CMS Issues Proposed Rule on Stage 2 Meaningful Use,

ONC Issues Companion Proposed Rule on 2014 EHR Certification Criteria

On February 23, 2012, the Centers for Medicare & Medicaid Services (CMS) released its proposed rule setting forth the requirements for providers attesting to Stage 2 "meaningful use" of "certified" electronic health record (EHR) technology under the Medicare and Medicaid EHR Incentive Programs. The proposed rule expands upon the Stage 1 criteria finalized in July 2010.

On February 24, 2012, the Office of the National Coordinator for Health Information Technology (ONC) issued its companion proposed rule setting forth the new standards, specifications, and certification criteria that EHR technology must satisfy in order to support the achievement of Stage 2 "meaningful use" and be classified as "certified" EHR technology in 2014.

Comments on these proposed rules are due 60 days after their publication in the Federal Register, which is scheduled for March 7, 2012. Please see Ropes & Gray's July 2010 alert for a summary of CMS's Stage 1 meaningful use final rule (Stage 1 Final Rule) and ONC's companion 2011 EHR certification criteria final rule.

Proposed Stage 2 Meaningful Use Criteria

Background

To qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs (both of which were established in the American Recovery and Reinvestment Act of 2009), professionals and hospitals deemed to be eligible providers under the Act must demonstrate that they are "meaningful users" of certified EHR technology. In the Stage 1 Final Rule, CMS established that "meaningful use" is to be defined and implemented in three stages, with each stage designed to achieve more sophisticated EHR utilization.

In this proposed rule, CMS sets forth the proposed criteria that eligible professionals and hospitals must meet in order to qualify for an incentive payment during Stage 2. The proposed rule also modifies several of the Stage 1 criteria, introduces changes to the program timeline, and outlines payment adjustments under Medicare for providers failing to demonstrate meaningful use of certified EHR technology.

Meaningful Use Objectives and Measures

Similar to the approach CMS devised for Stage 1, the proposed Stage 2 criteria for meaningful use are based on a series of specific objectives that are divided into core objectives and menu objectives. For providers to be meaningful users, they must meet all of the core objectives and a set of the menu objectives. Each of the specific objectives is tied to at least one proposed measure that all eligible professionals and hospitals must meet in order to demonstrate that they are meaningful users of certified EHR technology.

Under the original Stage 1 criteria, eligible professionals and hospitals must meet (or qualify for an exclusion from) all of the core objectives and five of the ten menu measures in order to qualify for an EHR incentive payment. CMS has proposed that for Stage 2, eligible professionals must meet (or qualify for an exclusion from) 17 core objectives and three of five menu objectives while eligible hospitals must meet (or qualify for an exclusion from) 16 core objectives and two of four menu objectives.

CMS also proposed several changes to existing Stage 1 criteria for meaningful use. Some of these changes would be optional for use by providers in Stage 1, but would be required for use in Stage 2, while other

proposed changes would not take effect until providers have to meet the Stage 2 criteria. The most significant proposed changes to the Stage 1 criteria include:

- Eliminating the core objective that providers must demonstrate the capability to "exchange key clinical information" among providers of care; and

- Replacing the requirement that providers "provide patients with an electronic copy of their health information" with a core objective that would instead require providers to provide patients with the ability to "view online, download and transmit their health information."

In addition, CMS has retained nearly all the Stage 1 core and menu objectives in Stage 2, while increasing many of the corresponding measure thresholds. Several Stage 1 objectives have also been consolidated in Stage 2. For instance, the objective to "implement drug-drug and drug-allergy checks" has now been subsumed in the core objective to "use clinical decision support to improve performance on high-priority health conditions." Lastly, CMS added new objectives for Stage 2, including the requirement that eligible professionals "use secure electronic messaging" to communicate with patients.

