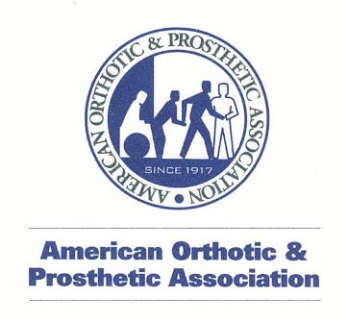

July 28, 2014

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-6050-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via www.regulations.gov (CMS-6050-P)

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

Dear Sir/Madam:

We are writing to provide comments to the proposed rule CMS-6050-P entitled, "Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items". This proposed rule was published in the May 28, 2014 Federal Register.

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.

General Comments

Prior Authorization: The Potentially Negative Impact on Amputees

As the largest insurer in the country and with a primarily geriatric beneficiary base, Medicare must consider the impact of any proposed coverage change on its beneficiaries. These individuals have a right to quality healthcare services, delivered efficiently by qualified healthcare providers, that addresses their medical needs expeditiously.

Prior authorization, as proposed, will result in unnecessary delays in the provision of medically necessary services, including but not limited to prosthetic and orthotic devices. Delaying access to prosthetic care early in the rehabilitation process may lead to serious health complications in patients whose health is already compromised by diseases such as diabetes, vascular insufficiency, or by a previous amputation. It is critical for amputees to begin the rehabilitation process as soon after amputation as possible, including the fabrication and fit of prosthetic devices. Prostheses allow new amputees to regain function and begin their rehabilitation process through physical therapy and other related healthcare interventions. The potential delay in care that the proposed prior authorization process will create may lead to increased health complications, co-morbidities, and poor clinical outcomes for Medicare beneficiaries who require a prosthesis.

More generally, AOPA fears patients will suffer: (1) delays in approval of prostheses; (2) potential time in a wheelchair while a replacement prosthesis is approved; (3) potential downgrade in the quality of device the patient receives, especially if prior authorization for the original device recommended by the physician and prosthetist is denied; (4) potentially be required to 'pay substantially out of pocket' to secure a high quality replacement limb. As we will reference in more detail below, ten (10) days is too long for any Medicare amputee beneficiary/patient to wait for a prior authorization approval.

AOPA believes that before any prior authorization program can be implemented, CMS must first consider the impact such a program may have on its beneficiaries.

Section I: Background

The significant differences between Durable Medical Equipment (DME) and Orthotics & Prosthetics (O&P) are clearly identified in the background section of the proposed rule, as well as in the Social Security Act itself. In addition to recognizing that DME and O&P are covered as separate benefit categories under the Medicare program, CMS must understand that provision of prosthetic services involves significant clinical care provided by appropriately qualified practitioners, as required by section 427 of the Benefits Improvement Act of 2000 (BIPA). BIPA 427 prohibits Medicare payments for prosthetics and custom fabricated orthotics unless the items are (1) furnished by a qualified practitioner and (2) fabricated by either a qualified practitioner or a qualified supplier. Certified and/or licensed prosthetists are among the qualified practitioners specifically identified in the statute, and are an integral part of the rehabilitation team that coordinates the efficient delivery of prosthetic care to the patient.

While prior authorization may be a reasonable payment methodology for durable medical equipment (DME), it typically requires no clinical expertise to dispense and is palliative, not rehabilitative in nature. Healthcare providers, such as prosthetists, provide significant clinical care as part of the delivery of the services they provide. The creation of yet another administrative hurdle, that of prior authorization, will only serve to hinder the prosthetist’s ability to deliver the immediate clinical care necessary to ensure the Medicare beneficiary receives a prosthesis in a timely manner and will result in inappropriate delays to their rehabilitation process.

AOPA believes that prostheses should not be included in the master list of items subject to prior authorization due to the significant differences that exist between DME and prosthetic items, as well as the requirement that provision of prosthetic services to Medicare beneficiaries requires the training, education, and clinical expertise of prosthetic healthcare professionals. **Those engaged in direct patient care encounters--physicians, therapists and O&P professionals—should be exempt from a prior authorization process.** If physicians, therapists and orthotic and prosthetic (O&P) professionals are not exempted from prior authorization, they must be considered as one category, and a prior authorization process should be applied consistently across these groups. All three of these players share portions of the market for Medicare O&P billings. If orthotists and prosthetists were subject to prior authorization, but physicians and/or therapists were not, this would result in unintended consequences in the market.

