

# HEALTH LAW UPDATE

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

## **Can We "HIT" the Ground Running In the New Year? CMS and ONC Issue Health Information Technology ("HIT") Regulations**

**January 8, 2010**

On December 30, 2009, the Centers for Medicare & Medicaid Services ("CMS") and the Office of the National Coordinator for Health Information Technology ("ONC") issued two significant rulemakings: (1) an interim final rule to adopt the initial set of standards, implementation specifications, and certification criteria for certified Electronic Health Record ("EHR") technology; and (2) a proposed rule to implement the EHR incentive payment program authorized by the HITECH Act,<sup>1</sup> including the much-anticipated definition of "meaningful use" of certified EHR technology. The interim final rule and the proposed rule are closely linked. Providers seeking to qualify for EHR incentive payments beginning in 2011 will need to demonstrate the "meaningful" use of certified EHR technology as defined in the proposed rule, and the standards, implementation specifications, and certification criteria adopted in the interim final rule will serve as the basis for testing and certification of qualified EHR systems that are a required support for "meaningful use."<sup>2</sup>

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<sup>1</sup> Health Information Technology for Economic and Clinical Health Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5), enacted February 17, 2009.

<sup>2</sup> Ordinarily when issuing a new rule, HHS will publish a notice of proposed rulemaking in the Federal Register and solicit public comments on the rule before issuing an interim final rule. In this case, however, the American Recovery and Reinvestment Act of 2009 ("ARRA") required the Secretary of HHS to adopt the initial set of standards, implementation specifications, and certification criteria to support meaningful use by December 31, 2009, and authorized the Secretary to do so by issuing an interim final rule. While the interim final rule will go into effect 30 days following publication in the Federal Register, ONC invites public comment for 60 days following its publication. In issuing the proposed rule to implement the EHR incentive payment programs, CMS also invites public comments for 60 days following publication of the proposed rule in the Federal Register. The rules will be published in the Federal Register on January 13, 2010. In the meantime, the Electronic Health Record Incentive Program rules can be viewed here: [http://www.federalregister.gov/OFRUpload/OFRData/2009-31217\\_PI.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2009-31217_PI.pdf), and the Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology are here: [http://www.federalregister.gov/OFRUpload/OFRData/2009-31216\\_PI.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2009-31216_PI.pdf).

Many in the provider community who have already purchased or plan to purchase CCHIT<sup>3</sup>-certified (or similarly certified) EHRs might have hoped that the certification would be a "turnkey" solution that would largely satisfy CMS' standards, implementation specifications, and certification criteria as issued in the interim final rule. However, as will be discussed in this Health Law Update, CMS has declined to adopt any previously recognized set of certification criteria for "meaningful use" purposes. As a result, it may be advisable for these providers to wait for further guidance from the ONC on the certification process. The interim final rule indicates that further guidance is expected in early 2010.

## **I. BACKGROUND ON ARRA AND MEANINGFUL USE**

The American Recovery and Reinvestment Act of 2009 ("ARRA") authorized an incentive payment program to offer reimbursement payments to certain Medicare and Medicaid providers who can demonstrate the meaningful use of certified EHR technology. Beginning in 2011, eligible professionals and hospitals that are "meaningful users" of EHRs meeting the standards, implementation specifications, and certification criteria adopted by the Secretary will be eligible for Medicare or Medicaid reimbursement payments. In each subsequent year of the incentive payment program, the reimbursement payment amounts will decrease incrementally. Further, beginning in 2015, professionals and hospitals that cannot demonstrate the meaningful use of EHR technology will be subject to monetary penalties in the form of decreased payments for services rendered to Medicare beneficiaries.

## **II. PROPOSED RULE -- CRITERIA FOR "MEANINGFUL USE" OF CERTIFIED EHR TECHNOLOGY**

The proposed rule outlines three overarching requirements included within the concept of meaningful use: (1) use of certified EHR technology in a meaningful manner; (2) connectivity of certified EHR technology in a manner providing for the electronic exchange of health information to improve the quality of health care; and (3) submission of clinical quality measures to CMS. The proposed rule sets forth a phased approach to defining meaningful use consisting of three stages, the first beginning in 2011 with later stages anticipated biennially in 2013 and 2015.

