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March 30, 2011

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Final Rule Concerning Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers [CMS-6028-FC] RIN 0938-AQ20

Dear Dr. Berwick:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide our comments regarding the Centers for Medicare and Medicaid Services' (CMS) *Final Rule Concerning Medicare, Medicaid, Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions, and Compliance Plans for Providers and Suppliers* [CMS-6028-FC] RIN 0938-AQ20. Our detailed comments are set forth below.

Improvements Made in the Final Rule

We strongly support CMS' assignment of physicians to the lowest risk tier. The vast majority of physicians are honest and law abiding, and physicians are already subject to rigorous oversight and state licensure requirements. As a result, additional scrutiny would be duplicative, time-consuming, and of limited value.

We support CMS' decision not to adopt "geographic circumstances" as a criterion for adjusting a provider or supplier's screening level. Application of geographic circumstances as a criterion for adjusting one's screening level would deny all providers and suppliers in the specified geographic area basic due process, and could negatively impact beneficiary access to care in the impacted area.

We support CMS' decision not to move physicians who have had their billing privileges denied, as opposed to revoked, to a higher level screening level. Physicians' billing privileges can be denied because of a clerical error or failure to meet enrollment requirements. Subjecting these physicians to a heightened risk screening would be inequitable.

We strongly support CMS' determination that there should be a good cause exception for suspensions that last more than 18 months unless the Office of Inspector General (OIG) or the Department of Justice (DOJ) has a pending action or investigation. Physicians should not be subjected to unlimited suspension periods, or periods that last 2 or 3 years, as CMS suggested in the proposed rule. Interminable suspension periods can constitute de facto termination for physician practices. We support CMS' creation of a good cause exception for suspensions of more than 18 months, and urge CMS to make every effort to expeditiously resolve suspensions. Further, we ask that CMS work closely with OIG and DOJ to ensure that inter-agency communications and efforts on suspensions are streamlined and timely, so as to minimize the number of suspensions undergoing lengthy OIG and DOJ review.

Physician Office-based DMEPOS Suppliers

In response to the proposed rule, we asked that physicians who supply office-based Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) be exempt from increased screening requirements, including the attendant application fee of $500 or more. In the final rule, CMS declined to heed our request, concluding instead that physicians who supply DMEPOS will be screened as all DMEPOS suppliers are screened—including, in some cases, unscheduled site visits, criminal background checks, and fingerprinting—and subject to the enrollment fee.

We have urged CMS to re-assign physician and non-physician practitioner office-based DMEPOS suppliers to Tier I because there are no widespread reports or documented patterns of fraud perpetrated by them. There are some specialty practices, such as ophthalmology and orthopedic surgery, where this will dramatically impact access for their patients despite the fact that there has been little to no documentation of widespread fraud, waste, or abuse in this category of DMEPOS. While there have been numerous government reports, investigations, and audits concerning fraud and abuse perpetrated by commercial DMEPOS, the record is scant with regard to physician office-based DMEPOS. In fact, the most widely reported DMEPOS fraud has involved physicians as the victims of identity theft as opposed to perpetrators of fraud.

Imposition of the enrollment fee on physician DMEPOS suppliers is unambiguously beyond the scope of CMS' statutory authority and contravenes congressional intent. Section 6401 of the Affordable Care Act (ACA), as amended, requires CMS to impose a $500 fee—adjusted annually—on "institutional provider[s]" enrolling in the Medicare program. Congress mandated the imposition of the fee to defer the government's administrative costs associated with more rigorous screening procedures. Though early versions of Section 6401 would have required HHS to impose a $200 application fee on physicians who provide "medical or other items or services," the final version included an amendment that struck the $200 application fee in ACA Section 10603. Congress and stakeholders fully anticipated that CMS would not have to subject physicians to heightened and costly screening measures.

Beyond CMS' overreach of statutory authority to impose the application fee on physicians, there are sound policy reasons not to impose heightened risk screening and the application fee on physicians. For the subset of physicians offering office-based DMEPOS, they do so to ensure that: (1) a particular item of DMEPOS meets the "size and fit" specifications for that particular patient; (2) the patient is properly instructed concerning the use of DMEPOS. This improves quality of care,

enhances patient compliance, reduces the risk of further injury, and is in line with the ACA's emphasis on comprehensive care.

