

July 20, 2010

Temporary Certification Program for Health Information Technology: Final Rule

AT A GLANCE

The Issue:

On June 24, the Office of the National Coordinator for Health Information Technology (ONC) published in the *Federal Register* a final rule establishing a temporary certification program for health information technology. The rule, available at <http://edocket.access.gpo.gov/2010/pdf/2010-14999.pdf>, is effective immediately.

This rule sets forward a new federal certification process for electronic health records (EHRs). Although much of the rule addresses the requirements and application procedures for an organization that wants to become an ONC-approved testing and certification body (ONC-ATCB), it also affects hospitals and physicians that want to receive meaningful use Medicare and Medicaid EHR incentive payments because hospitals and physicians and other eligible professionals must use certified EHRs to qualify. Additional requirements to demonstrate “meaningful use” of EHRs and qualify for the incentives were finalized by the Centers for Medicare & Medicaid Services (CMS) and released on July 13 (see the AHA Special Bulletin dated July 15 for a summary – a detailed Regulatory Advisory explaining the requirements is forthcoming).

The attached detailed summary describes the certification process final rule’s provisions affecting hospitals and physicians, the rules governing the ONC-ATCBs, certification of EHR Modules for privacy and security, and changes to Stark and anti-kickback guidelines for hospitals that provide EHRs to non-employed physicians.

Our Take:

The AHA is concerned that delays in promulgating this rule and the related meaningful use rules will make it extremely challenging, if not impossible, for hospitals and physicians to have certified EHRs in place when the Medicare EHR incentive program for hospitals begins on January 1, 2011. Beginning in fiscal year (FY) 2011, hospitals and physicians that demonstrate meaningful use are eligible for incentive payments, although CMS is delaying the start date from October 2010 to January 2011 to ensure processes are in place. Those who fail to demonstrate meaningful use by FY 2015 will be penalized. These challenging timelines are compounded by ONC’s decision to reject the AHA’s recommendation that it temporarily grandfather as “certified” the EHRs that hospitals and physicians already have installed and successfully use to meet the meaningful use criteria.

(Cont.)

It is important for hospitals to understand that although the Certification Commission for Health Information Technology (CCHIT) has announced that it intends to apply to be an ONC-ATCB, all products previously certified by CCHIT will have to be re-certified through this new process. No products certified for meaningful use are available today.

The final rule also changes how EHR technology is certified as interoperable for purposes of Stark and anti-kickback compliance for hospitals' donations of EHRs to non-employed physicians. Previously, CCHIT was recognized as the certification body. Effective immediately, only the ONC-ACTBs will be authorized to provide new certifications. Previous certifications by CCHIT are still valid for these purposes, as long as the certification was given within the 12 months immediately prior to the donation.

What You Can Do:

- ✓ Share this advisory with your senior management team.
- ✓ Ask your chief information officer to examine how this final rule will affect your plans to implement EHRs and achieve meaningful use. If you have not already done so, discuss with your EHR vendors the products they intend to certify.
- ✓ If you are planning to donate EHRs to non-employed physicians, check with your legal counsel to ensure that the donated technology meets all of the requirements for the Stark and anti-kickback protections.
- ✓ Look for the AHA's current Special Bulletin on the final rules on meaningful use and certification criteria and standards released on July 13, as well as forthcoming detailed regulatory advisories.

Questions:

If you have questions or need more information, please contact Chantal Worzala, director of policy, at cworzala@aha.org or (202) 626-2313.

AHA's Regulatory Advisories are produced whenever there are significant regulatory developments that affect the job you do in your community. An in-depth examination of this issue follows.



Regulatory **Advisory**

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BACKGROUND

The American Recovery and Reinvestment Act of 2009 authorized incentive programs under Medicare and Medicaid that will pay bonuses to “meaningful users” of certified electronic health records (EHRs) beginning in fiscal year (FY) 2011, then phase-in penalties for those failing to meet “meaningful use” beginning in FY 2015. To be eligible for the incentives, hospitals and physicians must use EHRs that have been certified through a new federal certification process established by the Office of the National Coordinator for Health Information Technology (ONC).

