Initial Commentary on
Temporary Certification Program Final Rule
September 23, 2010

Prologue

The American Recovery and Reinvestment Act of 2009 (ARRA), includes billions of dollars in Medicare and Medicaid incentive payments to providers and hospitals for the "Meaningful Use" of certified health IT products. The legislation requires the Department of Health and Human Services (HHS) to take regulatory action in several areas, including electronic health record (EHR) incentives for eligible professionals and hospitals (Meaningful Use), standards and certification criteria, a Certification Program, and privacy and security.

ARRA amended Section 3001(c)(5) of the Public Health Service Act (PHSA) to authorize the Office of the National Coordinator (ONC) for Health Information Technology to establish a Certification Program to accompany the Medicare and Medicaid EHR Incentive Programs. The National Coordinator has decided on a two-pronged approach for the Certification program – a Temporary Certification Program and a Permanent Program. ONC has released the Final Rule for the Temporary Certification Program, which will allow Authorized Testing and Certification Bodies (ATCBs) to test and certify Complete EHRs and/or EHR Modules. The Temporary Program will end when the Permanent Certification Program final rule is released in the future.

Key Provisions

The Final Rule establishes a temporary certification program for the purposes of testing and certifying health information technology. The National Coordinator will utilize the temporary certification program to authorize organizations to test and certify complete Electronic Health Records (EHRs)[1] and/or EHR modules,[2] thereby making certified EHR technology available prior to the date on which health care providers seeking incentive payments available under the Medicare and Medicaid EHR Incentive Programs may begin demonstrating meaningful use of certified EHR technology.

This regulation became effective on June 24, 2010, the day it was published in the *Federal Register*. The temporary rule will sunset on December 31, 2011, or, if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator. The permanent certification program will separate responsibilities for performing testing and certification, introduce accreditation requirements, establish requirements

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[1] A Complete EHR is EHR technology that has been developed to meet all applicable certification criteria. This final rule reiterates that for EHR technology to be considered a Complete EHR it would have to meet all applicable certification criteria. If EHR Modules are presented for testing and certification as an integrated bundle that would otherwise constitute a Complete EHR, ONC will consider them a Complete EHR for the purposes of being certified by an ONC-ATCB. Open source Complete EHRs and EHR Modules will be tested and certified in the same manner

[2] An EHR Module is any service, component, or combination thereof that can meet the requirements of at least one certification criterion.

for certification bodies authorized by ONC, and would include the potential for certification bodies authorized by ONC to certify other types of health IT besides complete EHRs and EHR modules.

The temporary certification program provides a process by which an organization or organizations may become an ONC-Authorized Testing and Certification Body (ONC-ATCB) and be authorized by the National Coordinator to perform the testing and certification of complete EHRs and/or EHR modules. In order to become an ONC-ATCB, an organization must submit an application to ONC to demonstrate its competency and ability to test and certify[3] complete EHRs and/or EHR modules. ONC anticipates that only a few organizations will qualify and become ONC-ATCBs under the temporary certification program. These organizations will be required to remain in good standing by following the Principles of Proper Conduct for ONC-ATCBs. At this time, applicants for ONC-ATCB status must be able to test for either ambulatory or inpatient settings. This provision will be reconsidered based upon comments for the proposed permanent certification program.

ONC and CMS anticipate that the requirements for meaningful use will be adjusted every two years. Additionally, there is the possibility that the requirements for an eligible professional or eligible hospital to meet meaningful use Stage 1 in 2013 (or 2014) could be different and possibly more demanding than they were for meaningful use Stage 1 in 2012. The potential exists that an eligible professional or eligible hospital who becomes a meaningful user in 2012 would need additional, not currently present, capabilities from certified EHR technology in order to meet meaningful use Stage 1 requirements in 2013. Open source complete EHRs and EHR modules will be tested and certified in the same manner.

HIMSS Statement of Position

HIMSS supports a two-pronged approach for the Certification program, with the HHS Temporary Certification Program operating through December 31, 2011, unless ONC determines the need to extend this temporary program. HIMSS was pleased that HHS clarified requirements for security testing of EHR modules.

While the final rule did address CCHIT (Certification Commission for Health Information Technology), and CCHIT has since been approved as an ATCB, **HIMSS urges ONC to reconsider its decision to not grandfather in EHR technologies that have current CCHIT certification**. The federal government spent millions of dollars, and the private sector spent both financial resources as well as countless hours, on the ONC-funded CCHIT certification initiative. Not grandfathering in these already-certified EHR technologies, certified using a process directly under ONC guidance, slows down providers' ability to accomplish meaningful use, and introduces wasteful, needless spending in the private sector.

Finally, there appears to be a policy gap between the intent of the regulations and their implementation. There are outstanding questions health professionals must have answers to. Due to the short time period between release of the final regulation and implementation expectations,

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[3] There is a distinct difference between testing and certification. Testing is intended to result in objective, unanalyzed data. In contrast, certification is expected to result in an overall assessment of the test results, consideration of their significance, and consideration of other factors to determine whether the prerequisites for certification have been obtained.

HIMSS notes that these unresolved questions are already creating an inability for entities to comply. **HIMSS urges ONC provide guidance quickly on the following issues:**
- There is confusion regarding whether or not certain products are considered "modules" or part of a "system". Must the following products be submitted for certification under the HHS Temporary Certification Program in order to meet MU requirements? If data from any of these products must be present in the EHR, does it follow that the product in which the data originated is – therefore – an EHR module, and hence must be certified?
  - Lab systems
  - Legacy databases
  - 3rd party software (role and types)
  - E-Prescribing
  - Data aggregators
  - Databases that inform EHRs
  - Data warehouses
- Of the products that need to be certified, what are the ATCB processes for facility site certification?

<u>Closing Remarks</u>

HIMSS is pleased to see this final rule on the Temporary Certification Program become reality in order to implement legislative direction to transform healthcare using IT. Through our robust member structure, we will continue to evolve our positions to reflect the current needs of IT professionals to improve the quality, safety, efficiency, and access for all of healthcare.

HIMSS believes that by linking credible health IT principles emanating from our members' needs and experiences will help our nation successfully transform healthcare using effective information technology. Questions on this position statement should be addressed to <u>Dave Roberts</u>, FHIMSS, HIMSS Vice President for Government Relations, via email or phone 703-562-8811.