August 28, 2014

Ms. Marilyn B. Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1614-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Medicare Program: End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Dear Administrator Tavenner,

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide comments on issues related to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies provisions included in the Proposed Rule CMS-1614-P, End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). AdvaMed member companies produce the medical devices and technologies that are covered under Medicare’s DMEPOS benefit. These devices and technologies play a critical role in allowing beneficiaries to lead healthy, productive, and independent lives in their homes and communities, thereby serving to fulfill the intent of Congress when it created this benefit.

AdvaMed is commenting on four keys areas of the rule. First, AdvaMed has concerns about several of CMS’s proposals to adjust DMEPOS rates based on rates paid in the Competitive Bidding Program (CBP). The proposed policies do not take into account the significant disruption to the market, the volume assumptions of participants in competitive bidding areas, and real patient access issues that could occur. Second, AdvaMed recommends that CMS exclude enteral nutrition therapy from its initial bundled payment proposal to ensure that bundled payments will not reduce beneficiaries’ access to quality enteral nutrition therapy services. Third, AdvaMed strongly opposes CMS’s proposals to limit coverage for certain bone conduction hearing devices and we believe CMS has inaccurately categorized them as hearing aids. Finally, we are concerned that CMS’s proposal to more clearly define those individuals qualified to fit customized orthotics is too restrictive and inappropriately excludes orthotic
Phasing in Adjustments to the DMEPOS Fee Schedule in Non-Competitive Bidding Areas (non-CBAs) Based on Information from the Competitive Bidding Program

AdvaMed recommends that CMS only gradually, and through a phased-in approach, apply adjustments to DMEPOS fee schedule amounts in non-competitive bidding areas (non-CBAs), on the basis of payment information obtained through the competitive bidding program. In our March 28, 2014 comment letter to CMS in response to the Advance Notice of Proposed Rulemaking for adjusting Medicare payments for certain DMEPOS items, AdvaMed argued for a phased-in approach to applying adjusted rates to areas of the country not subject to competitive bidding. We continue to believe this position is appropriate for several reasons as discussed below, and given the lack of discussion of this recommendation in the proposed rule, we reiterate our recommendation and related concerns here.¹

AdvaMed believes that a gradual, phased-in approach is necessary most fundamentally because the single payment amounts used in CBAs have been determined under a set of circumstances unique to each of those areas and which bear little, if any, relationship to the other areas of the country in which they would be applied. We point out that the Competitive Bidding Program has produced a limited number of contract suppliers in each CBA and these suppliers have presumably taken into account in their bids an increase in their market share of Medicare beneficiaries if selected as a winning bidder. For non-CBAs, CMS will be starting with payment information based on a dynamic that will not apply to the area. CMS will not be limiting the number of contract suppliers through a competitive bidding process, and, therefore, suppliers cannot expect a larger market of beneficiary customers. Without a larger market for their services, suppliers in non-CBA areas can be expected to incur higher costs for serving Medicare beneficiaries than contract suppliers in areas subject to competitive bidding. AdvaMed argues that CMS will be able to judge the impact of market size on non-CBA suppliers only through experience of phased-in adjustments across a variety of different non-CBA markets.

¹ In our comment letter from March 28, AdvaMed also argued that the statute reflects congressional intent for the gradual implementation of payment adjustments in non-CBA areas. While the ANPRM argues that the law requires that the Secretary by January 1, 2016 use payment information under the Competitive Bidding Program to adjust fee schedule amounts in all non-CBAs, we observe that the statute (viz. sections 1834(a)(1)(F)(ii) and 1834(a)(1)(G) of the Social Security Act) states only that the Secretary must use such information to adjust payment amounts for an area that is not a CBA [emphasis added]. We believe that if Congress had intended for immediate implementation of payment adjustments in all non-CBAs, it would have specifically indicated that intent in the language of the statute. Absent a clear indication that Congress sought simultaneous implementation in all non-CBAs, we believe that CMS not only has the authority to phase in the payment adjustments in various non-CBAs, but would in fact be carrying out congressional intent in doing so.
To reflect higher costs in non-CBAs because the number of suppliers will not be limited, AdvaMed further recommends that payments in these areas incorporate an upward adjustment for the smaller market share suppliers in these areas will be serving. By phasing in the adjustment process for payments made in non-CBAs, CMS will be able to test the appropriate magnitude of this upward adjustment.

