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Melanie Combs-Dyer
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Centers for Medicare & Medicaid Services
7500 Security Blvd.
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Submitted via e-mail to ReducingProviderBurden@cms.hhs.gov

Dear Ms. Combs-Dyer,

The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with more than 2,100 members from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or limb impairment resulting from a trauma, chronic disease or health condition. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

AOPA is pleased to offer the following comments regarding the proposed change to the DMEPOS Quality Standards that would include custom fabricated, direct milled diabetic inserts in the definition of "molded to patient model".

Diabetes is one of the fastest growing epidemics in the United States. Approximately 30 million people are currently being treated for diabetes, representing 1 in every 11 Americans. According to the National Diabetes Association, direct medical costs for diabetes exceeded $176 billion dollars in 2012. Medicare expenditures for diabetes treatment during this same time period approached $104 billion (59%). In 2012, Medicare reimbursed $71.66 million for custom fabricated diabetic inserts under the Medicare Therapeutic Shoe Program. This program provides an important benefit to Medicare beneficiaries diagnosed with diabetes and related foot conditions and includes the provision of one pair of diabetic shoes and up to three sets of diabetic inserts per calendar year. While $71.66 million is a relatively small amount when compared to the overall annual Medicare spend on diabetes care, the benefit is invaluable to Medicare beneficiaries who are at risk for further complications including potential amputation due to foot conditions related to diabetes. In short, diabetic shoe inserts comprise 0.069% of Medicare' spend on diabetes, and this small outlay results in averting foot ulcers,

troublesome wound healing, and a very significant number of amputations for Medicare beneficiaries.

The chart below provides an overview of Medicare expenditures broken down by provider group over the last several years. Medicare reimbursement for custom fabricated diabetic inserts has steadily decreased from 2012 until 2016 with an overall reduction of more than $20 million in the 5 year span, a 28% reduction in Medicare expenditures.

Medicare Reimbursement Trends for A5513

Year	Total Units	Total Dollars	Podiatrist %	O&P %	Pedorthist %	DME %
2016	1,203,673	$51,334,056	36%	36%	5%	11%
2015	1,267,118	$54,158472	36%	30%	6%	12%
2014	1,408,964	$59,362,946	35%	31%	7%	14%
2013	1,616,912	$67,462,650	36%	30%	6%	14%
2012	1,732,585	$71,663,414	36%	30%	4%	17%

This data reveals a troubling trend of reduced utilization of A5513, one that is most likely caused by providers deciding that they can no longer continue to provide these services at reimbursement rates that result in a net loss for their company. As stated later in our comments, AOPA believes that an additional 14% reduction in reimbursement for custom fabricated, direct milled inserts will drive more providers away from this line of business which will lead to fewer options for patients who require custom fabricated diabetic inserts as part of their plan of care for their diabetes management.

AOPA generally supports in principle major aspects of the proposed change to the DMEPOS Quality Standards and appreciates CMS' acknowledgement of technological advances in the manufacturing process of custom fabricated diabetic inserts. AOPA does have significant concerns, however, regarding the additional material that was published on the CMS website dedicated to reducing provider burden on November 7, 2017, specifically the Frequently Asked Questions (FAQ) document as well as information that was provided during the recent CMS Special Open Door Forum that was held on November 28, 2017. The FAQ document and the Special Open Door Forum appeared to reverse fields, conveying information that contradicted many of the issues that appeared to be resolved through the proposed change to the DMEPOS Quality Standards. These contradictions significantly reduce the positive impact of the proposed changes to the DMEPOS Quality standards as they propose to treat identical custom fabricated inserts differently solely due to the technique that was used in fabricating the insert. Establishing lower reimbursement rates for equivalent, virtually identical inserts that use different fabrication techniques, will only serve to reduce Medicare beneficiary access to these services and hinder further efforts to incorporate new fabrication technology into today's healthcare environment

