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Stacey V. Brennan, M.D., FAAFP
Medical Director, DME MAC, Jurisdiction B
National Government Services
8115 Knue Rd
Indianapolis, IN 46250-1936

Submitted Electronically to: DMAC_Draft_LCD_Comments@anthem.com

Dear Dr. Brennan:

The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a national membership that draws 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 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 believes that the draft LCD and Policy Article for lower limb prostheses that was published on July 16, 2015 is inherently flawed in both its intent and content and requests that it be rescinded immediately to allow appropriate time for productive discussions between the DME MAC Medical Directors and affected stakeholders including, but not limited to Medicare beneficiaries, physician organizations, orthotic and prosthetic organizations, amputee advocacy groups, and other interested parties. The proposed revision to the LCD and Policy Article is being inappropriately used to try to fundamentally change the L code system which is concise and is a proven methodology currently used to accurately code prosthetic devices. It negates the established K-levels and the criteria for which Medicare amputees are eligible to receive what types of prostheses, and also the way that lower limb prosthetic services are delivered to Medicare beneficiaries. The provisions of the draft LCD and Policy Article, in its current form, will severely restrict access to clinically appropriate and medically necessary prosthetic care, in a timely manner, to Medicare beneficiaries, resulting in significant harm to Medicare eligible amputees. An immediate rescission of the draft LCD and Policy Article, followed by productive discussions with affected stakeholders who possess a stronger knowledge regarding the standard of care for amputees than is

evidenced in this proposal is the only way that a reasonable policy that protects the integrity of the Medicare program while ensuring continued access to prosthetic services that most appropriately meet the specific clinical needs of the individual patient can be created. Providing a limited public comment period largely over a Congressional recess period, including a relatively brief meeting to allow for members of the public to express their concern about the draft policy does not, in any way, allow for sufficient opportunity for affected stakeholders to participate in the LCD and Policy Article development process.

While AOPA firmly believes that the pathway outlined above remains the only viable method to develop fair and meaningful policy governing Medicare coverage of lower limb prostheses, it is our obligation and responsibility to submit the following comments regarding our concerns about the draft LCD and Policy Article in its current form. AOPA's comments will include both general comments regarding its overall concern about the draft LCD and Policy Article followed by detailed comments regarding each section of the draft LCD and Policy Article. AOPA's comments will identify serious flaws within the draft LCD and Policy Article which may significantly impact a Medicare beneficiary's ability to continue to receive a high quality, clinically appropriate prosthesis that best meet their specific medical needs. However, we must emphasize that this proposal is not one that could be fixed with a few incremental changes; it is a seriously misguided pathway to retrenchment, to lower quality care and reduced independence for amputees that cannot be the framework for any viable policy. AOPA looks forward to working with you and the other DME MAC medical directors on developing a more reasonable policy that, first and foremost, considers the needs of the patient while also maintaining the integrity of the Medicare program.

General Concerns Regarding the Draft LCD and Policy Article

AOPA notes at the outset that the Local Coverage Determination ("LCD") at issue was simultaneously issued by all four of the DME MAC contractors nationwide. This, by definition, means the LCD is **not** a ***local*** determination. Nor is it a National Coverage Determination ("NCD") because it does much more than define what is and is not a covered reimbursement by Medicare. The complex of determinations, requirements, conditions and conclusions works a dramatic change in policy, provides legal conclusions, and otherwise promulgates legislative rules beyond the purview of the Medicare contractor's duties in making these determinations.

Such sweeping changes to Medicare policy can only be done by the Centers for Medicare and Medicaid Services (CMS) through its rulemaking procedures and subsequent public comment period. We worry that this change was implemented as an LCD instead of a CMS rulemaking to avoid providers' appeals, because although

providers can assist in beneficiaries' appeals of LCDs and NCDs, they may not initiate those appeals on their own.

The Draft LCD and Policy Article Would Restrict Medicare Beneficiary Access to Clinically Appropriate Prosthetic Care

AOPA believes that the draft LCD and Policy Article, in its current form, would severely limit a Medicare beneficiary's access to high quality, medically necessary prosthetic care. The draft LCD and Policy Article indicates that before a patient may receive a definitive prosthesis, they must first be fit with an immediate prosthesis for use while the post-amputation surgical incision is healing, followed by a preparatory prosthesis, consisting of only basic components, that will be used during a required rehabilitation program after the surgical incision is healed. According to the draft LCD and Policy Article, the provision of a definitive prosthesis will only be considered for coverage after these two previous steps have taken place. This is NOT the current standard of care—Medicare would be practicing medicine and writing a totally new, different, and deficient standard of care if the policy espoused in this proposal is finalized—one tantamount to a rationing program. The concept of requiring every amputee to be fit with an immediate post surgical prosthesis, followed by a preparatory prosthesis, and only then, a definitive prosthesis, represents archaic and antiquated standards of care for amputees. While there may be some amputees who may require this full progression of prosthetic care from amputation to provision of a definitive prosthesis, the draft LCD and Policy Article should not require all amputees to be fit with an immediate post surgical or preparatory prosthesis before they are eligible to be fit directly with a definitive prosthesis. Amputees are not "one size fits all"; they are individuals who may benefit clinically from the provision of a definitive prosthesis as soon as their physician and prosthetist believe they are able to do so. Requiring the progression from an immediate prosthesis, to a preparatory prosthesis, and finally to a definitive prosthesis will place arbitrary restrictions on the patient's clinical progress that will result in unnecessary delays in care, additional costs to both the Medicare program and the patient, and the denial of patient access to the most clinically appropriate prosthetic devices for the specific patient's individual needs.

The draft LCD and Policy Article contains a particularly egregious and discriminatory provision that classifies Medicare beneficiaries who use a walker or crutches as K1 functional level ambulators and Medicare beneficiaries who use a cane as K2 functional level ambulators regardless of their ability to use a prosthesis to qualify for higher functional status. In addition, the draft LCD and Policy article precludes coverage of a prosthesis for those amputees who cannot achieve "the appearance of a natural gait" while wearing the prosthesis. These statements, offensive to amputee Medicare beneficiaries, do not define any objective criteria for a 'natural gait.' An unconventional gait may, in fact, promote independence and future successful rehabilitative outcomes.

The statements are not supported by any scientific study that justifies the elimination of prosthetic coverage for amputees who cannot achieve a natural gait while wearing the prosthesis and the restriction or limitation of otherwise qualified individuals to lower functional status and, by default, limits Medicare beneficiaries who may require the temporary or full time use of a walker, crutches or a cane to ensure their safety and stability to only basic prostheses that are typically provided to household or limited community ambulators. The occasional use of a walker, cane, crutches or even a wheel chair is actually quite common for qualified community ambulators, whether because of a very active day that creates soreness or routine bathroom access during the night. Occasional use of such assistive devices among those wearing a prosthesis should have no bearing on the functional assessment of the patient and assignment of their functional level. To do so, i.e., to exclude these patients from eligibility for K-3 prostheses can only be considered as a discriminatory and potentially illegal practice.

The draft LCD and Policy Article contain provisions that require the patient to be cognitively capable, have sufficient neuromuscular control, and sufficient cardio-pulmonary capacity to effectively use a prosthesis while ambulating in order to be eligible for a prosthesis, especially those rated for use by amputees who are evaluated as K3 or higher ambulators. While co-morbidities, often very minor or well-controlled such as these may be considered when determining the style and type of prosthesis that best meets the patient's clinical and functional needs, they should not create barriers to coverage for patients with unrelated health conditions that may have no bearing on their ability to effectively use a prosthesis. Limiting access to proper prosthetic care for patients with additional health considerations is not in the best interest of providing overall quality healthcare or advancing independence by Medicare amputee beneficiaries.

AOPA understands the importance of rehabilitation as an integral part of a Medicare beneficiary's ability to use their prosthesis in a clinically appropriate and efficient manner. With that understanding in mind, the specific requirements in the draft LCD and Policy Article that the patient must successfully complete a comprehensive rehabilitation program prior to receiving a definitive prosthesis again appear to be arbitrary and not necessarily in the best interest of providing the prosthetic care that best meets the individual medical needs of the patient. For patients, especially those that reside in rural areas, that do not have readily available access to amputee specific rehabilitation programs, these requirements may prevent them from being eligible to receive any prosthetic intervention. For these patients, the draft LCD and Policy Article leaves them no option other than the use of a wheelchair to perform their activities of daily living. Patients should not be denied the right to walk after an amputation simply because they do not live in an area of the country where rehabilitation programs that meet the arbitrary requirements of the draft LCD and Policy Article are available.

AOPA believes that the restriction on the provision of a definitive prosthesis for 90 days following provision of a preparatory prosthesis may not be in the best interest of achieving the best outcome for the patient. AOPA believes that coverage of a definitive prosthesis should be available as soon as the patient is able to effectively ambulate using a definitive prosthesis, and patients should not be made to wait for 90 days in situations where their progress has exceeded the clinical benefit of a preparatory prosthesis.

In addition, the draft LCD states that any adjustments, repairs, or component replacements for the first 90 days following delivery of the prosthesis are included as part of the delivery of the prosthesis. This statement does not allow separate reimbursement for adjustments, repairs, or component replacement caused by loss, theft, irreparable damage or a change in the patient's condition or functional abilities. AOPA believes that adjustments, repairs, and component replacement necessitated by one of the circumstances above should continue to be eligible for separate reimbursement even when it is required within the first 90 days after delivery of the prosthesis.

Finally, the draft LCD and Policy Article indicates that Medicare coverage is limited to one socket code and descriptor per individual prosthesis. This limitation does not allow for the use of specific socket design features that may be necessary to meet the patient's clinical needs. The HCPCS coding system includes several codes that do not describe complete sockets, but describe specific socket design features (e.g. ischial containment, total contact, etc.). Failure to provide coverage for these medically necessary design features will force amputees to receive basic prosthetic sockets that do not provide the intimate fit and design necessary to maintain a proper interface between the prosthetic socket and residual limb and may result in injury to the patient.

The Draft LCD and Policy Article Can Be Interpreted as Indicating that Immediate, Preparatory, and Definitive Prostheses are All Inclusive Devices and that Addition Codes that Describe Separate Components Are Inappropriate

The statement in the draft LCD and Policy Article that prosthetic base codes are all inclusive and that addition codes should not be used to describe and bill for separate components is completely counterintuitive to the purpose of the L code system. When the L code system was developed in the late 1970s, it was recognized that the most efficient method to describe the virtually endless combination of components that could be incorporated into a prosthesis was to create a relatively small number of base procedure codes that described the most basic form of a particular prosthesis and a series of addition codes that, when billed in conjunction with the appropriate base code, represented the various components that made up the overall construction of the complete prosthesis. This system not only reduced the total number of HCPCS codes

required to describe a particular prosthesis but it also allowed for incorporation of new technology into the existing coding system by allowing the creation of new addition codes to accurately describe the function and features of new prosthetic components as they were introduced to the market. The L code system is truly unique in its base code/addition code nature but it has proven to be a successful system that has been used globally by both public and private payers for more than 35 years. The draft LCD and Policy Article, through its statement regarding the all inclusive nature of base procedure codes, essentially eliminates patient access to anything other than the most basic prosthetic components (e.g. SACH feet, single axis knees) that are included in the base code descriptors. Based on the fact that other sections of the draft LCD and Policy Article discuss, in detail, the appropriate use of addition codes, along with the severe negative impact this restriction would have on Medicare beneficiaries, AOPA must believe that it was not the intent of the draft LCD and Policy Article to restrict the use of the combination of base and addition codes to accurately describe a complete prosthesis.

