American Academy of Physical Medicine and Rehabilitation

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July 28, 2014

Ms. Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1600-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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 more than 8,000 physiatrists of the American Academy of Physical Medicine and Rehabilitation (AAMP&R), we appreciate the opportunity to submit comments to the proposed rule: Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items [CMS-6050-P] that was published in the Federal Register on May 28, 2014. Physiatrists are specialists in the field of physical medicine and rehabilitation (physiatry) and treat adults and children with acute and chronic pain, persons who have experienced catastrophic events resulting in paraplegia, quadriplegia, traumatic brain injury, spinal cord injury, limb amputations, rheumatologic conditions, musculoskeletal injuries, and persons with neurologic disorders or any other disease process that results in impairment and/or disability.

In this proposed rule, CMS proposes the development of a prior authorization process for DMEPOS that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization. AAPM&R agrees with CMS that it is important to reduce inappropriate utilization of orthotic and prosthetic (O&P) services. However, the Academy has several concerns about the proposed Medicare prior authorization process for certain DMEPOS identified in the proposed rule as determined by the agency's proposed criteria. Additionally, given the experience all Medicare providers have had in recent years with extensive administrative law judge hearing delays, the proposed rule's assurances on timeliness of prior authorization decisions ring hollow. **We urge CMS to implement proper safeguards in the Medicare prior authorization process to ensure that individuals with disabilities and chronic conditions receive timely access to specialized assistive devices, technologies, and related services.**

Proposed Prior Authorization for Certain DMEPOS Items

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CMS proposes that using a prior authorization process will help to ensure items frequently subject to unnecessary utilization are furnished in compliance with applicable Medicare coverage, coding and payment rules before they are delivered. **AAPM&R requests that CMS be fully transparent and provide clear standards indicating which documents are considered necessary in order to obtain provisional prior authorization.**

Additionally, the Academy urges CMS to recognize how important it is that the agency and its contractors take into consideration the entire clinical record of the patient when determining the medical necessity of prosthetic limb care for Medicare beneficiaries. For decades, physicians, including physiatrists, have worked closely with prosthetists as part of the rehabilitation team to provide optimal prosthetic care to Medicare beneficiaries. With the myriad of choices available and the rapid changes in prosthetic technologies on the market, physicians and prosthetists need more than ever to work collaboratively in selecting the most appropriate prosthetic care that meets the patient's individual medical and functional needs in the most cost effective manner.

While the ultimate responsibility of the prosthetic prescription falls solely upon the physician, the complex nature of custom prosthesis fabrication necessitates a collaborative relationship between the physician and prosthetist. As such, the medical documentation of the rehabilitation treatment team, including the therapist and/or prosthetist, should be considered in determining medical necessity. Thus, AAPM&R continues to urge CMS to include as part of the medical record all "supplier-produced records," and to recognize the importance of collaboration between healthcare providers to promote better patient care.

Proposed Criteria for Inclusion on the Master List of DMEPOS Items Frequently Subject to Unnecessary Utilization (Master List)

In this rule, CMS provides a proposed Master List of initial items that based on certain criteria including the item has been identified in a Health and Human Services Office of Inspector General (OIG) report, are frequently subject to unnecessary utilization and will be subject to prior authorization. AAPM&R believes that the OIG report entitled, "Questionable Billing by Suppliers of Lower Limb Prostheses," used to establish the principle that certain lower limb prostheses are items frequently subject to overutilization is flawed.

The Academy believes that the OIG utilized improper claims sampling techniques in reaching its negative findings that 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 practitioner or supplier is considered qualified to bill the codes that describe the items provided to the beneficiary. We believe that a failure to

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segregate claims by the qualifications of the practitioner or supplier has contributed to the OIG's finding that the billing practices of providers of O&P services are "questionable."

AAPM&R urges CMS 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 practitioners and suppliers.

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

In particular, CMS proposes that the agency or its contractors would make reasonable efforts to communicate the decision of any prior authorization request within 10 days of receipt of all applicable information. AAPM&R strongly believes that the proposed timeframe for issuing a prior authorization decision is unnecessarily long, which will jeopardize the patient's access to timely and appropriate care. Additionally, any delay in the prior authorization documentation process will directly result in further treatment delays. For example, an ambulatory patient, the delay in treatment may cause the patient to be forced to endure unnecessary pain for an extended period of time while CMS renders a decision. Worse yet, such a delay could render an amputee non-ambulatory for a significant period of time which paperwork and documentation are secured to prove the medical necessity of the care needed by the patient. For a patient awaiting his or her first prosthesis, 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.

AAPM&R recommends CMS institute a response deadline for Medicare Administrative Contractor (MACs) approval of an initial request (and all resubmitted requests) of five days, rather than 10 days; if a MAC does not respond to a prior authorization request within five business days, CMS should consider the device's prior authorization request approved.

