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**American Orthotic &  
Prosthetic Association**

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July 22, 2013

Marilyn B. Tavenner, Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

**Subject: Agency Efforts Toward a Clinical Template for Prosthetics—Issues  
Relating to Content and Process**

Dear Administrator Tavenner:

AOPA has watched with some concern over the past 60 days, since we discovered via the CMS website, that the agency had embarked on an effort to develop what we would call a Clinical Template for Prosthetics. I wanted to take this opportunity, before the process proceeds any further, to share those concerns with you.

Ironically, the first information about this Clinical Template effort was posted on the CMS website on May 7, 2013. You'll recall that on the following afternoon, May 8, you met with members of the Orthotic & Prosthetic Alliance. While our meeting with you on that date clearly did not solve the very significant problems relating to the multiple due process questions nor the devastating impediments to both patient care and coherent business practices triggered by RAC and pre-payment audits of prosthetics initiated by CMS contractor personnel, I want to underscore that attendees at the May 8 meeting were very impressed by two central commitments, or perhaps stated better, indications of intention, which you conveyed during that meeting:

- (1) your intention that CMS would publish two proposed rules on O&P before the end of the calendar year—one to establish the clinical template for prosthetics; and the second to finally implement the long-awaited (13 years) BIPA section 427 regulations on qualified providers of orthotics and prosthetics; and
- (2) your intention that the clinical template you spoke about would be a document that could be completed by the prosthetist, and reviewed and signed by the referring physician who had evaluated the patient, prescribed the prosthesis, and communicated his/her prognosis in terms of the expected functional level, or K-level that the patient could be expected to achieve once the prescribed prosthesis is received.

Unfortunately, agency actions subsequent to the May 8 meeting have left us with grave doubts regarding both the appropriateness of the process CMS appears to be using as well as the content of the Clinical Template. Quite simply, it seems that the agency staff is pursuing this effort in a manner very inconsistent with the two statements of intent you implied at the May 8 meeting.

You are aware that AOPA has been very concerned with the impact on patient care and the small business owners in the O&P profession resulting from the change of audit standards by the “Dear Physician” letter published in August, 2011 and implicit modifications that led to much increased reliance on physician documentation to establish medical necessity for a specific prosthetic device. Our concern was manifest through a challenge as to whether CMS utilized the required stakeholders’ protections in a process that met the requirements of the Medicare law and the Administrative Procedure Act. So far, CMS has published a draft document on its website with very low key notifications to potential stakeholders. A one hour conference call was held for dialogue, at which a limited amount of time was available for questions or comments. Unfortunately, a much larger number of stakeholders who indicated their desire to provide input or ask questions, were not accommodated with an opportunity to express and enter their position on the record. These steps do not satisfy the need for publication of any such proposal in the Federal Register, and the opportunity for a period of open comment toward a formal rulemaking. Those indispensable steps may be forthcoming later in the process, in a way that would render the process consistent with your stated intention of publishing a proposed rule, but we have not yet seen any evidence of the agency’s intent to do so.

Turning to the content of the form published on the CMS website on May 7, the agency staff has virtually replicated the template that was developed for power mobility equipment (PME). Medical necessity for a power wheelchair is dramatically different from medical necessity for a prosthetic limb. In fact, it is unequivocally obvious whether a patient has the medical necessity for a prosthetic limb—the patient is either missing a limb, or the patient is not. We suspect that the agency intended to match the functional aspects of the patient’s condition with specific types of componentry for the artificial limb. Suffice it to say that ‘retreading’ the PME template neither advances the cause of establishing the unique (and simpler) medical necessity issues for a prosthetic limb, nor does it render either any cognizance or deference to your stated intention of providing a template which would be a document that could be completed by the prosthetist, and reviewed and signed by the referring physician.

Perhaps these very serious flaws will be remedied later to bring this process into alignment with your stated intentions, but we want to underscore now the disparities in terms of both process and content, hoping that they are remedied. It is our desire to avoid any situation where the procedural errors implicit in the ‘Dear Physician’ letter are repeated in the intended Clinical Template document.

### **Two Additional Items of Dialogue with the Provider Compliance Group Requiring Broader Attention/Clarification**

There is another element which needs to have a very significant focus in this process. There has been much discussion (and writings) about the legitimacy of the prosthetist’s

notes as a part of the patient's medical record. There have been some serious inconsistencies between the statements of CMS staff vs. the statements of CMS' contractors (including the DME MACs) on this subject. While AOPA does not fully agree with it, Provider Compliance Group Director George Mills included a relatively clear statement of position on this topic in his letter to me dated April 10 when he said: "(W)hile CMS agrees that documents provided to the treating physician and included in the beneficiary's chart do become part of the 'medical record,' the prosthetist's notes are but part of the whole medical record and are considered in the context of documentation made by the treating physician. We emphasize that while an ordering physician may incorporate a prosthetist's documentation into a medical record, these documents are not sufficient by themselves to establish that an item or service is reasonable and necessary.."

