THE ORTHOTIC AND PROSTHETIC ALLIANCE

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Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-6050-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items [CMS-6050-P]

Dear Administrator Tavenner:

On behalf of the Orthotic & Prosthetic Alliance (the O&P Alliance), a coalition of the five major national orthotic and prosthetic organizations representing over 13,000 O&P professionals and 3,575 accredited O&P facilities, we appreciate the opportunity to comment on the proposed rule, *Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items*. The O&P Alliance is committed to ensuring that Medicare beneficiaries and all individuals with injuries, illnesses, and disabilities have access to, and coverage of, the full spectrum of professional orthotic and prosthetic patient care.

In light of this commitment, we wish to take this opportunity to express our thoughts and concerns about the proposed Medicare prior authorization process for certain DMEPOS devices and related services identified in the proposed rule as being subject to frequent unnecessary utilization. We challenge this characterization as it applies to orthotics and prosthetics and explain our reasons below. The O&P Alliance has serious concerns about the prior authorization process as it is proposed to be applied to O&P services and devices, as well as more granular concerns about the specific proposals set forth in the proposed rule. Only with significant changes to the proposed rule do we believe that prior authorization can be workable for a narrow subset of orthotic and prosthetic components.

In particular, we do not believe that the proposed prior authorization process is a good fit for orthotics and prosthetics due to the clinical nature of custom O&P patient care. An O&P practitioner does not merely accept a physician's order for a prosthetic limb and select one off a shelf for the beneficiary to use. Rather, the O&P professional is intimately involved in the

process of assessing individual patients' medical and functional needs, recommending a treatment plan in conjunction with physicians and therapists, and selecting, designing, fabricating, and fitting a prosthesis for use by the beneficiary. In some instances, the treatment plan may change during the course of fitting, such as when a patient rejects a particular prosthetic foot or knee joint and one with different functions must be used as an alternative. Depending on the needs and preferences of the patient, a particular prosthetic foot may be too heavy, or provide too much rotation, causing instability in the patient's gait.

Prosthetic fabrication and fitting is a detailed, time- and labor-intensive undertaking that is critical to maximizing the beneficiary's future function. The outcome of this course of treatment will determine the beneficiary's ability to perform daily activities, life skills, and other functions that enable independent living, community integration and, where applicable, return to work. Second-guessing and delaying such critical patient care by requiring prior authorization before direct patient care is provided may have unintended consequences that could be avoided through the utilization of alternative methods for overseeing the provision of O&P care.

Application of the Proposed Prior Authorization Process to O&P

We recommend that the Centers for Medicare and Medicaid Services (CMS) exempt all lower limb prostheses from the proposed prior authorization requirement for several reasons, including the following:

1. Impact on Patient Care

We believe that the prior authorization process, as outlined by CMS, will very likely result in delayed clinical treatment to Medicare beneficiaries, jeopardizing patients' access to timely and appropriate care. Under the proposed rule, a proposed "Master List" would be used to determine which prosthetic components require prior authorization and prosthetists would have to obtain prior authorization before treating a Medicare beneficiary with a need for lower limb prosthetic care. Specifically, the prosthetist would have to coordinate with the patient's physician to gather all necessary documentation, submit all requested documents, and wait for CMS to render a prior authorization decision. This could easily take weeks and during this time, patients would not receive the lower limb prosthetic care they legitimately need to achieve or maintain ambulation with reasonable comfort and to return to normal daily activities.

Any delay in the prior authorization documentation process will directly result in further delays of treatment. Although CMS states that it will make reasonable efforts to communicate the decision within ten days—twenty days for a resubmitted prior authorization request—CMS does not provide an avenue for relief if CMS fails to adhere to this timeline. Given the experience all Medicare providers have had in recent years with extensive Administrative Law Judge (ALJ) hearing delays, the proposed rule's assurances on timeliness of prior authorization decisions ring hollow.

This process has the potential to significantly compromise patient care. For an ambulatory patient, the delay in treatment may force the patient to endure unnecessary pain, as in the case of an ill-fitting prosthesis that needs replacement while CMS renders a decision. Worse yet, such a delay could significantly compromise the long-term functional potential of non-ambulatory amputees, while paperwork is secured regarding the medical necessity of the care needed by the patient. For a patient awaiting his or her first prosthesis post-amputation, this delay may contribute to continued loss of motor function and capability as the patient remains largely immobile while CMS's contractors deliberate on the propriety of the documentation. Prosthetics involves a lifetime clinical patient care relationship, not the delivery of durable medical equipment (DME) commodities. In sum, direct patient care activities—whether provided by physicians, by therapists, or by O&P certified/licensed professionals—should be excluded from any Medicare prior authorization rule.