### **A. Stage 1 Meaningful Use Criteria**

CMS has proposed a common definition of meaningful use for use in connection with both Medicare and Medicaid incentive programs.<sup>4</sup> The proposed rule provides

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<sup>3</sup> The Certification Commission for Health Information Technology ("CCHIT") was founded in 2004 and coordinated development of the first industry-wide certification procedure protocol for use in connection with EHR technology. In 2006, the Secretary of the Department of Health and Human Services ("HHS") endorsed CCHIT certification criteria for the regulatory safe-harbor and Stark exception qualification standards. CCHIT currently certifies the majority of EHR technology products available in the marketplace, and its certification criteria were extensively reviewed and considered by the ONC in developing its interim final rule. For more information, see <http://www.cchit.org/about>.

<sup>4</sup> The definition will serve as a minimum standard in the Medicaid context as each state may create certain additional objectives or measurements for meaningful use.

specific objectives and measurements for the Stage 1 meaningful use criteria while giving an overview of the anticipated focus of Stage 2 and 3 criteria. CMS notes that these initial criteria are based on currently available technology and that further rulemaking may amplify the Stage 1 measurements and/or objectives in connection with advances in available technology.

In general, CMS proposes that the Stage 1 meaningful use criteria focus on (1) electronic capture of health information in a coded format; (2) use of captured information to track key clinical conditions; (3) communication of captured information for care coordination purposes; (4) implementation of clinical support tools for disease and medication management; and (5) reporting clinical quality measures and public health information.

Meaningful use is defined based on the broad policy care goals developed and previously released by the HIT Policy Committee. Each policy goal has been refined to include several care goals, which in turn have been refined into specific objectives subject to minimum threshold measurements. The proposed rule provides a helpful table of Stage 1 Criteria for Meaningful Use for both eligible professionals and hospitals.<sup>5</sup>

As an example to illustrate this drill-down of policies into specific measurement criteria, the policy priority of "improving quality, safety, efficiency and reducing health disparities" has been divided into several care goals, including "use evidence based order sets and CPOE [Computerized Provider Order Entry]." A Stage 1 objective included within this care goal is the use of CPOE. For eligible professionals, the objective is defined simply as "use CPOE" and the associated threshold measurement is a use of CPOE for a minimum of 80% of all orders. For eligible hospitals, the objective is defined as "use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP)" and the associated threshold measurement is use of CPOE for 10% of all orders.

## **B. Measurement Escalation as Technology and Infrastructure Advance**

CMS has provided some guidance as to the currently projected measurement increases from Stage 1 to Stage 2 meaningful use criteria. Generally, CMS predicts that measures will become more rigorous as available technology advances, e.g. measures allowing for use and exchange of unstructured data will move towards structured formats and measures allowing for capability testing will increasingly require actual submission and exchange of information. CMS also anticipates that CPOE use measurement will be expanded from order entry to include actual electronic submission of those orders. The Stage 1 objective "incorporation of clinical lab test results into EHR as structured data" also likely will be expanded to a wider scope of diagnostic and test data.

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<sup>5</sup> See Table 2: Stage 1 Criteria for Meaningful Use, (Pages 103-08 of the proposed rule) *available at* [http://www.federalregister.gov/OFRUpload/OFRData/2009-31217\\_PI.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2009-31217_PI.pdf).

### **C. Submission of Quality Measures to Demonstrate Meaningful Use**

Eligible professionals and hospitals are required to submit clinical quality measures to CMS in order to demonstrate meaningful use. For 2011, CMS proposes that all eligible professionals and hospitals use an attestation method to submit summary information to CMS. CMS currently anticipates that by 2012 it will have established the capacity to receive and store electronic reports of quality measures and will have promulgated technical specifications to allow EHR vendors to timely provide electronic quality measure functionality. Based on these assumptions, CMS proposes further rulemaking requiring electronic submission of quality measures, but retains attestation as the current fall-back submission method.

### **D. Reporting Periods and Payment Year/Stage Alignment**

The term "payment year" is defined under the proposed rule as (1) for any eligible professional, any calendar year beginning with 2011, and (2) for any eligible hospital, any fiscal year beginning with 2011. Each payment year corresponds to a defined reporting period. CMS has defined the EHR reporting period to provide a shorter initial reporting period allowing for flexibility in a hospital or professional's first year of certified EHR technology use. Thus, a professional or hospital's reporting period is any continuous 90-day period beginning and ending within the first payment year for which an eligible professional or hospital receives an incentive payment. For all other years the reporting period consists of the entire payment year. This structure is particularly helpful for those providers and hospitals planning to establish meaningful use of certified EHR technology for the 2011 payment year as it allows eligible professionals to begin reporting as late as October 1 and eligible hospitals to begin reporting as late as July 1 of the 2011 payment year.

