March 8, 2013

George G. Mills, Jr., Director, Provider Compliance Group
Centers for Medicare and Medicaid Services
Office of Financial Management
Mail Stop C3-09-27; Room C3-09-17
7500 Security Boulevard
Baltimore, MD 21244

Subject: Jurisdiction D Pre-payment Audit Policy of Prosthetic Foot Claims and Its Resulting Discrimination Against Medicare Amputees and Other Disabled Persons

Dear Mr. Mills:

I am writing to request your action to ameliorate a recent, inappropriate and potentially illegal action undertaken by one of the Medicare contractors. Specifically, I am referring to the attached announcement issued by Jurisdiction D, announcing its intention to initiate pre-payment audits as to selected prosthetic foot claims. AOPA believes that this pre-payment policy actually amounts to a thinly-veiled effort by the contractor to modify provider behavior by discouraging any and all claims, regardless of merit, involving the more advanced (and therefore more expensive) technologies for prosthetic feet. This policy is trying to pressure providers to shift to less advanced (less expensive) technologies—in a manner which discriminates, and operates to the detriment of amputees, i.e. disabled persons as defined by the Americans with Disabilities Act.

The Jurisdiction D announcement makes clear that all claims in that region for the advanced prosthetic foot technologies will involve, at best, an automatic delay in reimbursement, with the prospect for such claims being rejected after the costly advanced technology feet have been delivered to Medicare beneficiaries. This policy places prosthetic practitioners at very significant financial risk in delivering these advanced technologies.

By contrast, if the prosthetic practitioner either persuades the prescribing physician to modify his/her prescription and/or the prosthetic practitioner submits a detailed work order to that physician which includes only <u>less advanced, less expensive prosthetic feet</u>, the claim can be expected to move through to payment by Jurisdiction D smoothly without delay or risk of any significant prospect of financial loss to the prosthetic provider.

This new policy by Jurisdiction D may not have the intent of discrimination, but the fact is that it basically forces providers to provide less sophisticated technologies to Medicare beneficiaries. This may be viewed as appropriate behavior for private sector insurance plans, but it is clearly inappropriate and illegal behavior for the Medicare program. Using reimbursement policies that compromise the integrity of care for Medicare beneficiaries has not been and should never be a tool used by Medicare contractors. We therefore request that you immediately reverse this new Jurisdiction D policy, instruct the Jurisdiction D contractor to cease and desist from such practices, and notify the remaining Jurisdictions to refrain from any similar policies that could operate to the detriment of disabled individuals, in this case Medicare amputees (though it would be equally invalid if such pre-payment audit policies where directed against limb-impaired disabled, *e.g.* prepayment policies as to Code L0631), and that amounts already withheld as a result of such pre-payment audits already conducted should be returned in full with interest to the prosthetic providers.

Fairness in the Medicare system demands strong and effective oversight and management of Medicare contractors. This represents an instance in which we believe that management has been lacking, and needs to be remedied immediately to avoid further severe and potentially irreparable damage to Medicare disabled beneficiaries. We hasten to add that any action by the agency or its contractors to shift from such prepayment audits selective as to specific codes for more advanced technologies, to universal prepayment audits of all codes for prosthetic limb componentry would clearly serve to exacerbate the discriminatory impact on disabled amputee beneficiaries, particularly in the historical light of this Jurisdiction D recently announced practice.

We would be pleased to discuss directly, on an expedited basis, any questions relating to this requested action. We believe immediate Medicare intervention is required.

Very truly yours,

Thomas F. Fise, J.D.
Executive Director

cc: Marilyn Tavenner, CMS Administrator
The Honorable L.F. Payne, MaguireWoods
Thomas A. Scully, Esquire, Alston & Bird
Thomas Mills, Esquire, Winston & Strawn

HCPCS L5980, L5981, AND L5987 – NOTIFICATION OF WIDESPREAD PREPAYMENT PROBE REVIEW

NAS Jurisdiction D DME MAC Medical Review will be initiating a widespread prepayment probe review of claims for each of the following HCPCS codes:

HCPCS	Description
L5980	Lower extremity prosthesis, Foot flex system
L5981	Lower extremity prosthesis, Flex-walk system or equal
L5987	Lower extremity prosthesis, shank foot system with vertical loading pylon

Widespread prepayment probe reviews are used to determine the extent of potential problem areas across multiple suppliers. This review is being initiated based on the results of Comprehensive Error Rate Testing (CERT) analysis and previous review results.