Three regulations will govern the incentive programs:

- A “meaningful use” rule from the Centers for Medicare & Medicaid Services (CMS) that sets out the requirements for providers;
- A rule from ONC on the certification criteria and standards that must be met by vendor products and EHRs systems that hospitals and physicians self-develop; and
- A certification process rule from ONC that establishes new certifying bodies for EHRs.

This Advisory summarizes key elements of the final rule from ONC establishing a temporary certification program for health information technology (IT). The rule, which is available at <http://edocket.access.gpo.gov/2010/pdf/2010-14999.pdf>, took effect upon publication in the June 24 *Federal Register*. CMS released its final rule on meaningful use July 13, the same day that ONC released its final rule on standards and certification criteria.

AS IT STANDS

ONC’s final rule establishes the requirements, application procedures and “principles of proper conduct” for an organization or consortium that wants to become an ONC-approved testing and certification body (ONC-ATCB) to certify EHR technology for meaningful use. ONC will begin this temporary program immediately; it will end December 31, 2011, when ONC expects to have a permanent certification process in place. If the permanent process is not in place at that time, the National Coordinator can establish it at a later date.

Under the temporary certification program, ONC will select one or more ONC-ATCBs. It will make applications available in early July and anticipates approving up to five entities.

ONC-ATCBs can certify either Complete EHRs or EHR Modules. Complete EHRs comply with all of the federal certification requirements tied to functions required for meaningful use. EHR Modules comply with only one or more of the federal certification requirements. ONC released the final rule outlining the certification requirements on July 13. The final

certification requirements will be closely linked to CMS' final meaningful use requirements, also released on July 13.

Hospitals and physicians (and other eligible professionals) will be responsible for demonstrating to CMS that they have installed either a certified Complete EHR or a combination of certified EHR Modules that, together, meet all of the federal certification requirements to receive incentive payments and avoid future payment penalties.

This rule is only the first step in having certified products on the market. ONC next must solicit, accept and evaluate applications from organizations seeking to be ONC-ATCBs. Once approved, those bodies must establish their certification processes and work with vendors and providers with self-developed systems to certify products. Only then can hospitals and physicians begin to install and upgrade EHRs that have been certified through this new federal process.

It is unclear how many ONC-ATCBs will be approved, how quickly they can be established, and whether they will be able to meet the likely high demand to certify both vendor products and self-developed EHRs.

Provisions Affecting Hospitals and Physicians

Grandfathering. The AHA is extremely concerned that ONC did not accept the AHA's recommendation that ONC temporarily grandfather as certified installed EHRs that allow hospitals and physicians to meet meaningful use. ONC concluded that grandfathering is inappropriate and would be inconsistent with the statutory requirements for certified EHR technology specified under the *Health Information Technology for Economic and Clinical Health (HITECH) Act*. ONC stated that it believes grandfathering is "risky from a programmatic perspective with respect to the potential for fraud," and questioned whether hospitals and physicians "would be willing to take the risk of attempting meaningful use without the certainty" of certification. It should be emphasized that certification does not in any way guarantee that a hospital or physician will meet meaningful use.

The AHA believes that grandfathering is necessary to avoid unnecessary replacements and upgrades of existing functional systems and to lessen market pressures. ONC's decision to reject grandfathering means that all providers will need to upgrade existing systems to a certified version or pursue and pay for certification of their installed system as "self-developed." This policy will likely delay many providers' ability to meet meaningful use, add costs, and increase market pressures.

Certification of Self-developed EHRs. As recommended by the AHA, the ONC clarified the definition of "self-developed EHRs" to limit the number of hospitals and physician groups that will need to individually certify the systems they use. ONC recognizes that providers often modify vendor products to suit their environment, and that such modifications should not necessitate re-certification as a self-developed product. ONC says it would be "unrealistic" to expect that certified EHR technology will remain "100% unmodified in all cases" and agrees that it is possible for eligible professionals and

hospitals to modify a Complete EHR or EHR Module's certified capability "provided that due diligence is taken to prevent such a modification from adversely affecting the certified capability or precluding its proper operation." Nevertheless, ONC concludes by saying that if an eligible professional or eligible hospital "would like absolute assurance that any modifications made did not impact the proper operation of certified capabilities, they may find it prudent to seek to have the Complete EHR or EHR Module(s) retested and recertified."