## **III. INTERIM FINAL RULE – INITIAL SET OF STANDARDS, IMPLEMENTATION SPECIFICATIONS AND CERTIFICATION CRITERIA FOR MEANINGFUL USE**

The interim final rule anticipates an incremental approach to adopting standards, implementation specifications, and certification criteria, taking into account the complexity of implementation and the need for EHR technology to mature in order to achieve interoperability. ONC intends to update the initial set of standards, implementation specifications, and certification criteria for subsequent Stages of meaningful use.

### **A. Certification Before and After the HITECH Act**

Although the interim final rule acknowledges the role that the Certification Commission for Health Information Technology ("CCHIT") has played in the process of certifying EHRs prior to the enactment of the HITECH Act, it does not specify a body which will have certifying authority going forward. CCHIT established the first comprehensive process to certify EHR technology in 2006. Since then, it has been certifying EHRs to allow providers to qualify for an exception to the federal physician

self-referral law and a safe harbor to the federal anti-kickback statute for electronic prescribing and donations of EHR technology.<sup>6</sup>

The HITECH Act provided that in adopting the initial set of standards, implementation specifications, and certification criteria to support meaningful use, HHS may adopt the standards that have gone through the ONC's certification process prior to the enactment of ARRA (e.g., the CCHIT standards); however, in HHS' view, the ONC's prior certification process does not accommodate the capabilities necessary to support the objectives of Stage 1 meaningful use encompassed by the EHR incentive payment program. As a result, in the interim final rule the Secretary declines to adopt previously recognized certification criteria developed in 2006 as any of the certification criteria in the interim final rule. Instead, ONC will proceed with a separate notice and comment rulemaking to establish policies for the certification of EHR technology in compliance with meaningful use and the process for authorizing and organization as a "certifying body." Therefore, providers may wish to wait for this forthcoming guidance before purchasing previously CCHIT-certified EHR systems, to be sure the purchased technology is appropriately certified by an authorized certifying body. Providers who have already purchased CCHIT-certified systems may still be able to have these systems certified for meaningful use, but again may wish to wait for ONC's forthcoming guidance in 2010.

## **B. Definitions of "Certification Criteria" and "Certified EHR Technology"**

The interim final rule adopts definitions of "certification criteria" and "certified EHR technology" that have been expanded from the HITECH Act consistent with the ONC's recognition that the requirements for certification of EHRs for meaningful use are broader than the ONC's previous certification requirements. Accordingly, not all previously CCHIT-certified EHRs will be prepared for certification based on the criteria adopted by the Secretary in the interim final rule. ONC believes that 65 previously CCHIT-certified ambulatory EHRs and 15 previously CCHIT-certified inpatient EHRs will be prepared for testing and certifying, representing 90% of all previously CCHIT-certified EHRs. Some of these 80 systems will require more preparation than others, depending on their capabilities and specifications. According to the cost analysis in the

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<sup>6</sup> CMS and the Office of Inspector General ("OIG") have promulgated an exception to the physician self-referral prohibition and a safe harbor under the anti-kickback statute for certain arrangements involving the donation of interoperable EHR systems. 71 Fed. Reg. 45140; 45110 (August 8, 2006). Under the exception and safe harbor, EHR software is deemed to be interoperable "if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the [physician/recipient]." In the interim final rule, ONC acknowledges that HITECH Act not only issued new responsibilities to the ONC related to the certification process, but also created an additional purpose for certification by linking it to providers' qualifying for EHR incentive payments. Accordingly, ONC has decided to issue a separate notice and comment rulemaking to establish the policies for certification and the process a certification body will need to follow to become an authorized certification body pursuant to the HITECH Act. ONC anticipates publishing this rule in early 2010.

interim final rule, ONC believes that average low and high cost per certification criterion for previously CCHIT-certified ambulatory EHRs for prepared testing and certification will be \$50,000 and \$150,000, respectively.

