CMS PROPOSED RULE: MEDICARE & MEDICAID ELECTRONIC HEALTH RECORD INCENTIVE PROGRAMS – STAGE 2

Introduction

On March 7, 2012 CMS published in the Federal Register a proposed rule for Stage 2 requirements for the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program. The proposed rule sets out meaningful use objectives and measures for Stage 2, proposes changes to certain Stage 1 objectives and measures, and proposes provisions relating to downward Medicare payment adjustments beginning 2015 for eligible professionals (EPs) that are not meaningful users of certified EHR technology for certain associated reporting periods.

EHR Meaningful Use Overview

The Medicare and Medicaid EHR Incentive Programs, enacted in 2009 by the American Recovery and Reinvestment, provide financial incentives to EPs who demonstrate meaningful use of certified EHR technology. The Medicare EHR Incentive Program defines podiatrists as EPs, but the Medicaid EHR Incentive Program does not. Podiatrists are therefore eligible to receive financial incentives for meaningful use of EHR technology under the Medicare program. The Medicare EHR Incentive Program offers an incentive of $44,000 over five years. To get the maximum incentive payment, EPs must begin participation by 2012. Podiatrists are not eligible to receive financial incentives for meaningful use of EHR technology under the Medicaid program. Some states, however, may provide an exception to this rule whereby podiatrists are eligible to receive incentives under the Medicaid program. This is possible because the Medicaid EHR Incentive Program is voluntarily offered by individual states. Exceptions will most likely occur in states where laws have been enacted or regulations have been adopted to ensure podiatric services cannot be eliminated from the state Medicaid programs. The Medicaid EHR Incentive Program offers an incentive of $63,750 over six years. Podiatrists may elect to receive payments only from the Medicare OR the Medicaid program, but not from both. Before 2015, podiatrists may switch programs only once after the first incentive payment is initiated.

To receive an incentive payment, providers must show they are “meaningfully using” certified EHR techonology by meeting thresholds for a number of objectives. CMS has established the objectives of “meaningful use” that everyone must meet to receive an incentive payment.

The EHR Incentive Program consists of three stages. Each stage has its own set of requirements that EPs must meet to demonstrate meaningful use. Stage 1 requirements are focused on providers capturing patient data and sharing that data either with the patient or with other health-care professionals. Stage 1 requires EPs to meet 15 required core objectives and 5 of 10 menu objectives. A list of the objectives can be found here. Stage 2 requirements, which are outlined in detail below, will expand the baseline set by Stage 1.

To successfully demonstrate meaningful use, EPs must also report clinical quality measures (CQMs). CQMs are a mechanism for assessing observations, treatment, processes, experience, and/or outcomes of patient care. Stage 1 requires EPs to report on 3 required core measures (substituting alternate core measures where necessary) and 3 additional measures (selected from a set of 38 measures). A list of the measures can be found here. Stage 2 CQM reporting measures are outlined below.

The following table indicates which Stage applies to an EP depending on its first payment year under the EHR Incentive Program.

First Year Payment	**Stage of Meaningful Use**										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2011	1	1	1	2	2	3	3	TBD	TBD	TBD	TBD
2012		1	1	2	2	3	3	TBD	TBD	TBD	TBD
2013			1	1	2	2	3	3	TBD	TBD	TBD
2014				1	1	2	2	3	3	TBD	TBD
2015					1	1	2	2	3	3	TBD
2016						1	1	2	2	3	3
2017							1	1	2	2	3

Stage 1 Meaningful Use Proposed Changes

CMS proposes several changes to Stage 1 objectives and measures. However, providers have the option of completing Stage 1 in 2013 under unrevised Stage 1 criteria. Alternatively, providers could voluntarily meet revised Stage 1 criteria in 2013. Beginning in 2014, providers must complete Stage 1 under the revised criteria.