First and foremost, AOPA appreciates CMS' willingness to acknowledge technological advances that have added a new fabrication technique for custom fabricated diabetic inserts. Historically, the only means of fabricating a custom made insert was to create a negative impression of the patient's foot which was then used to create a positive model of the patient's foot. The custom fabricated insert would then be molded over the physical model, creating a total contact, custom fabricated diabetic insert. CAD/CAM technology and advances in a process known as direct milling have resulted in a modified fabrication technique that utilizes a digital or virtual model of the patient's foot to facilitate the direct milling of a total contact, custom fabricated insert that is essentially identical in both material thickness and shore durometer to inserts fabricated using the more traditional method. CMS' acknowledgement of this alternate but equal fabrication process is a true indication of its interest in recognizing the objective of ensuring that Medicare beneficiaries have access to quality patient care, including the appropriate foot care for diabetic beneficiaries. The proposed change to the DMEPOS Quality Standards that includes the direct milling process under the definition of "molded to patient model" is the correct pathway to formally acknowledge this fabrication technique. The acknowledgement of this technology clearly indicates that CMS recognizes and understands that technological advances in all areas must be embraced as valuable assets in ensuring Medicare beneficiaries have access to the highest quality care.

Patient/Beneficiary Health Needs Must Be First and Foremost

It is important to remember that any changes to policy or regulation must be done with the interests of the Medicare beneficiary population as the primary reason for the change. While the proposed change to the DMEPOS Quality Standards is framed under the subject of "reducing provider burden" the impact on the Medicare beneficiary population is truly the important consideration. CMS' proposed acknowledgement of the use of virtual models to create direct milled inserts as meeting the requirements for the definition of "molded to patient model" significantly increases Medicare beneficiaries' access to quality custom fabricated diabetic inserts; conversely, a 14% decrease in payment will always translate into a reduction of patient/beneficiary access. Medicare beneficiaries with diabetes are among the most vulnerable patients due to complications of the disease such as poor circulation and peripheral nerve damage. Medicare beneficiaries who qualify for the Medicare therapeutic shoe program may not be able to tolerate the casting process that is used to fabricate custom diabetic inserts that are molded over a positive model of the patient's foot. Recognition of alternate fabrication techniques, such as those that use a virtual model and direct milling to create an insert that is equivalent, virtually identical to those fabricated using traditional methods, as meeting the definition of "molded to patient model" creates access for many diabetic patients that would not be otherwise able to receive and utilize custom fabricated diabetic inserts. Podiatrists, orthotists, pedorthists, and other providers and manufacturers of diabetic shoes and inserts have embraced the use of CAD-CAM as an effective means of creating a digital model of the patient's foot that is as precise as physical models created from plaster or foam. These digital models are used to direct

mill custom fabricated, total contact diabetic inserts that are indistinguishable from those that are molded directly over a positive model of the patient's foot and should be recognized as identical by CMS.

While AOPA appreciates CMS' efforts to acknowledge advanced technology and support efforts to reduce provider burden, we must express significant concern regarding information contained in the FAQ document as well as information that was disseminated during the Special Open Door Forum.

As further background, these diabetic shoe inserts which comprise 0.0689% of the Medicare spend for diabetic beneficiaries have been reimburse at roughly $45, and Medicare has indicated its desire to reimburse 14% less, or roughly $38 as to those inserts fabricated using the CAD-CAM scanning process, without a positive model of the patient. Few, if any, providers cover their costs at the present $45 reimbursement—it is hard to imagine how one could provide a patient visit to secure the model (whether via casting or virtually by scanning), fabricate the device, deliver the device to the patient, bill Medicare for it, and cover costs for any subsequent costs like ADRs, audits, and occasional ALJ hearings and not have costs well in access of the $45. Health care professionals, be they podiatrists, orthotic professionals or others provide these primarily as a service, a 'loss leader,' for the convenience of patients, some of whom may also have other needs met within the health care provider's practice. So, the suggested Medicare reduction of 14% to $38, most likely will prompt many of these well-intentioned health practitioners to say—"enough!" and withdraw from selling these low price, loss leader inserts.

