CMS Issues Proposed Stage 3 Meaningful Use Standards

On March 30, 2015, the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) published in the Federal Register proposed regulatory changes that move CMS' federal Electronic Health Record incentive program to the next stage. The proposed regulations can be found at *Department of Health and Human Services Medicare & Medicaid Services*, 80 Fed. Reg. 16732 (proposed March 30, 2015)(to be codified at 42 C.F.R. Part 495 and 45 C.F.R. Part 170).

Through publishing a Notice of Proposed Rule Making (NPRM), federal agencies propose rules in order to give interested persons an opportunity to submit comments to improve the final regulation. CMS's publication opens a 60 day comment period, which closes on May 29, 2015.

This alert seeks to summarize exactly how the CMS' proposed Stage 3 rules will change the standards for demonstrating meaningful use of electronic health records, and by doing so, seeks to provide you with the information necessary for you to contribute comments to the proposed rules.

Background

CMS's Electronic Health Record (EHR) Medicare and Medicaid Incentive Programs provide incentive payments to expedite and encourage eligible medical professionals, eligible hospitals, and critical care hospitals to adopt, implement, or upgrade certified Electronic Health Record (EHR) technology and to demonstrate the "meaningful use" of certified EHR technology.

Medical providers must demonstrate meaningful use by meeting certain requirements. Providers who fail to meet those requirements under the Medicaid EHR Incentive Program will forfeit their incentive payment. However, starting in 2015, providers failing to meet criteria under the Medicare EHR Incentive Program will face downward payment adjustments.

The program was designed to consist of three stages of meaningful use, with each stage consisting of increasing requirements. Providers advance through each stage.

Stage 1 was intended to establish requirements for the electronic capture of clinical data, including providing patients with electronic copies of their health information. Stage 2 focused on the data captured in Stage 1 being exchanged among health care providers and patients in order to improve coordination of care. Stage 2 also implemented a set of clinical quality measures (CQMs) for all providers to report in 2014, regardless of which stage they were in.

Stage 3

The proposed regulations published on March 30, 2015 outline the Stage 3 requirements of the EHR Incentive Program. The Stage 3 criteria will begin in 2017 and be mandatory for all providers in 2018, regardless of prior participation in EHR Incentive Programs.

According to CMS, Stage 3 is expected to be the final stage and is intended to continue the goals of the first two stages, by increasing interoperability of health data and sharing among providers. Furthermore,

Stage 3 focuses on the advanced use of EHR technology to promote improved patient outcomes and health information exchanges. Finally, CMS proposes to streamline the definition of meaningful use and ease providers' reporting burdens.

The CMS proposed rules come in at a lengthy 301 pages. They are accompanied by 431 pages of proposed certification standards issued by the Office of the National Coordinator for Health Information Technology (ONC), the office charged with coordinating national efforts to implement and use electronic health information. Taken together, the proposed rules should be thoroughly reviewed by health information technology specialists in order to ensure EHR systems technically comply with the rules.

Meaningful Use

The rules, however, go above and beyond technical compliance. How does CMS propose to change meaningful use standards change in 2017 and beyond?

Overall, the meaningful use rules have eight overall objectives. Each of those eight objectives contains a number of measures, or internal criteria. Many objectives also contain exemptions for eligible health care providers or hospitals that may have trouble meeting a certain standard due to a number of issues, such as having a low eligible patient population or being located in a location with poor broadband internet access.

Additionally, where noted below, CMS has proposed a rule and listed a number of alternates it would like to consider. A particularly useful way to determine whether you would like to comment on a proposed rule is to read the below synopsis, and if you object to the standard, then turn your attention to the relevant location in the NPRM to evaluate whether you would like to comment on a proposed alternative as superior to the proposed rule.

The following are the eight objectives for demonstrating meaningful use.

Protect Patient Health Information 80 Fed. Reg. 16745-16747

- Upon installation or upgrade of certified EHR system, providers must conduct or review a security risk analysis that addresses the security and encryption of data in a certified EHR system, implement security updates as necessary, and correct security deficiencies.
- Once per reporting period, providers must review the security risk analysis of their system and update the analysis as necessary.