The Draft LCD and Policy Article Would Wrongly Eliminate Consideration of a Patient's Potential to Achieve a Specific Functional Level Status as Part of the Functional Level Determination

The functional level assessment program has been a long standing and integral part of the lower limb prosthetic policy since its inception. An essential piece of the functional assessment system has not only been a measure of the amputee's current functional capabilities, but the expected functional capabilities of the amputee as they adapt to and become proficient with the daily use of a prosthesis in meeting their mobility needs and performing their activities of daily living. The consideration of a patient's **potential** functional abilities has always been an integral part of the assessment process. The draft LCD and Policy Article remove all consideration of what an amputee can be reasonably be expected to do once they have become proficient in using their prosthesis to ambulate effectively. Elimination of consideration of a patient's potential functional abilities as part of their overall assessment will result in the unnecessary and potentially unsafe restriction on their access to prosthetic services that best meet their long term prosthetic needs. AOPA believes that the elimination of the ability to consider a patient's potential functional abilities when determining which prosthetic devices they qualify for represents an incredible disservice to Medicare beneficiaries.

The Proposed Consolidation of Prosthetic Foot and Ankle Codes Will Severely Limit Medicare Beneficiary Access to Clinically Appropriate and Medically Necessary Prosthetic Foot and Ankle Components

The draft LCD and Policy Article includes a provision that will consolidate prosthetic feet described by HCPCS codes L5976, L5980, L5981, and L5987 into a single, generic

code that describes all dynamic response feet. The prosthetic feet represented by the four HCPCS codes above represent many products available on the market that provide unique and distinctive functions that meet the specific clinical needs of individual patients. Consolidation of these products into a single HCPCS code that does not adequately describe the specific functions of each product will severely limit beneficiary access to these products resulting in potential harm to patients who will be forced to use prosthetic feet that do not adequately meet their individual prosthetic needs.

The draft LCD and Policy Article also includes a provision that would consolidate HCPCS codes L5982, L5984, and L5986 into a single generic code that describes all axial rotation units. AOPA believes that discontinuation of L5986, which describes a multi-axial style prosthetic ankle will limit Medicare beneficiary access to prosthetic ankle components that provide the ability for the ankle to move in multiple planes, providing stability and efficiency to the lower limb prosthesis. Multi-axial style prosthetic ankles are a long accepted standard of care for amputees that require the ability to safely ambulate on uneven surfaces. The elimination of L5986 will force relatively active amputees to utilize single axis or fixed ankles, severely limiting their ability to ambulate effectively and efficiently.

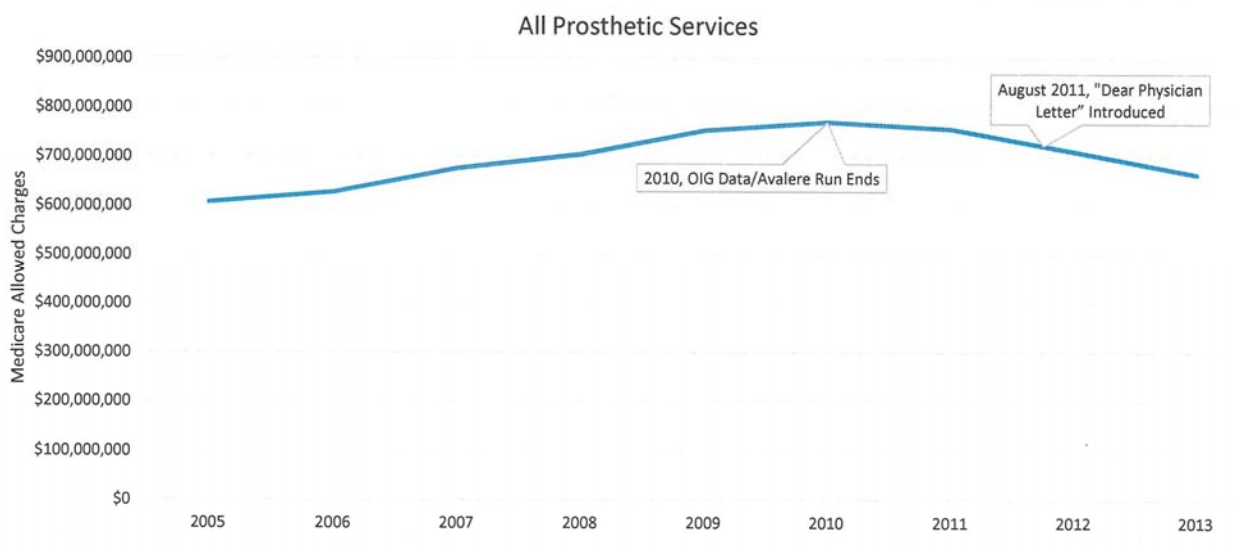
The Draft LCD and Policy Article Completely Removes the Prosthetist from the Rehabilitation Team that Assesses a Patient's Functional Capabilities

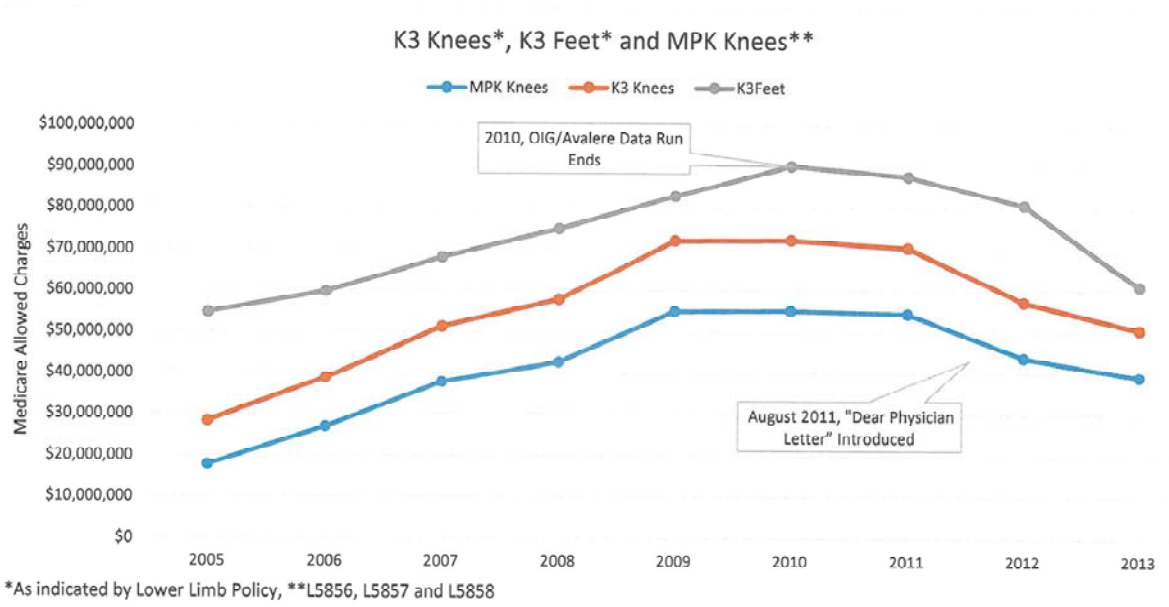
The draft LCD and Policy Article introduce the concept of allowing a licensed/certified medical professional (LCMP) to perform the comprehensive evaluation of an amputee's functional capabilities. The draft LCD and Policy Article state that this comprehensive assessment may be performed by the prescribing physician or delegated by the prescribing physician to the LCMP. The draft LCD and Policy Article defines a LCMP as "a physician (MD/DO), physician assistant (PA), nurse practitioner (NP), or physical therapist (PT) with training, experience, and whose scope of practice permits the comprehensive functional assessment of beneficiaries with amputations." This definition fails to recognize the clinical education, training, and expertise of a licensed or certified prosthetist in performing a functional assessment of an amputee. AOPA contends that licensed or certified prosthetists not only possess the knowledge to perform these functional assessments, but are often the most qualified medical professional to do so. The current minimum educational standard for a licensed or certified prosthestist is a master's level degree, the curriculum of which requires extensive education and training in the performance of functional based assessment of amputees. In addition to a master's degree education, prosthetists must complete an extensive residency program at an accredited residency site followed by a comprehensive written and practical examination before they may obtain certification or licensure as a prosthetist. This education, residency, and examination process far exceeds the majority of education and training available to the medical professionals

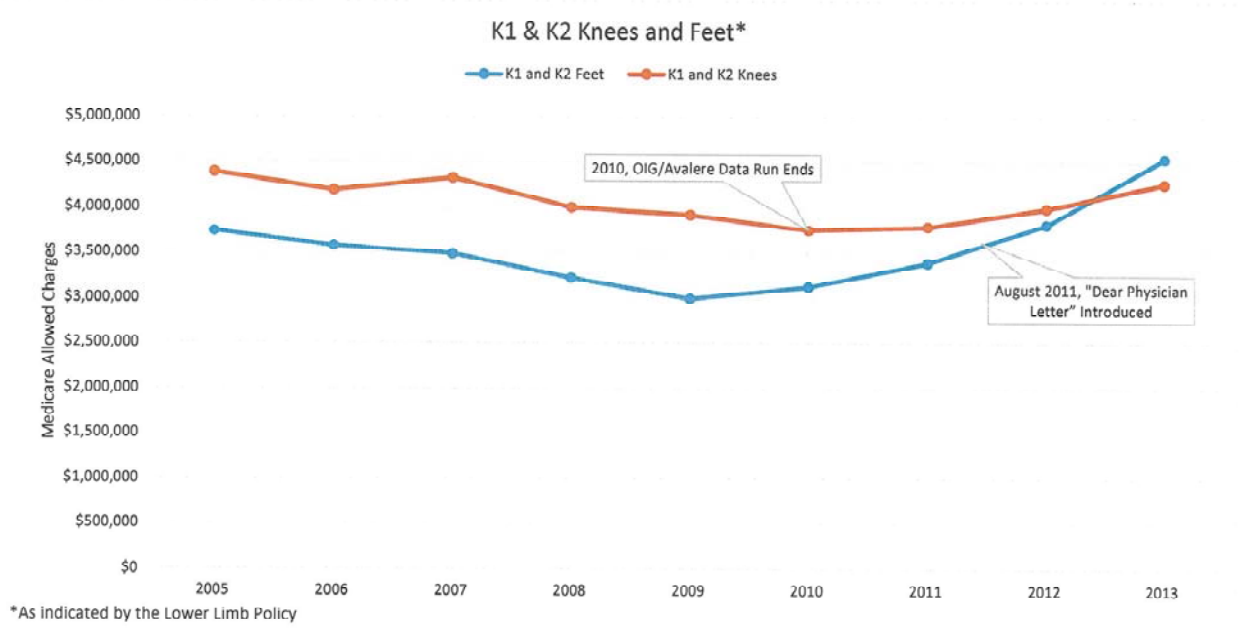
listed in the LCMP definition contained within the draft LCD and Policy Article. Failure to recognize the licensed or certified prosthetist as a LCMP for purposes of performing functional level assessment is a disservice to Medicare beneficiaries and may result in incomplete and inaccurate functional assessment which will further restrict an amputee's access to clinically appropriate and medically necessary prostheses. We are cognizant of the DME MACs' view that the certified or licensed prosthetist may have a potential conflict of/financial interest, and as is well known, we strongly disagree that any potential conflict of/financial interest of the certified or licensed prosthetist is any different than that which occurs with any other health care provider involved in direct patient care. That said, if we were to assume the DME MAC position, the LCMP definition ought to be broadened to include the certified or licensed prosthetist who is not himself/herself, nor is any person in the same practice group, directly treating the beneficiary (as there would not be any real or potential conflict of/financial interest to be addressed in such circumstance).

