November 29, 2017

Melanie Combs-Dyer
Director, Provider Compliance Group
Center for Program Integrity
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-8013

Dear Ms. Combs-Dyer,

The American Orthotic and Prosthetic Association (AOPA) would like to express its sincere appreciation to CMS for hosting the November 27, 2017 Special Open Door Forum regarding proposed changes to the DMEPOS Quality Standards addressing the use of a digital image to direct mill custom fabricated diabetic inserts. While the session was informative, AOPA has concerns that it would like to have addressed.

During the Special Open Door Forum, 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 <u>equivalent</u> 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 Mr. Kaiser 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.' CMS should consider a policy where equivalent devices derived using new technologies (like scanning) 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". Mr. Kaiser did not, however, 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. Again, we consider that result as completely inconsistent with established precedent, without any process for stakeholder input, contrary to innovation, 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 Carriers 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 different but related and equivalent items and therefore should continue to be reimbursed at the same amount established for A5513 per CMS' own instructions.

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 based on the instructions in the Medicare Carriers Manual. Additionally, if the reimbursement for direct milled inserts was reduced arbitrarily to account for the lack of a positive model, this reduction—one which is anticipated by the 2009 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 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 better, more efficiently made inserts.

As stated above, AOPA understands the history of fraud and abuse that 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 past issues of fraud and abuse. 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 lowering reimbursement levels arbitrarily and 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.

AOPA appreciates the opportunity to provide specific feedback regarding issues that were discussed during the Special Open Door Forum. In addition to the concerns addressed in this letter, AOPA will submit extensive comments on the proposed changes to the DMEPOS quality standards prior to the December 11, 2017 deadline.

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 specific concerns regarding the discussion during the Special Open Door Forum.

Sincerely,

Thomas F. Fise
Executive Director

cc: Rep. Pat Tiberi

Rep. Brad Wenstrup

Demetrios Kouzoukas

Carla DiBlasio

Kim Brandt

Laurence Wilson

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