Electronic Prescribing. 80 FED. Reg. 16747-16749

- Eligible providers must transmit more than 80% of prescriptions electronically. This is an increase from the 50% standard found in Stage 2. Authorizations for refills count towards the percentage. The proposed rule maintains exclusions for providers who write fewer than 100 eligible prescriptions during the reporting period and providers who are not within a ten-mile radius of a pharmacy that accepts electronic prescriptions.
- Eligible hospitals and critical access hospitals must transmit 25% of prescriptions electronically. This is an increase from the 10% standard found in Stage 2. CMS seeks comments on whether refills should count towards the percentage for eligible hospitals and critical access hospitals. The proposed rule maintains exclusions for eligible hospitals and critical access hospitals do not have a pharmacy

capable of accepting electronic prescriptions and those that are outside of a ten-mile radius of a pharmacy that accepts electronic prescriptions.

- In both cases, where permitted by state law, providers may count electronic prescriptions for controlled substances. In a continuation of Stage 2 objectives, over-the-counter medications are not included in the Stage 3 rule. However, CMS requests comments on whether over-the-counter medications should be included.

Clinical Decision Support

There are two measures within the Clinical Decision Support objective. 80 Fed. Reg. 16749-16750.

- Providers should implement five Clinical Decision Support (CDS) interventions to improve performance before diagnostic or treatment action is taken in response to the intervention. These interventions should be tied to four clinical quality measures or, alternatively, related to high-priority health conditions. At least one intervention must be related to improving healthcare efficiency. The proposed rules do not create specific pairings between CDS interventions and clinical quality measures, but rather encourage providers to focus on patient outcomes rather than clinical process measures.
- Providers must enable and implement drug-to-drug and drug-to-allergy interaction alerts for the entire reporting period.

Computerized Provider Order Entry (CPOE)

CPOE is defined as a provider's use of computer assistance to directly enter clinical orders from a computer or mobile device. Stage 2 expanded on Stage 1, which had only required laboratory orders to be computerized. The proposed Stage 3 rules add diagnostic imaging, and expand on the Stage 2 targets. Overall, the proposed Stage 3 rules have three measures to meet the CPOE objective and maintain an exclusion for providers who do issue fewer than 100 eligible orders in a reporting period. 80 Fed. Reg. 16750-16752.

- Eighty percent of medication orders must be made using CPOE. This is an increase from the 60% requirement in Stage 2.
- Sixty percent of laboratory orders must be made using CPO. This is an increase from the 30 percent requirement in Stage 2.
- Sixty percent of diagnostic imaging orders must be made using CPOE.

Patient Electronic Access to Health Information

Providers must satisfy both measures in order to meet the objective. The proposed rule retains an exclusion for providers located in counties where less than 50% of the population does not have access to broadband internet with a speed of at least 4Mbps. 80 Fed. Reg. 16752-16755.

- Eighty percent of patients must be able to view, download, and transmit their health information electronically within 24 hours of its availability to the provider; alternatively, patients must be able to access the information on demand, through a patient portal, personal health record, or an approved Application-Program Interface (API). A patient also must be able to have his protected health information sent direct to a third party the patient designates. This is an increase of the 50% threshold

in Stage 2 that also requires a faster response time because Stage 2 required the information to be available within four business days.

- At 80 Fed. Reg. 16755, CMS is seeking comments on three alternate proposals for measure one. The three alternate proposals vary on whether providers must allow both functions, either function, or only the API function.
- Providers must use clinically relevant electronic information to identify patient-specific educational resources and provide 35 percent of patients with electronic access to those resources during the reporting period. This is an increase of the ten percent threshold in Stage 2.

Coordination of Care through Patient Engagement

Under the proposed stage 3 rules, providers must meet the thresholds of two of the three measures for coordination of care through patient engagement in order to encourage patient involvement with their own healthcare. Providers must attest to the numerators and denominators of all three measures. 80 Fed. Reg. 16755-16758.