Concern Regarding Increased Medicare Expenditures for Lower Limb Prosthetics Have Been Addressed Through Other Channels

While AOPA would like to believe that the revisions included in the draft LCD and Policy Article are not motivated by concern over perceived increased Medicare expenditures for lower limb prostheses, a 2011 Office of Inspector General (OIG) report entitled *Questionable Billing by Suppliers of Lower Limb Prostheses* and a 2012 Associated Press (AP) article entitled *Big Rise in Artificial Feet Costs* were both cited as resources in the bibliography of resources that were used to develop the draft LCD and Policy Article. Shortly after the release of the 2011 OIG report, the DME MACs released a "Dear Physician" letter that established more stringent documentation requirements necessary to properly document the medical need for lower limb prostheses. AOPA has gone on record repeatedly to express its concerns about the Dear Physician letter and how it effectively changed policy. Regardless of AOPA's position, a clear result of this letter was a significant reduction in overall Medicare expenditures for lower limb prostheses, specific reductions in Medicare payments for K3 prosthetic feet, knees, and microprocessor controlled knees, and a concomitant increase in Medicare payments for K1 and K2 prosthetic feet and knees. The charts below represent Medicare paid claims data from 2005 through 2013 and provide a visual reference of the Medicare expenditures in question and the impact of the OIG report, the AP article and the Dear Physician letter on the specific Medicare expenditures.







Any purported aberration resulting in higher Medicare prosthetic costs were clearly reversed between 2010 and 2011, before either the OIG report or the Dear Physician letter. For better or worse, probably the latter, Medicare and its contractors precipitated a change, i.e., a reduction in quality of Medicare amputee patient care. The 2010-13 trend line is irrefutable evidence of this change. If the revisions included in the draft LCD and Policy Article are in any way financially motivated, AOPA contends that significant reductions in overall Medicare expenditures for lower limb prostheses and specific reductions in Medicare expenditures for K3 prosthetic feet, knees, and microprocessor controlled knees have already occurred, far beyond what should have. Financial concerns should not be addressed through policy based solutions—the changes to standard of care reflected in the above charts cannot be justified by the now 5-10 year old data that prompted the OIG report and the Dear Physician letter. The downward trends in 2010-13 dramatically demonstrate that any 2005-10 trending is now irrelevant ancient history.

Literature Resources Contained in the Bibliography Published on August 4, 2015 Do Not Support the Provisions of the Draft LCD and Policy Article

The draft LCD and Policy Article is not based at all on the current literature and science associated with the provision of prosthetic care. The proposed LCD and Policy Article is unsupported by anything resembling scientific/medical/literature justification. A bibliography was circulated in response to a request from AOPA which cited the portion of the DME MAC's own rules that assure scientific support as prerequisite for

development of any new or significant revision to an existing LCD and Policy Article. According to the CMS *Provider Integrity Manual* (PIM), section 13.7.1 - Evidence Supporting LCDs (Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13*)*:

LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question.

The bibliography that was published is haphazard at best, including news articles and legislative bills introduced but never enacted. The articles referenced as supposedly supporting the draft LCD and Policy Article have no bearing on any of the policy changes described in draft LCD and Policy Article. Indeed, many of them could be used to refute the proposed changes. Further, these references do not support the significantly diminished quality of care that beneficiaries would receive if the proposed changes were implemented. It is also clear that some of the articles referenced in the bibliography are not accessible for evaluation and comment, calling into greater question the quality of the science behind the DME MACs' proposed decision making.

The draft LCD and Policy Article is devoid of published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, the proposed changes are not supported by sound medical evidence, scientific data or published peer reviewed research studies. The current standard of practice is however fully supported by sound (peer reviewed) scientific evidence.

The changes proposed are not consistent with the current standard of practice, they are not derived from consultation with the referenced authors, indeed many of the experts cited in your bibliography have gone on record to strongly oppose the draft LCD and Policy Article stating that the proposed changes would diminish both the quality and access to prosthetic care across our nation.

The Draft LCD and Policy Article Memorializes Unrealistic and Unreasonable Requirements for Proof of Delivery Documentation

On February 12, 2015, the DME MACs published a joint bulletin that clarified the requirements for proof of delivery documentation. This clarification indicated that a list of HCPCS procedure codes and their official CMS descriptors did not provide adequate information about the device or components of a device that were delivered to the patient because it did not allow claims reviewers to verify the proper coding of the device or components by the supplier. The DME MAC bulletin indicated that proof of delivery documentation must include either a brand name/model number/serial number

for each component that was billed separately, or a complete narrative description (not the HCPCS code descriptor) of each component that was billed separately. Since the publication of this bulletin, there has been a marked increase in claim denials based on incomplete proof of delivery documentation. AOPA is on record in a recent request for CMS re-consideration regarding its concern over this bulletin and whether requiring a brand name, model number, or serial number on proof of delivery documentation represents a de facto labeling requirement. As labeling of medical devices lies within the specific authority of the FDA, not CMS or its contractors, AOPA believes the inclusion of the requirements from the February 12, 2015 bulletin in the draft LCD and Policy Article is incorrect and should be removed.

The Draft LCD and Policy Article will Have an Adverse Impact on ALL Amputees in the U.S

The clinically inappropriate and misguided provisions in the draft LCD and Policy Article will have a devastating impact, not just on Medicare amputee beneficiaries, but on all of the 2 million amputees in the U.S. Commercial payers tend to follow Medicare's policy lead. According to the Amputee Coalition there are roughly 2 million persons in the U.S. living with limb loss, and there are approximately 185,000 new amputees each year. Medicare's data for 2009 showed over 2 million prosthetic services with a total expenditure of $655 million including new prosthetic feet for 36,600 Medicare beneficiaries. Extrapolating, it appears there are likely about 10 million prosthetic services per year including all payer sources—those 10 million services and 2 million amputees will be affected by this policy—it must be accurate, reflect current best practices, with strong scientific support, and must not revert these 2 million amputees to an earlier, lesser standard of care. This proposal fails under each of these criteria.

The Draft LCD and Policy Article Would Have an Immediate and Negative Economic and Environmental Impact on Small Business Based Providers

AOPA believes that the draft LCD and Policy Article, in its current form, would have an immediate and negative environmental and economic impact on small business based providers. As private insurers often follow Medicare's lead in establishing medical policy governing coverage of prostheses, the proposed changes in the draft LCD and Policy Article can be expected to be reflected in the medical policies of both large and small private payers. The potential environmental and economic impact of the proposed policy changes on prosthetic providers, the vast majority of whom qualify as small businesses, is immeasurable. All proposed major policy changes must consider the potential environmental and economic impact on small business interests. In the case of the draft LCD and Policy Article, AOPA is not aware of any study or discussion on the potential impact the proposed changes would have on small business interests.

AOPA Concerns Regarding Specific Provisions within the Draft LCD and Policy Article

While AOPA has expressed our overall concern regarding the draft LCD and Policy Article in the paragraphs above, we would like to also address our specific concerns regarding the following individual provisions contained in the draft LCD and Policy Article.

Definitions

AOPA is concerned that the definition of an initial prosthesis as the first prosthesis reimbursed by Medicare, including a prosthesis provided for the first time after an amputation that occurs during the beneficiary's Medicare eligibility and replacement of an existing prosthesis obtained prior to or outside of the Medicare program may lead to confusion as HCPCS codes L5500 and L5505 both incorporate the term "initial" to describe direct prostheses that are fabricated using a direct formed to the patient, plaster socket. While these terms have very different meanings within their individual context, it is confusing to use the term "initial" to describe any style of prosthesis that is paid by Medicare as the first prosthesis for which the Medicare program provides coverage.

AOPA is concerned that the draft LCD uses the term "replacement prosthesis" to not only describe the complete replacement of an existing, definitive prosthesis, but also replacement of a major component of a prosthesis. There should be clear distinction between replacement of a complete prosthesis as compared to replacement of one or more components of a prosthesis. Replacement of components of a prosthesis should be addressed elsewhere in the LCD.

AOPA believes that in its definition of the term "immediate prosthesis" the LCD overlooks the HCPCS codes that describe immediate prostheses (L5400-L5460) not only describe immediate post surgical fitting, but also include the term "or early fitting." While most prostheses described by these codes are fit in the inpatient hospital setting, primarily during or immediately following amputation, there should be a reference to early fittings that may occur soon after surgery, including those that are fit after the patient is discharged from the inpatient setting.

AOPA believes that the description of a preparatory prosthesis as "unfinished" implies that the prosthesis is incomplete and not fully functional for use.

AOPA is concerned about the inclusion of the term "meeting standards for comfort, fit, alignment, function, appearance, and durability" in the LCD definition of a definitive prosthesis. There must be additional clarification regarding what qualifies a residual limb as mature. While the LCD defines a mature limb as one that has healed, reached

its optimal volume, and been shaped appropriately to accommodate the chosen socket configuration, it does not address the fact that residual limbs continue to change in volume and shape for a significant period of time after healing has occurred and a definitive prosthesis has been provided.

AOPA questions whether the definition of a Licensed or Certified Medical Professional (LCMP) and the requirement that their scope of practice permits the comprehensive functional assessment of beneficiaries with amputations should extend beyond the practitioners listed in the definition (Physician, Physician Assistant, Nurse Practitioner, or Physical therapist) to include Certified or Licensed Prosthetists. While AOPA understands the desire to use LCMPs without a direct financial interest in payment of a claim, the education, knowledge, and training of a certified or licensed prosthetist clearly also qualifies a certified or licensed prosthetist, who among those listed as potential LCMPs has by far the most training and experience with treatment including "comprehensive functional assessment of beneficiaries with amputation." We are cognizant of the DME MACs view that the certified or licensed prosthetist may have a potential conflict of/financial interest, and as is well known, we strongly disagree that any potential conflict of/financial interest of the certified or licensed prosthetist is any different than that which occurs with any other health care provider involved in direct patient care. That said, if we were to assume the DME MAC position, the LCMP definition ought to be broadened to include the certified or licensed prosthetist who is not himself/herself, nor is any person in the same practice group, directly treating the beneficiary (as there would not be any real or potential conflict of/financial interest to be addressed in such circumstance).

Immediate Prostheses

AOPA believes that the classification of initial prostheses described by L5500 and L5505 are incorrectly classified as preparatory prostheses. Prostheses represented by these HCPCS codes are complete prostheses that are fit immediately following surgery using a direct formed socket made of plaster and therefore should be classified as immediate prostheses. Classifying these prostheses as preparatory prostheses will not allow an amputee to be fit with a more durable preparatory prosthesis for use in preparation for fitting with a definitive prosthesis and may result in harm to the patient through the use of these prostheses for longer than is clinically beneficial. In addition, the LCD must not limit coverage of immediate prostheses to above knee or below knee amputations. Coverage must also be available for hemi-pelvectomy, hip disarticulation, and knee disarticulation amputations.

AOPA believes that the LCD must clarify that immediate prostheses will be denied as not medically necessary if the patient is unable or unwilling to use a prosthesis prior to fitting. If the patient indicates willingness to use the prosthesis prior to fitting, but for

reasons beyond the control of the prosthetist, is unwilling or unable to use the prosthesis after fitting, economic fairness demands that the immediate prosthesis should remain covered.

Preparatory Prostheses

AOPA believes that coverage for preparatory prostheses must be expanded to include patients who have had a hemi-pelvectomy, hip disarticulation, or knee disarticulation amputations in addition to above knee and below knee amputations listed in the LCD. AOPA is concerned about the requirement that a preparatory prosthesis is only covered after the surgical incision has healed. Preparatory prostheses should be covered once the surgical incision has healed sufficiently to allow for effective prosthetic intervention. AOPA is also concerned that preparatory prostheses will be denied as not medically necessary when fitted to a mature residual limb. The term mature is extremely arbitrary and does not account for continuous limb volume changes that may occur for some time after the amputation.

