CMS Issues Final Rule on Meaningful Use,

ONC Issues Companion Final Rule on EHR Certification Criteria

On July 13, 2010, the Centers for Medicare & Medicaid Services (CMS) released its final rule setting forth the requirements that providers must satisfy to become meaningful users of "certified" electronic health record (EHR) technology. The final rule includes a number of significant changes intended to provide more flexibility to providers to achieve meaningful use in order to qualify for incentive payments under the American Recovery and Reinvestment Act of 2009 (Recovery Act).

On the same day, the Office of the National Coordinator for Health Information Technology (ONC) issued its companion final rule setting forth the standards, specifications and certification criteria that EHR technology must satisfy in order to be classified as "certified" EHR technology.

Please see Ropes & Gray's alert of January 12, 2010 for a summary of CMS's notice of proposed rulemaking and ONC's interim final rule.

Changes in the Meaningful Use Final Rule

Background
To qualify for incentive payments, providers must demonstrate that they are "meaningful users" of certified EHR technology. CMS's regulations provide that "meaningful use" will be defined in three stages, with each stage designed to achieve a higher level of EHR utilization. Stage 1 is set forth in the current regulations, and Stages 2 and 3 will be developed in future rulemaking.

Significant Changes to the Meaningful Use Criteria
The final rule affords providers greater flexibility in achieving meaningful use in Stage 1. In contrast to the proposed rule (in which CMS took an all-or-nothing approach, requiring eligible hospitals to satisfy 23 objectives and eligible professionals to satisfy 25 objectives in order to be considered meaningful users), the final rule divides the objectives into a "core set" of objectives, all of which must be met, and a "menu set" of ten objectives from which providers can choose five to satisfy (although at least one of these objectives must relate to population and public health). Eligible hospitals are required to satisfy 14 core objectives and five menu set objectives, while eligible professionals are required to satisfy 15 core objectives and five menu set objectives. In Stage 2, providers will be required to meet all of the core and menu set objectives.

The following chart summarizes the core set objectives and the menu set objectives:

Core Set Objectives & Measures that Apply to both Eligible Hospitals & Eligible Professionals

Objective	Measure
Use computerized physician order entry (CPOE) for medication order	More than 30% of patients have at least one medication order entered using CPOE
Implement drug-drug and drug-allergy interaction checks	This functionality is enabled for the entire EHR reporting period
Record patient demographics	More than 50% of patients have demographics recorded as structured data
Maintain current and active diagnoses list	More than 80% of patients have at least one entry (or an entry that no problems are known) recorded as structured data
Maintain active medication list	More than 80% of patients have at least one entry (or an entry that the patient has no active medications) recorded as structured data
Maintain active medication allergy list	More than 80% of patients have at least one entry (or an entry that the patient has no known medication allergies) recorded as structured data
Record and chart changes in vital signs	For more than 50% of patients age two and over, height, weight and blood pressure are recorded as structured data
Record smoking status for patients 13 years old or older	More than 50% of all patients 13 years old or older have smoking status recorded as structured data
Implement one clinical decision support rule	Implement one clinical decision support rule
Report clinical quality measures	For 2011, provide aggregate numerator, denominator and exclusions through attestation For 2012, electronically submit the clinical quality measures
Provide patients with an electronic copy of their health information upon request	More than 50% of all patients who request an electronic copy of their health information are provided it within three business days
Capability to exchange key clinical information among providers electronically	Perform at least one test of certified EHR technology's capacity to electronically exchange key clinical information
Protect electronic health information created or maintained by EHR	Conduct or review a security risk analysis, implement security updates as necessary and correct identified security deficiencies as part of the risk management process

Core Set Objectives & Measures that Apply to Eligible Hospitals Only

Objective	Measure
Provide patients with an electronic copy of their discharge instructions at time of discharge upon request	More than 50% of patients who are discharged and who request an electronic copy of their discharge instructions receive the copy

Core Set Objectives & Measures that Apply to Eligible Professionals Only

Objective	Measure
Provide clinical summaries for each office visit	Clinical summaries are provided to patients for more than 50% of office visits within three business days
Generate and transmit permissible prescriptions electronically (eRx)	More than 40% of prescriptions written by eligible professionals are transmitted electronically using certified EHR technology

Menu Set Objectives & Measures that Apply to both Eligible Hospitals & Eligible Professionals

Objective	Measure
Implement drug-formulary checks	Provider enables this functionality and has access to at least one internal or external drug formulary for the entire EHR reporting period
Incorporate clinical lab results as structured data	More than 40% of clinical lab test results ordered during the EHR reporting period (whose results are either in a positive/ negative or numerical format) are recorded as structured data
Generate patient lists by specific condition	Generate at least one report listing patients with a specific condition
Identify patient-specific education resources using certified EHR technology	More than 10% of all patients are provided patient-specific education resources
Perform medication reconciliation	Provider performs medication reconciliation for more than 50% of transitions of care during the reporting period
Provide summary of care upon transition of care	Providers who transition or refer their patient to another setting of care or provider of care provide a summary of care record for more than 50% of transitions of care and referrals during the reporting period
Submit electronic immunization data to registries	Provider performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow-up submission if the test is successful
Submit electronic syndromic surveillance data to public health agencies	Provider performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies and follow-up submission if the test is successful