Section II: Provisions of the Proposed Regulations

Subsection A: Proposed Prior Authorization for Certain DMEPOS Items

This section of the proposed rule defines the term "unnecessary utilization" as the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules, as applicable. It also discusses the intent to use prior payment experience to establish which items are frequently subject to unnecessary utilization. The proposed rule indicates that reports published by the General Accounting Office (GAO), the Department of Health and Human Services Office of Inspector General (OIG), CMS, as well as CERT reports will be used to establish which items are frequently subject to unnecessary utilization. While AOPA does not take any issue with the value of these reports in general, the impact of inaccurate and/or flawed reports must be considered prior to using them as the basis for inclusion of a Medicare benefit category in any prior authorization program. AOPA has significant concerns regarding the specific report published by the OIG in August, 2011 regarding Medicare payment for lower limb prostheses that is identified later in the rule as the basis for inclusion of certain lower limb prosthetic codes on the master list of codes subject to prior authorization. These concerns will be addressed in AOPA's comments regarding subsection II.B. of the proposed rule.

Subsection B: Proposed Criteria for Inclusion on the Master List of DMEPOS Items Frequently Subject to Unnecessary Utilization

The proposed rule establishes three criteria for inclusion of a specific HCPCS code on the master list of items that may be subject to prior authorization. First, the item must appear on the Medicare DMEPOS Fee Schedule list. Second, the item must meet one of the following criteria:

- The item has been identified in a GAO or HHS OIG report that is national in scope and published in 2007 or later as having a high rate of fraud or unnecessary utilization.

OR

- The item is listed in the 2011 or later Comprehensive Error Rate Testing (CERT) program's Annual Medicare FFS Improper Payment Rate Report DME Service Specific Overpayment Rate Appendix (CERT DME Appendix)

Third, the item must have an average purchase fee of $1,000 or greater or an average rental fee schedule of $100 or greater, also referred to as the payment threshold.

AOPA has no concern regarding the first criteria, the requirement that an item must be included on the Medicare DMEPOS fee schedule in order to be considered for prior authorization.

AOPA has significant concern regarding the use of GAO or OIG reports as one of the criteria for identification of a HCPCS code for inclusion in prior authorization. The selection of report subjects by the GAO and OIG is often an arbitrary process and the subsequent reports are not subject to scrutiny or response by members of the public. These reports often publish information that, on the surface, indicate potential overutilization of specific procedure codes or services that may have reasonable explanations that do not involve overutilization. With no process in place to allow the public to refute the allegations raised by the report, it is accepted as fact and may inappropriately expose entire Medicare benefit categories to inclusion in prior authorization. This concern will be further addressed later in AOPA's comments regarding the specific OIG report that is being used to justify inclusion of selected lower limb prosthetic codes on the prior authorization master list.

The use of the CERT DME Appendix as a source for identifying services or codes with unnecessary utilization also concerns AOPA due to the relatively small sample of overall Medicare claims that CERT contractors use in establishing contractor error rates and the appendix that is generated from the results. AOPA contends that the specific purpose of CERT audits is to measure the performance of the administrative contractors who process Medicare claims. While the CERT does use the data it collects to identify potential areas of contractor weakness, the sample size is not statistically significant to be useful for purposes of identifying procedure codes or services that represent Medicare overutilization.

