

UPDATE ON CERTIFICATION



Highlights of Certification Requirements

Meaningful use requires using a system certified against all the requirements established by the Secretary of the Department of Health and Human Services.

The certification process has two phases: a temporary process through January 1, 2012 and then a permanent process.

By the end of December 2010, the temporary process was well underway. Six organizations were authorized to provide certification, and over 200 EHR or EHR modules had been certified.

Rules for the permanent certification process are effective as of February 6, 2011; everything is on track to start permanent certification starting in January 2012.

Introduction

To be eligible for incentive payments under the American Recovery and Reinvestment Act of 2009, hospitals and eligible providers must demonstrate “Meaningful Use” of “Certified” electronic health record (EHR) technology. The Certification process had two phases. On June 24, 2010, the Office of the National Coordinator (ONC) published the final rule for the temporary certification process that started immediately. In the temporary program, ONC designated authorized testing and certification bodies (ONC-ACTBs) to test and certify systems against Stage 1 criteria. On January 7, 2011, ONC published the final rule for the permanent certification program. The permanent program has two major differences from the temporary program: testing and certification will be separate processes, and authorized certification bodies (ONC-ACBs) will be responsible for surveillance to ensure that certified systems are working as expected in the field.

Industry Impact

EHR certification criteria for system capabilities track directly to the meaningful use capabilities. However, the certification criteria contain more specifics. For example, in the proposed rule for meaningful use, the hospital or eligible provider must record smoking status for 80 percent of their patients who are age 13 or older. The certification requirements for Stage 1 state that the system must, “Enable a user to electronically record, modify, and retrieve the smoking status of a patient to: current smoker, former smoker, or never smoked.” The requirements also cover the standards that must be used for vocabulary, content exchange and data transmission. For example, in Stage 1, medication information must use a code set integrated with Rx Norm. Certification also requires conforming to privacy and security protections. For example, for encryption of patient information: “a symmetric 128-bit fixed-block cipher algorithm capable of using a 128-, 192- or 256-bit encryption key must be used (e.g., FIPS 197 Advanced Encryption Standard, [AES], Nov 2001).”

The temporary and permanent programs have many similar elements. They cover complete EHRs and EHR Modules. An EHR module must meet at least one complete criterion for meaningful use. Both self-developed and vendor-supplied products can be certified. The certifying bodies must cover both ambulatory and inpatient EHRs. To ensure that all testing organizations are producing similar results, testing tools and techniques for all the criteria are being developed by the National Institute of Standards and Technology (NIST). ONC will approve all testing tools and techniques from NIST and other sources. It is important to note that an end user may combine different certified modules to meet the requirements (and take responsibility for integrating them), the opposite is not true. Just because an EHR or a module meeting several criteria is certified, that does not mean that individual components of that product are certified. Systems do not need to be implemented at a user site to be certified.

To qualify for incentive payments, hospitals and eligible professionals must be using a system certified against all the current requirements. A hospital or provider can choose not to meet up to five of the “menu” requirements and still be meaningful users; however, they must possess a system certified against all

the requirements. Also, when Stage 2 criteria are in effect, hospitals and eligible providers must be using a system certified against all Stage 2 criteria even if qualifying for Stage 1 of meaningful use.

The table below, taken from the final certification rule (page 1304) illustrates the differences between meaningful use and certification timelines.

First Payment Year	Payment Year			
	2011	2012	2013	2014
2011	Stage 1	Stage 1	Stage 2	Stage 2
2012		Stage 1	Stage 1	Stage 2
2013				Stage 1
2014				Stage 1
	Complete EHRs and EHR Modules certified by ONC-ATCBs or ONC-ACBs to all of the applicable certification criteria adopted for the 2011 and 2012 payment years meet the definition of Certified EHR Technology		Complete EHRs and EHR Modules certified by ONC-ACBs to all of the applicable certification criteria adopted for the 2013 and 2014 payment years meet the definition of Certified EHR Technology	

The Permanent Certification Process

The permanent program will involve two separate processes: testing and certification. Testing laboratories will be accredited by the National Voluntary Laboratory Accreditation Program (administered by NIST) and certification bodies will be accredited by an ONC-Approved Accreditor (ONC-AA) selected by ONC through a competitive bidding process. Organizations can be approved as authorized testing laboratories, authorized certification bodies (ONC-ACBs), or they can submit for both authorizations. EHRs must be tested first and then submitted to the ONC-ACB for certification. All testing tools will be approved by ONC (as they are in the temporary testing and certification program). All testing and certification bodies can be accredited for either complete EHRs and EHR modules (inpatient and ambulatory) or specific EHR modules. In the future, the scope may be expanded to include other HIT technologies.