2. Section 427 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)

In its efforts to reduce inappropriate utilization, CMS has an alternative available for overseeing and policing the provision of O&P care, without imposing the requirement of prior authorization. CMS and its contractors should finally and fully implement and enforce Section 427 of BIPA, an existing federal law enacted 14 years ago but never fully implemented through statutorily required regulations. Of overriding significance in BIPA is the requirement that a "qualified practitioner" or "qualified supplier" must provide the designated O&P service or device in order to be eligible to receive reimbursement by Medicare. The O&P Alliance continues to believe that CMS implementation of this existing federal law would dramatically reduce the need to impose DME-based solutions to address perceived problems in orthotics and prosthetics.

Linking the ability to receive Medicare payment for custom orthoses and prostheses to the qualifications of the practitioner or supplier providing the O&P care would significantly advance accountability and quality in this area, while reducing inappropriate utilization and any fraud and abuse that may be occurring. The O&P Alliance continues to believe that the DME Medicare Administrative Contractor (MAC) claims processing system does not currently contain sufficient "edits" to ensure that billing for custom O&P services and devices is limited to appropriately licensed, certified, accredited, or otherwise qualified O&P practitioners and suppliers.

As a result of CMS's failure to implement Section 427 of BIPA, once a supplier has been granted Medicare DMEPOS billing privileges, it is largely free to submit claims for any type of DMEPOS service, including many of those for which it is not appropriately licensed or certified. This, in turn, contributes to the alleged questionable billing practices of providers of O&P services. To reduce the incidence of overpayments, CMS should implement and enforce BIPA as a necessary step to curtailing overpayments for custom orthotics and prosthetics from unqualified providers and suppliers. If this were to occur, CMS would not need to impose on

O&P practitioners and suppliers a burdensome prior authorization requirement that will likely delay and potentially compromise patient care.

3. Office of Inspector General Report "Questionable Billing by Suppliers of Lower Limb Prostheses" (OEI-02-10-00170)

CMS cites a report issued by the U.S. Department of Health and Human Services Office of Inspector General (OIG) entitled, "Questionable Billing by Suppliers of Lower Limb Prostheses," U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, OEI-02-10-00170, (2011), to establish the principle that certain lower limb prostheses are items frequently subject to overutilization. The O&P Alliance believes this OIG report on lower limb prostheses is seriously flawed. We have met with the OIG and CMS in the past to rebut the errant analysis and conclusions in this report but have had limited response to our concerns. (We discuss this further in Section 6 of this letter.) For this reason, this report should not be used by CMS as the basis for the inclusion of lower limb prostheses on the Master List for purposes of prior authorization.

In its report, the OIG failed to identify whether providers and suppliers of O&P claims examined in their sample complied with BIPA, Section 427, which links the right of suppliers and practitioners to bill Medicare for O&P services and devices to O&P licensure, certification, and accreditation requirements. We believe this flaw caused the OIG to unfairly characterize the billing practices of legitimate and qualified providers of O&P services as "questionable."

While O&P practitioners and suppliers must meet all of the supplier and enrollment requirements to enroll in the Medicare program properly, there is apparently no screening mechanism (e.g., claim edits) in place in the payment processing of O&P claims to ensure that the supplier is considered qualified to bill the codes that describe the items provided to the beneficiary. We believe that a failure to segregate claims by the qualifications of the practitioner/supplier has contributed to the OIG's finding that the billing practices of properly qualified providers of O&P services are "questionable."

In the absence of these claim edits, we believe the sample used in the OIG report was effectively tainted and not representative of claims submitted solely by qualified O&P practitioners and suppliers. Many of the claims the OIG reviewed in that study that were determined to be "questionable" were likely submitted by unqualified suppliers who are not adequately familiar with the provision of complex and customized O&P care, proper O&P coding, functional level assessments, or local coverage determination requirements.