AOPA is concerned that the minimum dollar threshold of $1,000 for inclusion in prior authorization represents a dollar amount that incorporates the majority of prosthetic base procedure codes and a significant number of prosthetic addition codes. Unlike DME items, which typically represent low cost, high volume Medicare services, prosthetic services are typically low volume, high cost items. The same dollar threshold that is applied to DME should not also be applied to prosthetic services as they represent vastly different covered services under the Medicare program. As an alternative, AOPA believes that a formula should be developed that establishes an average fee schedule amount for similar services within a product category and then applies a multiplier to the average fee that is used to create the applicable minimum dollar threshold. For example, there are approximately 15 HCPCS codes that represent non-microprocessor controlled prosthetic foot components. If CMS were to calculate the average Medicare allowable for these codes and then apply a multiplier of 167% of the average allowable, a reasonable minimum dollar threshold applicable only to prosthetic foot components could be calculated. Applying an arbitrary minimum dollar threshold of $1,000 as the basis for inclusion on the master list essentially exposes every prosthetic base and addition code to the prior authorization process. While the current proposed master list,

based on the $1,000 threshold does not include every prosthetic addition code, it does include essentially all prosthetic base codes. Longstanding Medicare policy states that if a base code is denied as not medically necessary, related addition codes will also be denied as not medically necessary. The inclusion of all prosthetic base codes on the master list indirectly exposes every prosthetic addition code in the HCPCS code set to potential claim denial as a result of the prior authorization decision that is made for the base procedure code. In addition to a more reasonable minimum dollar threshold specific to prosthetic devices, AOPA requests the exemption of prosthetic base procedure codes from inclusion in the master list in order to avoid the indirect impact on every prosthetic addition code that the inclusion of base codes would represent.

AOPA is concerned that the provision in the proposed rule that allows the master list to be self updating annually based on the criteria established in the proposed rule will allow the future addition of new product categories to the master list without the ability for members of the public to refute or provide feedback on reports issued by the GAO or OIG. Updating of the master list is a very important matter, and any changes should be advanced via the same Administrative Procedures Act rulemaking process applicable to the development of this rule, without shortcuts. This concern is identical to AOPA's concern regarding the use of these reports as the basis for inclusion of product categories in the initial proposed master list that will be outlined further in these comments. These reports are often arbitrary in nature and often focus on perceived issues of overutilization rather than actual overutilization. AOPA believes that the final rule should, at a minimum, further clarify the role these reports play in the selection process for inclusion in the master list.

Subsection C: Proposed List of DMEPOS Items Frequently Subject to Unnecessary Utilization (Master List)

As identified earlier in the proposed rule, the criteria for inclusion in the master list, all of which must be met are:

- The item must be included in the DMEPOS Fee Schedule.
- The item must have an average purchase fee of $1,000 or greater or an average rental fee of $100 or greater per month.
- The item has been identified in a GAO or HHS OIG report that is national in scope and published in 2007 or later; or the item is listed in the 2011 or later CERT DME Appendix.

AOPA's comments regarding subsection C will be limited to those regarding the inclusion of lower limb prosthesis codes in the proposed master list as these are typically the only products provided by AOPA members to Medicare beneficiaries. AOPA has already provided detailed comments regarding the first two criteria above and will therefore limit its comments on this section to those related to the third criteria.

According to the proposed rule, the basis for inclusion of certain lower limb prosthetic HCPCS codes in the master list of codes eligible for prior authorization is the August 2011 OIG report titled, "Questionable Billing by Suppliers of Lower Limb Prostheses." AOPA has voiced its

concern regarding misconceptions represented in this report since its issuance and has sent multiple letters to the OIG, the DHHS Secretary, members of Congress, and CMS refuting the supposed findings of the report. AOPA believes the report is fundamentally flawed based on the following reasoning:

- The report claims that between 2005 and 2009, Medicare spending for lower limb prostheses increased by 27% while the number of Medicare beneficiaries receiving prostheses decreased by 2.5%. What the report failed to acknowledge or recognize was that almost half of the report increase in expenditures was a direct result of annual, inflationary based increases to the Medicare fee schedule (12%). When the annual increase to the fee schedule is considered, the increase in spending was only 15%. The OIG report missed entirely the fact that, largely related to the major advances in prosthetic technology fueled by DOD and VA funded research to address the needs arising from military injuries in Iraq and Afghanistan, had by that time reached Medicare and other amputee patients, offering dramatically advanced ability of patients using these devices to discharge the activities of daily living, improved mobility, better capacity to return to work, stronger independence, albeit that these more advanced technologies have somewhat higher costs. Advances in prosthetic technology such as microprocessor controlled componentry as well as vacuum based volume control systems were also not recognized as a potential reason for the slight increase in Medicare expenditures. While certainly not always medically necessary for all Medicare beneficiaries, these technological advances do represent a higher relative cost to Medicare for patients who can benefit clinically from them and remain eligible for coverage when documentation supports their medical need.