In addition, we note that CMS will not know in advance whether adjusted payment amounts applied in non-CBAs will yield a sufficient number of geographically dispersed suppliers willing to accept the lower payment amounts and provide Medicare beneficiaries access to specific products, and high quality products, that their physicians determine they need.

Adjusting payments for non-CBA areas also raises questions about statutory requirements that currently apply to contract suppliers under the Competitive Bidding Program but would not apply to suppliers in non-CBAs because these suppliers presumably would not be considered contract suppliers under Medicare law. These suppliers presumably would not be bound by requirements that apply to contract suppliers, such as mandatory assignment of claims or offering Medicare beneficiaries the same range of products offered to non-Medicare customers that apply to contract suppliers.

We therefore believe that Medicare beneficiaries in non-CBAs could face significant risks in terms of fundamental access to care, as well as access to quality products and services integral to those products, which their physicians prescribe for them. The reasonable response to these issues should be a gradual phase-in of fee schedule adjustments in non-CBAs.

We also note our more general concern in applying payment amounts from the Competitive Bidding Rounds to non-CBA areas. As we have stated on several prior occasions, the methodology CMS has used for determining single payment amounts under rounds of bidding to date has resulted in unreasonably low rates, largely because bidders have not had to submit binding bids and because single payment amounts have been set at the median of winning bids. This methodology also has led to bidders with little or no experience in providing a product to become winning bidders, particularly crucial for patients as the program has incorporated advanced technologies such as negative pressure wound therapy and infusion and insulin pumps into competitive bidding. We raise these issues once again as CMS considers an adjustment process which will be based on single payment amounts determined through the Competitive Bidding Program’s methodology.

**Applying Adjustments to DMEPOS Fee Schedule Amounts Only After Items Have Gone Through Two Rounds of Bidding**

With each successive round of bidding, CMS has expanded product categories and the number of HCPCS codes subject to the competitive bidding process. As a result, not every product category or products within individual categories have gone through multiple rounds of bidding. AdvaMed recommends, for any methodology adopted by CMS for determining payments for DMEPOS in areas not subject to competitive bidding, that rates be based on two full rounds of bidding to ensure that rates are as broadly representative as possible.
We point specifically to problems with two product categories added in the Round 1 Recompete—transcutaneous electrical nerve stimulation (TENS) and external infusion pumps, including insulin pumps—that argue for a delay in making fee schedule adjustments based only on the experience of one round of bidding in nine competitive bidding areas (CBAs).

One of our member companies manufacturing TENS devices undertook a phone survey of each of the contract suppliers’ winning bids to provide all of the items included in the General Home Equipment product category. They did so in order to help direct beneficiaries to specific sources for obtaining the TENS devices prescribed by their physicians. The company contacted each of 313 suppliers that won contracts for the General Home Equipment category in the 9 Round 1 Recompete CBAs, and found that 44 percent, or 139 of the 313 contract suppliers, stated that they did not supply TENS. AdvaMed is pleased with CMS’s decision to establish TENS as a separate category for the Round 2 Recompete, and we assume that CMS did so in response to the survey’s findings and other related issues. However, given the findings, we believe that contract prices for TENS from the Round 1 Recompete should be deemed invalid for purposes of adjusting prices in non-CBAs and that TENS go through two new rounds of bidding before applying CMS’s methodology to these areas.