The following charts summarize the core set objectives and the menu set objectives for Stage 2 as proposed:

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

Objective	Measure
Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders	More than 60% of medication, laboratory and radiology orders created are recorded using CPOE
Record patient demographics	More than 80% of patients have demographics recorded as structured data
Record and chart changes in vital signs	More than 80% of patients seen have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data
Record smoking status for patients 13 years old or older	More than 80% of patients 13 years old or older have smoking status recorded as structured data
Use clinical decision support to improve performance on high-priority health conditions	1. Implement 5 clinical decision support interventions related to 5 or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period 2. Enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period
Incorporate clinical lab-test results as structured data	More than 55% of all clinical lab test results ordered which results are either in a positive/negative or numerical format are incorporated as structured data
Generate lists of patients by specific conditions to use for quality improvement, reduction of	Generate at least one report listing patients with a specific condition

Objective	Measure
disparities, research or outreach	
Identify patient-specific education resources and provide those resources to the patient	Patient-specific education resources identified by certified EHR technology are provided to more than 10% of patients
Perform medication reconciliation	Provider performs medication reconciliation for more than 65% of patients transitioned into care
Provide summary of care upon transition of care or referral	1. The provider transitioning or referring his, her or its patient to another setting of care or provider of care provides a summary of care record for more than 65% of these patients 2. The provider transitioning or referring his, her or its patient to another setting of care or provider of care electronically transmits a summary of care record for more than 10% of these patients to a recipient that has no organizational affiliation and uses a different certified EHR technology vendor
Submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic immunization data from certified EHR technology to an immunization registry or immunization information system for the entire EHR reporting period
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis, implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process

Core Set Objectives & Measures that Apply to Eligible Hospitals Only

Objective	Measure
Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR)	More than 10% of medication orders created during the EHR reporting period are tracked using eMAR
Provide patients the ability to view online, download and transmit information about a hospital admission	1. More than 50% of patients who are discharged have their information available online within 36 hours of discharge 2. More than 10% of all patients who are discharged actually view, download or transmit their information to a third party
Submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic reportable laboratory results to public health agencies for the entire EHR reporting period

Submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic syndromic surveillance data to a public health agency for the entire EHR reporting period

Core Set Objectives & Measures that Apply to Eligible Professionals Only

Objective	Measure
Generate and transmit permissible prescriptions electronically	More than 65% of all permissible prescriptions written are compared to at least one drug formulary and transmitted electronically
Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care	More than 10% of patients who have had an office visit with the provider within the 24 months prior to the beginning of the EHR reporting period were sent a reminder, per patient preference
Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the provider	1. More than 50% of patients seen are provided timely (within 4 business days after the information is available to the provider) online access to their health information subject to the provider's discretion to withhold certain information 2. More than 10% of patients seen (or their authorized representatives) actually view, download or transmit to a third party their health information
Provide clinical summaries for patients for each office visit	Clinical summaries provided to patients within 24 hours for more than 50% of office visits
Use secure electronic messaging to communicate with patients on relevant health information	A secure message was sent using the electronic messaging function by more than 10% of patients seen

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

Objective	Measure
Access imaging results and information	More than 40% of all scans and tests where result is an image are accessible
Record patient family health history as structured data	More than 20% of patients seen have a structured data entry for one or more first degree relatives

Menu Set Objectives & Measures that Apply to Eligible Hospitals Only

Objective	Measure
Record whether a patient 65 years old or older has an advance directive	More than 50% of admitted patients 65 years old or older have an indication of an advance directive status recorded as structured data
Generate and transmit permissible discharge prescriptions electronically	More than 10% of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared to at least one drug formulary and transmitted electronically

Menu Set Objectives & Measures that Apply to Eligible Professionals Only

Objective	Measure
Submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic syndromic surveillance data to a public health agency for the entire EHR reporting period
Identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of cancer case information to a cancer registry for the entire EHR reporting period
Identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of specific case information to a specialized registry for the entire EHR reporting period

Reporting on Clinical Quality Measures

Under the Medicare and Medicaid EHR Incentive Programs, eligible professionals and hospitals are also required to report on specified clinical quality measures (CQMs) to qualify for incentive payments. Acknowledging the difficulty that quality reporting presents, CMS sought to achieve better alignment of Stage 2 CQMs with existing quality programs. For eligible professionals, CMS has proposed a set of CQMs beginning in 2014 that align with measures used in programs such as the Physician Quality Reporting System, the Medicare Shared Savings Program, and National Council for Quality Assurance for medical home accreditation. For eligible hospitals, CMS has put forth a set of CQMs beginning in 2014 that align with the Hospital Inpatient Quality Reporting and the Joint Commission's hospital quality measures. CQM reporting, under this proposed rule, would require eligible professionals to report 12 CQMs and eligible hospitals to report 24 CQMs.