The proposed changes to Stage 1 criteria include:

- CMS proposes to use the number of orders for medication as the denominator for the Computerized Physician Order Entry (CPOE) measure, based on “nearly unanimous feedback from providers.”
- For the objective of record and chart changes in vital signs, CMS would allow an EP to split the exclusion and exclude blood pressure only or height/weight only, and the age limitation for blood pressure would be revised to “patients age 3 and over only” and “for all ages” would be specified in the case of height and weight.
- For the objective of “capability to exchange key clinical information,” CMS considered 4 options: (1) removal of the objective, which CMS formally proposes because it says this objective has been “surprisingly difficult for providers to understand”; (2) require the test be successful; (3) eliminate the objective but require EPs to select either the Stage 1 medication reconciliation objective or the Stage 1 summary of care at transitions of care and referrals objective from the menu set; or (4) move from a test to one case of actual

electronic transmission of a summary of care document for a real patient either to another provider of care at a transition or referral or to a patient authorized entity.

- Starting in 2014, CMS proposes to replace Stage 1 objectives relating to providing patients with electronic copies of their health information and discharge instructions upon request and timely electronic access to their health information with a new (and required) "view online, download and transmit" objective for both EPs and hospitals, which is also being proposed for Stage 2 and described in more detail below.
- For the Stage 1 public health objectives, CMS proposes to add "except where prohibited" to the regulation text, because the agency wants to encourage submission of electronic immunization data even when not required by State/local law (the language change also applies to menu set objectives relating to electronic submission of reportable lab results and syndromic surveillance data).

Stage 2 Meaningful Use Objectives and Measures

Stage 2 maintains the core and menu structure for the EHR Incentive Program. The proposed rule would require EPs to meet, or qualify for an exclusion from, 17 core objectives and 3 of 5 menu objectives.

Nearly all of the Stage 1 core and menu objectives have been retained for Stage 2. However, the "exchange of key clinical information" core objective was replaced by a "transitions of care" core objective for Stage 2, and the "provide patients with an electronic copy of their health information" objective was replaced by an "electronic or online access" core objective. Additionally, multiple Stage 1 objectives were combined to make more unified Stage 2 objectives.

With regards to menu sets, CMS proposes that exclusions would not allow an EP to avoid meeting menu set objectives unless exclusions applied to all menu set objectives. In other words, if exclusions applied to 3 menu set objectives, the EP would still be required to meet the remaining 2 menu set objectives, unless exclusions applied to them as well. This policy will also apply to Stage 1 beginning in 2014.

This table lists all the Stage 2 meaningful use objectives and associated measures sorted by core and menu set. The table also includes the applicable exclusion(s), if any, and other information and commentary relevant to each of the objectives.

Stage 2 continues the policy that to be a meaningful user, an EP must have 50 percent or more of his or her outpatient encounters during the EHR reporting phase at a location(s) equipped with certified EHR technology. CMS notes that this can be accomplished in three ways: (1) certified EHR technology could be permanently installed at the location; (2) the EP could bring certified EHR technology to the location on a portable computing device; or (3) the EP could access certified EHR technology remotely using computing devices at the location. Beginning in 2013, CMS will not allow an EP to create a record of an encounter without using certified EHR

technology and then later input the information into certified EHR technology that exists at different location.

With respect to Stage 2 denominators, CMS proposes to adopt as the denominator for all measures “all patients”, not a mix of “all patients” or only those patients whose records are maintained using certified EHR technology. CMS also proposes to use 1 of 4 uniform denominators for each EP meaningful use measure: (1) unique patients seen by the EP during the EHR reporting period (stratified by age or previous office visit); (2) number of orders (medication, labs, radiology); (3) office visits; and (4) transitions of care/referrals.

In terms of the “seen by the EP” factor, in cases where the EP and the patient do not have an actual physical or telemedicine encounter, but the EP renders a minimal consultative service for the patient, the EP may choose whether to include the patient in the denominator as “seen by the EP” provided the choice is consistent. EPs who never have a physical or telemedicine interaction with patients must adopt a policy that classifies at least some of the services they render for patients as “seen by the EP” (but provides no examples). In cases where the patient is seen by a member of the EP’s clinical staff, the EP can include or not include those patients in their denominator at their discretion as long as the decision applies universally. In cases where a member of the EP’s clinical staff is eligible for Medicaid EHR incentives in their own right, patients seen by such clinical staff “under the EP’s supervision” can be counted by both the clinical staff person and the supervising EP as long as the policy is consistent. In terms of the EP visit denominator, the visit does not have to be individually billable in instances where multiple visits occur under one global fee. In terms of the EP “transition” denominator, a transition home without any expectation of follow-up care related to the care given in the prior setting by another provider is not a transition of care for purpose of Stage 2 MU measures.