Definitive Prostheses

AOPA believes that coverage for definitive prostheses must be expanded to include patients who have had a hemi-pelvectomy, hip disarticulation, or knee disarticulation amputations in addition to above knee and below knee amputations listed in the LCD. AOPA is concerned about language in the LCD that prohibits coverage of a definitive prosthesis until the patient has successfully completed a rehabilitation program. The ability of a patient to receive a definitive prosthesis should not be directly tied to their ability to complete a specific rehabilitation program but rather should be governed by their ability to progress through therapy from a preparatory prosthesis to a definitive prosthesis. Requiring a patient to complete a rehabilitation process when they may be otherwise ready to utilize a definitive prosthesis may result in unnecessary delays to their clinical treatment and may result in harm to the patient. AOPA is also concerned about the correlation between coverage of a definitive prosthesis and a patient's cognitive, neuromuscular and cardiovascular status. While severe cognitive, neuromuscular, or cardiovascular conditions may impact a patient's ability to use a prosthesis and should be considered in determining patient readiness for a definitive prosthesis, they should not, by themselves, be used to exclude a patient from eligibility for a K-3 prosthesis that can benefit the patient functionally in their definitive prosthesis. Many patients can and do successfully achieve advanced functional status while using a prosthesis despite other conditions that may affect their overall health. Substituting a remote claims reviewer, with no direct knowledge of the patient's overall health condition and ability to successfully use a prosthesis, for a prescribing physician who is managing the patient's healthcare is a mistake and will lead to inappropriate restrictions to access to the prosthesis that best meets the individual patient's clinical needs.

The LCD restricts the provision of a definitive prosthesis for 90 days following provision of a preparatory prosthesis. AOPA believes that coverage for a definitive prosthesis should be available as soon as the patient is able to effectively ambulate using a definitive prosthesis, and should not be made to wait for 90 days in situations where their progress has exceeded the clinical benefit of a preparatory prosthesis.

Components

Sockets

AOPA is concerned that limiting coverage to one socket code and descriptor per individual prosthesis does not allow for socket design features (e.g. total contact, ischial containment, flexible sockets, etc.). Many socket codes appear to describe complete sockets, but actually describe unique design features of a socket. Restricting the ability to provide socket design features that provide a therapeutic benefit to the patient may result in the provision of a prosthetic socket that does not meet the patient's specific clinical needs nor does it represent contemporary practice

AOPA is concerned that the socket replacement codes that are covered for preparatory prostheses do not include HCPCS codes that describe socket design features such as total contact, ischial containment, and flexible sockets. These socket design feature codes remain crucial to ensuring the proper fit of the prosthetic socket regardless of whether they are incorporated into a preparatory socket replacement or definitive socket replacement. Failure to provide coverage for these socket design features when replacing a preparatory socket may result in harm to the patient.

AOPA is concerned that the LCD does not provide coverage for test sockets used in ensuring the proper fit of a socket for a preparatory prosthesis. The use of up to 2 test sockets is covered for definitive prostheses and should also be permitted when fabricating a socket for a preparatory prosthesis as it is a valuable tool in ensuring the intimate fit of the socket that is required for the proper function of the prosthesis.

The LCD states that acrylic resin laminations "provide for an intimate fit and a firm, smooth, bearing surface" and that they are not separately payable when billed with molded sockets as "this function is included in the base code." AOPA disagrees with this statement. While a molded socket provides an intimate fit, lamination with acrylic resin provides strength and durability to the prosthetic socket. Historically, the base codes for lower limb prostheses have never included acrylic resin lamination in their descriptors and therefore should remain eligible for coverage as a separate and unique feature of the prosthetic socket. If the DME MACs and CMS believe that acrylic resin lamination is inherent in all lower limb prosthesis base codes, there must be an adjustment to the published Medicare fee schedule for the base codes to provide additional reimbursement for the more costly acrylic resin lamination—Medicare cannot

“finesse” the base code composition, i.e., it cannot arbitrarily increase what is included in the base code without a concurrent and commensurate increase in the reimbursement to reflect such a change to the base code..

The LCD states that a total contact addition to a prosthetic socket is “a socket feature where the intimate fit of the socket around the residual limb creates a negative pressure, therefore total contact design keeps the prosthesis in position without a pelvic joint and belt.” The LCD states that total contact design is inherent in the production of a molded socket and is therefore included in the payment for any molded socket. AOPA disagrees with this statement. Scientific studies exist that support the medical need for total contact as a socket design feature that is used to evenly distribute weight bearing forces throughout the entire socket, therefore reducing pressure and excessive weight bearing on the distal end of the residual limb. AOPA believes that total contact design is not inherent in the production of a molded socket and therefore must remain eligible for coverage as a separate and unique addition to a prosthesis that contains a molded socket and or add it into the base level reimbursement with the corresponding increase in reimbursement value.

Socket Inserts

The LCD indicates that socket inserts described by HCPCS codes L5645, and L5654-L5665 are non-custom socket inserts. AOPA contends that L5645 represents a socket design feature, not a socket insert, and that socket inserts described by L5654-L5665 actually represent custom fabricated socket inserts. The LCD indicates that socket inserts described by L5681 and L5683 represent custom fabricated roll on style prosthetic liners that are fabricated over a new model of the patient’s residual limb and L5673 and L5679 represent custom fabricated roll on style prosthetic liners that are fabricated over an existing model of the patient’s residual limb. The LCD fails to recognize that the HCPCS descriptors for L5673 and L5679 also describe roll on style prosthetic liners that are prefabricated and are available in predetermined sizes and thickness. The statement in the LCD that coverage for L5673 and L5679 is only available when a non-custom socket insert does not meet the clinical needs of the patient is inherently flawed based on the incorrect classification of products described by these codes as custom fabricated. The use of roll on style prosthetic liners has become the accepted standard of care when providing prosthetic socket inserts and must continued to be covered when medically necessary. Restricting coverage for these liners to situations where socket inserts that represent outdated technology are ineffective may cause harm to Medicare beneficiaries.

Suspension Systems

The LCD indicates that claims for more than one method or type of suspension per prosthesis will be denied as not reasonable and necessary. AOPA believes that there are a variety of clinical circumstances, including but not limited to, shortened residual limbs, highly active amputees, and unusually shaped residual limbs and or those with joint hip or knee joint instability that require multiple suspension systems in order to ensure safe and effective suspension of the prosthesis. AOPA contends that in these situations, multiple suspension types should remain eligible for coverage.

AOPA requests clarification regarding the LCD statement that some prostheses are complete or all inclusive systems and separate billing for a suspension system with these items will be denied as unbundling. We are not familiar with any definitive prostheses that would match this assertion. If the LCD is referring to an immediate or preparatory prosthesis, that limitation should be so stated. Otherwise we believe this statement is inaccurate and should be deleted.

Mechanical Suspension

AOPA believes that there is an error in the list of codes that cannot be billed with HCPCS codes L5666, L5673, L5679, L5681, and L5683. The list in the LCD includes L5671 as not separately billable when used with the codes above. The LCD then goes on to state that L5671 is covered when used with L5673, L5679, L5681, and L5683. AOPA believes that the list of codes that are not billable should not include L5671.

AOPA also believes that the LCD inappropriately restricts the use of L5671 to mechanical lock systems that rely on a shuttle lock and pin system. Lanyard based systems are also used to achieve a mechanical lock for suspension purposes and should be included in the LCD as covered services.

Suction Suspension

The LCD indicates that suction suspension is accomplished through the creation of a negative pressure seal between the socket and the insert or liner. AOPA believes that this definition must be expanded to included suction that is created by a seal between the residual limb and socket directly. AOPA also contends that passive suction is created not only when donning the prosthesis, as is indicated in the LCD, but also created and maintained through the use of sleeve or other mechanism that maintains the suction environment.

AOPA disagrees with the statement in the LCD regarding non-coverage of HCPCS codes L5781 and L5782 as “active” suspension systems that are not supported by published clinical evidence. These codes, which were implemented in 2003, are not

designated as suspension systems but rather volume management and moisture evacuation systems. There is significant Medicare claims data that indicates these codes have been eligible for coverage since their implementation and there is no reason why they should not continue to be covered for patients who require limb volume management and moisture evacuation in order to ensure a proper fit of their prosthesis.

AOPA does not understand why the provision of a suction suspension system is limited to K2-K4 functional level amputees. The proposed prohibition on coverage of suction suspension for K1 functional level amputees appears to be discriminatory and without clinical merit.

Feet and Ankles

AOPA believes that the LCD must be clarified to indicate that prosthetic feet and ankles may be billed using one base code along with appropriate addition codes. AOPA is concerned that the consolidation of existing HCPCS codes L5976, L5980, L5981, and L5987 into a single code described by KXXX1 will severely limit access to prosthetic feet that contain unique features and design that best meet the specific clinical needs of the patient. In addition, the Food and Drug Administration (FDA) has previously deemed prosthetic feet described by HCPCS codes L5976, L5980, L5981, and L5987 as safe and effective through its regulatory authority. The FDA alone has been delegated responsibility for effectiveness determinations. CMS has been delegated authority on coverage, but has not been delegated to rebut or reverse or otherwise pass judgment on legitimate FDA decisions on the effectiveness of devices. The decision in the draft policy to simply re-classify unique and different prosthetic feet into a single generic code may exceed CMS' coverage authority by venturing into decisions on the safety and effectiveness of prosthetic feet, a responsibility Congress delegated only to FDA, and not to CMS.

AOPA believes that, at a minimum, the LCD must reinstate HCPCS codes L5976 and L5981 in order to continue to adequately describe the unique features of various prosthetic feet available on the market. AOPA also believes that HCPCS code L5986 must be reinstated to properly describe separate multiaxial ankle components that may be added to a variety of prosthetic feet. AOPA contends that coverage for L5968 should not be restricted to K3 and K4 functional level amputees as there is significant clinical benefit for this feature for K2 functional level amputees. In addition, AOPA believes that KXX2 should be classified as an addition code, not a base code in the functional level table contained in the LCD.

AOPA contends that HCPCS code L5979 should be cross walked to a combination of KXXX1 and KXXX2 as the predicate product for L5979 incorporated a dynamic response foot into its design. The proposed crosswalk to L5978 does not adequately

describe the dynamic response foot that is included in the design of feet currently described by L5979.

AOPA believes that products described by L5969 should be eligible for coverage based on the fact that the FDA has deemed the predicate product for this code as safe and effective.

Knees

AOPA disagrees with the statement in the LCD that indicates that quick change self-aligning units will be denied as not reasonable and necessary. Products described by HCPCS code L5617 are often clinically appropriate for patients who must temporarily remove components of their prosthesis for medical reasons, such as the need to remove the components of their prosthesis in cramped seating situations.

Miscellaneous

AOPA believes that coverage for alignable systems should be extended to include socket replacements that also require the complete replacement of the alignable components that make up the prosthesis.

AOPA is concerned about inconsistency between the LCD and Policy Article regarding the proper use of ultra light material codes. The LCD indicates that ultra light material codes may be used to describe prosthetic components that are made of ultra light material such as titanium. The Policy Article indicates that ultra light material codes may only be used to describe ultra light materials that are incorporated into the design of prosthetic sockets. AOPA believes that ultra light material codes should be restricted for use to describe ultra light materials that are incorporated in the design of the prosthetic socket.

Protective Outer Surface Covering

AOPA contends that coverage for protective outer surface coverings should not be limited to situations where a patient is exposed to unusually harsh environmental conditions. While traditional prosthetic covers protect internal components from damage due to blunt force, they do not typically provide protection from basic environmental conditions such as rain, snow, or ice or exposure to bodily fluids through conditions such as urinary incontinence. As has been demonstrated in greater detail in prior communications, AOPA believes that coverage of outer protective surface coverings will help to maintain the function and durability of the prosthesis. (See Appendix A on Protective Outer Surface Covering which is incorporated by reference into these Comments).