Remote Testing. The certification bodies will be required to have the capacity to test and certify products remotely, such as over the Internet or through secure electronic transmissions. Remote certification, which the AHA recommended, will ease the cost and burden of certification for hospitals with self-developed EHRs or EHR Modules. ONC-ATCBs also may offer testing and certification at their facilities or at the physical location of the vendor or provider. In addition, ONC will require that the ONC-ATCBs have the capacity to certify EHRs where they have been deployed, such as at a hospital.

Certified HIT Products List and Attestation to CMS. ONC will make available on its website a master Certified HIT Products List (CHPL) that includes all products with current certification, including vendor names and version numbers. The website will be updated regularly with information from the ONC-ATCBs. ONC notes that providers will benefit from having a single, definitive source of information on which products have a current meaningful use certification. ONC states that it should maintain the CHPL (rather than allowing individual ONC-ATCBs to do so) to ensure that it is accurate and complete. An ONC-ATCB could, nevertheless, maintain on its own website a list of products it has tested and approved and/or create a link to the CHPL.

In addition to listing all certified Complete EHRs and EHR Modules, ONC states that providers that elect to use a combination of certified EHR Modules may also use the CHPL Web page to validate whether the EHR Modules they have selected satisfy all of the applicable certification criteria that are necessary to meet the definition of Certified EHR Technology. Regarding attestation, ONC states that the "CHPL Web page will include a unique identifier (such as a code or number) for each certified Complete EHR and each combination of certified EHR Modules that satisfies all of the applicable certification criteria necessary to meet the definition of Certified EHR Technology. The unique code or number...could subsequently be used to submit to CMS for attestation purposes."

Recognized Certification Bodies as Related to the Physician Self-referral Prohibition and Anti-kickback EHR Exception and Safe Harbor Final Rules. ONC's new certification process also has implications for donations of EHR technology to physicians. For hospitals' donations of EHR software, this change in the process for recognizing certification bodies is significant because such donated software must be, among other conditions, "interoperable" in order to comply with the requirements of the physician self-referral prohibition exception and anti-kickback statute safe harbor. For purposes of the exception and safe harbor, software was previously 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."

Effective June 24, ONC authorizes the ONC-ATCBs (and, when the permanent certification program begins, ONC-authorized certification bodies, or ONC-ACBs) as the only bodies that can certify EHR technology as interoperable for the purposes of meeting the Stark and anti-kickback requirements. Previously, ONC had recognized CCHIT for this purpose. CCHIT must reapply to become an ONC-ATCB (and is expected to do so). ONC believes that folding the previous “recognition” process into the ONC-ATCB and ONC-ACB “authorization” processes, as the final rule does, will lead to greater clarity and consistency for all stakeholders.

However, CCHIT’s loss of “recognized” status does not impact certifications made while CCHIT was a “recognized certification body.” ONC also points out that although EHRs certified by CCHIT in the period before June 24 can still qualify for donation under the EHR self-referral exception and anti-kickback safe harbor for a period of time (as long as the 12-month criterion is met), these EHRs will **NOT** meet the definition of certified EHR technology and, therefore, must be recertified by an ONC-ATCB in order to be used by an eligible professional or eligible hospital to demonstrate meaningful use.

Finally, ONC clarifies that ONC-ATCBs (and the equivalent organizations under the permanent certification process) “will not adopt different or additional certification criteria in order to meet the deeming provision to which complete EHRs or EHR Modules must be tested and certified.” ONC believes that the certification criteria adopted by the Secretary specify several important interoperability requirements and build the foundation for more advanced interoperability in the future.

Validity and Expiration of Certification Status Linked to Calendar Year. ONC will tie the validity and expiration of certifications to the calendar year in two-year cycles, meaning that certifications received in 2011 and 2012 will expire in 2013. ONC did not address whether inpatient and ambulatory certifications will operate differently to accommodate the different Medicare payment years for each setting (fiscal year for hospitals and calendar year for physicians).