For similar reasons, AdvaMed argues against using Round 1 Recompete contract prices for insulin pumps in establishing prices for this technology in non-CBAs. One of our member companies manufacturing insulin infusion pumps has found that the vast majority of contract suppliers, which prior to the Round 1 Recompete had never supplied insulin pumps, were not providing insulin pumps to beneficiaries; nor were these suppliers making available to beneficiaries all supplies related to the insulin pumps. Of the 40 suppliers accepting contracts, only two had meaningful experience providing insulin pumps and related supplies to Medicare beneficiaries. In one CBA, the 13 winning contractors had no experience providing insulin pumps and related supplies to Medicare beneficiaries, leading to service disruptions and compromised access to medically necessary and covered supplies. We note that external infusion pumps, including insulin pumps, have not been included among Round 2 Recompete product categories, and we applaud CMS for not expanding competitive bidding for this product category until access and other related problems have been resolved. We point out that Medicare beneficiaries needing insulin and other external infusion pumps have significant health issues and should not experience access problems for these technologies, related supplies, and equally critical support services. Until problems are resolved, AdvaMed recommends that CMS not use the single payment amounts for insulin pumps from the Round 1 Recompete to adjust Medicare prices for non-CBAs beginning January 1, 2016. In addition, we recommend that insulin pumps go through two new rounds of bidding before applying whatever methodology CMS adopts for setting payments in non-CBAs.

Methodology for Items and Services Included in a Limited Number of Competitive Bidding Programs

For items and services subject to competitive bidding that have been included in Competitive Bidding Programs (CBPs) in no more than 10 CBAs, CMS proposes that payment amounts for these items in all non-CBAs would be adjusted based on 110 percent of the simple (unweighted) average of the single payment amounts (SPAs) for the areas where CBPs are implemented.
Under this proposed methodology, no special policies would apply to rural and frontier states or to areas located outside the contiguous United States.

AdvaMed is concerned that this proposed policy would disadvantage beneficiaries living in many parts of the country that may experience limited access or lower quality items or services due to very low payments. (We also note that this proposed policy does not reflect our recommendation that competitive bidding information should not be used to adjust payments in non-CBAs until there have been two valid rounds of competitions related to a DMEPOS product.) In this regard, the following charts demonstrate how widely divergent the SPAs can be across the Round 1 Recompete CBAs for the same product code across the country.

<table>
<thead>
<tr>
<th>Code</th>
<th>Descriptor</th>
<th>Cincinnati-Middletown, OH-KY-IN</th>
<th>Orlando-Kissimmee-Sanford, FL</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0193</td>
<td>Powered Air Flotation Bed (Low Air Loss Therapy)</td>
<td>$799.50</td>
<td>$571.91</td>
<td>39.8%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2402</td>
<td>Negative Pressure Wound Therapy Electrical Pump, Stationary or Portable</td>
<td>$999.90</td>
<td>$698.71</td>
<td>43.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E0277</td>
<td>Powered Pressure-Reducing Air Mattress</td>
<td>$349.66</td>
<td>$182.81</td>
<td>91.3%</td>
</tr>
</tbody>
</table>

SPA data for E2402 strongly suggest that applying only a 10 percent increase to the unweighted average of SPAs for items bid in 10 or fewer CBAs would have problematic consequences. The table below lists the SPAs for E2402 in the nine Round 1 Recompete CBAs.
The average of these SPAs is $803.64. Under the proposed methodology, this would result in a national payment amount of $884.00 for E2402 (110 percent of $803.64). The resulting national SPA would be below the SPAs in two of the nine CBAs (highlighted above), both of which are in Florida. At the very least, this suggests that the national payment amount would be inadequate to ensure beneficiary access in non-CBA areas of Florida. And since the proposed payment amount makes no accommodation for non-contiguous areas of the country, rural areas, or high-cost areas of the country, there would appear to be a significant risk of problems in other parts of the United States as well. This is particularly true when one remembers that the SPAs are based on the median of “winning bids,” even in cases where not all the winning bidders agreed to become contract suppliers, meaning that at least half of the contract suppliers in the nine CBAs are actually being paid rates below what they originally bid.

Similarly, the SPA data for E0277 demonstrate an even more problematic outcome in that the proposed national payment amount, $314.06 (110 percent of the unweighted average of $285.51), would end up being lower than the SPAs for one-third of the 9 Round 1 Recompete CBAs (highlighted below).
It is clear from these data that the proposed policy cannot be finalized without significant risk of beneficiary access problems, at least in some parts of the country and for certain products. We believe that the national payment amount should be set higher than 110 percent of the unweighted average of the SPAs, at least for some products and in some areas of the country. Additionally, other policies to mitigate the access risks for certain areas as identified above should be considered.