Meaningful Use Reporting Period

The proposed rule revises the descriptions of the EHR reporting period to clarify that for providers who are demonstrating meaningful use for the first time, their EHR reporting period is 90 days regardless of payment year.

Demonstration of Meaningful Use

CMS proposes to continue its common method for demonstrating meaningful use in both the Medicare and Medicaid EHR Incentive Programs. At this time, CMS does not propose changes to the attestation process for Stage 2 meaningful use objectives.
Beginning in 2014, CMS proposes to allow a group reporting option in lieu of individual Medicare EP attestation.

Stage 2 Clinical Quality Measures

To meet Stage 2 requirements, EPs must report 12 clinical quality measures (CQMs). CMS has proposed 125 potential measures for EPs and expects to finalize only a subset of those proposed

measures. A list of the proposed measures can be found here. There are three measures related to diabetic foot care, 1 of which has not yet been endorsed:

- NQF # 0056: Diabetes Foot Exam
- NQF # 0519: Diabetic Foot Care and Patient/Caregiver Education Implemented During Short Term Episodes of Care
- Not Yet Endorsed: Chronic Wound Care: Patient Education Regarding Diabetic Foot Care

The CQMs fall into 1 of 6 domains:

1. Patient and Family Engagement;
2. Patient Safety;
3. Care Coordination;
4. Population and Public Health;
5. Efficient Use of Healthcare Resources; and
6. Clinical Processes/Effectiveness.

For 2013, CMS proposes that EPs submit data for the CQMs that were finalized in the Stage 1 final rule for 2011 and 2012.

For 2014, CMS proposes two reporting options (with two alternatives for the first option, of which CMS intends to finalize only one). Option1a requires EPs to report 12 CQMs from a specified list, including at least 1 measure from each of the 6 domains. The list is available as Table 8 in the proposed rule (pp. 52-60). If an EP's certified EHR technology does not contain patient data for at least 12 CQMs, then the EP must report CQMs for which there is patient data and report the remaining required CQMs as "zero denominators." Further, if there are no CQMs applicable to an EP's scope of practice or unique patient populations, EPs must still report 12 CQMs even if zero is the result in either the numerator and/or the denominator of the measure. Option 1b requires EPs to report 11 core CQMs from a specified list, plus 1 menu CQM from another specified list. The list is available as Table 6 in the proposed rule (pp. 49-50). Option 2 applies to EPs who participate in both the PQRS and the EHR Incentive Programs. Option 2 requires EPs to submit and satisfactorily report CQMs under the PQRS EHR Reporting Option. CMS further proposes that CQMs in Table 8 would apply to EPs for the EHR reporting period in 2014 and 2015 (and potentially subsequent years), regardless of whether an EP is in Stage 1 or Stage 2 of meaningful use.

Clinical Quality Measure Reporting Period

CMS proposes that for EPs in their first year of meaningful use for stage 1, the EHR reporting period would be any continuous 90-day period within the calendar or fiscal year, with a 12-month reporting period applying thereafter. However, for purposes of the payment adjustment (see below) if the EP is demonstrating meaningful use for the first time in calendar or fiscal year 2014, the EHR reporting period must end by September 30, 2014 to avoid the payment adjustment in 2015.

Clinical Quality Measure Reporting Methods

CMS proposes that CQM reporting methods may include attestation, reporting under the Physician Quality Reporting System reporting option, the group reporting options for EPs, the aggregate portal-based reporting methods, and the finalized reporting methods for hospitals. Providers must only submit CQMs that their certified EHR technology is explicitly certified to calculate.