Furthermore, the OIG concludes that the lack of a physician office visit to accompany a beneficiary's physician order for a prosthesis is indicative of potential abuse of the Medicare program. However, this is an oversimplification of the process of appropriate prosthetic care. For example, if the referring physician were the surgeon who performed the amputation, follow-up care from that surgeon, beyond the immediate post-operative period, would be atypical. The

more likely path is for the patient to receive a prosthetic prescription from the physician managing his or her overall care post-surgery.

The OIG report is premised primarily on the conclusion that costs of Medicare prosthetic care increased over a five-year period while the number of beneficiary claims remained flat. But, inexplicably, the OIG missed both intervening fee schedule increases, and more importantly, a quantum leap of technology advances in prosthetics driven by the Iraq-Afghanistan conflicts that resulted both in some increases in cost, but accompanied by significant improvements in patient mobility, independence and reduction in costly co-morbid conditions.

Before CMS implements a prior authorization requirement that has serious implications on the treatment of patients, the OIG should revisit the claim sampling used in this OIG report in order to ascertain precisely from whom the "questionable" claims were received, and to what extent these questionable claims were submitted by unqualified suppliers. We, therefore, reiterate our concerns with the findings contained in the OIG's report and urge CMS not to utilize this flawed report as the basis for inclusion of lower limb prosthetic components on the prior authorization Master List.

4. Inherent Difference Between DME and O&P

We continue to object to and oppose CMS's attempt to indiscriminately apply standards governing the DME industry to the very different clinical practice of orthotics and prosthetics. O&P patient care is a combination of clinical services that culminate in the provision of an orthosis or prosthesis that is custom-fabricated and fitted to the unique needs of each patient. This requires significant education, training, and competency.

As previously noted, pursuant to Section 427 of BIPA, only a "qualified practitioner" or "qualified supplier" may provide designated O&P services in order for them to be considered for reimbursement by Medicare. According to Section 427 of BIPA, qualified practitioners include individuals licensed by their state to provide O&P services and, in those states without an O&P licensure statute, individuals credentialed by one of the two major O&P credentialing bodies, the American Board for Certification in Orthotics, Prosthetics, and Pedorthics, Inc. (ABC), and the Board for Certification/Accreditation, International (BOC).

The credentialing process includes the requirement to pass rigorous national examinations. Furthermore, an individual must obtain at least a master's degree in orthotics and prosthetics before entering the field. Most graduate programs require that the individual complete 500 hours of clinical work. In addition, orthotists and prosthetists must complete a one-year residency in orthotics and a one-year residency in prosthetics, or a combined eighteen-month residency in both—if the individual wants to be certified in both orthotics and prosthetics. Lastly, orthotists and prosthetists work closely with physicians and therapists to provide direct patient care.

In contrast, DME is far more commodity-based. This is one reason why the Social Security Act contains a separate benefit category for Medicare orthotics and prosthetics, separate and distinct from DME. Although DME suppliers must act in accordance with Medicare directives, suppliers of DME need not demonstrate the level of competency required to fabricate and fit an orthosis or prosthesis. DME suppliers are not required to be licensed professionals or to obtain any advanced degree before becoming a DME supplier. Although DME suppliers must coordinate with physicians to comply with certain documentation requirements, DME suppliers do not typically provide direct patient care.

For these reasons, CMS should recognize the difference between DME and O&P and keep such distinctions in mind when designing programs such as the prior authorization process set forth in the proposed rule. CMS's attempt to expand its DME-based demonstration project for power mobility equipment to apply to direct O&P patient care and treatment does not reflect or appreciate the vast differences in the realities of DME versus O&P patient care.

Recommendations for Improving the Proposed Prior Authorization Process

The O&P Alliance has significant concerns about the proposed rule's application of the prior authorization requirement to lower limb prostheses. However, if lower limb prostheses remain in the prior authorization rule, there are a number of important changes that CMS could and should adopt in the final rule to make prior authorization viable for the O&P profession, without compromising patient access to care. The O&P Alliance urges CMS to amend its proposed prior authorization regulations in a manner that will address these issues, as explained in detail below.

