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John C. Lewin, M.D.

June 28, 2011

Donald M. Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Attn: ACO Legal Issues
Mail Stop C5-15-12
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Electronic Prescribing (eRx) Incentive Program [CMS-3248-P]

Dear Dr. Berwick:

The American College of Cardiology (ACC) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule that would revise the implementation of the 2012 payment adjustment associated with electronic prescribing (e-prescribing). The College is a 40,000-member nonprofit medical society composed of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The ACC is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The College provides professional education and operates national registries for the measurement and improvement of quality care. The ACC appreciates the opportunity to provide additional comments on the implementation of this critical program.

The College supports e-prescribing and encourages cardiovascular specialists to adopt e-prescribing technologies. The many benefits of e-prescribing are well-documented. As described previously, the ACC conducted an extensive campaign aimed at educating cardiovascular specialists regarding the rapidly approaching June 30 deadline for avoiding the e-prescribing penalty. E-prescribing articles were featured in all ACC publications, and a peer-to-peer education effort continues. The ACC in Touch blog has included a series of pieces written by clinicians and practice staff from their various perspectives. ACC Chapters also assisted in this outreach. Despite these extensive efforts and those of other medical organizations, the College remains concerned that many practitioners are unaware of the pending deadline of June 30. In today's economic climate and the threat of a 30 percent reduction in the sustainable growth rate, even a one percent penalty for e-prescribing may be tantamount to forcing the closure of a cardiovascular practice. The ACC appreciates CMS' willingness to reconsider the concerns expressed by the physician community regarding the implementation of the e-prescribing payment adjustment.

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

Statutory intent and implementation of the payment adjustment

The Medicare E-Prescribing Incentive Program was created as part of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) with the intention of incentivizing practitioners to adopt e-prescribing technology. The first few years included a bonus payment, while the later years require a penalty for those who do not e-prescribe. CMS claims that the statute requires a six month reporting period in the first half of 2011 for implementation, and yet, the statutory language describing the years for which practitioners are eligible for bonus payments is essentially the same as that used to describe the years for which there is to be a penalty. Given this, the ACC believes the language supports reading the statute to mean that the payment adjustment should be based on 2012 data and implemented accordingly. Implementing the adjustment based on 2011 data only serves to add to administrative burdens of practitioners at a time when they can ill afford the additional costs associated with those burdens. As stated in previous letters, ACC opposes the penalty reporting period as currently defined as being contrary to legislative intent.

Moreover, defining the reporting period in this manner is contrary to the manner in which CMS has implemented the bonus component of both the Medicare E-Prescribing Incentive Program and the Physician Quality Reporting System. To date, CMS has defined the reporting period as the current year and paid the bonus in the following year. Suddenly, CMS has opted to upend this process and is defining the reporting period as the year preceding that which is listed in the statute with the intention of applying the penalty in the year listed in the statute. This has complicated attempts to educate practitioners about the penalty. Additionally, it is further complicated by the fact that 2011 is also the reporting period for those interested in qualifying for the 2011 bonus payment. It is easy to confuse what must be done to qualify for the 2011 incentive with what actions must be taken in 2011 to avoid the 2012 penalty. The ACC urges CMS to delay the reporting period to make it less complex for practitioners and more likely that they will be understand the requirements and be able to avoid the penalty.

Measure description

The ACC appreciates CMS' recognition of inconsistencies between the E-Prescribing Incentive Program and the Electronic Health Record (EHR) Incentive Program. Changing the measure description for the 2011 incentive and for the 2013 payment adjustment is helpful. However, the proposed revisions do not quite go far enough. Those seeking to avoid the 2012 payment adjustment need assurance that using the e-prescribing component of a certified EHR system will meet the measure's requirements. That the proposed rule will be finalized after the end of the reporting period for the 2012 payment adjustment is an insufficient argument against modifying the measure for the 2012 payment adjustment reporting period, given that the majority of the proposal is designed to address concerns regarding that very reporting period. Instead, CMS should extend the reporting period and revise the measure to allow those who have implemented a certified EHR without intentions of participating in the EHR Incentive Program during 2011 the ability to avoid the 2012 payment adjustment.

