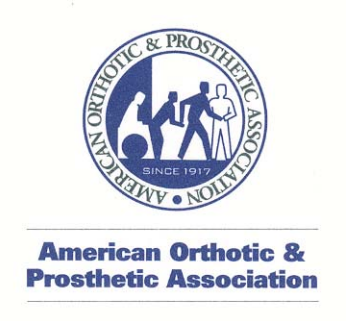

November 15, 2010

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-6028-P
P.O. Box 8020
Baltimore, MD 21244-8020

Dear Sirs:

We are writing to provide comments to the proposed rule CMS-6028-P regarding new enrollment procedures that was published in the September 23, 2010 Federal Register. The American Orthotic & Prosthetic Association (AOPA) is the largest national orthotic and prosthetic trade association with a membership of approximately 2000 corporations that draw from all segments of the field. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

AOPA supports CMS's desire to improve its ability to prevent inappropriate billing through better control of providers attempting to enter the Medicare program, as well as increased follow-up of those already enrolled as Medicare billers. AOPA has been a strong supporter of pending federal legislation, H.R. 2479, which would implement key fraud and abuse measures specific to orthotics and prosthetics. We have briefed senior CMS staff on the bills' provisions on at least two occasions and actually, we believe the provisions of H.R. 2479 would do more to fight fraud and abuse than will the steps proposed in this rulemaking.

We also recognize that there is a fine line between enhanced enrollment procedures necessary to prevent fraud and onerous regulations that damage small businesses and negatively impact their ability to provide patient care. We offer the following comments in the hope that the final regulations will take into account the already significant regulatory burden carried by suppliers providing care to Medicare beneficiaries.

I. CMS proposes to categorize providers by risk, with "high risk" providers subject to enhanced inspections, fingerprinting and background checks. Eventually, all DMEPOS providers will be classified as "high risk".
Comment:

- In states with Orthotic & Prosthetic licensure, O&P suppliers should be categorized as **low risk**, as are physicians, due to their O&P practitioners' licensure status. In

addition, there is no evidence of significant elevated risk for such licensed professionals.

- In states without O&P licensure, if 1) one or more of the supplier's practitioners are certified by the American Board for Certification of Orthotics, Prosthetics and Pedorthics or the Board of Certification/Accreditation, International (accrediting bodies already referenced in BIPA 2000 Section 427), or 2) the supplier itself has been accredited by one of these entities, it should also be treated as **low risk**. The practitioner being credentialed in either of these ways has demonstrated a commitment to quality, as well as a commitment of time in the business that reflects significantly lower risk of fraudulent activities.

  If the O&P supplier is not practitioner owned, but has been in business at least 3 years, it should be **low risk** due to a demonstrated lack of inappropriate billings over time. If it is not practitioner owned and has not been in business at least 3 years, it should be rated as a **moderate risk**.

  Risk levels of specific providers should not be made public.

  AOPA strongly objects to this risk assignment provision, among other reasons, because: (1) orthotics and prosthetics is not part of DME, and has significantly lower fraud and abuse risks; (2) there has not been sufficient consideration of the impact of number of years in business, or accreditation/certification status as factors that diminish risk.

II. Announced and unannounced visits pre and post enrollment for "moderate" and "high" risk providers

Comment:

This provision is not problematic, since O&P is already subject to unannounced visits pre- and post-enrollment through the National Supplier Clearinghouse and by accrediting organizations. However, the number of such visits must be reasonable for the circumstances and should only increase if there is an identifiable indicator of inappropriate activity necessitating and justifying increased scrutiny.

III. Background checks and fingerprinting

Comment:

Since we recommend that O&P suppliers are categorized as **low to moderate risk**, these provisions would not come into play.

However, there are serious concerns with CMS's ability to protect such information. In addition, the time and cost necessary to comply with these requirements is a significant burden on small providers, in light of all of the other requirements they are subjected to, such as surety bonds, accreditation and often licensure requirements. For reasons of reduced risk, time in business and demonstrated commitment to quality noted above, no certified practitioner or accredited O&P facility should be subject to background checks and fingerprinting.

We also question whether requirements such as fingerprinting will accomplish CMS's goal of being able to track violators, since CMS will have no way to assure that the person providing the fingerprints is the person rendering the care. It is also unclear how fingerprinting and background checks will achieve the goal of preventing identity theft for physicians.

IV. Risk levels will be subject to change, shifting to higher levels when necessary
Comment:
Taking action to raise a supplier's risk level seems reasonable only if the supplier has come under a payment suspension or if after investigation, the type of provider and the services it will render are not congruent on its enrollment application.

V. Implementation timetable of March 23, 2010 for new and reenrolling facilities and March 23, 2011 for existing facilities
Comment:
This timetable seems very ambitious. At a minimum, the DME MACs and the NSC will have to be able to identify providers and implement payment edits, both by specialty code, and link these together. Therefore implementation in six months does not appear feasible. Sufficient lead time is necessary for CMS to have operational and well tested computer programs in place to administer these requirements correctly and consistently. For all these reasons, one year additional delay, March 23, 2011 for new facilities and March 23, 2012 for existing facilities, should be adopted.

VI. Application fee
Comment:
For small businesses, a $500 application fee is not reasonable, especially on top of the required annual payment for a surety bond. CMS' obligation to allocate resources to control fraud and abuse is not new, and hopefully these efforts will more than pay for themselves via program expenditure savings. At this point, CMS has not demonstrated with even pilot data that either (a) these steps will actually stem fraud and abuse; nor (b) why any additional fee, let alone $500, should be levied. If such a fee is necessary, it must recognize the size of the business and waive the fee for smaller suppliers, i.e. total Medicare payments in the prior year of $500,000 or less.

