR Module in 2014, for instance, that eligible professional or eligible hospital would look for Complete EHRs and EHR Modules certified in accordance with certification criteria current in 2014, rather than Complete EHRs and EHR Modules certified as meeting certification criteria intended to support meaningful use Stage 1, Stage 2, or Stage 3. We request comments on ways to ensure greater clarity in the certification of Complete EHRs and EHR Modules.

We request public comment on whether we should establish a set date for the temporary program to sunset, such as 12/31/2011, instead of date that depends on a particular action—the authorization of at least one ONC-ACB. A set date would provide certainty and create a clear termination point for the temporary certification program by indicating to any ONC-ATCBs and other certification bodies that in order to be authorized to certify Complete EHRs and/or EHR Modules after 12/31/2011, they would need to be accredited and reapply to become ONC-ACBs. One potential downside to a set date would be the possibility that it would temporarily prevent certifications from being issued during the time period it takes potential ONC-ACB applicants to get accredited and receive their authorizations from the National Coordinator.