This policy is at odds with the meaningful use timetable put forward by CMS, in which providers starting late could meet Stage 1 meaningful use in 2013 and receive incentive payments. ONC states that, “[r]egardless of the year and meaningful use stage at which an eligible professional or eligible hospital enters the Medicare or Medicaid EHR Incentive Program, the Certified EHR Technology that they would need to use would have to include the capabilities necessary to meet the most current certification criteria adopted by the Secretary.”

In the final rule, ONC also calls attention to the possibility that the requirements for an eligible professional or eligible hospital to meet Stage 1 meaningful use in 2013 (or 2014) could be different and possibly more demanding than they were for meaningful use Stage 1 in 2011 and 2012. As hospitals plan their EHR adoption strategy, they should take into account the new federal regulations to upgrade their EHR to meet the 2013 certification requirement if they want to be compliant with meaningful use.

To ensure proper identification of when certification is valid, ONC will, through the ONC-ATCBs, mandate that all certifications require that a Complete EHR or EHR Module developer conspicuously include the following text on its website and in all marketing materials, communications statements and other assertions related to the EHR technology's certification:

This [Complete EHR or EHR Module] is 201[X]/201[X] compliant...and has been certified by an ONC-ATCB in accordance with the applicable certification adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments.

The final rule also makes clear that a certification issued to an integrated bundle of EHR Modules must be treated the same as a certification issued to a Complete EHR for the purposes of identifying when it is valid. ONC notes that individual EHR Modules certified as part of a bundle would not separately “inherit a certification just because they were certified as part of a bundle” unless the EHR Module developer sought and received a positive certification decision from an ONC-ATCB (or an ONC-ACB) for the individual EHR Modules.

ONC-ATCB Review of “Dot Releases.” Vendors often release “bug-fixes and other maintenance upgrades” (normally identified by a new “dot release” such as version 7.1.1 when 7.1 received certification). In the final rule, ONC clarifies that a previously certified Complete EHR or EHR Module may be updated for routine maintenance or to include new capabilities that affect capabilities both related and unrelated to the certification criteria adopted by the Secretary without its certification becoming invalid. However, ONC believes that “an ONC-ATCB should, at a minimum, review an attestation submitted by a Complete EHR or EHR Module developer indicating the changes that were made, the reasons for those changes, and other such information and supporting documentation that would be necessary to properly assess the potential effects the new version would have on previously certified capabilities.” The ONC-ATCB would determine whether the updates and/or modifications adversely affect previously certified capabilities and therefore need to be retested and recertified, or whether to grant “inherited” certified status to the new version without additional testing. If the ONC-ATCB awards a certification to a newer version of a previously certified EHR product, it would need to include this action in its weekly report to the National Coordinator.

Future Certification Requirements. ONC will require all Complete EHRs and EHR Modules previously certified under the temporary certification program to be certified anew under the permanent certification program. This likely will result in potentially unnecessary upgrades, particularly of EHR Modules.

ONC anticipates that “the testing and certification of Complete EHRs and EHR Modules to the [planned] 2013/2014 certification criteria would need to begin by mid-2012 in order for Complete EHRs and EHR Modules to be retested and recertified prior to the start of the next meaningful use reporting period,” or three months prior to the start of Fiscal Year

2013. The AHA asked for a much longer lead time of three years between when certification criteria are finalized and when providers must use EHRs certified to those criteria to meet meaningful use. We will continue to push for additional lead time.

Provisions Governing the ONC-ATCBs

Application Process. The application process will include two parts – the first requesting general information and qualifications and the second consisting of a “proficiency examination” to demonstrate knowledge of health IT and the certification criteria. A request for application must be submitted in writing to the National Coordinator.

ONC-ATCBs may request approval to test and certify either Complete EHRs or EHR Modules. If an ONC-ATCB will be certifying complete EHRs, it must do so for both ambulatory and inpatient EHRs. ONC-ATCBs may apply to test and certify EHR Modules that address only an ambulatory or inpatient setting. An ONC-ATCB authorized to test and certify Complete EHRs “would also have the capability and, more importantly, the authorization from the National Coordinator to test and certify EHR Modules,” but will not be required to do so. ONC will make publicly available the names of ONC-ATCBs, including the date each was authorized and the type(s) of testing and certification each has been authorized to perform.