AdvaMed has significant concerns with CMS’s proposed approach to adjust DMEPOS rates using payment amounts from the CBP. We believe that the data comparing various CBAs demonstrate the dangers of using competitive bidding data from a single round of competitions in a limited number of areas to adjust payments in non-CBAs. **AdvaMed urges CMS not to move forward with finalizing this proposal.** Additionally, AdvaMed strongly recommends that any final policy address the need for a transition, our concerns about access in the less populated areas due to scale and volume concerns, the need to apply only to products that have been through two rounds of competitive bidding, and the adequacy of payment needed to ensure access and quality of DMEPOS items and services for Medicare beneficiaries.

### National Limits for Regional Single Payment Amounts (RSPAs) Subject to Competitive Bidding and Included in More Than 10 CBAs

For items and services subject to competitive bidding and included in more than 10 CBAs, CMS proposes to adjust fee schedule amounts for these items and services provided in non-CBAs using a methodology based on regional single payment amounts (RSPAs) limited by a national floor and ceiling. The RSPA would be established using the simple unweighted average of the SPAs for an item from all CBAs that are fully or partially located in the region. The adjusted payment amount for the item would be equal to its RSPA but not less than 90 percent and not more than 110 percent of the national average.

AdvaMed believes that the same types of issues and problems noted above for competitions in 10 or fewer CBAs could also arise at the regional level for competitions in more than 10 CBAs. In particular, we are concerned that the national ceiling threshold, as defined in the methodology, would not adequately compensate suppliers in high cost areas. **AdvaMed urges CMS not to move forward with finalizing this policy.** In the event that CMS moves forward with implementation, AdvaMed strongly recommends that any final policy at least address the concerns raised above by either eliminating the national ceiling limits, or at a minimum, increase the national ceiling to recognize high cost areas.

### Proposed Payment Methodologies and Payment Rules for Enteral Nutrition Therapy Furnished under the Competitive Bidding Program

AdvaMed has serious concerns about CMS’s proposal to bundle DMEPOS items in the CBP, especially for enteral nutrition. We believe that it is premature for CMS to move forward with a bundled payment initiative for items of DMEPOS covered under the competitive bidding program and, in particular, is concerned that such a change will exacerbate problems beneficiaries have experienced with access to quality enteral nutrition services under the current
Competitive Bidding Program. We recognize that CMS is currently conducting bundled payment demonstrations under the Bundled Payments for Care Improvement Initiative in order to test the ability of this delivery reform model to improve both the quality and efficiency of care by aligning payment incentives to encourage greater cooperation and coordination among physicians, hospitals, and other health care providers. AdvaMed has supported the interrelated quality and efficiency improvement goals of delivery reform models and believes that our technologies can play a central role in realizing these goals.

However, we point out that bundled payments in the context of the Competitive Bidding Program contain two challenging problems that do not exist in the Bundling Initiative. First, payments in the Bundling Initiative, for the most part, have as their foundation regular fee-for-service payments that apply to hospitals, physicians, skilled nursing facilities, home health, and other providers choosing to participate in those programs. These fee-for-service payments have not been driven down to unreasonably low levels by a competitive bidding program. In addition, CMS has incorporated patient protections in the Initiative by linking the payments and gainsharing rewards to quality incentive programs. This would not be the case with the bundling proposal in the proposed rule related to competitive bidding. Finally, enteral nutrition therapy is an example of an item that should not be included in the proposal due to the wide variability in the range of products which define the product category as well as the potential negative impact a new payment system can have on patient care.

AdvaMed recommends that CMS exclude enteral nutrition therapy from its initial bundled payment proposal until an evaluation has been conducted to ensure that bundled payments will not reduce beneficiaries’ access to quality enteral nutrition therapy services. We do so for the following reasons:

- It is widely recognized that nutritional status plays an important role in health outcomes and health care costs. Malnourished patients are at risk of adverse outcomes including: increased morbidity, complications and mortality; longer hospitalizations; increased likelihood of hospital readmissions; and higher health care costs. Beneficiaries who require enteral nutrition therapy services are malnourished and often have multiple co-morbidities (diabetes, renal disease, HIV, cancer, and gastrointestinal malabsorption diseases) that put them at risk for additional and costly health complications. As such it is critical that Medicare beneficiaries who are nutritionally compromised have consistent access to high quality care.