Rehabilitation Program

AOPA must reiterate our concerns expressed in the preceding sections of our comments regarding participation in a rehabilitation program as a pre-requisite to coverage of all lower limb prostheses under the draft LCD and Policy Article. While AOPA agrees that there is clinical value to a new amputee's participation in a structured rehabilitation program, these programs may not be readily available, especially in rural areas. The concept that coverage for any prosthesis is entirely contingent on the patient's ability to participate and complete a formal rehabilitation program is discriminatory against amputees who may be clinically and functionally able to benefit from prosthetic care but do not have ready access to a formal rehabilitation program simply because of where they live. Coverage for lower limb prostheses for patients who can benefit clinically and functionally should as per present policy, remain available if documentation supports their ability to safely and effectively use a prosthesis, not contingent upon their participation in a rehabilitation program. In addition, coverage of a definitive prosthesis for a new amputee should not be solely contingent on their successful completion of a rehabilitation program. Rather, coverage of a definitive prosthesis should be tied to the patient's ability to benefit clinically and functionally from the use of a definitive prosthesis.

Functional Status (K-Level)

AOPA has expressed its concern regarding the elimination of considering a patient's potential functional abilities as part of their functional level assessment earlier in our comments. We would like to reiterate this concern as we believe that a true measure of a patient's functional capabilities to use a prosthesis that best meets their clinical needs must not only include evaluation of what the patient can achieve while wearing a prosthesis at a specific moment in time, but also their potential to reasonably expand their functional capabilities as they adjust to using the prosthesis on a daily basis. Restricting the functional assessment to a single snapshot of what the patient can do today, without any consideration of what they may be able to do in the future is truly a disservice to amputees and will result in the provision of prosthetic devices and components that do not adequately meet the long term clinical and functional needs of the patient.

AOPA would like to, once again, express its deep concern regarding the language in the draft LCD and Policy Article that limits a patient's functional level based on the use or potential use of an assistive device during ambulation. As previously stated, AOPA believes that the restriction of amputees that periodically use crutches or a walker to K1 functional status and those that periodically use a cane to K2 functional level status is egregious and discriminatory as it disregards entirely their functional capability to safely and effectively use a prosthesis that meets their functional needs. In addition, the

requirement that the amputee must achieve the appearance of a natural gait in order for a prosthesis to be covered is a completely arbitrary and largely undefined factor in determining coverage. Many amputees, especially those that have had amputations through or above the knee, ambulate with a somewhat irregular gait while wearing a prosthesis. An irregular gait that has no effect on the ability for the patient to benefit functionally from a prosthesis should have no bearing at all on the coverage decision for that prosthesis.

There are several additional "minimal requirements" listed in the draft LCD and Policy Article for a patient to be "functionally successful with a lower extremity prosthesis." These include sufficient trunk control, good upper body strength, adequate knee stability with good quadriceps strength and control, good static and balance or a Tinetti total score of > 24, and adequate posture. While AOPA agrees that all of these considerations are factors that may be considered by the patient's physician when performing a functional assessment, they should not be used to eliminate coverage for a lower limb prosthesis. There are instances where a patient may be relatively deficient in one of the areas listed in the draft LCD and Policy Article but the deficiency does not preclude them for effectively using a lower limb prosthesis. The implication that the patient must be able to demonstrate all of these "minimal requirements" before a prosthesis will be considered is extremely prejudicial and does not consider the patient's overall functional capabilities which should be the primary factor in establishing a clinically appropriate functional level.

Prescription (Order) Requirements

AOPA has no comment on this section of the draft LCD and Policy Article as it remains unchanged from long standing and accepted policy.

Medical Record Information

General

This section of the draft LCD and Policy article provides a reference to sections 5.7-5.9 of the *Medicare Program Integrity Manual* as the source for the provisions contained within. One of the provisions in this section states that "supplier produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes." This position has been directly contradicted by direct communication from CMS itself—so the point articulated by the principal (CMS), namely that the prosthetist's note ARE part of the patient's medical record, overrides statements of the agent (DME MACs)* AOPA contends that this statement in the draft LCD and Policy Article is inconsistent with the actual language of the *Medicare Program Integrity Manual* which states, "However, neither a physician's order nor a CMN nor a DIF nor a supplier

prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier." The draft LCD and Policy Article correlates supplier produced records and a supplier prepared statement as essentially identical documents, which AOPA believes is materially incorrect. AOPA contends that the medical records of the prosthetist do not represent a "supplier prepared statement", but rather documentation that should be considered as part of the patient's contemporaneous medical record. This concept is supported later in the *Program Integrity Manual* that states, "The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or HHA records and records from other health care professionals." AOPA has continually expressed our opinion that the education, training, and clinical knowledge of the certified or licensed prosthetist clearly qualifies them as a health care professional whose medical documentation is and should be considered a valuable contribution to the patient's contemporaneous medical record, not simply a "supplier prepared statement."

This opinion was confirmed in an April 10, 2013 letter written to AOPA by George Mills, Jr., Director of the CMS Provider Compliance Group. In his letter, Mr. Mills acknowledged that prosthetists notes are indeed a part of the patient's medical record, although only one piece of the overall medical documentation required to support the medical need for a claim.

The draft LCD and Policy Article continues to state that that, "records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary. AOPA has thoroughly reviewed sections 5.7-5.9 of the *Medicare Program Integrity Manual* and can find no reference to this statement. Furthermore, AOPA fails to understand why there is a prohibition against recognizing the medical records of the prosthetist due to their financial interest in the outcome of the claim when there is no prohibition affecting other healthcare professionals such as physicians, nurse practitioners, physician assistants, therapists, etc. These healthcare professionals provide direct patient care service to Medicare beneficiaries that result in the submission of claims to Medicare, yet there is no restriction on the validity of their records due to their financial interest in the outcome of the claim. Prosthetists are not simply suppliers who fill prescriptions. They have completed extensive training (recognized by Congress in BIPA 2000, Section 427), and possess a unique knowledge base and skill set that is equivalent to other healthcare professionals and should be recognized as such.

Continued Need/Continued Use

AOPA believes that repeated references in this section of the draft LCD and Policy Article to rental items and monthly rental payments should be omitted as lower limb prostheses are custom items that are purchased for the individual use of a specific patient. Lower limb prostheses are not provided on a rental basis nor is it ever clinically appropriate for them to be provided as rental items.

Proof of Delivery Requirements

AOPA is very concerned to see the recent publications on new Proof of Delivery Requirements memorialized as a proposed change to the LCD. We have recently filed an extensive communication to CMS on this topic, continue to evaluate this action which has been very disruptive, probably without necessity, to the delivery of prosthetics and orthotics, and we reserve the option to comment in more detail on this after our study on this matter is concluded, but we do oppose its inclusion in the draft LCD and Policy Article. (See Appendix B on Proof of Delivery which is incorporated by reference into these Comments).

Equipment Retained from a Prior Payer

Similar to our comments above regarding continued need/continued use, AOPA believes that the majority of provisions contained in this section refer to rental based items and therefore should be omitted as they are not relevant to Medicare coverage of lower limb prostheses.

Repair/Replacement

AOPA has no comment on this section of the draft LCD and Policy Article as it remains unchanged from long standing and accepted policy.

Policy Specific Documentation Requirements

General

AOPA would like to reiterate its contention that while L5673, L5679, L5681, and L5683 may represent custom fabricated socket inserts, L5673 and L5679 may also represent prefabricated socket inserts that do not require fabrication or fitting over a positive model of the patient's residual limb. When the ordering physician and treating prosthetist have documented the medical need for prefabricated roll on style liners as best meeting the clinical and functional needs of the individual patient, Medicare coverage must remain available.

AOPA would also like to re-state our concern regarding the statement in this section of the draft LCD and Policy Article that states, "the prosthetic record must contain

information (1) describing the beneficiary's participation in a rehabilitation program, (2) demonstrating that the beneficiary is sufficiently able to ambulate and manage the use of their preparatory prosthesis, and (3) documenting that the residual limb is sufficiently mature and stable to justify the provision of a definitive prosthesis." AOPA believes that each of these conditions represents an unnecessary and potentially harmful barrier to access to prosthetic care for those amputees who may not be able to achieve one or more of these requirements for reasons stated earlier in our comments, who are otherwise able to demonstrate that prosthetic intervention will improve their functional capabilities and allow them to ambulate safely and effectively using a prosthesis that is clinically and functionally appropriate for their specific medical needs.

AOPA would like to reiterate its contention that coverage for protective outer surface coverings should not be limited to situations where a patient is exposed to unusually harsh environmental conditions. While traditional prosthetic covers protect internal components from damage due to blunt force, they do not typically provide protection from basic environmental conditions such as rain, snow, or ice or exposure to bodily fluids through conditions such as urinary incontinence. AOPA believes that coverage of outer protective surface coverings will help to maintain the function and durability of the prosthesis.

Independent Medical Examination

AOPA has several concerns regarding the impact that the provisions in the draft LCD and Policy Article that address the requirement of an independent medical examination may have on the ability of patients to receive quality prosthetic care in a reasonable timeframe.

First and foremost, AOPA is concerned that the requirement for an independent, in-person examination documenting the overall functional abilities and limitations of the beneficiary by the ordering physician, or physician designated LCMP, prior to writing the order for the prosthesis, will severely delay the beneficiaries' access to prosthetic care in a timely manner. This is especially concerning if the physician chooses to designate a LCMP to perform the functional evaluation. In this scenario, the physician will have no ability to write an order for a lower limb prosthesis until after the patient has been referred to and seen by the LCMP, the LCMP has subsequently reported the results of their evaluation back to the physician, and the physician has reviewed the report, including potentially yet another patient –physician visit, indicated concurrence or disagreement with the report, and incorporated the results of the LCMP report into the patient's medical record. These steps alone may result in delays of weeks or, more likely, months before the physician is able to order a prosthesis that meets the clinical and functional needs of the patient. In addition, these steps may require multiple visits between the patient and the physician or LCMP, resulting in additional cost to the

Medicare program and to the patient as a result of coinsurance payments. Delays of this type are unfair to patients who are typically motivated to restore their functional capabilities as soon after amputation as possible.

AOPA's concerns about potential delays in the delivery of appropriate prosthetic care to Medicare beneficiaries are exacerbated further by the statement in the draft LCD and Policy Article that allows the physician 45 days to provide the report of their or the LCMPs functional evaluation. The draft LCD and Policy Article places no value on the medical documentation of the prosthetist for purposes of claim review. If the prosthetist must wait up to 45 days to obtain the completed functional level assessment for the patient, they have no ability to provide the most appropriate prosthesis for the patient's documented functional needs. This provision will force amputees to wait up to an additional 45 days after the physician writes the order before they can receive their prosthesis. Restricting access to medically needed prosthetic services for patients who can benefit both clinically and functionally is unacceptable and egregious.

Secondly, AOPA must reiterate its concern expressed earlier in this document that the definition of a LCMP does not include or consider a licensed or certified prosthetist as a qualified LCMP. AOPA strongly believes that licensed or certified prosthetists not only possess the knowledge to perform these functional assessments, but are often the most qualified medical professional to do so. The current minimum educational standard for a licensed or certified prosthetist is a master's level degree, the curriculum of which requires extensive education and training in the performance of functional based assessment of amputees. This education far exceeds the majority of education and training available to the medical professionals listed in the LCMP definition contained within the draft LCD and Policy Article. Failure to recognize the licensed or certified prosthetist as a LCMP for purposes of performing functional level assessment is a disservice to Medicare beneficiaries and may result in incomplete and inaccurate functional assessment which will further restrict an amputee's access to clinically appropriate and medically necessary prostheses.

AOPA is also concerned about the requirements in the draft LCD and Policy Article that physicians must also provide "reports of pertinent laboratory tests, x-rays, and/or other diagnostic tests performed in the course of management of the beneficiary." These provisions are extremely arbitrary in nature and beg the question as to why the reports of these test results have any bearing on the patient's ability to safely and effectively use a prosthesis during ambulation. While there should be consideration of the relative impact of co morbidities as part of the overall functional evaluation, this is an evaluation properly made by the physician who has actually been in the physical presence of, and has actually treated the patient, and not for remote claims processors whose qualifications with the entire range of medical treatments of all types, much less with the amputation and mobility factors for each patient is subject to question and whose

objective is generally to identify a reason to reject the claim and reduce payer financial liability, a financial conflict of interest in its own right.. Requiring prosthetic providers to obtain and provide the results of routine tests performed by the physician is an unreasonable and unnecessary expectation.

