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Proposed Changes to the eRx Incentive Program – Too Little, Too Late?

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Providers frustrated with the apparent disconnects between the Electronic Prescribing (eRx) and Electronic Health Record (EHR) programs may receive relief under a new proposed eRx incentive program rule [PDF] (the NPRM). The NPRM promises to: (1) modify the eRx program's functional definition of a "qualified" eRx system to permit the use of "certified" EHR technology under the EHR program, (2) provide additional significant hardship exemption categories for eligible professionals or group practices requesting exemptions from 2012 payment adjustments and (3) extend the deadline for submitting requests for consideration for certain significant hardship exemption categories for the 2012 eRx payment adjustments. Comments on the proposed changes to the eRx incentive program are due on **July 25, 2011**, and providers must request hardship exemptions under the new proposed extended deadline, of **October 1, 2011**.

Background

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. 110-275, authorized eRx. In 2009, CMS promulgated regulations implementing the eRx program, which offers incentive payments to providers that are "successful electronic prescribers" using "qualified" eRx technology. For providers that are successful electronic prescribers in the 2011 year, the eRx program offers an incentive of 1% of the provider's estimated Medicare Part B allowed charges for professional services furnished during the year. In 2012, however, the program begins to impose *penalties* on providers that have failed to successfully electronically prescribe. These penalties will equal approximately 1% of the same Medicare allowed Part B amounts in 2012, 1.5% in 2013, and 2% in 2014, when the program is currently set to end. CMS maintains a website devoted to the eRx program that provides additional general information and timelines. Each year, CMS issues a rule that provides the standards and procedures for the eRx program for subsequent years. In the most recent rule, the Physician Fee Schedule (PFS) for 2011 [PDF] (the 2011 PFS is found at 75 Fed. Reg. 73,553 through 76,566),

CMS provided the measures that determine whether a provider would be considered a "successful prescriber" for 2011. More importantly, CMS provided measures for the 2012 and 2013 years, when providers face penalties for a failure to meet the applicable definition of a successful electronic prescriber.

The eRx program, of course, is not the only CMS administered incentive program designed to encourage the adoption and use of electronic health record technology. Following the start of the eRx program, CMS also implemented the EHR program to encourage providers to adopt and meaningfully use "certified" and "complete" EHR technology. *Certified* technology, by CMS's own definition, must include the capability to electronically prescribe. Typically, with regard to certified EHR technology, the module or portion of the complete EHR that is devoted to eprescribing is only one small piece of a larger, wholly integrated "complete" EHR technology. The EHR program, in contrast to the eRx program, offers qualifying providers incentive payments beginning in 2011 and continuing through 2014 (for Medicare). CMS also maintains a website devoted to the Meaningful Use Incentive Program and has issued a helpful presentation [PDF] comparing incentives and penalties under each program.

Unfortunately, as many providers discovered, the eRx and EHR programs use similar but not identical standards for "qualified" and "certified" eprescribing technologies. In addition, while providers may not receive incentive payments under both programs at the same time, they may be subject to penalties under the eRx program even while they work to meet the overlapping requirements of the EHR program with regard to eprescribing. Providers, for instance, that failed to report at least 10 electronic prescriptions by June 30, 2011 will face a 1% penalty in 2012 even if they qualify for Stage 1 Meaningful Use during 2011. In February of this year, the pressure on CMS to resolve these issues was increased when the Government Accounting Office issued a report [PDF] detailing the confusing conflicts between the eRx and EHR programs and calling on CMS to resolve them before the imposition of eRx penalties in 2012.

Broadening the "Qualified" eRx Technology Descriptive Measure

The greatest disconnect between the EHR and eRx programs has been their respective definitions of acceptable technology. Importantly, the NPRM proposed to alter the measures proposed in the 2011 PFS to better align the eRx and EHR requirements. Under the existing eRx rule, providers are successful where they adopt a qualified eRx system. A provider has a qualified system under the program if the system:

- Generates a complete active medication list incorporating electronic data received from applicable pharmacies and pharmacy benefit managers, where available;
- Allows eligible professionals to select medications, print prescriptions, electronically transmit prescriptions, and conduct alerts (i.e., enabled a functionality that alerts prescribers to potentially unsafe situations, such as drug interactions or allergies);
- Provides information related to lower cost therapeutic equivalents (referenced to a tiered formulary is acceptable for now, until this function is more widespread); and
- Provides information on formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan (if available).

In addition, the system must convey the information described above according to the standards currently in effect for the Part D eRx program, including the standards of the National Council for Prescription Drug Programs (NCPDP).