- The report claims that overutilization of lower limb prostheses was identified by the OIG because in many cases of a replacement prosthesis there had been no record of claim submission history from the referring physician to Medicare, implying that the referring physician may never have actually evaluated the patient and established medical need for a prosthesis. AOPA, in its various letters regarding the OIG report, pointed out that in most cases, the initial referring physician for a new amputee is the surgeon who performed the amputation of the limb. In many cases, the relationship between the surgeon and the patient ends immediately after or soon after the amputation surgery occurs. In most cases, the surgeon discharges the patient to the care of his/her primary care physician, or refers the patient to another physician to coordinate the patient's rehabilitation, including the potential use and eventual replacement of a prosthesis. The assertion by the OIG that a lack of Medicare claim history from the surgeon performing the amputation is a basis for claiming unnecessary prosthetic utilization is an inaccurate and damaging assumption that was made without a true understanding of how prosthetic care is delivered within the Medicare system.

- The report indicated that the OIG also discovered instances where prosthetic claims were paid by Medicare for patients with no history of amputation. AOPA agreed with the OIG on this premise of the report and recommended that appropriate action should be taken to identify and prosecute those that were committing clear fraud, but cautioned that this was a relatively small group of "bad operators" that does not reflect the majority of honest, hardworking, and Medicare-compliant prosthetic providers.

AOPA has never received a response to any of its letters requesting an independent review of the findings of the OIG report and therefore has had no public opportunity to refute its findings or assumptions. It is for this very reason that AOPA believes reports from the OIG or GAO, by themselves, should not be used to identify potential product categories for inclusion in either the initial master list or any future master list subject to the annual self update provisions of the proposed rule.

Lower limb prostheses have not been included in any CERT DME Appendix published since 2011 so AOPA cannot offer any specific comments relative to the listing in this appendix. AOPA would like to offer the general comment that the CERT DME Appendix is extremely limited in scope, often times including less than 100 total claims within a sample of any given HCPCS code on the list. AOPA contends that the sample sizes included on the CERT DME appendix do not in any way reflect a significant scientific sample size large enough to justify the inclusion of a particular HCPCS code on the master list of codes eligible for inclusion in prior authorization.

Subsection D: Proposed Future Process for Implementing a Prior Authorization Program for Items on the Master List

AOPA applauds the provisions of the proposed rule that indicate that initial implementation of prior authorization will be limited in scope in order to "balance minimizing provider and supplier burden with the need to protect the Trust Funds." While AOPA remains concerned that prior authorization, even if it is initially limited in its scope, will represent an unnecessary and inappropriate burden to patient care providers, it is encouraged that CMS has acknowledged that burden and will attempt to reduce it, at least temporarily. AOPA also believes that in order for prior authorization to be implemented for a specific product category identified on the master list, a proper notice and rulemaking process must be used to allow affected parties to offer appropriate public comments. AOPA remains concerned, however, that the proposed rule makes no mention of a public comment period associated with the 60 day notice and publication in the Federal Register. While the 60 day notice is an appropriate time frame for notification, AOPA believes that in order to be effective, the public must have the opportunity to submit comments regarding product selection for prior authorization.

AOPA supports the provision in the proposed rule that grants CMS the authority to suspend or cease the prior authorization requirement program generally or for a particular item or items at any time. This provision provides CMS with the flexibility to react appropriately to unforeseen circumstances through providing the authority to suspend or cease the program without requiring a lengthy and unnecessary regulatory process.

