February 23, 2018

Seema Verma, Administrator
Center for Medicare & Medicaid Services, Dept. of HHS
300 Independence Avenue, NW
Washington, DC 20201

Dear Administrator Verma,

AOPA applauds Congress for having enacted Section 50402 of the Bipartisan Budget Act of 2018. This provision provides the statutory resolution, to challenges for patients and providers that arose when CMS' DMEMAC contractors on August 11, 2011 issued a "Dear Physician" letter that withdrew validity of the records and notes on the orthotist/prosthetist patient encounters as part of the medical record for purposes of Medicare's determination of medical necessity. The statute is now absolutely clear and unambiguous—Congress says that documentation created by the orthotist or prosthetist is part of a Medicare patient's medical record for purposes of determining the medical necessity of orthotic and prosthetic care.

While it seems undeniably clear that Section 50402 should be self-actualizing, rescinding the contractors' "Dear Physician" letter, we urge the quick, easy confirmatory implementation statement of this one-sentence provision by your agency.

The following statement was issued by CMS DMEMAC contractor Noridian earlier this week (see attached) which said, "As contractors, we require CMS instructions before implementing new legislation."

The CMS statement can be remarkably simple: The Dear Physician letter issued on August 11 is withdrawn and rescinded and both CMS and all CMS contractors must observe on all pending and future claims the clear words Congress enacted: "For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by eligible professionals described in section 1848(k)(3)(B).''

We therefore urge your issuing this on a high priority basis to assure claims are processed according to the current federal law.

Very truly yours,

James Weber, President

Thomas F. Fise, Executive Director

cc: Demetrios Kouzoukas, Principal Deputy Administrator
Kim Brandt
Laurence Wilson
Melanie Combs-Dyer
George Mills

August 11, 2011

Dear Physician – Documentation of Artificial Limbs

Dear Physician,

The Durable Medical Equipment Medical Administrative Contractors (DME MAC) have jurisdiction for processing claims from prosthetists for artificial limbs. In the event of an audit, the Medicare contractor may request medical records to demonstrate that the prosthetic arm or leg was reasonable and necessary. Since the prosthetist is a supplier, the prosthetist's records must be corroborated by the information in your patient's medical record. It is the treating physician's records, not the prosthetist's, which are used to justify payment.

The patient's functional capabilities are crucial to establishing the medical necessity for a prosthetic device. Many prosthetic components are restricted to specific functional levels; therefore, it is critical that physicians thoroughly document the functional capabilities of their patients, both before and after amputation. Clinical assessments of a patient's rehabilitation potential must be based on the following classification levels:

> **Level 0:** Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
>
> **Level 1:** Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
>
> **Level 2:** Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
>
> **Level 3:** Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
>
> **Level 4:** Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

The records must document the patient's current functional capabilities and his/her expected functional potential, including an explanation for the difference. Note that it is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications.

The physician's assessment of a patient's physical and cognitive capabilities typically includes:

- History of the present condition(s) and past medical history that is relevant to functional deficits
- Symptoms limiting ambulation or dexterity
- Diagnoses causing these symptoms
- Other co-morbidities relating to ambulatory problems or impacting the use of a new prosthesis
- What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used (either in addition to the prosthesis or prior to amputation)
- Description of activities of daily living and how impacted by deficit(s)
- Physical examination that is relevant to functional deficits

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- Weight and height, including any recent weight loss/gain
- Cardiopulmonary examination
- Musculoskeletal examination
    - Arm and leg strength and range of motion
- Neurological examination
    - Gait
    - Balance and coordination

The assessment points above are not all-inclusive and physicians should tailor their history and examination to the individual patient's condition, clearly describing the pre and post-amputation capabilities of the patient. The history should paint a picture of your patient's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the patient's ambulatory or upper extremity difficulties or impact on the patient's functional ability.

Note that when physicians are unable to provide the requested documentation to the supplier, the suppliers receive denials for the items billed which could result in your patient being financially responsible for all or part of the charges for the items/service received. If a supplier contacts your office to request additional clinical documentation, please partner with the supplier to establish what clinical records are needed to support that the service/item you ordered is medically necessary.

Section 1842(p)(4) of the Social Security Act mandates that:

> [i]n case of an item or service…ordered by a physician or a practitioner…but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner.

Providing medical records to the supplier is not a violation of the HIPAA Privacy Rule. Thank you for your cooperation in future documentation requests.

Sincerely,

Paul J. Hughes, MD
Medical Director, DME MAC Jurisdiction A
NHIC, Corp.

Stacey V. Brennan, MD, FAAFP
Medical Director, DME MAC Jurisdiction B
National Government Services

Robert D. Hoover, Jr., MD, MPH, FACP
Medical Director, DME MAC Jurisdiction C
CGS

Richard W. Whitten, MD, MBA, FACP
Medical Director, DME MAC Jurisdiction D
Noridian Administrative Services

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