CMS notes that the technology requirements for electronic prescribing under the two programs are similar, but not identical. For example, similar to a qualified eRx system, a certified EHR system must be capable of checking for drug-to-drug interactions or whether a drug is on the formulary. In contrast to the EHR program, however, the eRx program does not rely on a third party's certification to determine if a specific technology is qualified, but rather, providers rely on their own analysis or that of the system vendor of the technologies capabilities. Further, the EHR program's certification requirements do not necessarily require that the technology

issue information consistent with the Part D standards. That being said, providers that wish to use an EHR to eprescribe for Part D must still meet those standards.

CMS explains, within the NPRM, however, that these differences do not justify the continuing confusion created by the conflicts between the two programs. Accordingly, the NPRM proposes to allow providers the option to adopt either:

- An eRx system that the provider independently determines meets the existing requirements of the eRx program (as described above) or
- Any *certified* EHR technology as described at 42 C.F.R. § 495.4 and 45 C.F.R. § 170.102.

This proposed change does not, however, extend the June 30, 2011 deadline for reporting the eRx quality measures required to avoid the 1% penalty in 2012. Providers that have not already reported the required measure at least 10 times by that June 30 deadline will instead have to look to the NPRM's new hardship exemptions, discussed in the next section, to avoid the 2012 penalty.

> ***Comment:*** The proposed eRx rule does not extend or alter the deadline to report electronic prescriptions under the eRx incentive program even for providers that have elected to pursue EHR program incentives. The potential alignment of the two incentive programs will not come in time to alter providers' reporting responsibilities for 2011 under the eRx incentive program. Regardless of a provider's participation or progress toward attestation under the EHR program, those providers that fail to report at least 10 electronic prescriptions by **June 30, 2011** will face a 1% penalty in 2012 unless a hardship exemption is approved. The NPRM, however, is not a final rule and providers affected by this short timeline may want to comment on the need for an extension or delay in the 2012 and 2013 payment reductions.

Additional Hardship Exemption Categories for 2012

The existing eRx Incentive Program does not apply to all providers. As finalized in the 2011 PFS, the 2012 payment reduction will not apply to:

- An eligible professional who is not a physician, nurse practitioner, or physician assistant by June 30, 2011;
- An eligible professional who does not have at least 100 cases (claims for patient services) containing an encounter code that falls within the denominator of the eRx measure for dates of service between January 1, 2011 and June 30, 2011;
- An eligible professional who meets the definition of a *successful electronic prescriber* (by reporting the eRx measure 10 times via claims between January 1, 2011 and June 30, 2011); or
- An eligible professional or group practice if less than 10% of that professional or group's estimated total allowable charges for the 2011 period are comprised of services that appear in the denominator of the 2011 eRx measure.

Providers that do not fit within one of these four categories must look to the regulatory provisions providing for significant hardship exemptions if they are unable to meet the definition of successful electronic prescribers before the June 30, 2011 reporting deadline imposing 2012 payment reduction. In the 2011 PFS, CMS finalized only two such exceptions. Under that rule, CMS may, on a case-by-case basis, consider a provider's request for an exemption from the 2012 payment reductions where:

- The eligible professional or group practice practices in a rural area with limited high-speed internet access or
- The eligible professional or group practice practices in an area with limited available pharmacies that accept eprescriptions.

In addition, providers that intended to rely on either of these exemption categories were required to note that fact when they self-nominated to participate in the 2011 eRx program earlier this year. The NPRM adds four new exemption categories and, as discussed in the next section, extends the deadline for claiming an exemption based on any of the six categories to October of 2011.

Under the NPRM, CMS proposes to review the following hardship exemption requests on a case-by-case basis:

- *Meaningful Use Program*. An eligible professional or eligible professional in a group practice that registered for either the Medicaid or Medicare EHR program may qualify for a hardship exemption by providing CMS with identifying information. Identifying information is currently the EHR certification number. CMS proposed this exemption specifically to account for the fact that certified technology under the EHR program was not defined until September of 2010 and the decision to use the first six months of 2011 as the reporting period for the 2012 eRx program was not made public until the 2011 PFS was published on June 25, 2010.

As a result, CMS notes that it would be a "significant hardship for eligible professionals in this situation to have both adopted certified EHR technology and fully integrated this technology into their practice's clinical workflows and processes so that they would be able to successfully report the eRx measure prior to June 30, 2011…." CMS goes on to explain that it is considering the feasibility of requiring, as part of the required "identifying information," the serial number of the purchased EHR technologies. CMS specifically requested comments on this question, and providers that believe such a requirement would prove onerous should note their concerns to CMS.

