

Background

In order to receive electronic health record (EHR) incentive payments under the American Recovery and Reinvestment Act (“ARRA” or the “Stimulus Bill”), physicians will have to demonstrate “meaningful use” of a “certified” EHR system.

Currently, the Office of the National Coordinator for Health IT (ONCHIT) is involved in two separate rulemaking processes to define the process by which physicians will qualify for those incentive payments. The first proposed rule sets up a definition for “meaningful use.” The comment period for that regulation closed on March 15, and the final rule is expected to be released sometime this summer.

The second proposed Federal Rulemaking, which is the focus of this summary, lays out the process by which ONCHIT will certify EHR systems. On June 24, the Federal Health and Human Services Agency (HHS) published a Final Rule in the Federal Register laying out the process by which they will select organizations who will certify EHR systems.

The previous version of this EHR certification rule was published in March of this year, and the comment period closed in April. CMA filed comments based on a review of the proposed rule by CMA’s Council on Information Technology.

Importance of this Rulemaking Process for Physicians
It is important for physicians to note that they must use a certified EHR system to qualify for federal provider incentives. Now that this rule is final, it is expected that lists of certified EHR products will be available in early-to-mid fall. This will give physicians a starting point for selecting appropriate EHRs for their practices.

Temporary Process

In the previous version of this rule, HHS had proposed a two-step process. In order to expedite the EHR certification process, HHS proposed a Temporary Certification Program that would begin this summer and continue until December 31, 2011. The entities named to perform certification during this temporary program would be called ONC-Approved Testing and Certification Bodies (ONC-ATCBs).

The final rule released on June 24 only covers the Temporary Certification Program. The rules governing the permanent program will be published in a subsequent federal rulemaking next year.

While this temporary program is in place, the federal government will be establishing the rules and regulations for a permanent certification program. The permanent program will be more comprehensive and would begin in January 2012.

ONC-ATCB Approval Process

Organizations that are interested in becoming an ONC-ATCBs can request an application from ONCHIT in writing. Interested organizations must be able to test EHR systems in real-world situations, such as in a simulation lab. Organizations can either apply to certify complete EHR systems, or to only certify one “module” (such as e-prescribing software). ONCHIT will have 30 days to review and respond to organizations interested in becoming a temporary certification body. It is anticipated these temporary bodies, or ONC-ATCBs will be named early this fall.

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In the earlier version of this rule, HHS stated that they believed only one or two organizations would be capable of becoming ONC-ATCBs. Based on the level of interest around this proposed rule, they now believe that there will be multiple entities capable of meeting the requirements. This is a positive change for physicians, since more ONC-ATCBs will spread out the work, and products can be certified faster. It will also lessen the chances of one organization controlling the market for certified EHRs.

Certification

Once they begin their work, ONC-ATCBs will only be assessing whether or not EHR systems will enable physicians to demonstrate meaningful use. While they can, at their own discretion, assess EHRs based on other criteria, those other criteria will not affect federal certification.

ONCHIT will develop one website that will list all of the certified products, as well as a standard certification label that vendors can use to identify certified products. ONC-ATCBs will be required to report to ONCHIT no less than weekly regarding new products that have been certified.

Once an EHR is certified, it will not need to be recertified if the vendor makes minor upgrades to it. It will need to be recertified, however, when the transition to the permanent program occurs in 2012.

In a few rare cases, providers have self-developed EHRs. In these cases, a provider may have assembled an electronic medical record, an e-prescribing system, and other software into a custom bundle. In these cases, a provider will be allowed to request certification of the self-developed EHR.

Certification and Meaningful Use

By the draft definition, meaningful use will come in three stages – stage 1, which will be finalized this summer, stage 2, which will take effect in 2013, and stage 3, which will take effect in 2015. Because they will only be in effect until

the end of 2011, ONC-ATCBs will only be able to certify EHR systems to allow physicians to achieve stage 1 of meaningful use. Certifying EHR systems for stages 2 and 3 of meaningful use will be done in the permanent certification process, which may be different than the temporary process.

Timelines and Next Steps

Due to the urgency of naming ONC-ATCBs as soon as possible, HHS has waived the normal 30-day period for final regulations to take effect. Therefore, this rule became effective immediately upon publication (June 24). There is no further opportunity for public comment.

ONCHIT will now move to begin the application process for organizations interested in becoming ONC-ATCBs. Their stated goal is to begin naming ONC-ATCBs as soon as possible, in order to begin certification of products as early as this fall.

For physicians, now is a good time to prepare for the transition to EHR. Until the first list of certified EHR systems is published, physicians can spend time assessing practice EHR needs, mapping office workflow, and researching potential vendors. This will allow practices to move quickly once vendors are certified.

For More Information

Visit: <http://healthit.hhs.gov/tempcert>