1. Demonstrate the Program's Viability Before Full Implementation

CMS proposes to implement the full prior authorization process nationwide for lower limb prosthetics, even though it cautiously engaged in a demonstration project for prior authorization of power wheelchairs. The provision of power wheelchairs is fundamentally different, as explained above, from the provision of lower limb prostheses to Medicare patients. CMS used the demonstration project to test prior authorization for power mobility devices, focusing on specific regions before expanding the program to other areas of the country and other items of DME. This allowed CMS to make necessary adjustments and modifications to the proposed prior authorization process while adversely impacting as few patients and suppliers as possible.

The O&P Alliance urges CMS to take a similar approach if it chooses to implement prior authorization for O&P patient care. The demonstration project for DME continues, in an expanded form, even as CMS is proposing to implement this minimally tested framework on a national roll-out in the very different sector of O&P patient care. Implementing prior authorization for orthotics and prosthetics through a demonstration project would permit CMS and its contractors to establish best practices and procedures before imposing these requirements

on the entire population of Medicare O&P patients and professionals. It would also allow the O&P profession to acclimate to the change in claim reimbursement procedures, ensuring as smooth a transition as possible.

2. Establishing Standards for Prior Authorization

CMS proposes to require O&P professionals to request prior authorization for certain O&P devices and services as a condition of payment. In the proposed rule, however, CMS does not set forth the standards that will apply to issuing or withholding such authorization. Presumably CMS intends to defer to the contractors who oversee the claim submission and reimbursement process for O&P items and services, the DME MACs.

The O&P Alliance requests that CMS delineate clear standards as to which documents are required when submitting a prior authorization request. In recent years, O&P professionals have seen an increase in the amount and type of documentation required to support the medical necessity for the services they provide. In addition to a detailed physician prescription, certain circumstances require that the ordering physician's contemporaneous clinical documentation support the patient's diagnosis and the medical necessity for the O&P services ordered.

Unfortunately, the DME MACs have set forth policies in their Local Coverage Determinations (LCDs) regarding lower limb prostheses that eliminate the consideration of an O&P professional's clinical notes and assessments in determining the medical necessity of such O&P items. The O&P Alliance takes strong issue with these LCDs. Specifically, the DME MACs' LCDs indicate that "supplier–produced records" are not considered to be part of the medical record.[1] As each O&P professional is classified as a "supplier," whether operating independently or as part of a group, the LCDs effectively prevent any notes or assessments generated by the certified prosthetist who provides direct care to a patient with an amputation from being considered in the medical necessity decision-making process. Instead, the DME MACs rely entirely and exclusively on documentation generated by the treating physician.[2]

The O&P Alliance believes that justifying payment to the prosthetist based solely on the quality and content of the prescribing physician's medical records is not reasonable. The clinical notes of the prosthetist are critical to the medical necessity determination and should be explicitly considered part of the medical record. CMS will do the prosthetic patient a grave disservice if it denies coverage and payment of prosthetic care needed to restore mobility based on inadequate physician documentation alone. The qualified prosthetist represents the health

[1] *See, e.g.,* LCD L11464 (NHIC, Corp.); *see also* "Dear Physician" letter dated August 2011 regarding "Documentation of Artificial Limbs."

[2] The O&P Alliance points out that physicians are also classified as "suppliers," making the DME MACs' position even more untenable as it appears to eliminate physician notes from consideration as part of the medical record as well. The DME MACs appear to be distinguishing between entities with financial interests in the claim being submitted, but that too is an untenable position as Medicare contractors routinely rely upon documentation created by financially interested entities (e.g., physicians, hospitals, therapists) in making reimbursement decisions.

care professional with specialized prosthetic education, clinical training, and experience, who has historically been relied upon to recommend appropriate prosthetic designs for individual patient needs. To not consider the prosthetist's notes as a relevant component of establishing medical necessity flies in the face of logic, the Medicare statute, Congressional intent, and historical precedent. Unless this documentation issue is clarified in regulation, we believe that prior authorization will result in extensive delays in patient care due to up-front documentation burdens.

While the O&P Alliance disagrees with CMS's expectation that a treating physician's notes alone should be so specific as to independently justify medical necessity, we are far more concerned about the complete exclusion of the O&P professional's notes from such consideration. If it is CMS's intent to permit the DME MACs to continue to utilize such standards in making prior authorization decisions for O&P items, the O&P Alliance strongly objects to this aspect of the proposed rule. Therefore, the O&P Alliance requests that CMS clarify the standards for granting prior authorization prior to the implementation of such a process for O&P care.

