



# HEALTH IT LAW & INDUSTRY



## REPORT

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### Can We ‘HIT’ the Ground Running in the New Year? CMS, ONC Issue Health Information Technology Regulations

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**O**n 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 were published in the Federal Register on January 13, 2010. In the meantime, the Electronic Health Record Incentive Program rules can be viewed here: <http://edocket.access.gpo.gov/2010/pdf/E9-31217.pdf>, and the Initial Set of Standards, Implementation

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 summary, 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.

Because the key to both receiving incentive payments and avoiding financial penalties is being a meaningful user, members of the health IT community have been awaiting further guidance on meaningful use since ARRA was enacted in February of 2009. In developing the interim final rule and the proposed rule, CMS and ONC have gathered input and testimony from ONC’s Health IT Policy Committee and Health IT Standards Committee and have drawn largely upon the “meaningful use matrix” previously recommended by the HIT Policy Committee.<sup>4</sup>

## 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>5</sup> The proposed rule provides 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>6</sup> In Stage 1, there are 23 distinct objectives for hospitals and 25 for eligible professionals—all of which must be met in order to establish meaningful use. Most objectives are applied and measured in a uniform fashion to all eligible professionals and hospitals. In some instances, however, the specific objectives and threshold measurements associated with each care goal are adjusted differently as applied to eligible professionals and hospitals.

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

Specifications, and Certification Criteria for Electronic Health Record Technology are here: <http://edocket.access.gpo.gov/2010/pdf/E9-31216.pdf>.

<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 “meaningful use matrix” may be viewed in its final (August 2009) version here: [http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS\\_0\\_10741\\_888532\\_0\\_0\\_18/FINAL%20MU%20RECOMMENDATIONS%20TABLE.pdf](http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_888532_0_0_18/FINAL%20MU%20RECOMMENDATIONS%20TABLE.pdf).

<sup>5</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.

<sup>6</sup> See Table 2: Stage 1 Criteria for Meaningful Use (pages 103-108 of the proposed rule), available at <http://edocket.access.gpo.gov/2010/pdf/E9-31217.pdf>.

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.

For the convenience of our readers, we’ve listed each of the specific minimum thresholds for each measurement required by the proposed 2011 Stage 1 meaningful use objectives in Attachment 1 appearing at the end of this summary.

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

The Stage 1 meaningful use objectives that rely solely on capabilities included in the ONC’s definition of certified EHR technology and that are not reliant on the electronic exchange of information are subject to relatively high measurement thresholds. However, those objectives that rely on the electronic exchange of information have been subject to lesser initial measurements as CMS recognizes that most areas of the country currently lack sufficient infrastructure to support such exchange. Instead, such objectives in large part entail a single test of the eligible hospital or provider’s ability to exchange such information.

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.

## **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 begin-

ning 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.

CMS also proposes a phased alignment of payment year and Stage of meaningful use criteria. This phased approach is designed to ensure all providers and hospitals meet Stage 3 meaningful use criteria by 2015, while allowing providers and hospitals who establish meaningful use earlier to ramp up and first receive payments by first meeting applicable Stage 1 criteria. For those beginning in 2011, this would mean that Stage 1 criteria would apply in years 2011 and 2012, Stage 2 criteria would apply in years 2013 and 2014, and Stage 3 criteria would apply in 2015.

## **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 among systems. 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>7</sup>

The HITECH Act provided that in adopting the initial set of standards, implementation specifications, and

<sup>7</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 the 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.

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 an 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 expands the definitions of "certification criteria" and "certified EHR technology" in 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.

### **1. Certification Criteria**

The HITECH Act defined "certification criteria" to mean, "with respect to the standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications."<sup>8</sup> The interim final rule expands this definition, recognizing that there are additional capabilities that certified EHR technology will need to provide to meet the meaningful use standard. Each of these capabilities, not just those requiring a particular "standard" or "implementation specification," will need to be tested as well. If the definition does not address all the objectives of meaningful use Stage 1, ONC believes it will be difficult for eligible professionals and hospitals to determine whether their "certified" EHR technology also meets the requirements for meaningful use. Therefore, ONC defines the term to mean: "criteria (1) to establish that health information technology meets applicable standards and implementation specifications adopted by the Secretary; or (2) that are used to test and certify that health information technology includes required capabilities."