Testing and Certification. ONC-ATCBs will both test and certify EHR technology. Testing measures the degree to which EHRs or EHR Modules comply with standards and criteria. Certification uses the test results and additional information to assert that the EHRs or EHR Modules conform to the certification criteria and standards adopted by the Secretary. ONC-ATCBs will conduct testing using standards adopted by the Secretary using test tools and test procedures approved by the National Coordinator. ONC will publish a notice of availability for approved test tools and procedures in the *Federal Register* and post them on its website. ONC expects that many of these testing methods will be developed by the National Institute of Standards and Technology (NIST), although ONC may draw from other sources, and individuals or organizations may submit test tools and procedures to ONC for approval.

The primary responsibility of ONC-ATCBs is to apply the certification criteria adopted by the Secretary. Further, the final rule specifies that ONC-ATCBs must offer a testing and accreditation option using only the certification criteria adopted by the Secretary, although they also may offer options that include additional requirements (such as the “comprehensive” certifications currently offered by CCHIT).

ONC-ATCBs will not be required to test and certify whether an EHR Module integrates or is compatible with other Modules, “due to various impracticalities.” ONC notes, however, that nothing in the final rule would preclude an ONC-ATCB from offering a service to test and certify Module-to-Module integration, and recognizes the value of that kind of testing to providers.

In testing and certifying EHR Modules, ONC-ATCBs will incorporate all requirements related to a given meaningful use objective. For example, an e-prescribing Module would need to meet all related certification criteria, and not a subset.

Authorized Testing and Certification Methods. ONC-ATCBs will be required to conduct remote testing of Complete EHRs and EHR Modules. They also may offer testing and certification at their facilities or at the physical location of a development or deployment site (that is, where EHR technology was developed, or where it resides or is being or has been implemented, respectively). The final rule also clarifies that a Complete EHR or EHR Module need not be “live at a customer’s site” in order to qualify for testing and certification.

The Testing and Certification of “Minimum Standards.” In recognition that vocabulary code set standards may change over time, ONC will identify certain code sets as “minimum standards,” thereby allowing certified EHR technology to be upgraded to a permitted newer version of a code set without adversely affecting its certified status. New versions of adopted “minimum standard” code sets may be brought to the National Coordinator by the general public or be chosen by the Secretary. If the Secretary accepts a newer version of a “minimum standard” code set, nothing is required of ONC-ATCBs, Complete EHR or EHR Module developers, or the eligible professionals and eligible hospitals that have implemented certified EHR technology until the Secretary incorporates by reference a newer version of that code set in the list of federally adopted standards. In general, the HIT Standards Committee will be asked to assess and make a recommendation to the National Coordinator on adoption of a new version of a standard.

Certification Queues. ONC states that the ONC-ATCBs are required to develop an impartial process for handling requests for EHR testing and certification (for example, one not conditioned upon the size of the product developer, membership in any association or group, or the number of certificates already issued). ONC will not require products to be certified within a specific amount of time.

Reporting on Certified Products. ONC-ATCBs are required to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been tested and certified. This information must also include: (1) the clinical quality measures to which a Complete EHR or EHR Module has been tested; and (2) any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria. ONC-ATCBs also may include additional information in their weekly reports that that prospective purchasers and users of EHR products would find useful, such as a product’s compatibility with other software or other EHR Modules. Additional information also may be posted to individual ONC-ATCB websites.

Oversight. To conduct oversight of ONC-ATCBs, ONC reserves the right to conduct scheduled or unannounced visits. ONC expects that any confidentiality agreement executed between an ONC-ATCB and a customer, such as Complete EHR and EHR Module developers, would include ONC and its authorized representatives as parties who may observe the testing and certification of the customer’s EHR product(s).