- Twenty-five percent patient of patients must engage an approved electronic health portal, or Application-Program Interface (API). This is an increase of the five percent standard found in Stage 2, despite the difficulty providers have had in reaching that requirement.
- Thirty-five percent of patients must receive a clinically-relevant secure message regarding their health care. This measure can be met through messages sent or received by a patient. The content of the message cannot relate to scheduling, billing, or other administrative subjects.
- CMS seeks input regarding whether only the initiating provider should be able to count the communication, or whether a provider who contributes to the conversation may count the communication.
- Providers must incorporate information acquired from their patients or from non-clinical settings for 15 percent of patients. This relates to data acquiring from care providers such as nutritionists and physical therapists as well as patient-generated data.
- CMS seeks input regarding whether and how to incorporate non-clinical data into the EHR.

Health Information Exchange

Under the proposed Stage 3 rules, providers must demonstrate that a summary of care record is transmitted or captured electronically and incorporated into EHR for patients seeking care among different providers along the care continuum. With this objective, providers must meet the thresholds of two of the three measures and attest to the numerators and denominators of all three measures. All three measures have an exclusion for providers that conduct 50 percent or more of their practice within a population where 50 percent of that population does not have access to broadband internet with a speed of at least 4Mbps. 80 Fed. Reg. 16758-16762.

- For more than 50 percent of transitions of care and referrals to another setting of care or provider, providers must create an electronic summary of care and electronically exchange the summary of care record.
- The proposed measure continues to require the same information Stage 2 required: patient name, referring providers name and contact information, procedures, diagnosis, immunizations, laboratory

test results, vital signs, smoking status, functional status, demographic information, care plan, care team identification, discharge instructions, and reason for referral. Further required information will be found in the ONC proposed criteria for a Common Clinical Data Set.

- The first proposed measure has an exclusion for a provider who does not transfer or refer a patient during the EHR reporting period.
- For more than 40 percent of transitions of care and referrals from another setting of care or provider, providers must receive and incorporate an electronic summary of care record.
- The second proposed measure has an exclusion for a provider who receives fewer than 100 patients during the EHR reporting period.
- For the first and second measures, CMS requests comments regarding whether providers should be permitted to use any electronic means of transmittal or whether they must use a system that meets ONC standards. Additionally, CMS seeks comments on whether providers' systems must be interoperable.
- For more than 80 percent transitions of care and referrals from another setting of care or provider, providers must perform reconciliation for medications, medication-allergies, and current and active diagnoses.
- The third proposed measure has an exclusion for a provider who receives fewer than 100 patients during the EHR reporting period.
- CMS seeks comment on whether the reconciliation must be automatic or manual, the effects the reconciliation has on staffing issues, and whether any exclusions should be considered.

Public Health and Clinical Data Registry Reporting

The reporting requirements under Stage 3 rules for the public health measure are different for individual providers and for hospitals. Eligible Providers must report on 3 of the first five measures, while Eligible Hospitals and Critical Access Hospitals must report on four measures out of all six.

- For this standard, providers must be "actively engaged" with a public health agency or clinical data registry. This replaces Stage 2's "ongoing submission" standard. "Active engagement" means registering, testing, or transmitting information related to the following (80 Fed. Reg. 16762-16767):
    - Immunization Registry Reporting
    - Syndromic Surveillance Reporting
    - Case Reporting of reportable conditions
    - Public Health Registry Reporting
    - Clinical Data Registry Reporting
    - Electronic Reportable Laboratory Results
- The proposed rules have exclusions for all six of these measures, when a provider either does not administer the relevant program (such as immunizations) or is within a jurisdiction where no immunization registry is capable of accepting electronic records in compliance with electronic health record standards.

- In addition to being challenging for medical information and technology professionals, the CMS Medicare and Medicaid EHR Incentive Programs are a complex area of regulatory law. To avoid downward payment adjustments under Medicare and to receive incentive payments under Medicaid, it is imperative that your practice or facility understands the necessary processes and procedures needed to satisfy CMS' meaningful use requirements.

During the NPRM period, you have a unique opportunity to influence these very important rules. Please contact Evan Bonnett or your regular Hinshaw & Culbertson attorney if you have any questions or would like to discuss a strategy to comment before the NPRM period ends on May 29, 2015.