3. Barring All Medicare Contractors From Further Review of Medical Necessity

CMS proposes to review the medical necessity of certain items and services prior to their provision to Medicare beneficiaries under the prior authorization process. Prior authorization can only work if it provides virtual certainty to the provider that they will be reimbursed. That said, the O&P Alliance acknowledges that certain documentation requirements that are conditions of payment for O&P services and devices will not be satisfied at the time a request for prior authorization is submitted (e.g., proof of delivery, which will occur only after a prior authorization request has been approved and the provision of prosthetic care has occurred). As such, claims that receive a provisional prior authorization may be subject to later review and denial for certain reasons.

However, the O&P Alliance seeks assurance from CMS that the DME MACs and all other Medicare contractors—including Recovery Audit Contractors (RACs)—will be barred from further review of any such claim for purposes of determining medical necessity once the provisional prior authorization is granted, absent credible allegations of fraud.[3]

The DME MACs and other contractors should only be permitted to examine a prior authorized claim—pre- or post-payment—to determine if there are technical deficiencies related to proper proof of delivery, whether the claim is duplicative, and whether the beneficiary died after CMS or its contractors approved the prior authorization request. This is a critical safeguard for the O&P profession that CMS should specifically adopt in the final rule.

[3] The only possible exception to this prohibition on secondary review is the Comprehensive Error Rate Testing (CERT) auditor, given its responsibility for assessing the accuracy of the DME MACs' performance.

4. Timeframes for Prior Authorization

CMS has proposed to allow a contractor ten days to issue a decision on an initial request for prior approval and twenty days to issue a decision on a resubmitted request. CMS further proposed that the contractors will be expected to make a "reasonable effort" to comply with these timeframes rather than require compliance with the timeframes. Finally, CMS proposed to allow for expedited review when use of the standard timeframe "could seriously jeopardize the life or health of the beneficiary *or the beneficiary's ability to regain maximum function*."

A. Standard Review

Considering the important patient care implications such delays may have, the O&P Alliance believes that the standard time frames for issuing a prior authorization decision are too long. Simply compiling the documentation in preparation for submission of a prior authorization request will take days, if not weeks. Once the documentation is submitted, the CMS contractor should be required to act expeditiously in order to avoid further patient care delays. The O&P Alliance recommends that the timeframe for issuing a prior authorization decision on an initial request be established as five business days. This time frame would commence when the contractor receives the request for prior authorization and end when the contractor delivers its provisional authorization or denial to the supplier at the supplier's contact location.

For resubmitted requests for prior authorization, the O&P Alliance believes that the time frame for issuing a provisional decision should also be five business days. We do not understand why a longer time frame for issuing a decision is required when a resubmission is made, as it should be treated in the same manner as an initial request. The extended time frame appears to be punitive in nature and is not appropriate when patient care is being delayed.

Because any time frame for issuing a prior authorization decision will commence when the contractor receives the request, processes must be in place that allow for the immediate submission of the request and all supporting documentation. It is not appropriate to allow the contractors to require all submissions be directed to post office boxes, as they traditionally do with appeal correspondence. Instead, the O&P Alliance urges CMS to delay the implementation of any prior authorization requirement until systems are in place to allow for the secure electronic submission of requests and supporting documentation or for the submission of such materials via facsimile.

Finally, the O&P Alliance requests that contractors be required to adhere to the timeframes and procedures established under any final prior authorization rules. To ensure compliance, the O&P Alliance recommends that failure by a contractor to timely respond to a prior authorization request should be considered as a provisional prior authorization, permitting the O&P supplier to proceed with rendering patient care. At the very least, CMS should clarify what is considered to be "reasonable efforts" on the part of the contractors to comply with the established time frames. Finally, every denial must address the specific patient at issue and

must supply a sufficient rationale as to the reason for the denial. CMS's contractors must be strictly precluded from issuing any pro forma denials simply for their convenience, or blanket denials which essentially function as a mechanism to "re-start the clock."

B. Expedited Review

Under the proposed rule, expedited review is warranted if CMS or its contractors agree that the standard timeframe for rendering a decision may "seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function." However, the preamble of the proposed rule does not discuss when the beneficiary's ability to regain maximum function warrants the expedited review process. Additionally, in the Special Open Door Forum on Prior Authorization held in June, 2014, CMS failed to clarify that expedited review is available if the standard timeframe for rendering a decision may seriously jeopardize the beneficiary's ability to regain maximum function.