In order to evaluate compliance with Medicare coverage and coding rules, all suppliers billing Jurisdiction D for HCPCS codes listed above are subject to this review. Suppliers of the selected claims will receive an *Additional Documentation Request* (ADR) letter asking for the following specific information to determine if the item billed complies with the existing reasonable and necessary criteria:

- Treating physician's dispensing and written order; and,
- Documentation of dispensing order (if item is dispensed based on dispensing order); and,
- Patient's medical records (physician medical records, hospital records, nursing home records, home care nursing notes, physical/occupational therapy notes) that support the item (s) provided are reasonable and necessary; and,
- Documentation to support the functional level modifier used; and,
- Proof of delivery of item (s) ordered; and,
- The Advanced Beneficiary Notice (if applicable); and,
- Any other supporting documentation.

Failure to supply the above requested information within 45 days of the date on the letter will result in the claim being denied. Please fax requested documentation and a copy of the ADR letter to 1-701-277-7888 or mail to Noridian Administrative Services LLC P.O. Box 6727 Fargo, ND 58108-6727.

The ADR letter provided will also provide instruction for submitting documentation.

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Lower Limb Prostheses Local Coverage Determination (LCD) L11453 and Policy Article A25367.

Information about prepay reviews may be found in CMS Publication 100-8, *Program Integrity Manual* (PIM), Chapter 3 located at: http://www.cms.hhs.gov/manuals/downloads/pim83c03.pdf

Posted on January 23, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C3-01-24
Baltimore, Maryland 21244-1850

OFFICE OF FINANCIAL MANAGEMENT

Thomas F. Fise, J.D.
American Orthotics and Prosthetics Association
330 John Carlyle Street, Suite 200
Alexandria, VA 22314

MAR 18 2013

RE: CMS response to March 8 Correspondence regarding Prepayment Review of Prosthetic Feet in Jurisdiction D

Dear Mr. Fise:

This is in response to your organization's letter dated March 8, 2013 in which you expressed the American Orthotics and Prosthetics Association's (AOPA's) concerns about the initiation of prepayment review of high-level prosthetics in Jurisdiction D.

The Social Security Act in Section 1862(a)(1)(A) requires that Medicare only pay for services that are reasonable and necessary. Medicare statute authorizes CMS to enter into contracts with companies to conduct various types of claim review, one of which is prepayment review. The procedures for prepayment review are well-outlined in the *Program Integrity Manual* (Internet-only Publ. 100-8), primarily in Chapter 3.

I feel confident after speaking with the Durable Medical Equipment Medicare Administrative Contractors (DME MAC) Jurisdiction D contract management staff at Noridian Administrative Services (NAS) that the prepayment action announced in their bulletin articles is justified and appropriate. The review to be conducted is a wide-spread review on a limited number of claims. NAS is not implementing 100 percent prepayment review for all prosthetic claims.

The decision to conduct these reviews by NAS is supported by the following:

- Office of Inspector General Report, "Questionable Billing by Suppliers of Lower Limb Prostheses", August 2011,
- Associated Press article entitled "Medicare Puzzle: Big Rise in Artificial Feet Costs", February 15, 2012,
- Comprehensive Error Rate Testing program 2012 Medicare Fee-for-Service report showing a significant error rate for lower limb prostheses, and

- Findings from medical review activity being undertaken by other DME MACs showing a high rate of error.

There is no change in Medicare's policy with respect to coverage of high-level prosthetic feet. Providers are required to maintain medical documentation demonstrating that ordered items and services are reasonable and necessary; moreover, as with all durable medical equipment, prosthetics, orthotics and supplies Medicare looks to the documentation in the *treating physician records* as the primary source of information to support that the item or service is reasonable and necessary. This position is unchanged and a long-held tenet of the Medicare program. Nothing in NAS' announced prepayment review changes this dynamic.

