PUBLICATION

Proposed Stage 2 Meaningful Use Rule Worth a Close Read; Proposed Rule Also Affects Stage 1 for 2013 and 2014 [Ober|Kaler]

March 23, 2012

This article originally appeared in* Health Lawyers Weekly *(American Health Law Association).

On March 7, 2012, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule providing standards and guidance for Stage 2 of the Medicare and Medicaid EHR Incentive Program (the "Program" and commonly called the "Meaningful Use" program). The CMS rule was issued in conjunction with Stage 2 certification standards developed by the Office of the National Coordinator for Health Information Technology (ONC). Stage 2 of Meaningful Use is currently slated to begin no earlier than 2014 (for participants who met the Program's Stage 1 requirements in 2011 or 2012). Comments on both proposed rules are due by 5 p.m. on May 7, 2012.

Both of the proposed rules are dense with detail, and should be reviewed closely by interested parties (including both eligible providers and electronic health record vendors responsible for ensuring EHR system certification for Stage 2). The ONC's rules, while essential to understanding Program requirements, are primarily geared towards system engineers and software developers — providers who use EHRs will know when a system is "certified" that it has met the requirements of the ONC's rule. This article, accordingly, will focus on CMS' rule as it provides the requirements that most directly impact provider work flow.

The Stage 2 proposed rule does far more than simply provide an updated list of objectives, standards, and measures for Stage 2 of the Program. In addition to providing the proposed standards for Stage 2, the proposed rule makes some important changes to Stage 1 objectives and measures, provides important information regarding the pending payment adjustments (penalties) for those providers who fail to meet program requirements, proposes important exemptions and exceptions for certain providers (including, importantly, radiologists, pathologists, and similar eligible professionals who do not see patients), provides for a new group reporting option, and proposes an appeal process for program participants. This article will address the most widely applicable, surprising, or otherwise noteworthy provisions in what is a large, detailed, and comprehensive rule.

Changes to Stage 1 of the Program

Because Stage 1 had been extended for one year for certain program participants, Stage 2, which was originally scheduled to start (for the earliest participants) in 2013, was pushed back to 2014. Reflecting this delay, the proposed rule provides for some changes and updates to the requirements of Stage 1 that will be phased in during 2013 and 2014. For the most part these changes will be optional during 2013 (meaning that program participants have the option to comply with the changed standards or additional requirements proposed if they are in Stage 1 during 2013 or to comply with the Stage 1 standards as originally promulgated, but are required to comply with the proposed rule's changes to Stage 1 if they remain in Stage 1 during 2014). The proposed rule provides a concise summary of these changes on a chart at page 13705. The proposed Stage 1 changes are, for the most part, neither surprising nor obviously burdensome, but may require program participants to reassess their system capabilities to ensure that they are able to comply when the changes become mandatory in 2014.

Two changes to the Stage 1 program requirements are worth special mention. With regard to Computerized Physician Order Entry (CPOE), the proposed rule eliminates what had been an important division in the Stage 1 calculation of CPOE use. Previously, Stage 1 permitted hospitals to limit their calculations of "orders created" to those orders created *only* in the emergency department (ED). Hospitals, for instance, had to demonstrate that CPOE was used for 30% of all orders created *in the ED*. The new proposed standards appear to eliminate that division, and expand the requirement to encompass orders created in the ED *or in any other inpatient hospital setting*. While the numerator remains at 30%, the denominator will, for most hospitals, expand substantially. This change raises several issues for hospitals in Stage 1, including how "all" orders will be captured (especially where a hospital may not have integrated its EHR system in all inpatient areas) and whether existing order entry locations and work flow will provide sufficient opportunity for CPOE to meet the requisite 30% measure. Both eligible professionals (EPs) and hospitals should closely review the changes to the Stage 1 CPOE requirements to ensure that they will be able to comply by (or before) 2014, when the changes become mandatory.

In another, and perhaps the most surprising, change to Stage 1, CMS elected to eliminate three Stage 1 objectives relating to providing patients with electronic copies (or electronic access) to their health information. These three existing Stage 1 objectives have been replaced, for both physicians and hospitals, with a requirement to provide patients online access to their health information (through, for instance, a secure patient portal). Further, the proposed rule's measure of compliance would require both that 50% of all patients were provided the access *and* that at least 10% actually viewed and downloaded their information. In the preamble discussion of this change, CMS further notes that with regard to this requirement, "[p]roviders who are covered by civil rights laws must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations." At least on its face, this proposed new measure would appear to not only make providers responsible for ensuring that their patients follow up and access their own healthcare information, but, at least in some cases, would obligate the provider to provide the *means* for the patient to access that information. This new requirement, and its measurement, would become mandatory in 2014 for participants in both Stage 1 and Stage 2 of the Program.