AOPA has passed this information along to many in the field and it would be greatly enlightening to everyone if CMS, in conjunction with this template building process, would make a clear and public reiteration of the above statement in Mr. Mills' letter. AOPA would, of course, reserve the prerogative to petition and persuade CMS on according a greater value for the prosthetist's notes. CMS' reiteration of the above, in addition to educating O&P personnel, would also bridge the gap of abovementioned inconsistencies between statements of CMS personnel as contrasted with statements of CMS contractors on this topic.

Additionally, and finally, in early April Mr. Mills and I had a discussion, both by telephone and followed up via email relating to the asserted inconsistency between Medicare amputee beneficiaries having both a K3 or K4 level prosthesis if they also have a power wheel chair. The email component of that conversation is attached. There has been much discussion since that time of the possibility of claims edits to identify for greater scrutiny Medicare beneficiaries who have received both of these types of devices. We were, of course, pleased to learn from Mr. Mills that, "*(H)owever, CMS contractors would not auto-deny a prosthetic claim just because there was also a claim for a PMD without doing a full review of the medical records.*" AOPA believes it would be inappropriate and detrimental to Medicare amputee beneficiaries if any new policy were initiated which would assume in any way that possession of a power wheel chair is in any sense incompatible with that same patient being qualified for a K-3 or K-4 prosthesis. Perhaps more importantly, it is our position that any such policy change would constitute another substantial change to the standard of care for Medicare beneficiaries, and therefore could not be instituted legally except through a rulemaking process which would both assure due process for both patients and providers and allow stakeholder input via a notice and rulemaking process.

Both as to the overarching issue of medical necessity for a particular type of prosthesis (the bulk of CMS audit activity seems focused on trying to drive down the K level, presumably on the false assumption that K-levels are somehow being "upcoded"). In fact, the data from Medicare records actually contradict the assumption of upcoding,

since the actual total Medicare costs of K3/K4 level patients are lower than the total Medicare costs for K1/K2 level patients (despite the fact that a K3/K4 prosthesis alone is more expensive than a K1/K2 prosthesis). Please note the following from the comprehensive study conducted by Dobson-DaVanzo for the Amputee Coalition of Medicare costs for orthotics and prosthetics:

“ As shown in Exhibit 4.10, patients fit with K1/K2 devices had a comparable average Medicare PMPM payment to K3/K4 patients (\$5,460 PMPM compared to \$5,233). Despite the comparable Medicare PMPM payment, K1/K2 patients had more SNF admissions suggesting that patients with lower level devices were more likely to use facility-based care (2.02 SNF admissions for K1/K2 patients compared to 0.84 SNF admissions for K3/K4 patients;  $p < 0.05$ ). However, the number of acute care hospitalizations was comparable across K1/K2 and K3/K4 patients (1.25 admissions compared to 1.12 admissions).

“The fact that patients who received a K3/K4 prosthetic had comparable Medicare PMPM payments despite significantly higher DME payments (\$1,660 PMPM compared to \$1,153,  $p < 0.05$ ) suggests that patients who should receive a K1/K2 prosthetic due to lower functional status are not being fit with K3/K4 prosthetics. If K1/K2-level patients were receiving K3/K4-level prosthetics, we would expect to see higher PMPM payments among the K3/K4 cohort in the use of facility-based care, and would expect to see overall higher PMPM payments due to the higher DME costs for the prosthetic.”

### Comments on the Clinical Template

AOPA cannot agree with the format of the draft CMS Template that was released on May 7. As noted above, it is a “retread” of the PME template ignoring vast differences between the devices and related medical necessity issues, and it is inconsistent with your stated intentions for a template you spoke about that would be a document that could be completed by the prosthetist, and reviewed and signed by the referring physician.