We believe that the proposed wide-spread reviews to be conducted by NAS are appropriate. If there are specific claims you wish to bring to our attention that you do not believe are being reviewed appropriately, CMS will investigate as we have previously.

Sincerely,

George G Mills, Jr
Director
Provider Compliance Group
Office of Financial Management

March 8, 2013

George G. Mills, Jr., Director, Provider Compliance Group
Centers for Medicare and Medicaid Services
Office of Financial Management
Mail Stop C3-09-27; Room C3-09-17
7500 Security Boulevard
Baltimore, MD 21244

Subject: Jurisdiction B K-Level Policies and Their Resulting Discrimination Against Medicare Amputees and Other Disabled Persons; Claims Reviewers Overruling K-Level Determinations

Dear Mr. Mills:

I am writing to inform you, and to request your action to ameliorate a recent, inappropriate and illegal action undertaken by one of the Medicare contractors. Specifically, I am referring to the attached announcement issued by Jurisdiction B, which was presented as a 'clarification' of its policy relating to K-level determination and concomitant determination of eligibility for advanced prosthetic technologies. Unfortunately, what we have seen transpire in Jurisdiction B makes clear that this is not being applied as a clarification of existing policy, but instead is staking out dangerous new policies. As you know from our previous communications dating back to the "Dear Physician" letter issued August 11, 2011, AOPA has expressed grave concerns about the practice of CMS contractors establishing new policies for the Medicare program, in CMS's name, without observing the formal rulemaking responsibilities for government actions set forth in the Administrative Procedures Act.

It is clear that a new, and we believe profoundly inappropriate, policy is now being implemented, at least by Jurisdiction B, and quite likely in the other Jurisdictions. As with the misguided "physician documentation requirements" this new policy represents an acute disruption of patient care. According to prevailing Medicare policy, the K-level assessment is made by the amputee Medicare beneficiary's physician, with potential input from the prosthetist. This assessment amounts to that physician's prognosis of the likelihood of the patient's ability to become a community ambulator, able to discharge the activities of daily living most fully, with the mobility assistance provided by a specific advanced technology incorporated into a prosthetic limb.

Like any prognosis, this assessment is based on science and principles of medicine, practice and experience, and an underlying assumption as to the patient's medical progress. However, Jurisdiction B now states that assumptions as to medical progress cannot have a part in that patient assessment/determination. Even more disturbing than what Jurisdiction B has said, is what they have started to do. Specifically, we are aware of claims in which Jurisdiction B claims reviewers have been using details of the patient's health that are unrelated to their amputation or limb loss. These factors include the use of hypertensive medications to treat blood pressure, history of cancer treatment, history of peripheral vascular disease, body weight conclusions derived from scrutiny of every factor in the patient's medical record. Claims reviewers are relying on these factors as the basis for overturning the comprehensive K-level determination. Taking isolated facts about a particular patient's medical history out context and without the ability to directly engage the patient and then rendering a decision is venturing into dangerous territory. Claims reviewers are rejecting the determination made by trained professionals who have actually examined the patient, and substituting a lower K-level determination, even though the claims reviewer has never even seen the patient and often has little if any experience in prosthetics or the care of amputee patients.

AOPA believes that this type of contractor activity is totally inappropriate and represents a modification of the standard of care for Medicare beneficiaries. It further is an inappropriate misuse of contractor access to physician documentation as well as possible interference with the practice of medicine. Moreover, it creates new, inappropriate and unfair impediments that discourage claims, regardless of merit, involving the more advanced (and therefore more expensive) technologies for prosthetic feet. This activity seeking to 'downshift' the standard of care of these Medicare amputee beneficiaries to a new, lower level emphasizing a shift to less advanced (less expensive) technologies—occurs in a manner which discriminates, and operates to the detriment of amputees, i.e., disabled persons as defined by the American for Disabilities Act.