- There is significant variability in the enteral nutrition therapies prescribed for Medicare beneficiaries, including differences in the mode of administration and the type and quantity of enteral nutrients required. This variability would make it very difficult, if not impossible, for suppliers to develop a single bid that encompasses all aspects and all possible variations of enteral nutrition therapy. Submitting one bid that covers all of these methods of administration is inappropriate since the costs related to administering enteral nutrition vary significantly depending on whether it is administered via pump, syringe or gravity and changing the prescribed method of administration is a potential patient safety risk.
Enteral nutrition therapy is life-sustaining and there are unique significant and costly consequences that can result if a patient’s nutritional status declines due to not having access to the correct nutrition products and services. Prior to making significant changes to the reimbursement policy for enteral nutrition therapy, CMS should ensure that bundled payments will not interfere with beneficiaries’ access to quality care.

If, however, CMS chooses to include enteral nutrition therapy in the bundled payment proposal, CMS should establish a separate bundle for each mode of delivery and enteral formulas should be excluded from the bundles. It is imperative for CMS to establish a separate bundle for each mode of enteral nutrition delivery and to exclude enteral formulas altogether due to variability of the therapy that physicians may prescribe and significant differences in cost associated with enteral nutrition administered using gravity, syringe or a pump.

Furthermore, nutrients should be excluded from all bundles since patients require different quantities of formula and the costs and complexities of different formulas vary significantly. Attempting to fit the broad range of enteral formulas into a single bundled payment could have a seriously negative impact on beneficiaries’ access to appropriate enteral nutrition therapy and positive health outcomes. Enteral formulas are developed to provide the appropriate amounts and types of nutrients, based on patient needs. For example, disease-specific enteral formulas for patients with diabetes may contain unique, slowly digested carbohydrates to help minimize glycemic response. In addition to requiring different formulas, patients require varying quantities of enteral nutrition formula, which also has a significant impact on the cost of care. It is not reasonable to assume that a 290-pound patient would require the same amount of enteral nutrition as a 125-pound patient. A patient’s health could be compromised, with the patient becoming further malnourished or developing additional medical complications, if the patient is not provided an enteral formula that addresses his or her special nutrition needs or is not provided the quantity prescribed. Suppliers subject to bundled payments cannot predict the specific formulas or amount of formulas that their patients will need. Due to the wide variability of these factors and the significant differences in cost, it is impossible to establish a bundled payment amount that includes formulas. AdvaMed strongly believes that formulas must be excluded from any bundled payment policy.

**Continued Coverage For Prosthetic Bone Conduction Hearing Devices**

AdvaMed strongly disagrees with the CMS proposal to define bone conduction hearing devices as hearing aids as well as the proposed narrowing of the types of devices that will be considered auditory/hearing prosthetics eligible for coverage by Medicare. AdvaMed urges CMS to provide coverage for bone conduction hearing devices that are prosthetics, including currently covered osseointegrated devices, because they replace the function of all or part of the ear. We believe that CMS’s proposal to expand Medicare’s hearing aid exclusion to include: “all types of air or bone conduction hearing aid devices, whether external, internal, or implanted, including, but not limited to, middle ear implants, osseointegrated devices, dental anchored bone conduction devices, and other types of external or non-invasive devices that mechanically stimulate the cochlea” is based on an inaccurate understanding of the nature of the technologies it proposes to exclude from coverage. We also note that, if finalized, the
proposed rule will generally leave Medicare beneficiaries without an alternative treatment for one or both nonfunctioning ears. AdvaMed believes that certain bone conduction hearing devices do in fact meet the definition of prosthetic devices because they replace the function of the outer, middle and/or inner ear, and as such, clearly qualify as covered prosthetic devices as that phrase is defined in the Social Security Act:

**Prosthetic devices (other than dental) which replace all or part of an internal body organ** (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens . . . (SSA §1861(s)(8))

The application of the hearing aid exclusion should therefore be interpreted in the context of the intent to exclude routine medical care and conditions that are a consequence of the normal process of aging and that enables clear differentiation between hearing aids and auditory prosthetics.