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

### **2. Certified EHR Technology**

The interim final rule revises the definition of "Certified EHR Technology" to make it consistent with the revised definition of "certification criteria." It means "a complete EHR or a combination of EHR Modules, each of which: (1) meets the requirements included in the definition of a Qualified EHR; and (2) has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary." ONC believes this definition is flexible enough to accommodate future developments in the EHR technology industry and to allow a competitive marketplace for health IT software and related products.

## **D. 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.<sup>9</sup> 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, re-

<sup>9</sup> In the interim final rule, ONC defines "EHR Module" to mean "any service, component or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary." The use of several EHR Modules may allow a provider to qualify if, taken together, they meet the certification criteria; however, ONC makes clear that the provider in such case must also ensure the components integrate well. The term "Complete EHR" is defined to mean "EHR technology that has been developed to meet all applicable certification criteria adopted by the Secretary." ONC expects some Complete EHRs to have capabilities beyond those addressed by certification criteria adopted by the Secretary.

<sup>8</sup> PHSA § 3001(c)(5)(B).

habilitation therapy, dialysis, provider consults, and discharge and transfer.<sup>10</sup>

The initial certification criteria are intended to create flexibility in some instances where ONC anticipates updated, more efficient and innovative technologies to develop over time. To that end, in some cases the certification criteria require compliance with the version of a code set that is most current (the updated version being incorporated by reference). In drafting the criteria in this way, ONC allows Certified EHR technology to be updated as additional codes are added or existing codes revised, without losing its “certified” status.

## 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 to support 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). For the convenience of our readers, we have separately summarized each of the four categories of standards in Attachment 2 to this summary.

## 3. Adopted Implementation Specifications

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 health-care 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>11</sup> It remains to be seen whether and to what extent HHS will modify the meaningful use standards in response to these comments.

### Attachment 1 Proposed Stage 1 Minimum Thresholds for Measuring “Meaningful Use”

*Eligible Hospitals and Professionals must meet the following criteria:*

- Enable certified EHR technology functionality for implementation of drug-drug, drug-allergy, and drug-formulary checks
- 80% of all unique patients have at least one entry for each of the following types of structured data (“none” is an acceptable entry): current/active diagnoses; active medication; and active medication allergies
- 80% of all unique patients have demographics recorded as structured data
- 80% of all unique patients (2 and over) have recorded blood pressure and BMI, including growth chart for children 2-20
- 80% of all unique patients (13 and over) have recorded smoking status
- 50% of all clinical lab tests ordered with positive/negative or numeric result format are entered as structured data
- Generate one report listing patients with a specific condition
- Provide aggregate information regarding quality measures through attestation
- Implement 5 clinical decision support rules relevant to clinical quality metrics
- Check insurance eligibility electronically for 80% of unique patients
- 80% of claims filed electronically
- 80% of requesting patients receive an electronic copy of health information within 48 hours
- Perform at least one test of the following capacities: electronic exchange of key clinical information; electronic submission of data to immunization registries; electronic submission of reportable

<sup>10</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://edocket.access.gpo.gov/2010/pdf/E9-31216.pdf>.

<sup>11</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>.

lab results to public health agencies; provision of electronic syndromic surveillance data to public health agencies

- Conduct/review a security risk analysis and implement any necessary updates

*The following criteria apply only to eligible hospitals:*

- Use of CPOE for 10% of all orders
- 80% of requesting patients receive an electronic copy of discharge instructions

*The following criteria apply only to eligible professionals:*

- Use of CPOE for 80% of all orders
- 75% of permissible prescriptions are written and transmitted electronically using certified EHR technology
- Send reminder for preventative or follow up care to 50% of unique patients over the age of 50
- 10% of patients are provided timely electronic access to health information
- Clinical summaries provided for 80% of office visits

## **Attachment 2**

### **Adopted EHR Certification Standards**

#### ■ *Transport Standards*

Transport standards are standards used to establish a common, predictable, secure communication protocol, allowing different systems to exchange information. The interim final rule adopts Simple Object Access Protocol (SOAP) version 1.2 and Representational state transfer (REST). According to ONC, these standards are widely used and implemented by the health IT industry and were recommended for adoption by the HIT Standards Committee. Consistent with its incremental approach, ONC recognizes that other standards beyond SOAP and REST are currently being explored, and invites recommendations from the HIT Standards Committee regarding innovations in the marketplace of transport standards.