Menu Set Objectives & Measures that Apply to Eligible Hospitals Only

Objective	Measure
Record advance directives for patients 65 years old or older	More than 50% of patients 65 years old or older have recorded as structured data whether they have an advance directive
Submit lab result data to public health agencies	Provider performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful

Menu Set Objectives & Measures that Apply to Eligible Professionals Only

Objective	Measure
Send care reminders to patients	More than 20% of patients 65 years old or older or five years old or younger were sent an appropriate reminder during the EHR reporting period
Provide patients with electronic access to their health information within four business days	More than 10% of patients are provided timely electronic access to their health information, subject to the professional's discretion to withhold certain information

In addition to eliminating the all-or-nothing approach of the proposed rule, CMS also changed several of the underlying objectives and related measures. Most significantly, CMS revised the computerized physician order entry (or CPOE) objective to apply to both inpatient and emergency room settings. CMS also changed the measure to require that at least 30 percent of patients must have at least one medication order entered using CPOE. CMS also lowered the e-prescribing requirement (the ability to send a prescription directly to a pharmacy) from 75% of all prescriptions transmitted electronically under the proposed rule to 40% of all prescriptions transmitted electronically.

The final rule added new objectives to the menu set, including the use of EHR technology to provide patient-specific education resources and to record whether a patient has an advance directive. The final rule also recognizes that several objectives may not apply to certain provider types or specialties. For these objectives, providers may attest that the objective is not applicable. For example, one objective is to record smoking status for patients who are at least 13 years old. The final rule allows any eligible professional who sees only patients under age 13 to attest to the inapplicability of the objective.

Changes to Clinical Quality Measures

Providers are required to report on clinical quality measures. CMS defines clinical quality measures as "measures of processes, experience, and/or outcomes of patient care, observations or treatment that relate to one or more quality aims for health care such as effective, safe, efficient, patient-centered, equitable, and timely care."

In contrast to the proposed rule (which included 90 measures for professionals across specialty groups and 34 measures for hospitals), the final rule reduces the total number of measures for both eligible professionals and eligible hospitals, and eliminates specialty specific measures. Professionals must now report on six measures, including three core measures (blood pressure, tobacco use, and weight) or alternate core measures and three additional measures, and hospitals must report on 15 measures. Reporting is by attestation in 2011 and is expected to be by electronic submission thereafter.

Other Changes Affecting Eligible Hospitals

Consistent with the proposed rule, hospitals eligible to receive payments under the Medicare program are hospitals that receive payment under the hospital inpatient prospective payment system (e.g., acute care hospitals) and critical access hospitals (CAHs). However, in contrast to the proposed rule, hospitals eligible to receive payments under the Medicaid program now include CAHs (in addition to children's hospitals and acute care hospitals that meet certain Medicaid patient volume requirements).

Despite numerous objections from commentators, hospitals will be identified based on their CMS Certification Number (CCN). Accordingly, hospital systems with multiple hospitals that use a single CCN will receive a smaller incentive payment because the system will be eligible for a single "base amount" and will likely reach the discharge cap more quickly.

Eligible Professionals -- "Hospital-Based Eligible Professionals" Has Been Narrowed

Under the Recovery Act and the proposed rule, "hospital-based eligible professional" included those professionals furnishing substantially all of their professional services in a hospital setting (whether inpatient, outpatient or emergency room). Consistent with the Continuing Extension Act of 2010 (Pub. L. 111-157), the final rule defines hospital-based eligible professionals as those performing substantially all of their services in an inpatient hospital setting or an emergency room, meaning that professionals in outpatient settings can now participate (and will be subject to penalties beginning in 2015).

Changes to EHR Technology Certification Criteria

ONC issued its own final rule setting forth the standards, specifications and certification criteria that EHR technology must satisfy in order to become certified. ONC's final rule amends its interim final rule to provide greater flexibility, clarify certain certification requirements, and conform its criteria to CMS's final Stage 1 objectives/measures. Most notably, the final rule eliminates the transport standards in response to concerns that they were insufficiently specified to achieve interoperability and could potentially cause conflicts with other adopted standards. ONC anticipates that the elimination of the standards will encourage innovation.

The release of the final rule follows the finalization of another rule by ONC that establishes a temporary certification program for EHR technology. That rule described how organizations can become authorized by the National Coordinator for Health Information Technology to test and certify EHR technology. The National Coordinator began accepting applications on July 1 and expects that organizations will begin certifying EHR technology shortly after obtaining authorization. ONC plans to post on its website all EHR technologies certified by these organizations.

Timeline for Implementation

Implementation of the Medicare and Medicaid EHR incentive payment programs is rapidly approaching. In response, CMS has provided the following timeline of anticipated implementation dates:

- Fall 2010: ONC projects that certified EHR software will be available for purchase.

- January 2011: Eligible professionals and eligible hospitals may begin registering for the EHR incentive program.

- April 2011: Eligible professionals and eligible hospitals may begin attesting to compliance with meaningful use requirements.

- Mid-May 2011: Incentive payments under the Medicare program will be available.

- Rolling Basis: States will initiate their Medicaid incentive programs subject to CMS approval.

We continue to monitor developments with respect to the EHR incentive programs, especially those changes that may affect the hospital, physician and IT communities. If you have questions on the incentive programs, please contact any of the attorneys listed below or the Ropes & Gray attorneys with whom you regularly work:

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