### **C. Adopted Certification Criteria, Initial Standards, and Implementation Specifications**

The standards, implementation specifications, and certification criteria adopted by the Secretary are meant to promote the interoperability, usability, and privacy and security of health information technology. They establish the required capabilities for Certified EHR technology and serve as the basis for the testing and certification of Complete EHRs and EHR modules. ONC makes clear that these requirements apply to Certified EHR technology and do not establish all of the requirements for eligible professionals and hospitals to follow in qualifying for incentive payments.

#### **1. Certification Criteria**

The specific certification criteria set forth in the interim final rule are aligned with the specific objectives for meaningful use Stage 1, as discussed above. For example, one of the objectives set forth in proposed rule is the use of EHRs for CPOE. To that end, the certification criterion adopted by the interim final rule requires EHRs to be capable of enabling the hospital user to electronically record, store, retrieve, and manage, at a minimum, the following orders: medications, laboratory orders, radiology/imaging orders, blood bank, physical therapy, occupational therapy, respiratory therapy, rehabilitation therapy, dialysis, provider consults, and discharge and transfer.<sup>7</sup>

#### **2. Adopted Standards**

ONC adopts the initial set of standards and implementation specifications for Certified EHR technology to support the requirements for meaningful use Stage 1, focusing in particular on standards which will increase interoperability and privacy and security of health information technology. As recommended by the HIT Policy Committee, ONC has organized the standards into four categories: (1) vocabulary standards, (2) content exchange standards, (3) transport standards, and (4) privacy and security standards. In addition to setting forth the adopted standards to support meaningful use Stage 1, the interim final rule also includes a list of standards that ONC believes Certified EHR Technology should most likely be capable of meeting meaningful use Stage 2. These standards represent estimates and have not been adopted by ONC. ONC anticipates receiving recommendations from the HIT Standards Committee in support of these estimates to support meaningful use Stage 2 (beginning in 2013).<sup>8</sup>

#### **3. Adopted Implementation Specifications**

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<sup>7</sup> The complete table of the initial certification criteria adopted by ONC is displayed in pages 51-61 of the Initial Set of Standards, Implementation Specifications, and Certification Criteria, available here: [http://www.federalregister.gov/OFRUpload/OFRData/2009-31216\\_PI.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2009-31216_PI.pdf).

<sup>8</sup> The complete discussion of these standards is displayed in pages 62-85 of the interim final rule, accessed at [http://www.federalregister.gov/OFRUpload/OFRData/2009-31216\\_PI.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2009-31216_PI.pdf).

ONC recognizes that implementation specifications, which provide configuration instructions and constraints for implementing a specific set of standards, are integral to achieving interoperability. However, the interim final rule does not include implementation specifications to support meaningful use Stage 1 because, as the HIT Standards Committee has pointed out, most implementation specifications are not yet tested or are not appropriate for adoption before meaningful use Stage 2. ONC is seeking public comment on whether any implementation specifications are appropriate and industry-tested, and the Secretary will consider adopting implementation specifications if it finds convincing evidence of the maturity and usability of suggested specifications.

#### 4. Additional Considerations

ONC solicits public comment regarding the accounting-for-disclosures requirements. The HITECH Act obligated the Secretary to require HIPAA covered entities to account for disclosures related to treatment, payment, and health care operations made through EHRs. Accordingly, the interim final rule adopts basic certification criteria that require EHR technology to be capable of recording disclosures for these purposes. ONC does not propose a requirement that EHR technology be capable of recording disclosures for other purposes in the interim final rule because it recognizes certain technical challenges exist. For example, EHR technology may lack the ability to differentiate between disclosures made for different reasons. Similarly, it may be difficult for technology to store all necessary information related to disclosures for the required three year period. Accordingly, ONC is seeking public comment on the feasibility of requiring EHR technology to be capable of recording the purpose of a disclosure.

#### **IV. CONCLUSION**

Commentary from various stakeholders in the healthcare industry reflects concern about whether the meaningful use requirements set forth in the proposed rule and interim final rule are realistically achievable or whether they might be too burdensome for the hospital and provider community.<sup>9</sup> It remains to be seen whether and to what extent HHS will modify the meaningful use standards in response to these comments. If you have any questions, please do not hesitate to contact any of the attorneys in our Healthcare Practice Group listed below.

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<sup>9</sup> See *e.g.*, the letter from the American Hospital Association (AHA), found at <http://www.aha.org/aha/press-release/2009/091231-pr-hit.html>.

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