Policy Article

General

There is a discrepancy between the draft LCD and draft Policy Article regarding coverage of adjustments, repairs and component replacement during the first 90 days following delivery of the prosthesis. The draft LCD states that any adjustments, repairs, or component replacements for the first 90 days following delivery of the prosthesis are included as part of the delivery of the prosthesis. This statement does not allow separate reimbursement for adjustments, repairs, or component replacement caused by loss, theft, irreparable damage or a change in the patient's condition or functional abilities. Clearly, all patients are not identical in their progress and the pace of their healing after amputation, and this aspect of the rule cannot evade this fact—the average patient is not all patients. AOPA believes that adjustments, repairs, and component replacement necessitated by one of the circumstances above should continue to be eligible for separate reimbursement even when it is required within the first 90 days after delivery of the prosthesis. This concept is supported in the draft Policy Article and should also be added to the draft LCD.

Facility Requirements

AOPA has no comment on this section of the draft Policy Article as it remains unchanged from long standing and accepted policy.

Adjustments, Repairs, and Component Replacement

AOPA would like to reiterate its contention that economic fairness demands that adjustments, repairs, and component replacement necessitated by loss, theft, irreparable damage, or a change in the patient's condition or functional capabilities must continue to be eligible for separate reimbursement even when it is required within the first 90 days after delivery of the prosthesis. Any policy assertion to the contrary is a departure from the ongoing components of the respective code, and if the package of services and risks included in the code are to be expended, this must be accompanied by a commensurate incremental increase in the reimbursement value of the code to reflect these new obligations on the providing health professional/prosthetist.

Miscellaneous

The draft Policy Article indicates that a user adjustable heel height (L5990) is a convenience item and will be denied as non-covered. AOPA expressed its opinion regarding this issue in correspondence to the DME MAC Medical Directors dated June 5, 2007. As a result of this correspondence, L5990 was deemed not medically necessary as opposed to statutorily non-covered. While this may seem to be a non-issue on the surface, AOPA believes it is relevant, as a medical necessity based denial provides appeal rights for providers who believe that there is a specific medical, vocational, or therapeutic need for the adjustable heel height feature for specific patients. AOPA believes that statutory coverage for L5990 should be available in the final version of the Policy Article—at minimum, nothing has changed since the 2007 decision that this be treated as not medically necessary instead of statutorily non-covered..

Coding Guidelines

The draft Policy Article inappropriately restricts the use of L5671 to mechanical lock systems that rely on a combination of a shuttle lock and pin system. Lanyard based systems are also used to achieve a mechanical lock for suspension purposes and should be included in the LCD as covered services.

AOPA disagrees with the statement in the draft Policy Article that describes socket inserts described by L5673, L5679, L5681, and L5683 as custom fabricated socket inserts that are either fabricated from a new positive model of the patient's residual limb (L5681, L5683) or custom fabricated or custom fit over an existing positive model of the patients residual limb (L5673, L5679). The proposed LCD fails to recognize that the HCPCS descriptors for L5673 and L5679 also describe roll on style prosthetic liners that are prefabricated and are available in predetermined sizes and thickness and do not require custom fitting over an existing model of the patient's residual limb in order to function properly.

AOPA would like to reiterate our concern about inconsistency between the draft LCD and Policy Article regarding the proper use of ultra light material codes. The LCD indicates that ultra light material codes may be used to describe prosthetic components that are made of ultra light material such as titanium. The Policy Article indicates that ultra light material codes may only be used to describe ultra light materials that are incorporated into the design of prosthetic sockets. AOPA believes that ultra light material codes should be restricted for use to describe ultra light materials that are incorporated in the design of the prosthetic socket as stated in the draft Policy Article.

Foot/Ankle Coding Changes

AOPA would like to once again express its grave concern regarding the coding changes for prosthetic ankles and feet that are included in the draft LCD and Policy Article. AOPA is concerned that the consolidation of existing HCPCS codes L5976, L5980, L5981, and L5987 into a single code described by KXXX1 will severely limit access by Medicare amputee beneficiaries to prosthetic feet that contain unique features and design that best meet the specific clinical needs of the patient. In addition, the Food and Drug Administration (FDA) has previously deemed prosthetic feet described by HCPCS codes L5976, L5980, L5981, and L5987 as safe and effective through its regulatory authority. The FDA alone has been delegated responsibility for effectiveness determinations. CMS has been delegated authority on coverage, but has not been delegated to rebut or reverse or otherwise pass judgment on legitimate FDA decisions on the effectiveness of devices. Provisions in the draft LCD and Policy Article to simply re-classify unique and different prosthetic feet into a single generic code exceed CMS' authority on coverage issues, and venture into the safety and effectiveness of prosthetic feet, a matter delegated to FDA only, and NOT to CMS.

AOPA believes that, at a minimum, the LCD must reinstate HCPCS codes L5976 and L5981 in order to continue to adequately describe the unique features of various prosthetic feet available on the market. AOPA also believes that HCPCS code L5986 must be reinstated to properly describe separate multiaxial ankle components that may be added to a variety of prosthetic feet. AOPA contends that coverage for L5968 should not be restricted to K3 and K4 functional level amputees as there is significant clinical benefit for this feature for K2 functional level amputees.

Additionally, AOPA contends that HCPCS code L5979 should be cross walked to a combination of KXXX1 and KXXX2 as the predicate product for L5979 incorporated a dynamic response foot into its design. The proposed crosswalk to L5978 does not adequately describe the dynamic response foot that is included in the design of feet currently described by L5979.

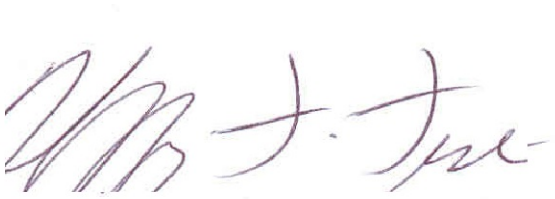
Conclusion

In conclusion, AOPA believes that the draft LCD and Policy Article for lower limb prostheses that was published on July 16, 2015 is inherently flawed in both its intent and content. Finalizing the draft LCD and Policy article in its current form, or based on the framework of this proposal will result in unacceptable restrictions to high quality, medically necessary prosthetic services for Medicare amputee beneficiaries. AOPA requests that the draft LCD and Policy Article be rescinded immediately to allow appropriate time for productive discussions between the DME MAC Medical Directors and affected stakeholders including, but not limited to Medicare beneficiaries, physician

organizations, orthotic and prosthetic organizations, amputee advocacy groups, and other interested parties. The extensive comments provided by AOPA regarding the general and individual provisions of the draft LCD and Policy Article do not represent, in any way, acceptance of the proposed provisions as an appropriate or scientifically based vehicle for modification of the existing LCD, nor as being in any respect in the best interest of Medicare beneficiaries.

AOPA looks forward to your response regarding our comments.

Sincerely,



Thomas F. Fise, JD
Executive Director

American Orthotic & Prosthetic Association

July 26, 2013

Paul J. Hughes, M.D.
Medical Director
DME MAC, Jurisdiction A
NHIC, Corp.
75 Sgt. William B. Terry Drive
Hingham, MA 02043

Robert D. Hoover, Jr., M.D., MPH, FACP
Medical Director
DME MAC, Jurisdiction C
CGS Administrators, LLC.
2 Vantage Way
Nashville, TN 37228

Stacey V. Brennan, M.D., FAAFP
Medical Director
DME MAC, Jurisdiction B
National Government Services
8115 Knue Road
Indianapolis, IN 46250

Richard W. Whitten, M.D., MA, FACP
Medical Director
DME MAC, Jurisdiction D
Noridian Healthcare Solutions
900 42nd Street South
Fargo, ND 58103

Robert F. Szczys, M.D., F.A.C.S.
Medical Director
Noridian Healthcare Solutions
Pricing, Data Analysis, & Coding
PO Box 6757
Fargo, ND 58108-6757

Dear DME MAC and PDAC Medical Directors:

The American Orthotic and Prosthetic Association (AOPA) would like to express its concern regarding a recent article posted by each of the DME MACs and the PDAC entitled, "Appropriate Coding and Billing of Lower Limb Prosthetic Covers and Covering Systems".

AOPA understands the need to confirm the medical necessity of any service provided to a Medicare beneficiary and fully supports efforts to eliminate fraud, abuse and waste in the Medicare program but respectfully disagrees with several statements and contentions made in this article.

The first paragraph of the article indicates the need for both a custom shaped protective cover and a flexible outer surface covering system on the same prosthesis is rare. AOPA disagrees with this statement based on the fact these services provide separate and distinct functions from one another. Separate HCPCS codes were created to describe the unique features of each of these components. As such, they can and should be able to be

billed together on the same date of service as long as documentation supports the independent medical need for both services.

The second paragraph of the article states, "Lower limb prosthetic covers (L5704-L5707) are complete products and afford shape, protection, and waterproofing for normal daily usage of the prosthesis." AOPA agrees the clinical purpose of a custom shaped protective cover described by the HCPCS codes above is to protect the components of the prosthesis from damage caused by blunt force. In addition, a custom shaped protective cover may also protect the patient's "sound" limb from potential injury due to blunt force trauma from exposed prosthetic components. They do not, however, provide protection from absorption of water, weather, dirt, dust or exposure to other liquids or bodily fluids. A standard prosthetic cover is fabricated using a foam based material, often of an open cell design. In certain environments, these covers will actually absorb dirt, dust, and fluids which may lead to premature corrosion or wear of the prosthetic components. The addition of a flexible outer protective covering system, which has been explicitly designed to provide additional protection from exposure to dirt, dust, moisture, weather, and other fluid contaminates, is needed to obtain this protection. Failure to provide a flexible outer surface covering may ultimately contribute to a reduction in the useful lifetime of prosthetic components and ultimately to increased cost to the Medicare program via reimbursement for replacement components.

The third paragraph of the article states a "protective outer surface covering is used by a beneficiary who has special needs for protection against unusually harsh environmental situations where it is necessary to protect the lower limb prosthesis beyond the level afforded by L5704-L5707." AOPA wholeheartedly disagrees with this statement. Due to the absorptive nature of materials typically used in the construction of a custom shaped protective cover (L5704-L5707), minimal exposure to normal environmental conditions such as rain, snow, dust, etc may result in prolonged exposure of prosthetic componentry to contaminates which may significantly reduce the useful lifetime of the prosthesis.

The fourth paragraph states "documentation to support the medical necessity of a protective outer surface covering system must indicate the type of extraordinary activities that would justify the need for extra protection afforded by this highly durable item. Again, this type of extra protection is not routinely necessary." AOPA agrees documentation must support the medical need for any separately billed prosthetic component, including a flexible protective outer surface covering system, but disagrees these components are only medically necessary when extraordinary circumstances exist. AOPA believes that protective outer surface coverings offer significant protection from contamination by common environmental elements such as rain, snow, dirt, dust, etc. and would like an interpretation of what is considered "extraordinary circumstances."

AOPA is also concerned about requiring suppliers to include information regarding the type of protective outer surface covering provided on the claim itself. There is no precedent for this requirement in existing lower limb prosthesis policy. While the DME MACs may request this information as part of any pre-payment or post-payment review, requiring this information to be included with the claim submission itself represents an unnecessary burden on suppliers.

