DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C3-09-27
Baltimore, Maryland 21244-1850

PROVIDER COMPLIANCE GROUP

Thomas F. Fise
Executive Director
American Orthotic and Prosthetic Association
330 John Carlyle Street, Suite 200
Alexandria, VA 22314

APR 10 2013

Dear Mr. Fise:

I am in receipt of your letter dated March 8, 2013 in which you expressed the American Orthotic and Prosthetic Association's (AOPA) concerns about statements made by Centers for Medicare & Medicaid Services (CMS) staff and Jurisdiction B Durable Medical Equipment Medicare Administrative Contractor (DME MAC) staff regarding the appropriateness of prosthetist's notes and their inclusion in the treating physician's beneficiary records. Specifically, you recount a conversation with Susan Miller, MD from the CMS Coverage and Analysis Group where she reportedly confirmed that when prosthetists provide the treating physician with their records, they become part of the beneficiary's medical record. 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. I believe that there are semantics that confuse your interpretation of Dr. Miller's statement that are clarified below.

Section 1862(a)(1)(A) of the Social Security Act requires that Medicare only pay for items or services that are reasonable and necessary. In addition, Section 1833(e) of the Social Security Act precludes payment unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." Medicare looks to the documentation in the *treating physician's records* as the primary source of information to support that the item or service is reasonable and necessary. This requirement is described in detail in CMS' Program Integrity Manual (Internet Only Manual 100-8). Chapter 5, Section 5.7 explains:

> For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable).

This section goes on to explicitly exclude supplier created records, physician attestation letters, etc. as being sufficient on their own to justify reimbursement.

> If an item requires a CMN or DIF, it is recommended that a copy of the completed CMN or DIF be kept in the patient's record. However, neither a physician's order nor a CMN

> nor a DIF nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) or DIF (if applicable) or information on a supplier prepared statement or physician attestation (if applicable).

In practical application of these requirements, documentation from providers with a vested financial interest in the outcome of the claim decision *is not* used as the primary source for making a reasonable and necessary determination.

The DME MAC medical directors recognize that certified orthotists and prosthetists have a unique skill set and training necessary in providing care to Medicare beneficiaries. Similarly, licensed respiratory therapists, registered nurses or physical therapists working for a durable medical equipment supplier have training and experience that is also important for patient care. While recognizing the value and quality of the education of these individuals, CMS is also cognizant of the program vulnerability when relying on the documentation of the supplier (or supplier's employee) to make a reasonable and necessary payment determination.

As explained above, there is a historical and statutory basis for Dr. Miller's "medical record" statement. While 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.

I hope you find this explanation useful. Please do not hesitate to contact me if you have additional questions at George.Mills@cms.hhs.gov.

Sincerely,

George Mills Jr.
Director
Provider Compliance Group