AOPA requests clarification regarding the provisions of the proposed rule that require, as part of the prior authorization process, the same information necessary to support Medicare payment of claims. AOPA members have struggled for years with inconsistencies among Medicare contractors regarding what clinical documentation is required for payment of claims for lower limb prostheses. While each of the DME MACs has published and maintains Local Coverage Determinations (LCDs) and Policy Articles (PAs), they only provide general coverage guidelines and leave much of the decisions regarding medical necessity to the contractor's discretion. AOPA believes, and short-term reports/statistics from the DME MACs

on claims denials confirm, that a significant shift in documentation requirements occurred when the OIG published its August 2011 report on improper Medicare payments to suppliers of lower limb prostheses. Following the publication of this report, the DME MACs released a joint "Dear Physician" letter that indicated that supplier produced records could not be used as the determining factor in confirming the medical necessity of a particular prosthesis and that the records of the referring physician would be used as the primary source of confirmation of medical need. In AOPA's opinion, this letter represented a complete shift in the payment policies of the DME MACs and unfairly held the prosthetist accountable for the documentation practices, or lack thereof, of the referring physician. AOPA members have faced a pattern of consistent claim denials since 2011 based on missing or incomplete documentation in the referring physician's records, regardless of the quality or amount of clinical documentation housed in the clinical notes of the treating prosthetist.

AOPA believes that if prior authorization is to be implemented for lower limb prostheses, CMS must, at a minimum, accept and acknowledge the records of the treating prosthetist as a significant part of the patient's contemporaneous medical record. While AOPA understands the importance of the role of the physician in treating the Medicare beneficiary, prosthetists are more than simple suppliers who are filling a prescription written by a physician. The prosthetist is a certified, often licensed, healthcare professional with specific training and education in the fabrication, fit, and adjustment of artificial limbs. Physicians often rely on the prosthetist to consult with them as to the design and appropriate componentry of the prosthesis that will best meet the functional needs of each patient. Failure to recognize the role of the prosthetist as a healthcare professional that is an integral part of the rehabilitation team will be a true disservice to Medicare beneficiaries, physicians, and other members of the rehabilitation team. AOPA therefore requests that the final rule, at a minimum, recognizes the professional status of the prosthetist and his or her role on the rehabilitation team, through the acceptance of their clinical documentation as a significant part of the medical record used to determine Medicare coverage as part of the prior authorization process.

To become certified and/or licensed as a prosthetist, an individual must complete three different requirements: (1) obtain a bachelors degree or, as of 2012, a masters degree, (2) successfully complete an extensive clinical residency (one year), and (3) pass a detailed certification exam (ABC or BOC) and any licensure exams administered by individual states where required. Prosthetists receive extensive education and training regarding the comprehensive care of amputees including fabrication, fitting, and follow up care for patients with prosthetic limbs. An important part of this education includes the proper documentation of the patient's pre and post amputation functional capabilities which is a determining factor of medical necessity and the documentation for Medicare coverage of certain prosthetic components. While physicians have a role to play in the healthcare of amputees, their education on prosthetics and orthotics is comparatively limited. Accordingly, any prior authorization process ultimately adopted by Medicare should balance the need for physician information, usually indicated by the medical prescription, with the clinical expertise that only a certified and/or licensed prosthetist possesses.

The Medicare LCD for lower limb prostheses states that, "Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to:

1. The beneficiary's past history (including prior prosthetic use if applicable); and
2. The beneficiary's current condition including the status of the residual limb and the nature of other medical problems; and
3. The beneficiary's desire to ambulate.

This statement clearly recognizes the role of the prosthetist in determining the patient's functional abilities and the subsequent assignment of a functional level classification for Medicare coverage purposes. AOPA believes that the final rule must acknowledge the acceptance of the prosthetist's clinical documentation as valid when making Medicare coverage decisions including decisions on prior authorization requests.

In addition, when an amputee requires either a new or replacement prosthesis, the need is typically an immediate one. Without a properly fitting prosthesis, the patient loses their ability to ambulate and must often use a wheelchair or other equipment to perform activities of daily living and may be at risk for developing skin ulcers secondary to undue pressure.

The need for that patient to regain ambulation is crucial in re-establishing their ability to function to the greatest extent possible. Delays in the provision of a prosthesis while medical records from the referring physician and other healthcare professionals are collected and organized for submission of a prior authorization request may severely impact the patient's ability to continue their rehabilitation or simply function in everyday life. The acceptance of the prosthetist's clinical records as sufficient documentation of the medical need for the prosthesis will expedite the process of providing the prosthetic care crucial to the patient's continued well-being.