Retention of Records. ONC-ATCBs will be required to retain all records related to tests and certifications and provide copies of the final results of all completed tests and certifications to ONC upon conclusion of the temporary certification program. ONC will retain all records received from ONC-ATCBs “in accordance with applicable federal law,” making it unclear how long ONC will in fact retain records. The AHA had recommended that the record retention period for ONC-ATCBs and ONC match the retention period for eligible professionals and eligible hospitals to demonstrate use of certified EHRs to CMS (six years in the final rule for meaningful use), plus two or more additional years to ensure that records are available during an audit.

Good Standing as an ONC-ATCB and Impact of Revocation of ONC-ATCB Status. ONC will monitor compliance with the Principles of Proper Conduct for ONC-ATCBs on an ongoing basis and revoke ONC-ATCB status if significant violations occur. ONC identifies Type-1 and Type-2 violations, with Type-1 violations including violations of law or temporary certification program policies that threaten or significantly undermine the integrity of the temporary certification program (such as false, fraudulent, or abusive activities), and Type-2 violations including failure to adhere to the Principles of Proper Conduct for ONC-ATCBs and engaging in other inappropriate behavior.

ONC may suspend an ONC-ATCB’s operations when there is reliable evidence indicating that the ONC-ATCB committed a Type-1 or Type-2 violation and that the continued testing and certification of Complete EHRs and/or EHR Modules could have an adverse impact on patient health or safety.

ONC believes “it would be an extremely rare occurrence for an ONC-ATCB to have its status revoked and for the National Coordinator to determine that Complete EHRs and/or EHR Modules were improperly certified.” However, if this should occur, the final rule specifies that retesting and recertification by an ONC-ATCB are the only means by which to ensure that the EHR technology satisfies the certification criteria.

Affected technology would retain its certified status only for 120 days after publication of the ONC notice that the technology had been improperly certified. If the technology is not recertified by another ONC-ATCB, then providers that have installed the product must replace it with a different certified product within 120 days or be out of compliance with the meaningful use requirements. ONC says that any decertification of EHR technology will be made widely known by ONC through publication on its website and list serve, which ONC believes will help eligible professionals or eligible hospitals identify whether the certified status of their EHR technology is still valid. The AHA asked for a longer grace period.

Sunset of the Temporary Certification Program. As noted earlier, the final rule specifies that the temporary certification program will end on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then on a subsequent date that is determined to be appropriate by the National Coordinator. On and after the sunset date, ONC-ATCBs will be prohibited from accepting new requests to test and certify EHR technology. However, they will be permitted up to six months after the sunset date to complete all testing and certification activities for requests received prior to the sunset date.

After that, all EHR technology will have to be tested and certified under the permanent certification program.

Certification of Privacy and Security Capabilities for EHR Modules

ONC adopted a "technically infeasible" approach to testing and certifying privacy and security criteria for EHR Modules. This means that a module developer must satisfy each privacy and security certification criterion **unless** it can be demonstrated that:

- A particular criterion is "inapplicable" or it would be "technically infeasible for the EHR Module to be tested and certified in accordance with some or all of the... criteria;" or
- The Modules are presented for testing and certification as a "pre-coordinated, integrated 'bundle' that otherwise could constitute a complete EHR."

The AHA had recommended that ONC leverage an approach from the HIPAA Security Rule, making each privacy and security certification criterion "addressable" in the same way that certain security implementation specifications are applied under the Security Rule. Under this "addressable" approach, each EHR Module submitted for certification either would have needed to include each particular privacy and security capability or the submission would need to provide an explanation of why specific criteria are not relevant to the Module's EHR functionality as well as its purpose and operational context. However, ONC did not adopt the security rule's "addressable" approach because ONC believes that "one purpose of certification is to assure eligible professionals and eligible hospitals that an EHR Module includes a specified capability or set of capabilities."

Nevertheless, the ONC-adopted approach appears similar to that recommended by the AHA and likely may have no significantly different consequences for privacy and security certification of EHR Modules. Under the ONC-adopted approach, the EHR Module developer will be required to provide sufficient documentation to support a claim that a particular privacy and security certification criterion is inapplicable or that satisfying the certification criterion is technically infeasible. The documentation would enable the ONC-ATCB to independently assess and make a reasonable determination about whether the module should be exempt from having to include a particular privacy or security capability. Assuming that the ONC-ATCB releases such relevant assessment information publicly or includes it as part of any explanation of the particular module's certification, ONC's approach is likely to offer hospitals and eligible professionals nearly identical details about the precise privacy and security functionalities of a certified module as the AHA-suggested approach was intended to ensure.