Additionally, CMS does not have any business looking into the manufacturing process in the first place—there is certainly no Congressional delegation of authority to CMS over manufacturing processes. Congress has delegated authority over manufacturing/fabrication processes to the Food and Drug Administration, which exercises substantial controls under their federal Good Manufacturing Practice regulations which have large sections dedicated to regulating manufacturing processes. So, FDA, which does have Congressional authority over both the legality of marketing new and "me too" devices as well as manufacturing processes, has allowed fabrication of diabetic shoe inserts using scanning without a positive model of the patient as a 510(k) "me too," the same device as the more traditional casting method of fabrication. Remarkably, CMS, which does **not** have Congressional authority over either the legality of marketing new or "me too" devices or manufacturing process, is attempting to abrogate authority it does not possess to negate FDA's findings, and instead postulate that diabetic shoe inserts using scanning without a positive model of the patient is NOT a "me too" but is a new device, requiring different coding. CMS is obliged to defer to FDA both as to manufacturing/fabrication, and as to whether technologically advanced processes constitute a new device and need for different code treatment.

AOPA's specific concern is in regard to question 12 of the FAQ which asks about Medicare pricing for inserts that are created through the combination of a digital model and direct milling process. The CMS response to this question states the following:

> "The 2018 fee schedule amount would be $38.67, based on the requirements of section 1833(o)(2)(A) and 1834(h) of the Social Security Act. This amount is based on the payment limit established in the statute in 1988 for therapeutic shoe inserts, updated by the covered item update factors at section 1834(h)(4) of the Social Security Act."

AOPA understands the regulations that dictate the pricing of Medicare covered services including the gap-filling methodology used to deflate pricing to 1988 levels and subsequent application of annual update factors. However, we must question how, after appropriate deflation and inflation factors were applied, CMS arrived at the fee for direct milled, custom fabricated diabetic inserts. These inserts are equivalent, "me too's" of the long-standing A5513 version fabricated from a positive model of the patient and they must have the identical reimbursement, regardless of fabrication process. CMS' approach seems contrived to extract an arbitrary fee that is less than the current allowed amount for inserts described by A5513 and more than direct formed inserts described by A5512. Again, AOPA must point out that the only difference between custom fabricated inserts that are physically molded over a positive model of the patient's foot and those that are direct milled based on a virtual model of the patient's foot is in the fabrication technique. The insert itself is of the exact material thickness and shore durometer regardless of how it was fabricated. There seems to be a disconnect between the proposed change to the DMEPOS quality standards which includes direct milled inserts in the definition of the term "molded to patient model" and the CMS statement that direct milled inserts will be reimbursed at a lower rate than other inserts that are classified as molded to patient model. A 14% reduction in reimbursement for inserts manufactured with advanced technology is not consistent with CMS' efforts to recognize technological advancements and will make these items more of a loss leader, potentially causing companies to pull out of this line of business and thereby decrease access to this important preventive care option that actually decreases total health costs of the diabetic patient in the long run.

AOPA strongly believes that if CMS is willing to propose a change to the DMEPOS quality standards that will accept and acknowledge the use of digital models to direct mill custom fabricated inserts to meet the definition of molded to patient model, the inserts must be appropriately coded using A5513 and reimbursed fully according to the established Medicare fee schedule for A5513. The current average Medicare allowable amount for custom fabricated diabetic inserts that are described by HCPCS code A5513 is approximately $45. This amount already represents a loss leader for providers as it includes all components of the delivery of the insert including patient evaluation, fabrication and fitting of the insert, any necessary follow up care and adjustments, and preparation and submission of a claim to Medicare. The cost to provide all of the

components necessary to deliver a custom fabricated diabetic insert certainly exceeds the current Medicare reimbursement rate for A5513. An arbitrary 14% reduction in the allowed amount for custom fabricated inserts that utilize a virtual model and direct milling fabrication process to create an insert that is identical in quality and material to those molded over a physical model of the patient's foot will represent further loss to providers. Unfortunately, providers will be forced to consider whether they can financially provide inserts that are fabricated using this technology at a reimbursement rate that will result in a significantly higher net loss than already exists under the current fee schedule for A5513 and may limit Medicare beneficiaries' access to this technology as a result. As stated earlier in its comments, AOPA believes that any changes to policy or regulation must be done so with the interests of the Medicare beneficiary as the most important factor in the decision. Limiting access to technology through arbitrary reductions in reimbursement is not in the best interest of Medicare beneficiaries. The proposed change to the DMEPOS Quality Standards acknowledges that the use of a virtual model to direct mill a custom fabricated, total contact diabetic insert meets the definition of "molded to patient model". This acknowledgement should be extended to include classification of custom fabricated direct milled inserts as appropriately coded using A5513, including reimbursement at the same rate.