The O&P Alliance urges CMS to address this issue in depth prior to issuing a final rule. The O&P Alliance believes that many patients' ability to regain maximum function may be diminished if they are forced to wait for their O&P care while prior authorization is requested. This can be substantiated by such examples as patients developing delay-related contractures or sustaining injuries from falls associated with not having a prosthesis to provide bilateral support.

In fact, for all patients awaiting the provision of their first post-amputation prosthetic limb, the O&P Alliance believes that expedited review should be granted in order to prevent any delay in such critical patient care. Expedited review should also be routinely granted in instances where a patient's prosthesis is no longer usable and, as a result, the patient is not able to functionally ambulate until a new limb is provided. Finally, in instances where a plan of care has received prior authorization but, for whatever reason, the patient's plan of care changes during the process of fabrication and fitting, the final rule should mandate the use of expedited review for alternative treatment plans.

The O&P Alliance also seeks clarification from CMS that the expedited time frame of two days will also apply to any resubmissions required for items and services that qualified originally for such review.

5. Resubmissions and Appeal Rights

CMS proposes to allow resubmissions of requests for prior authorization that receive provisional denials. CMS requested comments on the number of resubmissions that should be permitted. CMS also proposes to permit suppliers that receive provisional denials but elect to provide the O&P services and devices anyway to appeal any resulting claim denial.

The O&P Alliance is gravely concerned about the prospect of O&P practitioners being forced unnecessarily into the administrative appeals process in order to provide patient care they

believe is necessary, but documentation from the physician is delayed for whatever reason. This is particularly concerning given the extensive delays in the administrative appeals process. Therefore, we would like to propose an alternative for resolving disagreements over medical necessity documentation similar to that used with the RACs—an opportunity for discussion between the practitioner, the patient (if appropriate), and the applicable contractor's medical director following two unsuccessful resubmissions.

Under this process, O&P practitioners would submit the initial request for prior authorization and be given two opportunities to resubmit to correct any deficiencies identified by the contractor. After receiving provisional denial of the second resubmission, a practitioner (and his or her patient, if applicable) would be granted the opportunity to have a face-to-face or telephonic conference with the contractor's medical director to discuss why the prior authorization request continues to be denied and to make the case for the medical necessity of the services and devices at issue.

It is critical to restate, however, that the resubmission process and any discussion process that might be established, must be based entirely upon practitioners being given adequate reasons for any provisional denials that are issued. A supplier will not be able to correct any deficiencies in its initial request for prior authorization unless those deficiencies are specifically identified by the contractors. Merely indicating that the item is not medically necessary, without any rationale, is not sufficient. CMS has not included any requirements for specificity or detailed reasons for denials in its proposed rule and the O&P Alliance strongly urges CMS to develop such requirements prior to finalizing any prior authorization process.

6. Master List Criteria

To be included on the Master List, CMS proposes that the item must have been identified as being subject to frequent overutilization (through a Comprehensive Error Rate Testing (CERT) or OIG report) and have a payment threshold of "an average purchase fee of $1,000 or greater or an average rental fee of $100 or greater." This standard is problematic as applied to orthotics and prosthetics for two reasons.

First, Medicare's LCDs for lower limb prostheses explicitly prohibit "supplier-generated records" from being considered as part of the medical record for purposes of determining medical necessity and payment for prosthetic services rendered. This has the effect of invalidating the clinical notes of the prosthetist when CMS contractors, including CERTs, and RACs, as well as ALJ's and the OIG, assess the medical necessity of lower limb prosthetic claims. This was a key reason for high error rates found by the OIG in its August 2011 report entitled, "Questionable Billings by Suppliers of Lower Limb Prostheses," cited above, as well as the basis for high error rates identified by the CERT in this area.

The O&P Alliance has strongly challenged this interpretation of the Medicare documentation requirements since 2011. We believe this flawed interpretation of the Medicare

documentation requirements has vastly inflated the degree of alleged overutilization in this area, which is now being used to identify lower limb prostheses as appropriate for prior authorization. Because of this, we urge CMS to narrowly define the prosthetic codes from the Master List to which it applies prior authorization.