CMS would move closer to the mark if your efforts were re-directed to a Clinical Template for the Prosthetist to Complete. If you move in that direction, such a document would include specific information for the prosthetics to provide regarding:

- Documentation of the patient’s current use of a prosthesis if applicable
- A clinically based assessment of the patient’s previous, current, and potential functional capabilities and an explanation of any difference if applicable
- Documentation of the patient’s desire to ambulate with a prosthesis
- Documentation of the patient’s activities of daily living and the ability of a prosthesis to provide assistance in performing them

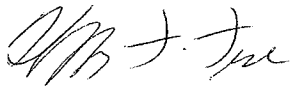
We also reiterate our hope that the process will follow procedures which include public notice in the **Federal Register** and an opportunity for all stakeholders, including patients,

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providers and others, to provide testimony and written statements regarding the proposal so the best possible clinical template can be developed that will satisfy the needs of CMS and all stakeholders.

Thank you for your consideration of these concerns. Please feel free to contact me if we can further explicate or dialogue on these topics.

Very truly yours,

A handwritten signature in black ink, appearing to read "T. Fise", written in a cursive style.

Thomas F. Fise  
Executive Director



## Don DeBolt

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**To:** Tom Fise  
**Subject:** RE: Follow Up

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**From:** Mills, George G. (CMS/OFM) [<mailto:george.mills@cms.hhs.gov>]

**Sent:** Saturday, April 13, 2013 9:01 PM

**To:** Tom Fise

**Cc:** Combs-Dyer, Melanie K. (CMS/OFM); Nicolaisen, Jill A. (CMS/OFM); Handrigan, Michael T. (CMS/OFM); Stacey V Brennan MD ([stacey.brennan@wellpoint.com](mailto:stacey.brennan@wellpoint.com)); Robert Hoover ([ROBERT.HOOVER@cgsadmin.com](mailto:ROBERT.HOOVER@cgsadmin.com)); 'paul.hughes-md@hp.com' ([paul.hughes-md@hp.com](mailto:paul.hughes-md@hp.com)); Dick Whitten ([Dick.Whitten@NORIDIAN.COM](mailto:Dick.Whitten@NORIDIAN.COM)); Miller, Susan (CMS/OCSQ)

**Subject:** RE: Follow Up

see responses below

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**From:** Tom Fise [[TFise@AOPANet.org](mailto:TFise@AOPANet.org)]

**Sent:** Wednesday, April 10, 2013 10:11 AM

**To:** Mills, George G. (CMS/OFM)

**Cc:** Tavenner, Marilyn (CMS/OA)

**Subject:** RE: Follow Up

George,

Thanks very much for your formal responses to my two letters forwarded this morning. Now, we are left to try to determine what those two formal letters actually mean. In that regard, I have two further questions, and one comment.

(1) You mention the potential conflict of interest (you refer to a "vested financial interest") which the prosthetist purportedly has in asserting that the prosthetist's records alone, even if legitimately considered to be part of the medical record, cannot justify medical necessity. In truth, every provider involved in rendering care in our health care system is beset with conflicts or potential conflicts. Are you asserting that the potential conflict of the prosthetist is any different from:

(a) the potential conflict when the internist decides to direct that a patient receive either a chest x-ray, or an EKG that is performed on the machine that is located in that physician's office and owned by that physician's practice; or

(b) the potential conflict of the surgeon who recommends that the patient needs to have a Nissen fundoplication performed, rather than treating the patient's reflux with long term proton pump inhibitor therapy; or

(c) the potential conflict of the gastroenterologist who recommends that the patient have a colonoscopy which that physician will perform?

I ask because I do not believe that CMS has established medical necessity guidelines in any of the above circumstances in an effort to address the potential conflicts/"vested financial interests" there which parallel the dramatic guidelines you have asserted with respect to the potential conflict of a prosthetist who works in conjunction with the patient's physician to develop a prosthetic treatment plan for that patient.

**Response:** *While the examples you provide do represent potential areas of concern, there are statutory provisions to mitigate those risks through legislation (e.g., Stark, anti-kickback). Moreover, the statute has specifically designated those providers that are allowed to independently bill Medicare for their patient care services. In addition, the services provided by these clinicians must be reasonable and necessary for payment. Contractors often review the physician's records to determine if the chosen procedure or test*



was appropriately documented and reasonable and necessary. CMS has a long-standing policy prohibiting contractors from accepting DMEPOS supplier-created records as sole documentation of medical necessity. CMS and its contractors encourage close communication between the DMEPOS supplier and the referring physician. This often includes providing the treating physician with the DMEPOS supplier's documentation; however, as noted in the Medicare Program Integrity Manual (Internet-Only Manual, Publ. 100-8, Chapter 5, Section 5.7), these notes (even if co-signed by the physician) are not enough themselves to justify medical necessity. There must be documentation in the physician's records to justify that the service is reasonable and necessary. This standard is applied to all DMEPOS items not just O&P.

