



American College of Surgeons

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July 22, 2011

Donald M. Berwick, MD, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3248-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Electronic Prescribing (eRx)
Incentive Program

Dear Dr. Berwick:

On behalf of the more than 75,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the proposed rule: *Medicare Program; Proposed Changes to the Electronic Prescribing (eRx) Incentive Program* that was published in the *Federal Register* on June 1, 2011. The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice.

The Centers for Medicare and Medicaid Services (CMS) eRx Incentive Program applies either an incentive payment or a payment adjustment to the Medicare Part B Physician Fee Schedule allowed charges for eligible professionals based on whether they are successful electronic prescribers. Under this rule, CMS is proposing to: modify the 2011 eRx quality measure; provide additional significant hardship exemption categories for eligible professionals and group practices to request an exemption during 2011 for the 2012 eRx payment adjustment due to a significant hardship; and extend the deadline for submitting requests for consideration for the two current significant hardship exemption categories for the 2012 eRx payment adjustment.

The ACS supports CMS' continued efforts to increase patient safety and quality of care through the use and adoption of eRx. The ACS also greatly appreciates CMS' recognition of the additional hardships the current incentive program, if not altered, may impose on certain eligible professionals. We offer suggestions below on ways to further refine some of the improvements to the program that CMS makes in the proposed rule.

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Dr. Berwick
July 22, 2011
Page 2

MODIFICATION OF THE CY 2011 ELECTRONIC PRESCRIBING QUALITY MEASURE

CMS requires reporting of an eRx quality measure to determine whether an eligible professional or group practice is a successful electronic prescriber for the purposes of the 2011 eRx incentive as well as for the 2012 and 2013 payment adjustments. The eRx quality measure documents whether an eligible professional or group practice has adopted a “qualified” eRx system, which is a system capable of performing the following four functionalities:

- Generates a complete active medication list incorporating electronic data received from applicable pharmacies and pharmacy benefit managers (PBMs), if available.
- Allows eligible professionals to select medications, print prescriptions, electronically transmit prescriptions, and conduct alerts (that is, written or acoustic signals to warn the prescriber of possible undesirable or unsafe situations including potentially inappropriate doses or routes of administration of a drug, drug-drug interactions, allergy concerns, or warnings and cautions). This functionality must be enabled.
- Provides information related to lower cost therapeutically appropriate alternatives (if any) (that is, the ability of an eRx system to receive tiered formulary information, if available, until this function is more widely available in the marketplace).
- Provides information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan, if available.

CMS proposes to expand the definition of a qualified eRx system for the purposes of the eRx Incentive Program so that EHR technology that is certified under the EHR Incentive Program can also be recognized as a qualifying system under the eRx Incentive Program. CMS proposes to revise the description statement of the eRx quality measure of a “qualified” eRx system to indicate that the measure documents whether an eligible professional or group practice has adopted a qualified eRx system that performs the four functionalities listed above **or** is certified EHR technology. The ACS supports this change and agrees with CMS that this expands the definition of a “qualified” eRx system for the purposes of the eRx Incentive Program without changing the original intent of the measure, which is to “evaluate the extent to which eligible professionals generate and transmit prescriptions and prescription-related information electronically.”



Dr. Berwick
July 22, 2011
Page 3

SIGNIFICANT HARDSHIP EXEMPTION CATEGORIES FOR THE 2012 PAYMENT ADJUSTMENT

Current Significant Hardship Exemptions for the 2012 eRx Payment Adjustment

The current eRx Incentive Program includes two circumstances under which an eligible professional or group practice may request consideration on a case-by-case basis for a significant hardship exemption for the 2012 eRx payment adjustment:

- 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 for eRx.

We support the continued use of these currently existing significant hardship exemptions. In order for eligible professionals and group practices to identify these categories for purposes of requesting a hardship exemption, CMS created a G-code for each of the above situations. We believe that the continuation of the use of the current G-codes to request these exemptions would be the most administratively straightforward way of requesting the hardship exemption.

Proposed Additional Significant Hardship Exemption Categories for the 2012 eRx Payment Adjustment

CMS proposes to add additional significant hardship exemption categories to the two categories listed above for the 2012 eRx payment adjustment. The ACS greatly appreciates CMS' efforts to create additional hardship exemptions for those eligible professionals for whom compliance with the eRx program poses a significant hardship. Some eligible professionals are limited in their ability to meet the requirements to be successful e-prescribers because of the nature of their practice or because of limitations of the eRx measure and, as a result, would be inappropriately penalized under the eRx payment adjustment. We discuss each of the proposed additional hardship exemption categories below.