Payment Adjustment for Non-Meaningful Users

For 2015 and later, Medicare EPs who do not successfully demonstrate meaningful use will be subject to payment adjustments (i.e. be penalized) in their Medicare reimbursement. EPs who are

successful meaningful users in 2013 will avoid payment adjustments in 2015. EPs who first meet meaningful use in 2014 will avoid the adjustment if they are able to demonstrate meaningful use at least 3 months prior to the end of the calendar or fiscal year and meet the registration and attestation requirements on October 1, 2014. In order to avoid the 2015 payment adjustment EPs must attest no later than Oct 1, 2014 and so must begin their 90 day EHR reporting period no later than July 2, 2014.

Payment adjustments are as follows:

- For 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment if the EP is not a successful electronic prescriber for 2014, 98 percent)
- For 2016, 98 percent
- For 2017 and each subsequent year, 97 percent
- For CY 2018 and subsequent years, if the Secretary finds that the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent shall be decreased by 1 percentage point for EPs who are not meaningful EHR users from the applicable percent in the preceding year, but in no case shall the applicable percent be less than 95 percent.

CMS proposes three hardship exemptions to the payment adjustments:

1. Insufficient internet access 2 years prior to the payment adjustment year
2. Newly practicing EPs for 2 years
3. Extreme circumstances (during either of the 2 years preceding the payment adjustment year) such as unexpected closures, natural disasters, EHR vendor going out of business, etc.

The exemptions are granted on an application basis. Applications for exceptions #1 and #3 would need to be submitted no later than July 1 of the calendar year before the payment adjustment year (for example, no later than July 1, 2014 for the CY 2015 payment adjustment). CMS will employ an

application process for exception #2 and will provide additional information on the timeline and form of the application in future guidance.

Administrative Reviews Process

CMS proposes to provide a limited appeals process for providers challenging whether the provider met the regulatory standards and methods promulgated by CMS in its rules (not the standards and methods themselves). The appeals process would apply to both Stage 1 and Stage 2 meaningful use. CMS provides guidance on the appeals process on its website.

CMS further proposed three types of permissible appeals:

1. Eligibility Appeals – These appeals relate to circumstances outside the provider's control that prevented the provider from participating in the EHR incentive program. Appeals would be due not later than 30 days after the 2-month period following the payment year.
2. Meaningful Use Appeals – These appeals would provide an opportunity for providers to challenge adverse audit or other findings that they did not demonstrate meaningful use or did not use certified EHR technology. Appeals would be due no later than 30 days from the date of the demand letter or other finding that could result in the recoupment of an EHR incentive program.
3. Incentive Payment Appeals – These appeals would be used to challenge the claim count used to calculate the incentive payment amount (EPs could not contest individual claims payment and coverage decisions). Appeals would be due no later than 60 days from the date the incentive payment was issued or 60 days from any Federal determination that the incentive payment calculation was incorrect.

Providers must raise all relevant issues at the time of the initial filing of appeal. Providers must also show that at the time of the initial appeal filing any issue raised in the appeal is not precluded from administrative and judicial review.

Informal decisions will be rendered within 90 days after the initial appeal filing. Providers who are dissatisfied with the decision could file a request for reconsideration (due within 15 days from the date of the informal review decision). Final decisions on the request for reconsideration would be within 10 days after the request and all supporting documentation and data are received.

Medicaid EHR Incentive Program

CMS also proposes changes to the Medicaid EHR Incentive Program. The proposal does not include changes to the list of those who are eligible professionals under the Program.

Attestation Estimates

CMS estimates that it will take EPs 8 hours and 12 minutes to complete attestation for the core set of objectives and measures, between 3 and 21 minutes to complete attestation for the 3 menu

set objectives and associated measures, and 2 hours to complete, prepare and electronically submit 12 CQMs. This table provides burden estimates by meaningful use objective.

EHR Certification

In addition to the Stage 2 meaningful use proposed rule, a companion proposed rule regarding EHR certification standards was also released. The proposed rule, from the Office of the National Coordinator for Health IT, sets the standards that EHRs must meet to become certified and thus eligible for use by EPs seeking to become meaningful users. The proposed rule governs changes needed to EHR systems to meet Stage 2 criteria and revised Stage 1 criteria.