- The proposal states that the $500 application fee will be required at the time of submission of an enrollment application for each Medicare PTAN, meaning that one will be required for each office location. However, the $500 per location fee is unsupported and improper. A simple $500 fee per company, or paying for up to four facility locations but not more per company, or $500 for the first location and $50 for the next ten all make some sense. A flat $500 per location does not, since clearly larger companies with multiple locations pose lower risk.

- The proposal also says that Medicare contractors would not begin processing the paperwork to support continued eligibility to receive payment until the enrollment application fee is received and credited to the US Treasury. We question this…it appears to be more about distrust or punishment of providers and seems to provide no particular service or benefit to beneficiaries.

For all these reasons, there is no justification to assess new fees to providers to support CMS enforcement activity that should be ongoing anyhow. Moreover, CMS' proposed actions in the rule ignore the much more practical and effective measures to stem fraud and abuse outlined in H.R. 2479, and instead of stopping the fraud at the outset (as seems to be the stated objective), rely unduly on straightforward delays in delivering payments to all providers. This punishes all legitimate providers, and without any assurance that delays will solve the fraud problem.

VII. Obligations of CMS to reduce and minimize the burden of rule, especially on small business

Comment:

Providers, particularly small entities, will likely have trouble continuing to provide services to patients with no cash flow from the government while the investigation into suspected fraudulent activity plays out. In the past at CMS, it was not uncommon for the 180-day timeframe to be extended at least once, but there usually was a reduction in the percentage of payments suspended to address any potential interruption of services to beneficiaries during the extended suspension period. Under the proposed rule, it does not appear CMS would retain that flexibility , which could cause serious issues if providers are unable to remain financially viable and need to cease or reduce beneficiary services.

CMS also includes currently enrolled DMEPOS suppliers and home health agencies because site visits are viewed by CMS as a way to ensure that such entities remain operational and continue to meet supplier and other Medicare, Medicaid and CHIP standards. CMS says that this has consistently been a high-risk area for CMS and one where the OIG and GAO have repeatedly found CMS' oversight efforts to be lacking. This may be a basis for CMS doing site inspections of existing facilities, but this can be done without this new rule. This is not an appropriate basis for automatically considering all DME and all O&P existing facilities moderate risk without any further justification.

In addition, with regard to the "high" risk category, although government enforcement efforts to date have shown fraud, waste and abuse issues with HHAs and DMEPOS suppliers in certain geographical regions (e.g., South Florida, Texas and California), it is not clear that issues with such entities are national. Because the criminal background checks and fingerprints are onerous requirements that are not currently used by Medicare, CMS should limit itself to introducing such requirements in high risk geographic areas, rather than nationally, at least at this stage.

CMS has neither provided the data nor made the convincing case that its proposed changes will deliver results to justify the extent the rules would intrude on normal patient care and business practices. We urge CMS to adopt a more realistic approach that cracks down on fraudulent providers, without either considering every provider to be a crook, or adding huge regulatory burdens that could put honest, legitimate, hard-working O&P providers out of business.

VIII. Suspension of payments for any credible allegations of fraud

Comment:

In any decision on whether or not to suspend payment, it is imperative that there should be recognition of the difference between fraudulent activity and simple claims submission errors. There also needs to be less vague criteria for implementing a suspension than a "credible allegation of fraud" or "an indicia of reliability." These terms need to be defined in a manner that sets a relatively high bar in terms of probability of fraudulent activity, e.g. an allegation by a competitor, or by one unhappy customer does not reach the threshold of a "credible allegation of fraud."

IX. Enrollment moratoria

Comment:

While this may be reasonable in some limited situations, CMS must have the ability to make such decisions based on specialty, <u>not</u> on broader supplier type. It would be

grossly inappropriate for all DMEPOS providers to be put under such a moratorium, when, for example, fraud concerns did not include O&P.

X. Due Process

Comment:

There is a compelling need if CMS is to proceed with this new role, for CMS to introduce much better controls to limit over reaching and to assure providers due process rights. Suspensions are targeted to 180 days for many companies—eliminating Medicare payments for that long would threaten their very existence. The proposed rule would give CMS the ability to impose a temporary moratorium on potentially high risk providers and suppliers with no rights of judicial review of the agency's decision.

In addition, temporary enrollment moratoria will be allowed for newly enrolling providers and new practice locations based on such reasons as evidence of fraud, a disproportionate number of providers in a benefit category relative to the number of patients or a rapid increase in enrollment in a specific category, again, without specifying any due process rights to protect providers. Such moratoria could be limited in geographic locations and provider type and would be imposed for six months with a possible six month extension. The absence of defined rights for O&P providers certainly makes this appear to be a federal "taking" without due process.

XI. Mandatory compliance plan

Comment:

Many of these requirements are already in place through O&P accreditation, licensure, non-mandatory OIG compliance plans and under HIPAA, therefore this requirement is somewhat redundant. In addition, any compliance plan must be specialty specific and not try to fit all DMEPOS providers into the same requirements. CMS has already recognized some of the differences between O&P and DME in its quality and supplier standards.

AOPA appreciates the opportunity to provide comments on these provisions and would be happy to provide any additional information that might be helpful to finalizing these regulations.

If you have any questions or need any additional information, please contact Kathy Dodson, Senior Director of Government Affairs, at 571 431-0810 or kdodson@aopanet.org.

Sincerely,

Thomas F. Fise, JD
Executive Director