AOPA's concern was certainly not alleviated during the Special Open Door Forum when AOPA asked the following question:

"The DME MACs have essentially been looking for a signal from CMS that they should pay these "positive model of patient" codes, if the final custom-fab devices is as good or better. Instead of doing that, CMS now seems committed, apparently without any public/expert/stakeholder in whatsoever, to extracting a 14% toll from providers if they use a process that results in an equivalent device for the patient. Since this is contrary to the provision in the Medicare Claims Processing Manual provision that requires identical allowable whenever a code is "exploded" is there either an administrative/rule making process or precedent for this effort by CMS to spin off a new 'in between' code, instead of continuing to pay for this device as an A5513?"

The reply from Joel Kaiser of CMS was neither very responsive nor dispositive. In his response, Mr. Kaiser frequently referenced the past history of fraud and abuse involving diabetic inserts. An historic view of codes and environment in the early 1990's, while interesting, is (a) not relevant in a post-ACA, computer-driven environment of new technologies today. CMS' response would ignore the statutory 'productivity adjustment,' of ACA that anticipated greater efficiency and automatically extracts annual, and repeated Medicare fee reductions in payment to account for those improved efficiencies and technologies; (b) violates the Medicare Claims Processing Manual, and (c) would break precedent with CMS action in past instances where codes have been 'exploded.' AOPA believes that CMS should consider a policy where equivalent devices derived using new technologies, such as direct milling based on virtual models should retain identical coding with the equivalent device, with CMS being free to occasionally,

but certainly not universally, to request that the fabricator generate a positive model from the results of the scan.

In response to the question regarding the 14% reduction in reimbursement for custom fabricated, direct milled diabetic inserts, Mr. Kaiser stated that the statute is very clear regarding establishing the fee schedule amount for new devices and that a base price would be established either through historical prices available from the base year in the statute, 1987 for DMEPOS, or by "gap filling" based on current prices of "comparable equipment". AOPA would like to reiterate that custom fabricated, direct milled diabetic inserts are not a new device, but rather a new fabrication technique that is used to create a device adequately describe by A5513. Mr. Kaiser did not provide any information on how the base price for direct milled, custom fabricated diabetic inserts was established, subsequently deflated and inflated using the gap-filling methodology, and ultimately arriving at an "anticipated value" of $38.67. Mr. Kaiser also did not explain how or why an alternate fabrication technique that uses new technology to create an identical device would warrant the calculation of a new fee schedule amount to begin with. AOPA considers this result as completely inconsistent with established precedent, without any process for stakeholder input, contrary to innovation, contrary to the federal statute's annual productivity adjustment, and violative of the Medicare Claims Processing Manual. So, Mr. Kaiser did not address the instructions memorialized in section 60.3.1 of chapter 23 of the Medicare Claims Processing Manual that states, **"when there is a single code that describes two or more distinct complete items (e.g., two different but related or similar items), and separate codes are subsequently established for each, continue to apply the fee schedule amounts that applied to the single code to each of the items described by the new codes."** Since the only difference between direct milled and molded to patient model diabetic inserts is in the method used to fabricate them, they are clearly equivalent items fabricated via similar but not separately identified process and therefore should continue to be reimbursed at the same amount established for A5513 per CMS' own instructions. Advancements in technology or improvements in manufacturing processes do not always result in new devices and should not result in the establishment of reduced reimbursement.

Mr. Kaiser did mention repeatedly during the Special Open Door Forum that the fee schedule that was established for A5513 included reimbursement for creating a positive model of the patient's foot and since there is no positive model created when fabricating direct milled inserts they cannot be reimbursed at the same level as A5513. AOPA believes that this logic is flawed for several reasons, most notably the direct conflict with instructions in the Medicare Claims Processing Manual. Additionally, if the reimbursement for direct milled inserts is reduced arbitrarily to account for the absence of a physical positive model, this reduction—one which is anticipated by the ACA's productivity adjustment--does not follow the requirements of the statute that Mr. Kaiser referred to during the call. In addition, CMS has already implemented a 2% reduction each and every year since 2011 in reimbursement for DMEPOS codes through the ACA

initiated productivity adjustment which by definition accounts for lower fabrication costs through the use of technology. Establishing a lesser reimbursement for custom fabricated, direct milled inserts appears to penalize providers twice for utilizing innovative technology to create equivalent, inserts through an alternate fabrication technique.