**Hearing aids** improve hearing by amplifying sound using existing functional anatomy, rather than replacing part of the anatomy that is not functioning. Hearing aids do not follow a medical/surgical intervention, do not require a physician prescription and can be self-prescribed and selected by individuals.

In contrast, **auditory prosthetics** replace all or part of the function of the ear, restore hearing without amplifying sound waves, follow a medical/surgical model that requires intervention by a specially trained physician and provide acoustic energy to one or both cochlea by transmission of the energy through the bone.

The advanced technology of certain bone conduction hearing devices does not rely on amplification of sound, does not provide traditional “aid” to hearing, and does not rely on a functioning ear to transmit sound. Rather these bone conduction hearing devices bypass (thereby replacing) the patient’s nonfunctioning or malfunctioning outer, middle and/or inner sections of the ear, transmitting sound directly to the patient’s cochlea for transmission to the auditory nerve. As CMS has stated in the Benefit Policy Manual, these devices are “indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.” They are used only for patients
who have no alternative treatment and who therefore will be left with no alternative treatment should CMS’s proposal be finalized. Moreover, these devices cannot be self-selected by patients, but instead require a physician prescription and a medical (and in certain cases, surgical) intervention by specialized physicians.

We note that the proposed rule reverses CMS’s 2006 decision to cover osseointegrated implants as prosthetics, without providing a clear explanation of why these technologies are now considered hearing aid devices by the agency. These devices function precisely the same way they did in 2006 when CMS correctly recognized that they were prosthetics that replaced the function of the middle ear. We also point out that in 2004 and 2005, Entific Medical System produced extensive evidence for CMS showing that osseointegrated bone conduction device qualified as covered prosthetics not subject to the hearing aid exclusion, and that these surgically implanted devices were reasonable and necessary and should be covered by Medicare. Since 2005 a number of new devices that function the same as osseointegrated devices, in that they replace the function of the middle ear, but utilize different mechanisms to direct sound to bone, e.g., sound is directed to bone via a tooth as opposed to an osseointegrated post. These devices all require diagnosis, a treatment plan formulated by a physician, and a prescription. They also are utilized only when hearing aids are medically inappropriate and cannot be utilized to treat a patient’s deficit.

AdvaMed urges CMS to continue to provide coverage of cochlear implants, brain stem implants, and osseointegrated implants, to extend coverage to dental anchored bone conduction devices since these devices also meet the definition of covered prosthetics and are not hearing aids, and to provide coverage to other clinically proven bone conduction hearing device technologies based on the following principles:

- Patients with conductive hearing loss, mixed hearing loss and single sided deafness should have a covered benefit for treatment with a prosthetic.
- Devices with the following characteristics should be considered hearing prosthetics: (a) replace all or part of the function of the ear, (b) restore hearing without amplifying sound waves, and (c) provide acoustic energy to one or both cochlea by transmission of the energy through the bone.
- Proper use of prosthetics follows a medical/surgical model which requires a diagnosis and treatment plan. Therefore, coverage of a prosthetic should include a requirement that the device be available only upon a physician prescription and only for conditions where a hearing aid cannot provide a clinical benefit or is medically inappropriate.
- Hearing aids are not prosthetics in that they amplify sound through the existing anatomy, rather than replacing part of the anatomy. Hearing Aids do not require medical/surgical intervention and can be self-selected by individuals.

Using this approach will provide patients with access to necessary technology and encourage device manufacturers to continue to innovate and develop more advanced and effective prosthetic solutions, without unnecessarily expanding coverage for patients with routine conditions that can be treated by hearing aids that should be paid for on an out-of-pocket basis.
If finalized, the proposal will harm Medicare beneficiaries by eliminating the possibility of Medicare coverage for the only medical treatments available to replace a dysfunctional hearing system in individuals with conductive hearing loss, middle ear hearing loss or single-sided deafness. Congress certainly did not intend to single out this small patient population as not deserving of covered medical treatment.

In addition, AdvaMed is concerned that the proposal will stifle innovation and advances in auditory prosthetics and will send a negative and damaging message to the medical technology development community as a whole—that Medicare coverage is unpredictable, even when there is long established policy in favor of coverage. Such unreliability makes it impossible for investors to make reasoned decisions about future investments and will lead to the freezing of meaningful innovation.