Certification of Integrated Bundles. Under the process established in the final rule, integrated EHR Modules will receive an exemption from the requirement that each Module satisfy each privacy and security certification criterion only if the integrated bundle would otherwise constitute a Complete EHR. For example, multiple EHR Modules that have been integrated and "bundled" but fail to meet the definition of a Complete EHR would not qualify. Rather the bundle would be viewed as an EHR Module that provides multiple capabilities. On the other hand, an integrated bundle of EHR Modules that meets the

complete EHR definition would be treated as a complete EHR and listed on ONC's master certified health IT products list with the notation that it is an integrated bundle of EHR Modules.

Where one or more of the constituent EHR Modules is/are demonstrably responsible for providing all of the privacy and security capabilities for the entire pre-coordinated, integrated bundle of EHR Modules (whether from a single vendor/developer or from different vendors/developers) that would otherwise constitute a complete EHR, the other Modules would not need to be tested and certified to adopted privacy and security certification criteria. For example, four developers each develop one Module (EHR Modules A, B, C and D) and form an affiliation to present these Modules for testing and certification as an integrated bundle. The developers identify that EHR Module "C" is responsible for providing the privacy and security capabilities for the bundle. Consequently, EHR Modules A, B and D would not be required to also be tested and certified to the adopted privacy and security certification criteria.

However, in situations where an "integrated bundle" of Modules includes one or more services offered by different module developers that have been implemented on different technical architectures or hosted over the Internet on one or multiple different servers, ONC does not believe that it would be possible for one or more of the EHR Modules to be "demonstrably responsible" for providing all of the privacy and security capabilities for the bundle. ONC specifically cites as examples of this circumstance the current capability of a web-based EHR Module to offer authentication for another EHR Module that may be installed on an eligible professional's laptop as well as the use of one or more web-based services to provide an audit log for actions that take place outside of that service.

Certification of Modules with Privacy and Security Functionality Only. Modules providing only specific privacy and security functionality nevertheless may be certified as EHR Modules. However, as ONC states, the Module itself must be capable of performing the capability required by a certification criterion. The module cannot delegate the responsibility to another service or function. Such delegation would provide no proof that the Module could actually perform the specific capability, only that the Module was capable of telling something else to perform. Accordingly, having the capability to instruct or direct another service or function to perform is not sufficient for privacy and security certification of a Module.

Regulatory Impact Analysis. ONC estimates that there will be five applicants for ONC-ATCB status and a large number of requests for certification of self-developed EHRs – 10 to 67 designed for the ambulatory setting and 318 to 959 designed for the inpatient setting. The proposed rule assumed that there would only be commercial or open source EHR Modules seeking ONC-ATCB testing and certification.

ONC rejects any notion that it should dictate the minimum or maximum amount an ONC-ATCB can charge for testing and certifying EHR technology. It does assume that competition in the testing and certification market will reduce the costs of testing and certification as estimated by CCHIT (\$30,000 to \$50,000 for Complete EHRs and \$5,000 to

\$35,000 per EHR Module) but says it is unable to provide a reliable estimate at this time of what the potential reduction in costs might be.

NEXT STEPS

Share this Advisory with your senior management team and ask your chief information officer to examine how this final rule will affect your plans to implement EHRs and achieve meaningful use. If you have not already done so, you or your CIO should discuss with your EHR vendors the products they intend to certify. If you are planning to donate EHRs to non-employed physicians, ask your legal counsel to ensure that the donated technology meets all of the requirements for the Stark and anti-kickback protections.

Watch for AHA Regulatory Advisories on the meaningful use final rule from CMS and the certification criteria and standards final rule from ONC.

If you have questions, please contact Chantal Worzala, director of policy, at (202) 626-2313 or cworzala@aha.org.