Stage 2 Program Requirements

For the most part, the proposed rule follows CMS' earlier intention to expand Stage 1 requirements in Stage 2. There are, however, several new or changed objectives (or measures) that program participants should review carefully. The entirety of the new Stage 2 objectives and measures can be reviewed quickly in the chart provided within the rule beginning at page 13734. The majority of the new objectives for Stage 2 will be added to the "menu set" of optional items, rather than the "core set" of required objectives. Three objectives, however, are being made a part of the "core set" and will, accordingly, be required of all program participants when they begin Stage 2. CMS explained that "the additional time made available for Stage 2 implementation makes possible the inclusion of some new objectives in the core set."

First, Stage 2 will require, as discussed above, that all participants provide patients with a secure, online means to access their health information. For both hospitals and professionals, this requirement will replace the Stage 1 requirement to provide patients with an electronic copy of their health information (or discharge information). As a related requirement, the rule also proposes a new core objective for hospitals: "Provide patients the ability to view online, download, and transmit information about a hospital admission." As in the case of the replaced requirement, CMS will measure compliance with this requirement based on both the hospital's actions (that at least 50% of all discharged patients are provided access in this fashion) *and* patient actions (requiring that at least 10% of all patients granted the requisite access actually log on and view, download, or transmit the available information). Similarly, hospitals are also reminded that civil rights laws may require them to provide assistance or even the means to access the information for disabled patients.

Second, hospitals will be required to "Automatically track medication orders using an electronic medication administration record (eMAR)." CMS' inclusion of this objective follows the recommendation made by the HIT Policy Committee. CMS defines eMAR technology as "any technology that automatically documents the administration of medication into Certified EHR Technology using electronic tracking sensors (for example radio frequency identification (RFID) or electronically readable tagging such as bar coding)." The CMS rule also notes that a more extensive definition of eMAR technology is provided in the proposed ONC rule. CMS proposes that to meet the objectives, hospitals must use eMAR for at least 10% of all medication orders created by authorized providers in the hospital's emergency or inpatient environments. As noted above, hospitals should investigate their chosen EHR technology to ensure that it can both capture *all* medication orders and that there is sufficient data entry points to ensure that the requisite threshold can be reached, given the larger denominator that the proposed rule would impose.

Finally, professionals, under the proposed rule, would be required to "use secure electronic messaging to communicate with patients." CMS goes on to explain that "secure electronic messaging" would *not* include typical email, as that means of communication fails to offer an appropriate level of security. Instead, CMS suggests that the required messaging could occur through stand-alone secure applications, patient portals, or a patient's Personal Health Records (PHRs). This requirement, accordingly, would appear to dovetail with the requirement that professionals provide patients secure, web-based access to their health information. As in the case of that objective, CMS proposes basing its calculation of a provider's compliance on actions taken by the provider's patients; to meet the required threshold, at least 10% of a professional's unique patients must send the professional a secure message using the provided messaging portal.

Clinical Quality Measure (CQM) Reporting

The rule proposes extensive and detailed changes to the Program's use of CQMs. Notably, time periods for reporting CQMs are clarified, comments are solicited on nearly 175 proposed CQMs, and CMS provides a detailed explanation of the process that will be used to change and update CQMs. Participants specifically tasked with CQM management or reporting should consult the rule's detailed guidance at pages 13742 through 13763 of the proposed rule, including the extensive list of new or changed CQMs. Of special note, eligible professionals should review pages 13745 through 13748, where CMS proposes (and specifically request comments on) three alternative methods for eligible professionals to report CQMs. Two of these proposed options would require professionals to select and report on a certain number of core and menu set measures. The last option, however, would seek to align the EHR Incentive Program's CQM reporting with that required under the Physician Quality Reporting System (PQRS). Under this third option, professionals who reported as required under PQRS using Certified EHR Technology would satisfy the EHR Incentive Program's CQM reporting requirements.

Group Reporting to Demonstrate Meaningful Use

The proposed rule explains that, eventually, CMS hopes to move away from attestation as a method of demonstrating meaningful use and towards more automated, direct reporting options through EHR technology itself. At this point in time, however, CMS does not believe the available technology will support such direct reporting sufficiently to end the need for attestation. As a step towards direct reporting in the future, however, the rule proposes a system whereby group practices may submit a single "batch file" for all group members, rather than requiring individual attestation through the Program website.