The interim final rule recognizes that advanced interoperability will require the adoption of specific vocabularies and code sets that can be interpreted by EHR technology and presented into a readable format for its users. Because implementing code sets and vocabularies is a complex task, ONC declines at this point to adopt specific vocabularies and code sets for a number of exchange capabilities in the “Transport Standards” category. In the interim final rule, ONC instead adopts certification criteria that require the capability of presenting health information in a human readable format (such as a computer screen or handheld device). In particular, ONC requests public comment regarding the adoption of more specific criteria for vocabularies and code sets for meaningful use Stage 2.

#### ■ *Content Exchange and Vocabulary Standards*

Content exchange standards are used to share clinical information such as clinical summaries and prescriptions. The context exchange and vocabulary standards have been broken down into the requirements for eight different functions: (1) exchanging a patient summary record; (2) performing a drug formulary check; (3) electronic prescribing; (4) conducting certain administrative transactions; (5) quality reporting; (6) sub-

mission of lab results to public health agencies; (7) submission to public health agencies for surveillance or reporting; and (8) submission to immunization registries.

For exchanging a patient summary record, Certified EHR technology is required to be capable of (a) using the Health Level Seven (“HL7”) Clinical Document Architecture Release Level 2 CCD or ASTM CCR, and (b) displaying a patient summary record in a human readable format after received. These two content exchange standards are adopted as alternatives, but ONC anticipates adopting a single patient summary record standard for meaningful use Stage 2. With respect to the vocabulary standards for use within a patient summary record, the following fields are required to be populated: problem list; medication list; medication allergy list; procedures; vital signs; units of measure; lab orders and results; and discharge summary.

One of the proposed meaningful use Stage 1 objectives is to have an automated drug formulary check as a required capability for Certified EHR technology. To that end, the interim final rule adopts a standard for performing a drug formulary check that requires Certified EHR technology to be capable of using NCPDP Formulary & Benefits Standard 1.0.

For electronic prescribing, Certified EHR Technology must be capable of using NCPDP SCRIPT 8.1 or NCPDP SCRIPT 8.1 and 10.6. With respect to the vocabulary standard for electronic prescribing, the rule adopts a standard that requires the use of codes from the drug vocabulary used in the RxNorm.

For conducting certain administrative transactions, the rule adopts the standard that Certified EHR technology must be capable of using applicable HIPAA transaction standards and Medicare Part D standards adopted by the Secretary. These certification criteria are intended to incorporate by reference the HIPAA transactions standards requirements as they are updated or modified.

With respect to the quality reporting function, Certified EHR Technology must be capable of using the CMS PQRI 2008 Registry XML Specification. In addition, ONC anticipates adopting future standards in consultation with CMS, and requests public comment on whether a different standard, the HL7 Quality Reporting Document Architecture Implementation Guide will be sufficient for use in EHRs during meaningful use Stage 1.

For purposes of submitting lab results to public health agencies, ONC adopts the content exchange standard that Certified EHR technology must be capable of using HL7 2.5.1. ONC adopts the same vocabulary standard for this function as described above for the exchange of patient summary records. ONC indicates that in the future, enabling the use of UCUM and SNOMED CT for the exchange of information will enhance interoperability.

For submission to public health agencies for surveillance or reporting, ONC adopts the use of HL7 .3.1 or HL7 2.5.1 as a content exchange standard, but declines to adopt a vocabulary standard at this time.

For submission of information to immunization registries, ONC adopts the standard that requires Certified EHR technology to be capable of HL7 2.3.1 or HL7 2.5.1 as the content exchange standard, and the HL7 standard code set CVX-Vaccines Administered as the vocabulary standard.

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■ *Privacy and Security Standards*

Privacy and security standards, such as authentication and access controls, are intended to be integrated across all other types of standards adopted. Throughout the interim final rule, ONC emphasizes the importance of Certified EHR technology in providing enhanced privacy and security capabilities. Accordingly, the adopted certification criteria have been aligned to the HIPAA Security Rule requirements. For certain capabilities such as access control, ONC has not adopted specific standards because it believes that the industry is continuing to develop better and more efficient methods to achieve this capability and it wishes to encourage inno-

vation. For other capabilities such as encryption, ONC believes that industry best practices already exist and so has adopted specific criteria. ONC indicates that these required privacy and security capabilities for Certified EHR technology may assist providers in improving the safeguards required by HIPAA. However, ONC makes clear that the privacy and security certification criteria adopted in the final rule are not intended to alter existing requirements under the HIPAA Security and Privacy Rules, nor does compliance with the privacy and security certification criteria ensure compliance with HIPAA requirements.