The distinction between testing and certification has been confusing. Testing results in objective, unanalyzed data of the results from the tests specified by NIST. Certification involves interpreting the results of the testing as well as conformance with other requirements as specified by the Secretary, such as proper labeling of the EHR or vendors and developers having a process for receiving and addressing complaints about certified products. Testing bodies will test what is requested by the vendor, developer or site requesting certification. The ONC-ACBs will review the application of privacy and security requirements to determine if all appropriate requirements were tested. ONC-ACBs must have the capability to certify systems remotely at development or deployed sites. (Testing sites are “expected” to provide remote testing.)

The ONC-ACBs will have duties beyond certification. They also must provide surveillance for certified systems to make sure that they are performing as expected in the field. They will submit annual surveillance plans to the ONC-AA that will ensure the plans are in conformance with guidance on “consistent, objective, and reliable methods” for surveillance. The ONC-ACBs will submit reports on the results of this surveillance to ONC. ONC can also suggest annual areas of focus for the surveillance. If certified EHRs are not providing the capabilities for meaningful use as implemented in the field, the ONC-ACB is responsible for determining why this has occurred (flawed testing, incorrect implementation, or system change by the vendor).

The Details Relevant to End Users

Below is a summary of the parts of the rule that could affect end users.

Systems that have been certified by an ONC-ACTB or ONC-ACB will remain certified systems until new certification requirements become effective (expected in January of 2013). The rare exception would be if the certification body was



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determined to have a flawed certification process and the flaws created a threat to patient safety.

All EHRs will need to be tested and certified against new requirements adopted by the Secretary (expected in 2013 and then every two years). This could involve changes to Stage 1 requirements or new requirements for Stage 2. In 2013, systems will need to be recertified, since users must possess a system that meets all the current certification requirements.

ONC-ACBs may, but are not required to, offer "gap" certification for EHRs and EHR modules. Gap certification would involve testing and then certifying only the capabilities that have changed or were added when new certification requirements were issued.

If new certification criteria do not change the requirements for an EHR module, nor the privacy and security requirements applicable to that module, the ONC-ACBs may, but are not required to, provide updated certification for that module.

The ONC-ACB must accept applications from vendors/developers of certified products that have undergone a maintenance fix or enhancement to have the new version of their product "inherit" the certification from a prior product. The vendor/developer needs to submit an attestation of what has changed in the product and why.

For more details, see the final rule published in the Federal Register on January 7, 2011: <http://origin.www.gpo.gov/fdsys/pkg/FR-2011-01-07/pdf/2010-33174.pdf>. The summary of the requirements starts on page 1326. The rest of the discussion, starting on page 1262, includes a discussion of the comments on the draft rule and why ONC decided to accept or reject them.

Recommendations

Of course, one of the first things to do is to make sure that the products provider organizations are using are certified against the Stage 1 requirements. The complete list is available at <http://onc-chpl.force.com/ehrcert>. The way a product has been certified affects end users' flexibility in meeting the meaningful use requirements. If the vendor has certified only a complete EHR (as many have), then provider organizations must possess all the parts of that EHR to have a certified product. Some of the vendors list the components of that EHR, others do not — the elements making up the certified product should be confirmed with the vendor. If provider organizations want to use another certified product to meet some of the requirements, they would need to purchase that product in addition to the complete EHR. The alternative would be to have the combination of products "site certified" at the provider organization's expense. If the vendor has chosen not to certify a product, site certification would be the only option.

The next step is to track the proposed requirements for Stage 2 of meaningful use and make sure that the vendor has, or is developing, the capabilities to meet the new requirements.

About the Author

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