AOPA believes that recognition of the prosthetist's clinical notes for purposes of confirming the patient's potential functional abilities as well as their desire to ambulate, both of which are crucial components of the coverage decision for the prosthesis, will alleviate many of the hurdles that AOPA members have experienced in obtaining coverage for medically necessary prostheses. While the physician's records remain a vital part of the process, it often does not include specific information regarding these two areas. Acceptance of the prosthetist's documentation, along with the documentation from the physician's record will allow for a more complete medical record that contains the information required for Medicare coverage.

The section of the proposed rule that discusses prior authorization decisions provides some indication that prior authorization requests that are granted a provisional affirmation may still be denied based on technical requirements that can only be evaluated after the claim has been submitted for formal processing. Examples of technical denials cited in the proposed rule include duplicate claims and proof of delivery. AOPA understands the need to allow for technical denials based on reasons like the ones cited in the proposed rule; however, there is no clear indication that prior authorization requests that receive a provisional affirmation may not be denied for medical necessity reasons once a formal claim has been submitted for processing. AOPA believes that this assurance must be memorialized in the final rule in order for any prior authorization program to be palatable. During a recent CMS Open Door Forum call, two separate CMS officials clearly stated that claims that had received a provisional affirmation during the prior authorization process would not, generally, be subject to denial for medical necessity as well as further review through post payment audits. While these statements were encouraging, they remain exactly what they are; statements on a telephone

call. Nonetheless, having stated this during the Open Door call, we believe that CMS should be prepared to also state these points within the regulation itself. AOPA believes that in order for any prior authorization program to be acceptable to its members, the final rule must provide specific language that not only guarantees payment of claims that have received provisional affirmation through the prior authorization process (not including denial for technical reasons), but also confirms that these claims will not be subject to future audits. For purposes of this provision, "future audits" would be limited to pre-payment review, post payment review, CERT audits, RAC audits, etc. Failure to provide some guarantee that claims that receive a provisional affirmation through prior authorization would not be relieved from being subject to future claim denial or audit accomplishes nothing other than imposing another administrative hurdle in an already overly burdensome claim processing system.

AOPA is very concerned regarding the proposed timeframe for prior authorization decisions regarding lower limb prostheses, specifically as they relate to the efficient and timely provision of prosthetic care to Medicare beneficiaries. The proposed rule states that CMS or its contractors would make "reasonable efforts" to communicate a prior authorization decision within 10 days of receipt of all applicable information. The proposed rule does not indicate what constitutes a "reasonable effort," nor does it indicate any consequence if the 10 day period is surpassed. The proposed rule only states that final timelines for communicating an affirmed or non-affirmed decision to the requester would be described in the CMS manual and on the CMS prior authorization website. AOPA believes that the final rule must clearly define specific timeframes that must be met by CMS or its contractors regarding communication of prior authorization decisions, including specific processes that must be followed if the timeframe for the decision is exceeded. Unlike many DME items that can be delivered to patients after a significant delay in communicating a prior authorization decision, unnecessary delays in the provision of a lower limb prosthesis may significantly impact a patient's ability to begin rehabilitation and restore function, and in extreme circumstances could represent a life threatening situation. Early prosthetic intervention is often a crucial element of the rehabilitation process and should not be impeded by arguments over whether a contractor made a "reasonable effort" to communicate a prior authorization decision. While the proposed rule does include a provision that requires an expedited review of the prior authorization request in situations where a delay could seriously jeopardize the life or health of the beneficiary, there remains no discussion of who makes that decision and what happens if the expedited review is delayed. The final rule must provide specific guidelines regarding the consequences that will occur if the prior authorization decision is delayed for any reason.

While AOPA does not fundamentally disagree with the provision of the proposed rule that allows an unlimited number of prior authorization request resubmissions, it does question the doubling of the timeframe for resubmission decisions from 10 days to 20 days. This seems to be punitive in nature and only serves to further delay the provision of critically needed care to Medicare beneficiaries. While AOPA understands the need to prevent the submission of incomplete prior authorization requests, the 20 day timeframe for decisions on resubmissions appears to be excessive and represents further administrative burden to providers who are acting in good faith. AOPA requests that the final rule consider reducing the timeframe for decisions involving prior authorization resubmissions to the same time period as initial decisions. Five days is the longest time for a decision on prior authorization that is compatible with maintaining quality patient care. The final rule should establish a five day maximum lag time to approve or to deny with an explanation. In order to ensure that a decision is made in a

timely manner, if a decision has not been made in five days, accompanied by specific reference and details pertaining to the specific beneficiary (no blanket disapprovals as a matter of CMS delay and convenience), the prior authorization request must be deemed approved and final so that patient care may proceed. Patients who have to wait longer for services as the result of either a CMS or contractor delay, or a minor omission will be unfairly impacted by these delays in care.