Second, a significant problem with this proposal is that the vast majority of codes for prosthetic limbs and components are reimbursed well above the proposed payment thresholds. This relatively low threshold (i.e., $1,000) for lower limb prostheses indicates widespread future application of prior authorization to lower limb prosthetics. Although the stated payment thresholds may be appropriate for some or all DME, the payment thresholds are inappropriate for O&P services and devices. Therefore, the O&P Alliance urges CMS to consider significantly increasing the payment threshold for inclusion of O&P items on the Master List, by at least double or triple the proposed amounts.

In addition, we believe that lower limb prostheses base codes should be excluded from the Master List. If a Medicare patient is missing a limb, there is little doubt that, if motivated to ambulate, a prosthetic limb will be deemed medically necessary. The OIG and DME MAC reports focused on prosthetic components—not base codes—and whether the complexity of these components matched the functional potential of the beneficiary.

In the delivery of prosthetic care, a claim describes a basic device designated by a base code as the first line item with additional codes listed on subsequent lines to fully describe the orthosis or prosthesis provided. Only the most basic of prosthetic limbs would be described by the base code alone; the additional codes correspond to accessory components necessary for the appropriate fit and function of the prosthesis, as well as higher level components, some of which carry additional criteria for a patient's functional capability to establish medical necessity.

Under the prior authorization process, if a base code for a prosthetic limb is denied, then the addition codes will be denied as well, regardless of whether those components are independently listed on the Master List or subject to prior authorization. This effectively would create a much larger set of prosthetic codes subject to prior authorization than originally proposed by CMS. Thus, the O&P Alliance requests that CMS explicitly exclude prosthetic limb base codes from being subject to prior authorization, instead applying the process only to certain prosthetic components that are additions to the base code.

Finally, the O&P Alliance would like to point out that two of the codes currently listed on the Master List in the proposed rule do not satisfy the criteria established for inclusion. Codes L5705 (custom shaped protective cover, above knee) and L5964 (addition, endoskeletal system, above knee, flexible protective outer surface covering system) have an average purchase fee of less than $1,000. As such, these codes should be removed from the Master List.

7. Ten-Year Period for Prior Authorization

We also urge CMS to reconsider its proposal to apply prior authorization to items and services for a full ten-year period, once they have been added to the Master List and subjected to this process. A shorter time frame or an exceptions process to remove items from prior authorization would enable CMS to adjust to congressional or judicial changes in the law that might affect the designation of items and services subject to prior authorization. It would also allow CMS to remove items and services from the Master List if strong indicators exist of very limited overutilization over the course of time.

8. Increased Costs to Medicare From Prior Authorization

The O&P Alliance fully expects that delays in processing and responding to prior authorization requests will increase costs to the Medicare program associated with extended acute care and Skilled Nursing Facility (SNF) stays while patients wait for prior authorization approvals, longer patient rehabilitation times, increased physician and therapist visits and services to fully document, up front, the medical necessity of prescribed O&P care, all potentially leading to more frequent and more severe comorbidities.

For example, each day's delay in obtaining a prior authorization decision for a SNF patient who requires a prosthesis represents another per diem charge from the SNF, additional physician visits, and delays in the patient's ability to ambulate and engage in therapies. Any delay in receiving therapeutic, prosthetic care compromises a patient's overall potential for success in returning to his or her activities of daily living and full participation in community living. We urge CMS to take these additional costs into account when issuing the final prior authorization rule.

Conclusion

CMS's proposed rule regarding prior authorization raises many concerns to O&P professionals and their patients. The O&P Alliance is committed to improving outcomes, reducing unnecessary Medicare expenditures, and restoring our patients' functionality and quality of life. We continue to believe that prior authorization is not a good "fit" for O&P care and that many other alternative policies could be implemented by CMS to reduce unnecessary utilization and improve patient care. That said, there are a number of important improvements to the proposed rule that could dramatically improve the prior authorization process if CMS insists on applying it to orthotics and prosthetics. We look forward to continuing to work with CMS on these important issues.

We appreciate your time and attention on this important matter. To contact the O&P Alliance directly, please call Peter Thomas, O&P Alliance Counsel, at 202-872-6730 or email Peter.Thomas@ppsv.com. Thank you for your consideration of our views.

Sincerely,

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