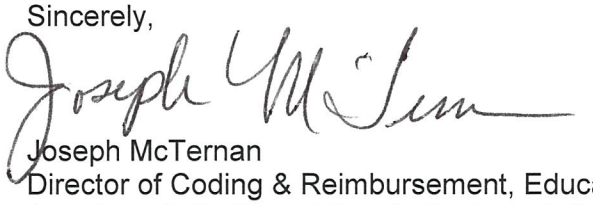
Finally, AOPA is concerned about the lack of due process in the publication of this article. The first notice which prosthetists, their patients, product manufacturers and other stakeholders received of this substantial Medicare policy change as to scientific, coverage and reimbursement changes with respect lower limb prosthetic covers (L5704-L5707) hereinafter referred to as 'covers', and protective outer surface covering systems (L5962,

L5964, and L5966) hereinafter referred to as 'skins' was via the five paragraph announcement that was posted on the Noridian website on July 18, 2013. We are also very concerned about the process being used for implementing such scientific, coverage and reimbursement changes. New terms such as "unusually harsh environmental situation" and a new documentation requirement to indicate the type of "extraordinary activities that would justify the need for extra protection afforded by this highly durable item" were introduced without definitions or reliable explanation/examples. Scientific determinations that 'covers' offer "sufficient protection and waterproofing for patients who require lower limb prosthetics," and that the added protection of 'skins' is "extra protection" that is "rarely necessary" have been posited without any provision of any literature references or other scientific rationale to support these broad conclusions, and no reference to any manufacturer assertions/warranties that would support such conclusions. Our additional concern relates to how these substantial changes as to scientific, coverage and reimbursement changes could be implemented and whether either CMS or its contractors have already, or intend to utilize the required stakeholder's protections in a process that meets the requirements of the Medicare law and the Administrative Procedure Act. The website publication clearly does not satisfy the need for publication of proposals for such substantial changes in the ***Federal Register***, the opportunity for a period of open comment toward a formal rulemaking, and other due process protections of stakeholders who may be profoundly impacted by such changes. Those indispensable steps may be forthcoming from CMS later in the process, in a way that would render the process consistent with your publishing a proposed rule addressing these requested changes, but we have not yet seen any evidence of the agency's intent to do so. We wanted to take this opportunity, before the process proceeds any farther, to share these due process concerns with you.

AOPA appreciates the opportunity to express its concern regarding this article and looks forward to a continued constructive dialogue regarding Medicare coverage of custom shaped protective covers and flexible protective outer surface coverings.

If I can be of any assistance, please feel free to contact me at jmcternan@aopanet.org or via telephone at (571)431-0811.

Sincerely,



Joseph McTernan
Director of Coding & Reimbursement, Education, and Programming
American Orthotic and Prosthetic Association

American Orthotic & Prosthetic Association

August 25, 2015

Shantanu Agrawal, MD
Deputy Administrator and Director
Center for Program Integrity
Centers for Medicare and Medicaid
7500 Security Boulevard
Baltimore, MD 21244

Laurence Wilson, Director
Chronic Care Policy Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Agrawal and Mr. Wilson:

The text of this letter below this paragraph is identical to the letter I had forwarded to Laurence Wilson on August 13, 2015. Mr. Wilson had indicated that he thinks the letter would be more appropriately directed to the Director of Program Integrity. Inasmuch as the contractor action which we are contesting is almost identical to an action taken by another contractor, PDAC, which (at least has been under Mr. Wilson's jurisdiction) in late 2011 prompted our appeal to Mr. Wilson for a correction in light of the content of device labeling (including model number and serial number having been assigned to FDA, and not to CMS). Due to the fact that in response to our letter and legal memos then, the PDAC did indeed withdraw its proposed action, I have decided that I should send the letter addressed to both of you jointly. If there is any overlap in responsibility as to this topic, I trust that you will resolve it, and if this is to be resolved under, and an answer to come from, the Office of Program Integrity, I am sure Dr. Agrawal may need, at minimum to consult with Mr. Wilson as to the history of the matter, dating back to PDAC in late 2011.

On February 12, 2015, CMS' DME MAC contractors informed O&P patient care facilities of its intent to impose new Proof of Delivery requirements that would provide that the only 'safe harbor' to demonstrate acceptable delivery would be if someone, presumably the manufacturer, although the patient care professional could undertake in an ad hoc manner to incorporate certain information onto the device itself or on its accompanying labeling. As the only alternatives are very uncertain, and as the DME MACs have stated they will no longer accept the HCPCS code descriptor—which was after all created to describe the device with great clarity and certainty—as an acceptable description in the absence of a serial number, the new policy amounts to a de facto imposition by CMS/DME MAC contractors of the requirement for placement of a serial number on all devices as a CMS requirement. This is not the first time this issue has been raised in discussion with this agency. In late, 2011, the PDAC informed manufacturers of a then-new requirement to include a model/serial number and identifying text in the labeling of all O&P devices.

We approached CMS/your office then indicating that we were unaware of CMS/PDAC possessing specific authority to require product labeling on medical

devices, although we have been aware that specific legislative authority as to medical device labeling was afforded to the Food and Drug Administration, as well as being aware that FDA has statutory authority to create a regulatory structure for Unique Device Identifiers (UDIs).

At that time we said: "This issue demands a balance of expertise in the areas of CMS/Medicare laws, as well as FDA law relating to foods, drugs, cosmetics and medical devices. Appended to this report, and referenced herein, is a summary analysis presented by the law firm of Foley Hoag, reflecting the knowledge and experience, among others, of Thomas Barker, Esquire, formerly General Counsel to the U.S. Department of Health and Human Services, relating to CMS/Medicare issues. Also attached is a similar analysis on FDA law, which reflects the knowledge and experience of Richard Cooper, Esquire, formerly the Chief Counsel to the U.S. Food and Drug Administration. The respective analyses from the firms of Foley-Hoag and Williams and Connolly are attached, and these reports essentially speak for themselves, and they should be viewed in tandem."

Based on these two analyses we stated that CMS needed to withdraw the requirement articulated by its PDAC contractor communication on September 22, 2011 of any statements mandated to be affixed to specific medical devices, in advance of the originally stated effective date of February 1, 2012. In response, we received a notification from the PDAC that this requirement was being withdrawn.

So, there is a sense of déjà vu as a different CMS contractor again tries to impose essentially the same labeling requirement. This communication is comprised of three parts.

1. What is wrong with the new Proof of Delivery requirement, and in some respects that includes some of the things that have not changed since early 2012 when CMS recognized the problem and withdrew the PDAC requirement;
2. A recitation of key aspects of FDA and HHS/CMS governing law still applicable to this de facto imposition of an CMS-mandated labeling, model/serial number process;
3. A brief analysis of relevant case law/legal decisions and analysis which demonstrate collectively that just as was the case in the 2011-12 efforts, so this new parallel requirement must also be withdrawn.

We reiterate the request that again, this 2/12/15 policy needs to be reversed/withdrawn with denials based on it reversed. Thank you, and please do not hesitate to contact me if there are any questions regarding either or both of the attached analyses.

Sincerely,

Thomas F. Fise
Executive Director

cc: Andy Slavitt, CMS Administrator
AOPA Board of Directors

IV. RECENT PROOF OF DELIVERY REQUIREMENTS: BOTH SUBSTANTIVE AND AUDIT CONCERNS

The below is a good background, which might fall under the general heading – "If it Ain't Broke, Why Do the DME MACS Insist on Trying to Fix It?"

(1) The first and most compelling point is the fact that the **DME MACs will no longer accept the HCPCS code descriptor as a narrative description of the device when a brand name or model number/serial number is not available**. The example I would offer is on spinal orthoses where the code descriptor is so detailed that it describes the anatomical landmarks that the orthosis extends to as well as the level of control it provides. I cannot think of a more complete narrative description that can be included on a proof of delivery. Take L0486 as an example. The code descriptor is as follows: TLSO, triplanar control, two piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from symphysis pubis to sterna notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in the saggital, coronal, and transverse planes, includes a carved plaster or cad-cam model, custom fabricated. **According to the DME MACs, the code descriptor, which describes the specific height of both the anterior and posterior sections of the orthosis as well as the specific level of control it provides, is not acceptable for them to determine that the device provided was coded properly.** That is simply a *ridiculous* statement.

(2) The second point relates to the DME MACs potentially again overreaching HHS/CMS' legal authority to dictate product labeling and branding, relating specifically to the"preferred" method of documenting the specific information about the device that was provided. The DME MAC bulletin, a link to which is below, indicates that "the preferred method is use of a brand name and model number, brand name and serial number or manufacturer name and part number to identify the product." The bulletin then goes on to state, "If this type of information is not available for the product, suppliers may use a detailed narrative description of the item; however, it must contain sufficient descriptive information to allow a proper coding determination. This "narrative description" of the item is not the HCPCS code narrative." The concern is that **while the bulletin states that a brand name, model number/serial number is not required, that in instances where a manufacturer may choose not to assign a brand name or model number/serial number to a prefabricated product, the DME MACs may deem the proof of delivery documentation as invalid leading to unnecessary claim denials**. There is currently no requirement that Class I products must have any form of unique identifier as was addressed in the recent UDI rule, and *products assigned by FDA to Class 1, exempt from GMPS (as is the case for most O&P devices) are not obliged to carry any brand name, model number or serial number.* **It is unfair for a device which fully complies with all requirement imposed by the government body that has been authorized by Congress to control medical device labeling may be disadvantaged as to reimbursement via a 'preference' of contractors for an agency that does not have any authority from Congress to dictate or require labeling.** The fact that, for whatever reason, a manufacturer chooses not to brand a particular device should not impede the ability for O&P facilities to be reimbursed by Medicare when providing it. Essentially this **same issue has been argued and decided previously (see the attached).**

CONCLUSION, Letter of Richard Cooper, Esquire

Williams & Connolly, Former FDA General Counsel, 12/22/11

FDA, not PDAC or CMS, has been granted explicit and unique statutory authority under the FDCA to create and administer a UDI system and to regulate medical device labels and labeling generally. PDAC and CMS may legitimately ask device manufacturers to "tag" for purposes of identification single units of devices they submit to PDAC for coding review, but PDAC and CMS may not impose requirements on the labels or labeling of devices being released for sale in the market. That is the province of FDA. Therefore, the authorities and analysis presented in the foregoing discussion require that CMS withdraw the PDAC requirement, and that PDAC defer to FDA with respect to requiring identifiers on devices.

Excerpts from Attorney Cooper's Rationale

A SEPARATE DEVICE-IDENTIFICATION REQUIREMENT IMPOSED BY PDAC WOULD FRUSTRATE CONGRESS'S PURPOSE OF HAVING A SINGLE UDI SYSTEM, AND WOULD CREATE UNNECESSARY BURDENS ON MANUFACTURERS, HEALTHCARE PROVIDERS, AND DATABASE USERS.

A A Separate Device-Identification Requirement Would Frustrate Congress's l)purpose of Having a Single UDI System.

By specifying that FDA should create a unique device-identification system, Congress plainly intended that each device have only one identifier, and that that identifier conform to a system that would be created and administered by FDA. That congressional intent precludes CMS or any other agency from creating a second device~identification requirement, which would cause the identifiers in FDA's system to be not unique. Therefore, whether PDAC intends its device-identification requirement to serve as a UDI system or to serve only a more limited purpose of facilitating billing and reimbursement activities, PDAC's creation of a second device identification requirement would frustrate the congressional purpose that is manifest in FDCA section 519(f).

B. A Separate Device~Identification Requirement Imposed by PDAC Would Create Unnecessary Burdens on Manufacturers, Healthcare Providers, and Database Users.