AdvaMed therefore recommends that CMS not finalize its coverage proposal for bone conduction devices. CMS instead should provide Medicare beneficiaries with conductive hearing loss, mixed hearing loss, and single-sided deafness with a covered benefit for treatment with a prosthetic. That rule should be structured to give beneficiaries access to new innovations in auditory devices that replace all or some of the functions of the hearing system that follow a medical/surgical treatment model, and that are consistent with the Medicare definition of a prosthetic and the goal of Congress in providing a prosthetic benefit.

Definition of Minimal Self-Adjustment of Orthotics under Competitive Bidding

Current regulations distinguish off-the-shelf (OTS) orthotics from those requiring customized fitting by an individual who has “specialized training.” OTS orthotics are those that require minimal self-adjustment. The regulations define “minimal self-adjustment” as an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform, and do not require the services of a certified orthotist or an “individual who has specialized training.” The proposed rule would provide additional specifications for defining an “individual who has specialized training.” Such individuals would include (in addition to the orthotist already specified in regulation) (1) physicians as defined in Medicare law, (2) a treating practitioner that would include a physician assistant, nurse practitioner, or clinical nurse specialist, (3) an occupational therapist, or (4) physical therapist. CMS adds that clinical providers such as assistants, fitters, and manufacturer representatives that work under the supervision of the individual with specialized training would not be considered qualified to provide custom fitting.

While AdvaMed appreciates CMS’s interest in clarifying policy on who should be included among those individuals qualified to fit “custom-fitted” orthotics, we are at the same time very concerned that the proposed policy is overly restrictive and can create access problems for beneficiaries needing customized prefabricated orthotics, particularly in areas with shortages of the practitioners enumerated in the proposed rule.

Our specific concerns include the following. First, the proposed definition fails to recognize the essential role of trained orthotic manufacturer representatives (OMRs) in the supply of custom-fitted orthotics to Medicare beneficiaries—a role that such individuals have played at the request of physicians for years. To allow OMRs to continue fitting customized prefabricated
orthotics, AdvaMed recommends that CMS adopt specific training and education standards (such as those already adopted by many orthotic manufacturers) to qualify “individuals with specialized training” to adjust custom-fitted orthotics. AdvaMed would welcome the opportunity to work with CMS in the development of such standards.

In order to fit prefabricated customized orthotics, OMRs typically must complete a specialized training program that incorporates classroom education, hands-on fitting laboratories, online courses, field observation, written exams, and final verification of competency through supervised services. These training and evaluation safeguards, together with field experience and physician involvement support the continued recognition of OMRs to provide medically necessary orthotic fitting services to Medicare beneficiaries and others—services that have been performed safely and effectively for decades.

Second, by requiring that individuals have “equivalent” training and education as certified orthotists in order to fit customized prefabricated orthotics, CMS fails to recognize that OMRs have performed customized prefabricated orthotic fitting services at the request of physicians for many years. We are aware of no safety or quality concerns identified by the federal government or other government agencies as a result of these longstanding practices.

In addition, State physician delegation laws generally permit physicians wide discretion to delegate complex medical tasks. AdvaMed does not consider it appropriate for CMS to disregard State licensure laws by eliminating physicians’ ability to delegate the fitting of custom-fitted orthotics to a trained individual. Along these same lines, AdvaMed also notes that CMS’s proposed policy for defining an “individual who has specialized training” will have the effect of overriding many State laws, which recognize a broader range of persons who have specialized expertise and who are allowed to fit customized orthotics.

AdvaMed therefore recommends replacing the proposed rule language with a definition for an “individual who has specialized training” that specifies that such individuals include those qualified to provide custom-fitted orthotics under a State license, or trained persons operating under the general supervision of a physician or orthotist.

We appreciate the opportunity to comment on Competitive Bidding and DMEPOS issues in the proposed ESRD rule. If you have any questions, please do not hesitate to contact me at dmay@advamed.org or Richard Price at rprice@advamed.org.

Sincerely,

/s/

Don May
Executive Vice President
Payment and Health Care Delivery Policy