We are concerned, however, with CMS' proposal to make all exemption requests after June 30, 2011, paper-based if the Web-based tool or interface has not been created by the time of publication of the final rule. We request that CMS work to create the Web-based tool with all due speed in order to reduce the administrative burden and complexity of implementing a paper-based system. The ACS believes that the submission of paper-based exemptions would be particularly burdensome and could create confusion for eligible professionals, a flood of paperwork for CMS, and could even potentially result in inappropriate exemption denials.



Dr. Berwick
July 22, 2011
Page 4

Eligible Professionals Who Register to Participate in the Medicare or Medicaid EHR Incentive Programs and Adopt Certified EHR Technology

CMS proposes to exempt those eligible professionals who register to participate in the EHR Incentive Program and adopt certified EHR technology, but may have delayed adoption of eRx technology until the list of certified EHR technology became available. Given that certification and listing of EHR technologies on the Office of the National Coordinator for HIT Certified HIT Products List did not begin until September 2010 and that CMS did not propose to use the first half of 2011 as the reporting period for the 2012 eRx payment adjustment until the calendar year (CY) 2011 Physician Fee Schedule proposed rule went on display on June 25, 2010, we agree that it would be a significant hardship for eligible professionals in this situation to have both adopted certified EHR technology and fully integrated the technology into their practice's clinical processes to start successfully reporting the eRx measure prior to June 30, 2011. We agree that this group of eligible professionals should be exempt from the payment adjustment, and we believe that this exemption is important to support and encourage eligible professionals to become meaningful users of EHR technology.

However, the ACS is concerned that in order to be considered for the hardship exemption, eligible professionals are required to provide identifying information as to the certified EHR technology that has been adopted. We are not confident that access to identifying information such as the serial number or certification number for the certified EHR technology is readily available to eligible professionals. We believe that legal implications of providing false information to the government on the EHR program attestation will adequately deter eligible professionals from providing false information to CMS in order to obtain this exemption. In addition, information on those eligible professionals who are successfully participating in the EHR Incentive Program is data that CMS will already possess.

Inability to Electronically Prescribe Due to Local, State, or Federal Law or Regulation

CMS proposes to exempt eligible professionals who practice in jurisdictions where local, State, or Federal laws limit or prevent them from electronically prescribing. For example, this exemption would apply to eligible professionals who prescribe controlled substances, which are illegal to electronically prescribe in some states. The ACS agrees with CMS that without this exemption, these eligible professionals face a significant hardship because many of these eligible professionals meet the threshold of 10 percent of their Medicare claims deriving from the list of denominator codes, yet they do not have adequate opportunities to meet the eRx requirements due to local, State, or Federal laws.



Dr. Berwick
July 22, 2011
Page 5

Limited Prescribing Activity

CMS proposes to exempt those eligible professionals who have prescribing privileges but prescribe infrequently, including those eligible professionals who prescribed fewer than 10 prescriptions between January 1, 2011 and June 30, 2011, regardless of whether the prescriptions were electronically prescribed, yet still meet the 10-percent threshold for application of the payment adjustment. The ACS agrees that these eligible professionals would face a significant hardship to become successful e-prescribers.

Insufficient Opportunity to Report the Electronic Prescribing Measure due to Limitations of the Measure's Denominator

CMS proposes to exempt those eligible professionals (such as surgeons) who may have an eRx system, electronically prescribe, and have denominator-eligible visits, but do not normally write prescriptions associated with any of the types of visits included in the eRx measure's denominator. We agree with CMS that it would be a significant hardship for these eligible professionals to be successful e-prescribers as the bulk of their prescribing activity occurs in other circumstances that are not accounted for by the measure's denominator. In the case of surgeons, many of the prescriptions that are written for their patients are associated with care given during the global period for a surgery and thus not associated with an e-Rx incentive program denominator code. As such, the ACS supports this proposed exemption.

OTHER ISSUES

Requesting a Hardship Exemption and Extending the Submission Deadline

CMS proposes that eligible professionals or group practices would be able to submit significant hardship exemption requests using a Web-based tool or interface, but if CMS has not completed development of such a Web site prior to the publication of the final rule, eligible professionals and group practices would be required to submit applications for hardship exemptions by mail. The ACS believes that the creation of a Web-based tool or interface to request these exemptions would be the least burdensome option available for both eligible professionals and CMS, and we strongly urge CMS to implement the Web-based tool or interface prior to the publication of the final rule.