Group member's compliance with Program requirements would still be measured on an individual basis - the new submission process would not permit "averaging" for instance, or any similar combining of statistics. Similarly, the batch reporting would not include CQMs. It would, however, permit any two or more professionals

associated with a group practice under one tax ID number to submit a single batch file of core and menu set compliance data rather than submitting each professional's data separately. The individual professional's incentive payment would be automatically assigned, under this option, to the group's tax ID number (selected during program registration). It is worth noting that CMS is not altering any other related requirements for professional reporting — eligible professionals must still demonstrate that 50% of their encounters took place in a setting with EHR technology. CMS is not proposing, however, any minimum participation threshold for the group reporting option — a professional remains responsible for collecting all required data, but may report that data as part of a group batch report even where only 5% (or less) of the professional's patient encounters took place with that particular group.

Importantly, CMS also specifically requested comments on a "group reporting option that allows groups an additional reporting option in which groups report for their EPs [as] a whole rather than broken out by individual EP." At page 13766 of the proposed rule, CMS has provided a list of questions that it believes would be relevant with regard to such an option, and program participants are encouraged to respond.

Hospital-Based Professionals

As many are aware, the much debated definition of a "hospital-based professional" was finalized by a legislative compromise that was unsatisfactory to many provider types. As a result of the compromise, professionals who perform the majority of their services in a hospital environment are not permitted to take part in the EHR Incentive Program. In explaining the reasoning behind this decision, CMS has often cited the "double-counting" of hospital patients (by both the professional and the hospital) and the "double-payment" (paying both the professional and the hospital for a system purchased by the hospital) that could result from alternative definitions. The proposed rule notes that CMS has received many comments on this issue, noting specifically that some provider groups may operate within a hospital environment, but do so using their own, separate and separately purchased EHR technology.

CMS has specifically requested detailed comments on this issue, including, where appropriate, documentation supporting the assertion that specialized hospital units are using separate and separately purchased EHR technology. This information will be reviewed to determine whether a new policy on certain hospital-based professionals would be appropriate. In the event of such a policy, the proposed rule notes that "additional attestation elements would be required" (including, presumably, an attestation that there has been no "double-counting" and will be no "double-payment") and that attesting professionals would be subject to audit and False Claims Act penalties.

Payment Adjustments

Program incentives, provided to those who meaningfully use EHR technology in conformance with program requirements, begin to transition to "payment adjustments" (penalties) for those who fail to meaningfully use EHR technology in 2015. The proposed rule provides that who will receive a payment adjustment (of 1%) in 2015 will actually be decided in 2013. A program participant who receives an incentive in 2013 will not face a payment adjustment in 2015. An eligible professional or hospital who does not receive an incentive payment for the 2013 year, however, will *also* face a payment adjustment in 2015. The proposed rule provides an exception for hospitals and professionals who have never before attested to program requirements (including during 2013). For these first-time attesters, CMS has proposed permitting a 90-day reporting period during 2014. For hospitals (whose reporting and payment years are based on the federal fiscal year) this would mean the last possible date to register and attest (and avoid a payment adjustment in 2015) would be July 1, 2014. For professionals (whose obligations are based on the calendar year) it would be October 1, 2014.

With regard to the payment adjustments, the proposed rule also discussed the statutory provision that permits the Secretary, beginning in 2018, to reduce payments to non-compliant professionals by an additional 1% where it is determined that less than 75% of *all* eligible professionals meet program requirements. In no event, however, may the applicable payment percentage be reduced beyond 95%. Taking this into account, the proposed rule notes that the payment percentages for non-compliant professionals could be reduced to 96% in 2018 and 95% in 2019 and beyond.

Exceptions From the Payment Adjustment

The rule proposes multiple payment adjustment exception categories for both hospitals and professionals.