- *Local, State or Federal Laws or Regulations*. An eligible professional or group practice is unable to electronically prescribe due to local, state, or federal laws or regulations. As an example, CMS notes that prescribers who primarily prescribe narcotics, which may not be electronically prescribed in some states.
- *Limited Prescribing Activity*. An eligible professional has prescriptive authority, but has limited prescribing activity. As an example, CMS notes that a nurse practitioner may have the authority to prescribe, but may rarely write prescriptions under his or her own NPI.
- *Insufficient Opportunities to Report*. An eligible professional or group practice electronically prescribes and has denominator-eligible visits, but does not typically write prescriptions associated with any of the types of visits included

in the eRx measure's denominator. As an example, CMS notes that surgeons may not frequently prescribe during denominator-eligible visits.

Providers submitting an exemption request must supply CMS with the following information:

- Identifying information, such as their name, mailing address, TIN and/or NPI;
- The hardship categories that the provider believes apply;
- A detailed explanation as to how the provider meets the requirement of the identified exemption category (for instance, a provider that cites a hardship related to state or local law should cite and explain the effects of that law); and
- An attestation of the accuracy of the information provided.

CMS notes in the NPRM that it hopes to open a website or web-based interface that will allow providers to submit requests electronically, but that it is not certain if that project will be completed by the date of the Final Rule. In the event that it is not, providers must submit requests via mail. CMS elected not to permit fax or email submissions based on concerns that the requests may contain social security numbers or other personally identifiable information.

Comment: CMS is specifically seeking comments concerning the adequacy of the new categories added for 2012, the detail that should be required in claims for hardship exemptions (including, for instance, whether providers should be required to provide the serial number of their EHR technology), as well as the need for additional significant hardship exemption categories for the 2013 or 2014 eRx payment adjustment. Providers may also choose to comment on the requirement that exemption requests be forwarded by mail, especially where CMS already receives *personally identifiable information* from many providers in many other contexts through both electronic and fax submissions. Finally, providers that have already implemented EHR technology that is not a qualified system under the eRx program should consider commenting on the need to rely on a hardship exemption to avoid a payment reduction

where they have otherwise complied in good faith with the EHR program requirements.

Deadline Extension for Certain Hardship Exemptions – October 1, 2011

Providers that intended to rely on either of the two hardship exemption categories identified in the 2011 PFS were required to make their request at the time they self-nominated to participate in the 2011 program earlier this year. CMS now proposes to modify the hardship exemption procedures to permit exemption requests under any of the six categories, including the new proposed hardship categories, until **October 1, 2011**.

This proposed deadline, however, assumes that the proposed rule will be finalized on or before this date. CMS explains that October 1 was selected so that it would have the time required to process the requests and to make the "case-by-case" determinations that it expects will be necessary prior to the implementation of the 2012 payment reductions. There is no guarantee, however, that CMS will complete its review of any particular exemption request before January 1, 2012. Accordingly, providers that will eventually qualify for the exemption may still have their payments reduced for some portion of 2012 while the request is "in process." CMS expects that, as requests are approved in 2012, it will need to reprocess provider claims for that year to ensure that providers that have been granted exemptions are not penalized. CMS further notes that this deadline may be abrogated by the date of a final rule on these matters. To the extent that a final rule is published after the proposed October 1, 2011 deadline, CMS proposes that providers be required to submit their requests within **five business days** of the effective date of that final rule.

Finally, CMS notes that it intends for its determination under the exemption process to be final. Providers whose requests are denied would have no appeal rights and would not be permitted to request that CMS reconsider its decision.

> ***Comment:*** CMS's proposed extension of the deadline for the submission of exemption requests will leave providers as little as five days to prepare essential and final submissions. Providers that do not believe that these

extensions and processes are sufficient should submit comments to CMS by **July 25, 2011**.

Ober|Kaler's Comments

Under the proposed regulation, CMS seems to provide a solution to providers that have been frustrated by the conflicting requirements of the EHR and eRx programs. The proposed solution, however, will require most providers to submit detailed hardship exemption requests on very short notice. CMS will review hardship exemption requests on a case-by-case basis, and providers will have no rights to appeal or reconsideration following a decision they believe to be incorrect or unfair. This proposed solution may burden providers that acted in good faith to comply with the program.

For additional information on EHR, eRx, PQRI, HIPAA, HITECH, and Health Information Technology, please visit Ober|Kaler's Health Information Technology Practice page.