Practical examples illustrate our point. If a patient undergoes cataract surgery, post-cataract glasses may be required upon leaving the physician's office. If the patient is unable to acquire the item from the treating physician and must, instead, obtain the item from another supplier, serious adverse consequences could result, including a delay in care, continuous or exacerbated pain, or additional, increased injury. These care impediments result in a real cost to the Medicare program. Moreover, in some cases, Medicare allows only one item of DMEPOS per patient. In this event, if the item is not initially properly fitted and sized, the patient may later have to pay out-of-pocket for a replacement item. Further, the clinical judgment and expertise of the treating practitioner in selecting a particular item is essential and should be based on the evaluation of the patient at the time of dispensing. This would also be the appropriate time to instruct the patient and address any questions or concerns on the utilization of the item. If a patient is sent elsewhere to obtain an item and the fit is incorrect or the patient receives insufficient information about an item, the patient will likely return to the practitioner's office with questions or for assistance. Clearly, physicians who offer office-based DMEPOS provide their patients a quality and continuity of care that would otherwise be unavailable. And, physicians who supply DMEPOS generally do so to convenience their patients, not to generate significant revenue.

CMS' determination in the final rule also does not account for existing Stark Law restrictions applicable to physicians vis-à-vis DMEPOS. Under the Stark Law, there is a litany of requirements physicians must meet in order to provide DMEPOS to their patients, and the law significantly limits the universe of DMEPOS office-based physicians can provide. In addition, referring patients to an unknown commercial DMEPOS could actually increase the risk of fraud and abuse.

In light of the foregoing, we urge CMS to revise the final rule and place physician and non-physician practitioner office-based suppliers in the lowest risk tier. Assignment of these physicians to higher risk tiers is contrary to legislative intent and will compromise care access.

In addition, we request that CMS provide information to us regarding the incidence of office-based physician DMEPOS supplier fraud. Despite our requests in the past for this information, we continue to be uninformed of data that either suggests fraud by these suppliers or supports CMS' inclusion of office-based physician DMEPOS suppliers in the moderate or high risk tiers. As stated previously, it is our belief at this time that there is very little to no evidence of office-based physician DMEPOS supplier fraud. However, if we are misinformed, we would like to see this information, so that we may educate the physician community about the problem.

Temporary Moratoria

In our comments regarding the proposed rule, we asked CMS to exercise temporary moratoria authority judiciously, and CMS did say in the final rule that the agency will attempt to narrowly tailor providers subject to temporary moratoria. We support this effort by CMS, as we believe that physicians should not, as a rule, be included in such moratoria.

We also urged CMS to limit temporary moratoria to a 30-day duration, rather than the 6-month standard duration that CMS proposed. Further, we recommended that physicians be excepted from heightened screening requirements following temporary moratoria. In the final rule, CMS nevertheless concluded that temporary moratoria would have a 6-month duration, and would result in higher risk tier assignments for physicians upon conclusion. We continue to believe that 6 months is too long a duration for temporary moratoria, and is certain to result in de facto terminations. And, because we do not believe that physicians, as a group, present a heightened risk to the Medicare program, we urge CMS to reconsider the inclusion of physicians in a higher risk tier following moratoria.

Evidentiary Standard for Suspension

In responding to the proposed rule, we objected to CMS' definition of a new evidentiary standard for suspension, namely, a "credible allegation of fraud." CMS defined this new standard as an allegation identified through any source, including fraud complaint hotlines, claims data mining, provider audit patterns, civil false claims cases, and law enforcement investigations. We pointed out that these informational sources, while useful in identifying actual fraudulent activity, will undoubtedly also be avenues for unfounded allegations. The proposed rule also provided that allegations will be considered "credible" when they have a mere "indicia of reliability." We argued that standard is too low and is inconsistent with the actual statutory standard. We noted that, currently, CMS employs fraud suspensions when there is "reliable information that fraud or willful misrepresentation exists," a higher, and more reliable, evidentiary standard.

In the final rule, CMS states, "We did not intend to detail a precise evidentiary standard in this definition; rather we intended to give examples of the typical sources of allegations of fraud and explain that assessing the reliability of an allegation is a process that will occur on a case-by-case basis." We urge CMS to provide clarity regarding what, precisely, constitutes a "credible allegation of fraud," as an explicit definition of what activity will, and will not, constitute grounds for suspension is required. Physicians should not be subject to a penalty as severe as suspension without proper notice and understanding of what CMS views as the evidentiary bar, and ambiguity on this point is contrary to notions of due process and fairness.

Conclusion

The AMA is committed to working closely with federal and state agencies to develop and implement program integrity measures that safeguard scarce federal health care dollars. We appreciate CMS' ongoing effort to listen to our suggestions and make reasonable changes to its proposals, and hope that this letter will aid CMS in further improving the programs and requirements discussed herein. Should you have any questions on this letter please contact Mari Savickis, Assistant Director, Federal Affairs at mari.savickis@ama-assn.org.

Sincerely,

Michael D. Maves, MD, MBA