(2) With respect to your letter on K-level, are you asserting that it is appropriate for a non-physician claims reviewer employed by one of the Medicare contractors who has never seen the Medicare beneficiary, solely on the basis of a review of that patient's medical record, to reverse and overrule the professional judgement of that patient's treating physician in assessing the doctor's prognosis of the appropriate K-level, and thereby that physician's prognosis of the potential mobility for the patient that physician has been treating with what the physician has determined is the appropriate prosthetic care for that patient? I should add that your letter seems to ignore the central modification Jurisdiction B seems to be making that was brought into question by my letter--that potential, or theoretical determinations, which are implicit to every physician prognosis, for some inexplicable reason are not appropriate in a K-level determination?

**Response:** All medical review or prior authorization activity conducted by Medicare is based on medical records without CMS staff (or contractor staff) seeing the patient. This has been the procedure for medical review in the Medicare program since July 1966. The medical record, from a claim review standpoint, allows the reviewer to determine the plan of care of the patient, including the diagnosis, planned treatment(s) and, most importantly, why those treatment(s) were selected. In most cases, the expectation is that care is based on generally recognized clinical standards of care. A well-documented record will convey this information.

With respect to contractors and claim review, CMS has minimum clinical standards for contractor staff who perform complex review of DMEPOS claims. The clinicians are skilled in medical necessity review and are encourage to use their clinical judgment in their review of claims. In addition, contractors may also engage additional consultants to assist in their review of claims in areas where specific expertise may be necessary. Staff base their review decisions on criteria outlined in CMS manuals, national and local coverage policies when making claim determinations. In addition, there is a robust appeals process which allows an independent review of the case. CMS conducts diligent oversight of contractors to ensure that correct decisions are made. As noted on our call about the example cases you submitted, other than the claim for a repair CMS agreed with the decisions reached by the contractors.

Finally, I would also urge your caution to the extent that, as referenced in your letter, Medicare or its contractors may be inclined to construe the presence of some type of mobility device (whether PMD, wheelchair, or walker) in the patient's medical records as if it demonstrates an inconsistency with medical necessity for a K-3 or K-4 determination. Like all of us, these patients periodically wake up during the night needing to access the bathroom, and not wearing the prosthesis while sleeping and not inclined to take the time to put on the prosthesis prior to accessing the bathroom, it is very common to utilize such a mobility device in these limited circumstances.

**Response:** In response to this comment and our the other day about a K3 or K4 level beneficiary receiving a PMD:



In your example, you talked about a K3 or K4 level beneficiary who needed a PMD to go to the bathroom at night while not wearing the prosthesis. Going to the bathroom at night is an activity of daily living. We agree that there may be some situations where a K3 or K4 level beneficiary may possibly qualify for a PMD, our experience is that these situations are rare. In such a situation, all of the requirements of the National Coverage Decision relating to Mobility Assistive Equipment still apply. Medicare is responsible to provide the least complex item that will meet the beneficiary's needs. Just as a reminder, this could include use of other assistive devices, such as a quad cane or walker, optimally-configured manual wheelchair or even a POV (scooter) before requiring a PMD. However, CMS contractors would not auto-deny a prosthetic claim just because there was also a claim for a PMD without doing a full review of the medical records. For your reference here are the Medicare Local Coverage Determination requirements for a PMD:

#### BASIC COVERAGE CRITERIA:

All of the following basic criteria (A-C) must be met for a power mobility device (K0800-K0898) or a push-rim activated power assist device (E0986) to be covered. Additional coverage criteria for specific devices are listed below.

A. The patient has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. A mobility limitation is one that:

- Prevents the patient from accomplishing an MRADL entirely, or
- Places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or
- Prevents the patient from completing an MRADL within a reasonable time frame.

B. The patient's mobility limitation cannot be sufficiently and safely resolved by the use of an appropriately fitted cane or walker.

C. The patient does not have sufficient upper extremity function to self-propel an optimally-configured manual wheelchair in the home to perform MRADLs during a typical day.

- Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function.
- An optimally-configured manual wheelchair is one with an appropriate wheelbase, device weight, seating options, and other appropriate nonpowered accessories.

As I also noted on the call, the existence of the PMD itself does not mean that the prosthetic claim itself would be incorrect, the PMD claim could be incorrect, or both claims incorrect/correct.

Thanks for clarifying these factors. And we appreciate the inclusion of codes 51 and 55 in the Recovery Audit record limits.

Tom