Implementation of a device-identifier system necessarily involves substantial investments of time, money, and energy. Equipment and software must be developed and purchased for reading the identifiers, databases must be reprogrammed to track the new data, and linkages must be established between the new identifiers and any prior identifiers previously in use for each

device. *See* Eastem Research Group, Unique Identifiers for Medical Devices .....Final Report 4-2 to 4-3 (Mar. 22,2006) (report prepared for FDA), *available at* http://www.fda.gov! MedicalDevicesIDeviceRegulationandGuidancelUniqueDeviceIdentification/ucm054169.htrn. As the research regarding UDI systems has established, the setup costs are likely to be substantial. *See iei*

Inc PDAC requirement would compel manufacturers, providers, and database users to pay these costs twice: once to implement the PDAC requirement, and again to implement FDA's system. Moreover, government data-collection systems and databases would also have to be revised at least twice (and, possibly, more than t\vice if FDA's 001 system or PDAC's device identification requirement changes or if other agencies impose additional device-identification requirements). Although it is possible that some of the equipment used to implement the PDAC requirement could be used for FDA's system, such savings are likely to be cumbersome to realize. To achieve the savings, the two systems would have to use compatible technology. Consequently, database users that purchase equipment and software to work with the identifiers required by PDAC would have to guess at what FDA's system will be, so that they can purchase equipment compatible with both. Moreover, sunk costs incurred to deal with PDAC's identifiers would constrain FDA's choices and encumber its design process. Providers -and government agencies -would want FDA to choose a system compatible with the equipment and they had purchased to implement PDAC's identifiers. FDA would face pressures to design its system accordingly, even at the potential loss of effectiveness; and its implementation of the UDI system, which was statutorily mandated with the specific understanding that FDA would create and administer it, would be encumbered by the process of investigating this issue of backward compatibility.

Moreover, putting PDAC identifiers into circulation would increase the likelihood of errors by medical personnel. even if PDAC's identifiers ultimately gave way to a system designed by FDA. Faced with an older set of identifiers under the PDAC requirement and a newer set under FDA's system, medical providers and database users (including governmental database users) would have to transition from one set of identifiers to another. 'During this shift, errors would be likely to occur, as people and database systems adjusted. The risk of errors would be still higher if product identifiers required by PDAC were to continue to be used even after FDA's system had become operational. In that scenario, devices would need to have two identifiers at the same time; and medical staff and database operators would have to choose which of the two to use or to use both. Indeed, however tempting it might be to think that PDAC's identifiers would vanish exactly when FDA's became operational, realism counsels that there would almost certainly be a period of overlap. During that period, avoidable errors in medical care and in data analysis almost certainly would occur.

It would be unreasonable to impose these burdens and costs in order to have device identifiers before FDA promulgates its UDI system.

A SEPARATE DEVICE-IDENTIFICATION REQUIREMENT IMPOSED BY PDAC WOULD BE CONTRARY TO FDA'S PLENARY AUTHORITY TO REGULATE DEVICE LABELS AN!> LABELING.

As explained *supra* at page 2. Congress has delegated to FDA, through the Secretary, plenary authority to regulate device labels and labeling; and FDA has exercised that authority.

I understand that Thomas Barker of Foley Hoag LLP, has opined that the statutes CMS administers do not authorize it to impose requirements for device labels or labeling. If, nevertheless, CMA can impose such requirements under general statutory authority, then other federal agencies that also lack specific authorization to impose requirements on device labels and labeling could impose such requirements under their general statutory authority. For example, The Department of Homeland Security could require that the labels and labeling of imported devices (and those of other imported products regulated by FDA) bear information relating to product identification (to accord with that Department's data-management systems), importation and place of manufacture. The Department of Defense ("DoD") could require that the labels and labeling of

devices (and those of other products regulated by FDA) that it purchases bear information relating to product identification (to accord with DoD's data-management systems) and appropriate military uses. The Department of Veterans Affairs could require analogous information on devices and drugs it purchases for its programs for veterans. The Department of Agriculture could impose an analogous requirement as to food purchased for the school lunch program. And so on.

Plainly, such proliferation by multiple agencies of requirements for product labeling would unduly interfere with the systems for labels and labeling created and administered by FDA during the decades since the enactment of the FDCA in 1938. Multiple such requirements would also unduly burden manufacturers.

Moreover, depending on whether, and if so how, such agencies would regulate the size and location of the information they would require, their requirements could make it more difficult for physicians, consumers, and others to use product labels and labeling effectively and efficiently. Such an effect would obstruct the major purpose of FDA's regulation of product labels and labeling.

CONCLUSION, Letter of Thomas Barker, Esquire

Foley Hoag, Former HHS General Counsel, 12/20/11

We believe CMS should instruct the PDAC to withdraw the proposed product labeling requirement. First, the Secretary of HHS has never granted labeling authority to either the Contractor or to CMS. Instead, this authority has been explicitly delegated to the FDA. As such, CMS and its contractor should refrain from prescribing UDI or medical device labeling requirements, and defer to the FDA's explicit authority in these areas.

Excerpts from Attorney Barker's Rationale

With regard to the PDAC's explicit authority to regulate the content of a medical device label, we are aware of no authority granted to either the contractor or to CMS by the Secretary of HHS to regulate labeling. The FFDCA is the primary law under which the FDA takes actions against regulated products, including medical devices. Specifically, sections 201(k) through 201(m) of the FFDCA address labeling definitions, sections within Chapter III address prohibited acts including "adulteration" and "misbranding" of medical devices,

1 The PDAC announcement can be found online at ht!Ps:llwww.dmepdac.com.

2 *See* FFDCA § 20 I (k), 21 U.S.C. 321. *See also* 21 CFR Part 801.

and sections within Chapter V set forth specific instances whereby medical devices will be considered to be adulterated or misbranded. Although the statute generally authorizes the Secretary of HHS to enforce the provisions of the FFDCA, the Secretary has delegated its authority to the Commissioner of Food and Drugs (with authority to redelegate) "functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act.,,3 We believe that CMS contractors thus lack any explicit authority to place labeling requirements upon manufacturers -this is the sole jurisdiction of the FDA.

It is perhaps less clear whether or not PDAC or CMS have implicit authority to place labeling requirements on products submitted for coding verification purposes. There is an argument that because the PDAC is not regulating device labels, but rather imposing a requirement on specific categories of products that it is billed for and pays for; such a requirement falls well within the scope of CMS' general authority to determine medical necessity or ensure devices meet the durability, utility, and appropriateness requirements for coverage.[4] However, nowhere in the statute authorizing CMS' coverage authority is the Agency granted authority to amend, append, or modify a device label, which remains the exclusive jurisdiction of the FDA. Medicare coverage authority extends to determinations of whether an item or service is "reasonable and necessary for the diagnosis or treatment of illness or injury." Beyond this initial determination, Congress also provided a general framework within which categories of benefits could be covered by the Agency and its contractors-naming certain categories as covered and naming other products and services categories as excluded.[6] Yet, neither the medical necessity determination, nor the category determination, grants CMS or its contractors the authority to regulate the content of a device label.

Having extensively reviewed the statutes and regulations governing CMS authority we have found no evidence that CMS has ever been granted authority to require certain information on a device label. It is notable that, as the FDA continues the process of developing a framework wherein the label of a device will be required to bear a unique identifier, CMS's role is relegated to that of a stakeholder.[7] At a September Unique Device Identification workshop, Tamara Syrek Jensen, Deputy Director of the Coverage & Analysis Group at CMS described CMS' role as that of an "end user" and not as regulator with regard to a product's label. While the PDAC and CMS will be given significant deference should this issue rise beyond a discussion with the contractor, we maintain there is a strong

3 FDA Staff Manual Guides, Volume II -Delegations of Authority, Regulatory Delegations of Authority to the Commissioner Food and Drugs, SMG 1410.10 (Effective 5/18/2005).

4 *See* Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services, Section 110.

5 §1862(a)(1)(A) of the Act, 42 U.S.C. § 1395y(a)(1)(A).

6 In addition to the medical and other services listed in § 1861(s) of the Act, 42 U.S.C. § 1395x(s), examples of items and services that are explicitly covered or not covered are found in § 1861(n) of the Act (durable medical equipment), 42 U.S.C. § 1395x(n). *See also id.* at § 1862(a)(7) and (8) of the Act (specifying some exclusions from coverage), 42 U.S.C. § 1395y(a)(7), (8).

7 *See generally* the Food and Drug Administration Amendments Act of2007, Pub. L. 110-85, requiring the establishment of a Unique Device Identification System.

argument that PDAC lacks the authority to require certain information on a permanently affixed label. This view is confirmed and reinforced by the memorandum by Richard Cooper, Esquire, which accompanies this document.

For the foregoing reasons, we believe CMS should instruct the PDAC to withdraw the proposed product labeling requirement. First, the Secretary of HHS has never granted labeling authority to either the Contractor or to CMS. Instead, this authority has been explicitly delegated to the FDA. As such, CMS and its contractor should refrain from prescribing UDI or medical device labeling requirements, and defer to the FDA's explicit authority in these areas.

Sincerely,

Thomas Barker
Ross Margulies

WINSTON
&STRAWN
LLP

1700 K Street, N.W.
Washington, D.C. 20006-3817
T: +1 (202) 282-5000
F: +1 (202) 282-5100
www.winston.com

THOMAS L. MILLS
Washington D.C. Managing Partner
(202) 282-5714
Tmills@winston.com

Gentlemen and Ladies:

You've asked us to address whether the recent Bulletin issued by all of the DME MACs setting forth new "Proof of Delivery" ("POD") requirements for billing Medicare and Medicaid for Orthotics and Prosthetics was lawful. In our view, from an administrative law and health care regulatory standpoint, it is not. Following is a brief summary of the more extensive analysis we provided you.[1]

Even if CMS had the authority to require the additional labeling requirement – which, as shown, it does not – the requirement so imposed violates the Administrative Procedure Act ("APA"). Under the APA, an agency action is a legislative rule if "the agency intends to create new law, rights or duties". *General Motors Corp. v. Ruckelshaus,* 743F.2d 1561 (DC Cir. 1984). *See also General Electric Co. v. EPA*, 290 F. 3d 377, 382.83 (D.C. Cir. 2002) ("an agency pronouncement will be considered binding as a practical matter if it ... is applied by the agency in a way that indicates it is binding"), and *Texas v. United States*, 787 F. 3d 733, 382-83 (D.C. Cir. 2002) (explaining that there are "two criteria to determine whether a purported policy statement is actually a substantive rule: whether it (1) imposes any rights and obligations and (2) genuinely leaves the agency ... free to exercise discretion.

Here the Bulletin states unequivocally that using an HCPCS code narrative is "not adequate for the POD purposes". Accordingly, any POD documents that use the HCPCS code narrative as the detailed description of the item "will be denied for insufficient delivery information" and the associated reimbursement claim will be denied. And although stating that use of the three preferred methods of identification are not the only methods acceptable, as a practical matter, they are.

The conclusion that the new POD requirement is a legislative rule means that it must be subjected to notice and comment under the APA, 5 U.S.C. § 553 (b), (c) 2012. CMS has not satisfied that requirement, and the DME MACs have no legislative rulemaking authority. So the POD proposal fails for that reason alone.

[1] We will not repeat here the extensive and erudite treatment by Foley Hoag LLP and Williams & Connolly LLP of the lack of CMS' authority to require serial numbers or other labeling requirements entrusted by federal law to the FDA. We look rather at administrative and health care law aspects of CMS' proposal, and, as next shown, the proposal fails in those respects also.

Moreover, the APA requires agency action to be set aside if it is arbitrary and capricious. 5 U.S.C § 706 (2) (A) (2012). In the seminal case, *Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 42-43 (1983) the Supreme Court held that the "agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made."

Here, there is a wholesale failure of the agency to identify the basis for the POD requirement: CMS has identified no over-arching problem of billing for orthotics and prosthetics relating to mis-identification of the item: CMS has found NO facts compelling the adoption of an across-the-board POD requirement for orthotics and prosthetics. And, even if it had, it articulated no rational or any basis whatsoever for concluding that the HCPCS description is no longer sufficient for proof of delivery purposes.

Taken together with the compelling arguments of Foley Hoag LLP and Williams & Connolly LLP, that the labeling requirement is *ultra vires* CMS' authority, the POD proposal is arbitrary and capricious, and therefore unlawful, for multiple reasons.

Tom Mills
Chair, Health Care Practice
Winston & Strawn LLP