- Applicable to both hospitals and professionals, the rule proposes excepting entities that practice in an area without "sufficient internet access." Entities hoping to claim this exception must demonstrate that, in the year two years prior to the payment adjustment year (with applications submitted by July 1 for professionals and April 1 for hospitals) of the fiscal or calendar year prior to the payment adjustment year. CMS explains that the exception requests, in this case, would be reviewed on a case by case basis to determine the reasons for the lack of internet connectivity and to determine if such lack truly caused a "hardship."
- Applicable to both hospitals and professionals, the rule proposes excepting "new providers." For professionals, this exception would last for two years from the date they "begin practicing." For hospitals, the period of exception would be "at least one full year cost reporting period." This exception would also require the submittal of an application, and the proposed rule promises that additional information on the timing of application submissions will be forthcoming.
- Applicable to both hospitals and professionals, the rule proposes excepting providers that fail to meet Program requirements due to "extreme circumstances" (such as a natural disaster, a hospital or practice closure, or an EHR vendor going out of business). Providers who wish to claim this exception would be required to submit an application to be reviewed on a case-by-case basis by the same deadlines as the exception for insufficient internet access.
- Finally, applicable only to professionals, CMS is soliciting comments on (but not yet proposing) an exception that would except from payment adjustments professionals whose practices mean they: (1) lack face-to-face or telemedicine interaction with patients, (2) lack follow-up with patients, and (3) lack control over the availability of EHR technology. CMS is considering a two-year exemption for professionals that meet these criteria, but is also considering an exception that would not be time-limited. CMS notes, however, that by statute, no professional can receive an exception that lasts more than five years. Finally, CMS specifically requested comment on whether such an exception should be considered on an individual basis, or whether it should be granted on an "across-the-board" basis to certain specialties (such as pathologists and radiologists).

Proposed Administrative Review Process

The proposed rule notes that the HITECH Act prohibits "both administrative and judicial review of the standards and methods used to determine eligibility and payment (including those governing meaningful use)." CMS has determined, however, that an appeal process would be available in "limited circumstances" (specifically in response to an audit finding, or in response to a determination that a provider failed to meet applicable Program standards).

CMS has promised to provide additional information and guidance regarding appeals on a dedicated CMS website. Within the proposed rule, however, CMS has provided some general guidance:

- CMS is proposing to accept only three kinds of appeals:
  - *Eligibility Appeals* - A provider would demonstrate that it meets all Program requirements, save one or more that it was prevented from meeting by circumstances beyond its control. CMS explains that it will determine what is truly "outside the control of the provider" and, as an example, notes that a failure of CMS systems, could, for example, fit this description. These appeals must be filed no later than 30 days after the two month period following the payment year.
  - *Meaningful Use Appeals* - Where a provider could contest adverse audit findings. These appeals must be filed within 30 days from the date of the demand letter or similar finding.
  - *Incentive Payment Appeals* - Where a professional could contest the calculations used to determine his or her incentive, or contest a recoupment of previous payments. CMS notes that all appeals involving incentive payments based on a hospital's cost report must be raised first with the PRRB, though the PRRB would not have jurisdiction over Eligibility or Meaningful Use appeals. These appeals must be filed no later than 60 days after the payment was issued, or 60 days from the date of any federal determination that a payment amount was incorrect.
- All filings must be made electronically, through a dedicated CMS website.
- Filing deadline extensions may be granted for extenuating circumstances.
- All relevant issues must be raised at the time of filing, or with an amended filing within 15 days, or face dismissal.
- Providers are under the burden to demonstrate that the issue being appealed is not precluded from review under the HITECH Act.
- Providers have the burden of demonstrating that the issue is ripe—for instance, that CMS has been given ample opportunity to resolve the issue through other, less formal means and that attempts at such resolutions are documented.
- To the extent that additional documents are requested by CMS, providers would be allowed only seven business days to provide them, or face summary dismissal.
- Decisions would be rendered within 90 days, barring extensions.
- A Final Reconsideration request may be submitted following an initial decision within 15 days of the initial decision.
- This informal administrative review must be exhausted before a provider may seek review in federal court.

Medicare Advantage Organizations

The proposed rule devotes pages 13780 through 13786 to a detailed discussion of the unique application of the Program's general rules to Medicare Advantage (MA) organizations. Separate rules apply to MA organizations that may be eligible for certain incentives on behalf of their employed or contracted professionals or as a result of an affiliation with an eligible hospital. The proposed rule reviews and clarifies certain payment rules, definitions, appeal rights, exceptions, and similar topics specifically as the rule's proposals impact MA organizations. MA organizations who intend to seek EHR incentive funding (or applicable payment adjustments) should specifically review this portion of the proposed rule.

Ober|Kaler's Comments

Comments on the proposed rule are not only requested but are vital, given some of the proposed changes discussed above. Providers (and other interested parties) should review the proposed rule to determine now whether comments are necessary or appropriate to their particular situation. CMS, with regard to Stage 1, proved receptive to provider comments, especially with regard to the burdens associated with meeting certain

objectives and the time necessary to implement complete EHR technology and properly adjust facility and office work-flow. There is no reason to believe that CMS' generally receptive attitude toward thoughtful and well-presented provider comments will not hold true during the finalization of Stage 2 standards.