Timing

In addition to revisions to the e-prescribing measure description, CMS includes additional categories for exemptions from the payment adjustment in the recently released proposed regulation. Certain specialists, such as electrophysiologists, cardiothoracic surgeons and others, may face significant challenges meeting the requirements without such exemptions. That said, the

College continues to be concerned. Given that comments on the proposed regulation are not even due until after June 30 and there is no guarantee the regulation will be adopted as proposed, the ACC is unable to advise cardiovascular specialists that they will be able to take advantage of the exemptions. Instead, at this point, the College is forced to continue to encourage all practitioners that they must comply with the regulation as finalized in the 2011 Medicare Physician Fee Schedule. Unfortunately, any benefits to be gained from finalizing the proposed regulation may be lost because of timing concerns.

The new exemption categories would only apply for the 2012 payment adjustment based on the proposed rule. The proposed rule fails to address the 2013 payment adjustment, despite the overlapping reporting periods and the uncertainty created by a rule that will not be finalized until close to the end of the 2013 payment adjustment reporting period. The ACC urges CMS to finalize any exemptions created for the 2012 payment adjustment to apply to the 2013 payment adjustment, as well.

Specificity

Additionally, the Agency's proposal does not contain enough specifics to give practitioners confidence that their application for an exemption would be accepted. No regulatory text is contained in the proposal. Instead, practitioners are left to guess at how CMS intends to structure the individual exemptions. While the preamble is helpful, it is no substitute for specific regulatory text. For instance, the explanation for the proposed exemption for limited prescribing activity seems to indicate that someone who wrote 12 prescriptions between January and the end of June would be subject to the penalty if that individual met the other requirements and all or a substantial majority of those prescriptions were not electronically prescribed. What about the case of a practitioner who implements a certified EHR and registers his or her intent to participate in the EHR Incentive Program, but is unsuccessful at achieving that goal? Is implementation and a good faith intention to participate in the EHR Incentive Program during 2011 sufficient to qualify the individual for the exemption? What constitutes proof of a good faith intention to participate? The ACC urges CMS to clarify and define the exemptions in a broad manner that provides sufficient information to practitioners so as to enable them to determine with a significant degree of certainty that they do in fact qualify for the exemption, while still providing enough flexibility to allow all those facing hardships to qualify.

Certification number

The regulation specifically requests comments regarding the feasibility of requiring eligible professionals to provide a serial number in addition to the certification number for the certified EHR technology or other information identifying and verifying the specific product implemented. The ACC opposes requiring the provision of additional identifying information regarding the particular certified EHR technology. The certification number alone is sufficient for the EHR Incentive Program, and it should be for this program as well. Additionally, clinicians are unlikely to possess such information and acquiring it will create additional burdens for them. Thus, the ACC believes that the provision of the certification number should furnish CMS with the necessary proof of purchase.

Limited prescribing activity exemption

Cardiovascular specialists in particular may have difficulty reaching the 10 prescription requirement. Many prescriptions may not be written at the time of a visit listed as a denominator code. Cardiologists may respond to refill requests or telephone calls during that time, but these

prescriptions do not count toward the minimum of ten because they are not written at the time of the visit. Some drugs may be prescribed based on the results of a particular diagnostic test, but the codes for diagnostic tests are also not denominator codes. Considering only prescriptions written at the time of an office visit may have the unintended consequence of increasing the number of office visits because physicians will be forced to schedule a visit rather than simply writing the required prescription in the normal course of business in order to meet the measure and avoid the e-prescribing penalty.