Given that CMS is required to grant hardship exemptions on a case-by-case basis, we believe it is important to reduce the number of unnecessary applications for the exemptions that are submitted to CMS. Many practices will not be aware of whether 10 percent of their estimated total allowed charges are associated with the eRx Incentive Program denominator codes, so we recommend that



Dr. Berwick
July 22, 2011
Page 6

CMS notify providers prior to the proposed October 1st exemption submission deadline whether 10 percent of their total allowed charges are comprised of services that appear in the denominator of the 2011 eRx measure. This will reduce the number of unnecessary exemption requests submitted by eligible professionals who are unsure of whether they will be subject to the payment adjustment. Another way to reduce the number of exemption requests would be to not require eligible professionals to reapply for additional exemptions each year. Instead, allowing eligible professionals to submit an attestation where they can state that nothing has changed in their practice since the previous year would be a more administratively straightforward option for CMS.

CMS proposes to extend the deadline to allow eligible professionals until October 1, 2011, to submit significant hardship exemption requests (both for the two currently existing exemption categories and the additional proposed exemption categories). We support this extension of the deadline.

In the event that the final rule is not posted to the *Federal Register* Public Inspection Desk before October 1, 2011, CMS proposes that physicians would have until five business days after the effective date of the final rule to submit a hardship exemption request. Even if CMS launches a Web portal for physicians to submit their hardship exemption requests, we do not believe that five business days after between public inspection of the final rule will be sufficient for physicians to submit exemption requests. Rather, we recommend that CMS allow at least 60 days from the date of public inspection of the final rule for physicians to apply for a hardship exemption. When the rule is finalized, physicians will need time to analyze the final exemption categories and submit their requests. It will also allow sufficient time for CMS to notify providers whether 10 percent of their total allowed charges are comprised of services that appear in the denominator of the 2011 eRx measure.

CMS' Review of Request

CMS expects to process all such significant hardship exemption requests before the Agency begins making claims processing changes later this year to adjust eligible professionals' payments starting on January 1, 2012. However, CMS anticipates, in some cases, that it may not be able to complete its review of the exemption requests before the claims processing updates are made to begin reducing eligible professionals' and group practices' PFS amounts by 1 percent. In such cases, if CMS ultimately approves the eligible professional's or group practice's request for a significant hardship exemption, CMS proposes that it would reprocess all claims for services furnished up to that point in 2012 that were erroneously paid to eligible professionals and group practices at the reduced PFS amount. While the ACS understands CMS' approach to develop a contingency plan in the event that the Agency is unable to review all the exemption requests in time, this plan may place additional administrative and operational burdens on practices because they will not know how



Dr. Berwick
July 22, 2011
Page 7

much they will eventually be paid. This plan will also result in added work for CMS to reprocess claims. As such, CMS should work to avoid this result if at all possible.

Appeals Process

CMS proposes that once the review of the eligible professional's or group practice's request for consideration for an exemption has been made and the eligible professional or group practice has been notified of CMS' decision, that decision will be final. The ACS strongly urges CMS to consider having a mandatory appeals process. We believe that this rule may not be finalized in a timeframe that gives eligible professionals adequate time to educate themselves or their staff on the Web-based tool or interface and errors that may occur while completing the application. Thus, eligible professionals or group practices should be granted the ability to appeal the CMS decision.

COLLECTION OF INFORMATION REQUIREMENTS

Information Collection Requests Regarding Proposed Additional Significant Hardship Exemption Categories for the 2012 eRx Payment Adjustment

Regarding the number of eligible professionals that could request a hardship exemption, CMS approximates that the maximum number of eligible professionals that will potentially need to request a hardship exemption is equivalent to about 209,000. According to participation numbers from previously administered eRx Incentive Programs, CMS believes that the number of impacted eligible professionals will be lower than 209,000 since 92,132 eligible professionals participated in the 2009 eRx program, and the preliminary data for 2010 show that about 100,444 have participated. CMS believes it is more accurate to predict that about 109,000 eligible professionals may submit a significant hardship exemption request since over 100,000 eligible professionals are already participating in the program.

We believe that the number of exemption requests will be significantly higher than CMS' current estimate. CMS' estimate is based on the number of eligible professionals that participated in the eRx Incentive Program and preliminary data for 2010. However, before January 1, 2010, the program was a voluntary pay-for-reporting program, but starting on January 1, 2012, a payment adjustment will be applied regardless of participation in the program. As such, a greater number of eligible professionals will be subject to the payment adjustment, and CMS should expect to receive more requests for consideration of a hardship exemption.

We appreciate the opportunity to offer comments on this proposed rule. We will continue to carefully monitor future correspondence on this issue and work with our membership to help educate



Dr. Berwick
July 22, 2011
Page 8

them on the implementation of the e-Rx Incentive Program. If you have any questions about our comments, please contact Bob Jasak in the American College of Surgeons Division of Advocacy and Health Policy. He can be reached at bjasak@facs.org or at (202) 672-1508.

Sincerely,

A handwritten signature in black ink that reads "David B. Hoyt". The signature is written in a cursive style with a large, stylized "H" at the end.

David Hoyt, MD FACS
Executive Director