In addition, AOPA believes that if a prior authorization submission receives provisional affirmation, and there is a subsequent need to provide prosthetic components that were not included in the original provisional affirmation, but remain consistent with the functional level assessment that governed the provisional affirmation, those components should remain covered under the existing provisional affirmation. While this is a relatively rare occurrence, requiring a new provisional affirmation will only delay the provision of medically necessary prosthetic care. In situations where changes to componentry are required that are not within the previously affirmed functional level classification, there should be an expedited review of the revised prior authorization submission. AOPA believes the final rule should allow for minor changes without further prior authorization or expedited review of the prior authorization when more significant changes are required.

Subsection E: Liability

AOPA supports the provision of the proposed rule that allows Medicare beneficiaries to make informed decisions regarding acceptance of financial liability for claims that do not receive provisional affirmation through the prior authorization process. The Advanced Beneficiary Notice (ABN) remains the only method to allow a patient to accept financial responsible for a service that is expected to be deemed not medically necessary. While waiver of liability provisions continue to protect Medicare beneficiaries from financial liability for claims denied as not medically necessary, the proposed prior authorization process provides information to the patient, prior to receiving a DMEPOS item, regarding Medicare's coverage decision for the item. A non-affirmative prior authorization decision allows the patient to be informed, through the issuance of a properly executed ABN, that Medicare will most likely deny the service as not medically necessary. The patient can then make an educated decision regarding the provision of the service and subsequent shift of financial liability from the provider to the beneficiary.

Summary of AOPA Comments

In summary, the CMS proposal to institute Medicare prior authorization for prosthetics (as well as a seemingly undefined eventual role in orthotics), in the form published on May 28, is not a viable plan that could work for continued delivery of quality and timely prosthetic patient care for Medicare amputees.

From the perspective of the most important person in the picture, the patient, there is virtually nothing about prior authorization which could benefit the patient in any way. Rather, it threatens patients with possible: (a) downgrade of the prosthetic limb they receive; (b) delays in approval, which mean a delay for rehabilitation that will certainly increase co-morbid conditions; and (c) higher out-of-pocket costs if the patient requires a high quality replacement limb. From a beneficiary perspective, the best thing that could happen is for CMS to withdraw this proposal and drop prior authorization for all aspects of direct prosthetic patient care.

AOPA continues to believe that prior authorization is not an effective method for protecting the Medicare Trust Fund **AND** ensuring efficient and appropriate access to prosthetic care for Medicare beneficiaries. If prior authorization for lower limb prostheses is to have ANY chance of being palatable for providers, and not dangerous for Medicare amputees, CMS must incorporate the following revisions in the final rule:

1. **Prior Authorization Must Constitute a Guarantee of Medicare Payment**

2. **RAC Audits and Pre-Payment Review Must Cease Immediately Once Prior Authorization Regulations Are Issued in Final Form**

3. **There Should Be a Higher Dollar Threshold for Lower Limb Prostheses to Be Subject to Prior Authorization**

4. **There Must Be Certainty in the Prior Authorization Process That Prior Authorization Decisions are Made and Decision Conveyed, with Explanation, in No More than 5 Days**

5. **CMS Must Acknowledge that the Prosthetist's Notes and Records on Patient Visits ARE a Legitimate part of the Medical Record, on the same basis as those of the physician, therapist or other licensed and/or accredited health care provider.**

AOPA appreciates the opportunity to participate in the valuable notice and rulemaking process and looks forward to the CMS response to its concerns regarding the proposed implementation of prior authorization for certain DMEPOS items.

Sincerely,

Thomas F. Fise

AOPA Executive Director