While the requirement of writing 10 e-prescriptions may not seem like an insurmountable hurdle, there are certain subspecialties where writing prescriptions is fairly rare. For example, electrophysiologists do not write many prescriptions. In fact, for some, the requirement of 10 within a six-month period is excessive. Instead, these subspecialists largely focus on providing consultations and performing procedures. Occasionally, they will prescribe anti-arrhythmia drugs, but this is done fairly infrequently. Patients of electrophysiologists may be on multiple medications – diabetes medications, cholesterol-lowering agents, etc. – but these medications are generally prescribed and managed by other physicians, including general cardiologists, primary care physicians and others. However, because consults are now billed as office visits, generally of the type within the denominator, these physicians will be subject to the penalty. Congress presumably did not intend to punish subspecialists who do not write many prescriptions over the course of the year in this manner. It is unclear if they would qualify for the limited prescribing activity exception if they prescribe more than 10 prescriptions during the 2012 payment adjustment reporting period, but less than would be considered frequent by any objective measure of determining frequency. Thus, the ACC urges CMS to clarify the requirements for qualifying for this exemption. The ACC encourages CMS to do so in a manner that expands the opportunities for practitioners to report the use of e-prescribing, including refills and prescriptions written based on the results of diagnostic tests.

Exemption request process

As described in the proposed rule, the process for requesting hardship exemptions has the potential to be overly burdensome and complex for practitioners, especially those in small practices without much administrative support. This is even more problematic if CMS is unable to develop a user-friendly web-based tool or interface in a timely fashion. A mail-based process will be much slower and more complex to administer and use than a web-based system.

Additionally, it is unclear if a group practice will be able to submit its request for hardship exemptions in bulk or if the individual practitioners will be required to make the requests themselves, one at a time. The ACC urges CMS to allow for the submission of such group requests, even if it is a subset of the clinicians in the practice that are eligible for such an exemption. Additionally, the ACC urges CMS to allow exemption requests to be submitted on behalf of clinicians by group practice staff. This will free practitioners from the administrative work and enable them to perform the critical clinical work for which they are trained.

The ACC encourages CMS to set up a system that will allow practitioners to electronically submit supporting documentation that may be needed to justify their request for a hardship exemption. Enabling such a system would streamline the process and reduce the administrative burden for both the Medicare contractor and the practitioner. Additionally, the College urges CMS to include a self-audit mechanism that prevents requests from being submitted if they are incomplete. The College would welcome the opportunity to work with CMS to test such a web-based portal to ensure usability.

In the event that CMS is forced to rely on mail, rather than a web-based portal, the ACC urges CMS to create a system that will allow practitioners to determine that their requests have been received and are being processed. This will also reduce the administrative burden for Medicare contractors and practitioners because it is highly likely that those who submit requests will contact the contractor to ensure that their requests have been received.

Exemption request deadline

It has taken many months to educate cardiovascular specialists on the current e-prescribing program, and still, many remain unaware or are struggling to comply. And yet, CMS proposes to allow a mere five business days after finalizing this rule for practitioners to submit hardship requests. Educating practitioners on the availability of the new process and how to file for an exemption, as well as allowing them time to gather the necessary information will certainly take more than five days. The ACC believes that at a minimum, practitioners should be allowed 30 days from the publication of the final rule in the *Federal Register* to submit requests for a hardship exemption.

Appeals

Given that their livelihoods are at stake, practitioners should be given the opportunity to request reconsideration of or to appeal decisions regarding their requests for hardship exemptions. While one percent may not seem like a great deal, that one percent may make a difference between a practice remaining open or closing in light of declining reimbursements overall. The ACC understands CMS' concerns regarding implementation of the fee schedule, but the stakes are high enough that it is worth the additional time it may take to reconsider potentially inappropriate denials. Because of this, the ACC urges CMS to allow for reconsiderations of hardship exemption request denials.

In light of these various concerns, the ACC urges CMS to extend the 2012 e-prescribing payment adjustment reporting period to one that allows for time to implement new, well-defined exemption categories. We would welcome the opportunity to discuss these concerns further. Please direct any questions or concerns to Lisa P. Goldstein at (202) 375-6527 or lgoldstein@acc.org.

Sincerely,



David R. Holmes, Jr., M.D., F.A.C.C.
President

Cc: Jack Lewin, M.D. – CEO, ACC