

# UPDATE ON CERTIFICATION



## Highlights of Certification Requirements

Systems need to provide the capabilities required for meaningful use, comply with standards, and ensure privacy and security of data.

The requirements for Stage 1 are final.

ONC has issued the final rules for the temporary certification process.

Certification bodies are expected to be operational in late summer of 2010.

To receive incentive payments, users will need to be using a currently certified system — Stage 1 in 2011 and 2012, Stage 2 in 2013 and 2014, and Stage 3 in 2015.

## Introduction

The American Recovery and Reinvestment Act of 2009 will inject billions in incentive payments into the healthcare system. To be eligible for incentive payments, hospitals and eligible providers must demonstrate “‘Meaningful Use’ of ‘Certified’” electronic health record (EHR) technology. The Office of the National Coordinator for Health IT (ONC) has already published a final rule that specifies the capabilities, standards, and privacy and security requirements that will be required for Stage 1 certification. On June 24, 2010, ONC published the final rule for the temporary certification process that starts immediately. In the temporary program, ONC will designate authorized testing and certification bodies (ACTBs) that will be authorized to test and certify systems against Stage 1 criteria. Applications to become testing and certification organizations will be available on June 24, 2010. It is expected that ACTBs will be operational in late summer or early fall of 2010. The ACTBs will be replaced by permanent testing and certification bodies after December 31, 2011. The final rule for those organizations will be published later.

## 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 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, 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).” All the details of the certification requirements can be found at <http://edocket.access.gpo.gov/2010/E9-31216.htm>.

To qualify for incentive payments, hospitals and eligible professionals must be using a currently certified system. Certification for Stage 1 will be good through 2012, Certification against Stage 2 requirements will be required in 2013 and 2014, and use of a Stage 3 certified system will be required starting in 2015. Highlights of the temporary certification process are provided below.



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- Certification covers ambulatory and inpatient systems, and both vendor-supplied and self-developed systems.
- Complete EHR systems (meeting all the certification requirements) or EHR modules (meeting the requirements of one required capability) can be certified.
- A module must cover one complete criterion. For example, the module would have to provide all three types of required decision support in CPOE.
- If purchasing certified modules, the end user is responsible for ensuring that these modules will integrate together to meet meaningful use requirements.
- Systems will be certified as providing specific types of quality reporting.
- Systems must have been certified within 12 months of their donation to obtain an exemption under the Stark rules.
- Vendors will need to recertify that systems meet new requirements at each stage.
- Systems certified under Stage 1 may need to be upgraded to meet meaningful use incentive requirements in 2013.
- ATCBs must have the capability to test and certify systems remotely. They may also offer onsite testing at their facility, a development facility or a user site.
- Systems do not need to be implemented at a user site to be certified.
- Testing involves an objective assessment of whether all the requirements specified by the Secretary of Health and Human Services are met.
- After testing, systems will be certified based on test results
- To ensure that all testing organizations are producing similar results, testing tools and techniques for all the Stage 1 criteria are being developed by the National Institute of Standards and Technology (NIST). The current versions are available for review and comment on NIST's website ([www.nist.gov](http://www.nist.gov)).
- ONC will approve all testing tools and techniques from NIST and other sources. ACTBs will use these tools in creating testing scenarios.

### Recommendations

The certification requirements became final on February 13, 2010. Provider organizations can use those criteria to audit their current systems to identify gaps and then enter into discussions with the vendor as to when the gaps will be filled. However, until the meaningful use criteria are final, this assessment won't be complete. Given that the process of certifying systems will start soon, providers should ask their vendors when they plan to apply for certification. Because meaningful use incentives require a currently certified system, and the requirements will increase in 2013, system purchases and implementation plans should consider current and expected future requirements. For example, bedside medication administration with bar code verification was not proposed as a Stage 1 requirement; however, it is almost certainly a future requirement for meaningful use incentives. Therefore, this capability should be included in any IT strategy or selection. Any vendor contracts should have provisions that include updates to meet future certification criteria as part of regular covered maintenance.

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