Medicare Payment Adjustments and Exceptions

As required under the Recovery Act, CMS outlined the Medicare downward payment adjustments to take effect in 2015 and designed a process by which payment adjustments would be determined by the provider's performance during a prior reporting period. In this proposed rule, CMS has proposed that any successful meaningful user in 2013 would avoid payment adjustment in 2015. Further, any Medicare provider that first meets meaningful use in 2014 would avoid the penalty in 2015 if the provider is able to demonstrate meaningful use at least 3 months prior to the end of the calendar or fiscal year as well as meet the registration

and attestation requirements by July 1, 2014 for eligible hospitals, or October 1, 2014 for eligible professionals.

CMS also proposed three exceptions to these payment adjustments: (1) lack of availability of internet access or barriers to obtaining IT infrastructure, (2) a time-limited exception for new eligible professionals or hospitals, and (3) unforeseen circumstances such as natural disasters. CMS is soliciting comments on potential additional exceptions.

Timeline for Implementation

With respect to the timeline for implementing the meaningful use criteria and corresponding incentives, CMS proposed to extend the duration of Stage 1 to allow providers an additional year to implement Stage 2 criteria (in the Stage 1 Final Rule, CMS established that any provider who first attests to Stage 1 criteria for Medicare in 2011 would have to begin using Stage 2 criteria in 2013). Accordingly, for these providers, the proposed rule delays the implementation date of the Stage 2 criteria until 2014 (with Stage 3 expected to be implemented in 2016). We note, however, that all providers must begin at Stage 1, and CMS has clarified that each stage lasts for two years.

Proposed 2014 Edition EHR Certification Criteria

ONC issued its own proposed rule setting forth the standards, implementation specifications and certification criteria that EHR technology must satisfy in order to support the achievement of Stage 2 meaningful use and become certified as of 2014. ONC has clarified that these proposed criteria are to be referred to as the "2014 Edition EHR certification criteria" while the currently adopted certification criteria are to be referred to as the "2011 Edition EHR certification criteria."

The 2014 EHR Edition certification criteria aim to be responsive to the proposed changes to the Medicare and Medicaid EHR Incentive Programs, including the new and revised objectives and measures for Stages 1 and 2 of meaningful use. Most noteworthy, ONC altered the definition of certified EHR technology, introducing the concept of a "Base EHR," which is defined as a fundamental set of EHR capabilities that all providers would need to implement or be able to access. Capabilities included in the Base EHR, as proposed, include the ability to provide clinical decision and physician order entry, support, and the capacity to exchange health information with other sources and to protect the confidentiality, integrity, and availability of health information stored and exchanged. According to ONC, "Base EHR" would then need to be paired with certain additional EHR technology so the overall system is tailored to meet specific meaningful use stages and goals.

According to ONC, its proposed certification criteria are intended, among other objectives, to improve patient safety through the application of user-centered design processes and adherence to appropriate quality systems principles. ONC is seeking public comment on these proposals and others related to the improvement of patient safety. In addition, ONC is requesting public input on ways to improve data portability as well as feedback on the concept of price transparency as it relates to various certified EHR technologies.

ONC has proposed revisions to the permanent certification program for health information technology (HIT). The proposed rule also includes modifications to the certification processes ONC-Authorized Certification Bodies (ONC-ACBs) would need to follow to certify EHR Modules.

The anticipated sunset of the temporary certification program is expected to occur upon the effective date of a final rule for this proposed rule.

We continue to monitor developments with respect to the Medicare and Medicaid EHR Incentive Programs, especially those changes that may affect the hospital, physician, and information technology 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.

Michael D. Beauvais
Joanna L. Bergmann