AOPA understands the history of fraud and abuse that is asserted to have led to the creation of very specific descriptors for diabetic inserts but that history is no longer relevant. The specific requirements for base layer thickness and durometer of the inserts in the current HCPCS code descriptors for diabetic inserts has effectively eliminated any past issues of fraud and abuse that occurred twenty plus years ago. CMS' acknowledgement of the use of a digital model to create a custom fabricated diabetic insert through a direct milling process as meeting the definition of "molded to patient model" required by the DMEPOS quality standards shows its commitment to the acceptance of new technology. This acknowledgement should not be undermined by unfairly lowering reimbursement levels arbitrarily and likely contrary to the statute, therefore restricting Medicare beneficiary access to technology that creates an equivalent insert to those made by molding the insert over a model of the patient's foot. The only seemingly legitimate interest by CMS could be comparing the two outcome products for equivalency—that could be achieved by occasionally asking manufacturers who use the scanning technology to deliver a sample patient model for use to confirm manufacturing process equivalency.

In summary, AOPA generally supports the proposed change to the DMEPOS Quality Standards that would acknowledge the use of a virtual model to create a custom fabricated, direct milled diabetic insert as meeting the definition of "molded to patient model". AOPA does not support the subsequent information that was published in the CMS FAQ document nor the information that was disseminated during the Special Open Door Forum. Likewise, AOPA cannot support an arbitrary reduction in reimbursement for diabetic inserts custom fabricated form a virtual model that are identical to those that are custom fabricated from a positive model of the patient's foot. The proposed reduction in reimbursement is not based on a legitimate process, is contrary to Medicare's own instructions in the Medicare Claims Processing Manual, and has CMS reversing the decisions of FDA, the only federal entity to which Congress has delegated authority relating to identifying truly new medical devices and regulation manufacturing/fabrication processes. AOPA believes that due to the fact that inserts that are fabricated over a positive model of the patients foot and inserts that are created using a virtual model and direct milling process are essentially identical, both in material thickness and shore durometer, and according to CMS' proposal, both meet the definition of "molded to patient model." They have equivalent measurements, are identical in appearance and performance, and so they should both be properly classified under existing HCPCS code A5513 and reimbursed according to the established Medicare fee schedule for A5513.

From a patient's perspective, CMS and its contractor's actions on this issue is confusing at best and may lead to unnecessary medical complications at worst. First, the DME MACs stated that direct milled inserts did not meet the definition of A5513 and therefore were not eligible for Medicare coverage and must be billed using A9270 (non-covered service). This would require Medicare beneficiaries to pay for these inserts directly. Then CMS proposed a change to the DMEPOS Quality Standards that would recognize direct milled inserts to meet the definition of "molded to patient model". This apparent good (and logical) news was followed up by an announcement of an unsupported, largely incomprehensible and illegal suggestion of a 14% reduction in reimbursement for inserts that are identical to those that have been previously classified as A5513 but utilize the direct milling process in fabricating the insert. This reduction in reimbursement will surely drive providers away from a market that they have continued to operate in at a loss in order to provide quality patient care. Medicare beneficiaries surely deserve better, even as to a device that comprises only 0.0689% percent of Medicare diabetic costs, but which makes it less likely that the Medicare beneficiary will suffer an amputation.

In addition to the comments above, AOPA has been a party to and entirely supports the comments of the Orthotic and Prosthetic Alliance which will be submitted separately.

Please feel free to contact me directly at (571) 431-0802 or via e-mail at tfise@aopanet.org or Joe McTernan at (571) 431-0811 or jmcternan@aopanet.org to discuss AOPA's concerns regarding the proposed changes to the DMEPOS Quality Standards.

Sincerely,

Thomas F. Fise
Executive Director

cc: Rep. Pat Tiberi

Rep. Brad Wenstrup

Demetrios Kouzoukas

Carla DiBlasio

Kim Brandt

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