To address circumstances where applying the standard timeframe for making a prior authorization decision could seriously jeopardize the life or health of the beneficiary, CMS proposes an exception to the initial review timeline. The Academy agrees that an exception should be made in these circumstances. However, CMS does not provide additional information on how CMS and its MACs will determine when an individual's medical condition warrants expedited review. **AAPM&R recommends that CMS provide more detailed criteria and examples for when an expedited review is warranted, including when an individual's ability to function is sufficiently impaired that immediate access to a device could improve or prevent deterioration of function. Additionally, the Academy requests that conditions such as significant functional improvement and maintenance or prevention of deterioration be included as reasons to expedite review.**

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Another safeguard that AAPM&R believes should be put in place is a mandate that contractors provide detailed reasons for denying a prior authorization request, and require that Medicare contractors resolve disputes concerning medical necessity documentation through open discussion between the Medicare contractors' medical personnel and the service provider. The Academy believes that CMS and its contractors should cite a specific reason for denying a prior authorization request. If CMS denies a prior authorization request three times, we recommend that Medicare contractors resolve disputes concerning medical necessity documentation through mediation with the DMEPOS supplier. Specifically, the MAC's medical director should grant the DMEPOS supplier the opportunity to have an in-person or telephonic conference to discuss the denials, which would allow the supplier to make his or her case as to why the item or service at issue is medically necessary.

CMS proposes that a provisional affirmation is a preliminary finding that a future claim meets Medicare's coverage, coding, and payment rules. However, claims receiving 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. AAPM&R agrees that duplicative claims and claims that are not substantiated by delivery of a device should be denied. However, the Academy believes that CMS should provide assurance that once it grants provisional prior authorization, the DME MACs and other Medicare contractors will be prohibited from later examining the claim to determine the medical necessity of the furnished DMEPOS item, except in these limited circumstances. **Thus, we urge CMS to clarify that DME MACs may only conduct a pre- or post-payment review of the claim to determine whether the claim was duplicative; to determine whether the beneficiary died after CMS rendered its prior authorization decision; and to determine if the claim fails to satisfy any technical requirements such as proper proof of delivery.**

The agency also specifically solicits public comment on whether the proposed process would meet its objective of ensuring beneficiary access to care and protecting the Medicare Trust Funds without placing undue burden on practitioners and suppliers. The AAPM&R does not believe that as proposed CMS is meeting this objective. In fact, the Academy believes that the proposed prior authorization process will not only create undue burden on the practitioner and suppliers of O&P services, but will delay patient care.

Thus, the Academy would like to bring to CMS's attention Section 427 of the Beneficiary Improvements and Protection Act of 2000 ("BIPA"). An existing federal law enacted 14 years ago but never fully implemented through statutorily required regulations. BIPA requires 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 Academy believes that enforcement of this section of the existing federal law would dramatically reduce the need to impose the additional administrative burden of prior authorization.

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As a result of CMS' failure to appropriately enforce 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. We believe that this contributes to the alleged questionable billing practices of providers of O&P services. Additionally, AAPM&R does not believe that currently the DME Medicare Administrative Contractors (MACs) have claims processing system "edits" that enable the MAC to ensure billing for custom O&P services and devices is limited to appropriately licensed, certified, accredited, or otherwise qualified O&P practitioners and suppliers. The Academy believes that linking Medicare reimbursement for custom orthotics and prostheses to the qualifications of the practitioner or supplier providing the care would significantly advance accountability and quality in this area, while reducing inappropriate utilization.

The Academy recommends that CMS enforce BIPA to curtail the incidence of overpayments for custom orthotics and prosthetics from unqualified providers and suppliers; therefore, avoiding the need to implement the unnecessarily burdensome prior authorization requirement that will likely delay patient care.

AAPM&R is committed to improving quality of care and restoring beneficiaries' functionality and quality of life. Additionally, the Academy strongly believes that it is imperative to ensure beneficiaries receive medically necessary care while minimizing the risk of improper payments. However, the Academy believes that prior authorization is not the appropriate process for O&P care and other alternative policies are more applicable to reduce unnecessary utilization and improve patient care.

The Academy appreciates the opportunity to comment on this proposed rule. The AAPM&R looks forward to continuing dialogue with CMS on this important issue. If you have any questions about our comments, please contact Jenny Jackson, Manager of Finance and Reimbursement in the AAPM&R Division of Health Policy and Practice Services. She may be reached at jjackson@aapmr.org or at (847)737-6024.

Sincerely,

Peter Esselman
Chair
Quality Policy and Practice Research

cc:
Phillip Bryant, DO
Chair
Reimbursement and Policy Review Committee