This new policy by Jurisdiction B may not have the intent of discrimination, but the fact is that it interferes to reverse the physician's judgment and to provide less sophisticated technologies to Medicare beneficiaries. This may be deemed, by some, to be appropriate behavior as a matter of private sector insurance plans, but it is clearly inappropriate and illegal behavior for the Medicare program.

We recognize the value that claims reviewers can provide in preventing waste, fraud and abuse in the Medicare program. However, such value arises from claims reviewers finding inconsistencies between diagnoses and prescriptions, noting critical missing documentation or coding mistakes, or analyzing suspicious patterns in treatments. By contrast, there is no value to claims reviewers attempting to substitute their medical judgment for that of trained professionals, particularly when the claims reviewers have never even examined the patient. Congress recognized the need for actual examinations of patients in the Affordable Care Act, when it directed that physician orders for certain medical equipment not be issued unless the physician certifies that he or a member of his staff has physically seen the patient. We do not see why claims reviewers should not be held to the same standard.

We therefore request that you immediately reverse this new Jurisdiction B policy, instruct the Jurisdiction B contractor, as well as contractors in other Jurisdictions, to limit the ability of claims reviewers to override the K-level determination of physicians unless the claims reviewers have actually examined the patient. Amounts already withheld as a result of any cases in which a claims review has resulted in a reduced Medicare amputee beneficiary K-level below that determined appropriate by the patient's own physician should be returned in full with interest to the prosthetic providers, and these beneficiaries be cleared for treatment and reimbursement consistent with the K-level the physician established.

Fairness in the Medicare system demands strong and effective oversight and management of Medicare contractors. This represents an instance in which we believe that oversight management has been lacking, and needs to be remedied immediately to avoid further severe and potentially irreparable damage to Medicare disabled beneficiaries. If Medicare is unhappy with the existing K-levels and how these decisions are being made by the physicians who are involved in actually treating Medicare amputee beneficiaries, CMS has the ability to change those policies—but NOT in the manner in which Jurisdiction B has attempted. Rather, the policies could be reviewed in an open, full, notice and comment rulemaking process that would afford beneficiaries an opportunity to be informed and to participate in crafting any new or revised policies.

We would be pleased to discuss directly, on an expedited basis, any questions relating to this requested action. We believe immediate Medicare intervention is required.

Very truly yours,

Thomas F. Fise, J.D.
Executive Director

cc: Marilyn Tavenner, CMS Administrator
The Honorable L.F. Payne, McGuireWoods
Thomas A. Scully, Esquire, Alston & Bird
Thomas Mills, Esquire, Winston & Strawn

National Government Services

Jurisdiction B Daily News

Documentation for K Levels for Prosthetics

National Government Services, the Jurisdiction B Durable Medical Equipment Medicare Administrative Contractor (DME MAC) has received several inquiries in regards to what documentation must appear in the medical record to support the K level for prosthetics.

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 information must be documented by the **treating physician and the prosthetist**.

The medical record should reflect that a comprehensive medical assessment has occurred. The medical record should include, but is not limited to, past history, current functional capabilities and the beneficiary's expected functional potential, including an explanation for the difference, if that is the case. The medical record should establish the severity of the beneficiary's condition and the immediate and long term need for the prosthetic and the therapeutic benefits the beneficiary is expected to realize from its use. An entry in the medical record of therapeutic effectiveness or benefit based on speculation or theory alone cannot be accepted. When restoration of function is cited as a reason for use of the prosthetic, the exact nature of the deformity or medical problem should be clear from the medical evidence submitted. Also, the manner in

which the prosthetic will restore or improve the bodily function should be explained by the treating physician. The K-level selected must be consistent with the overall health status of the beneficiary.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of prosthetic.

Note: Suppliers are reminded per the Centers for Medicare & Medicaid Services (CMS) Internet-Only Manual (IOM) Publication 100-08, *Program Integrity Manual*, Chapter 5, Section 5.7-5.9, supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.

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 organization's letter dated March 8, 2013 in which you expressed AOPA's concerns about a bulletin article published by the Jurisdiction B Durable Medical Equipment Medicare Administrative Contractor (DME MAC) entitled Documentation for K Levels for Prosthetics. The article outlines the documentation requirements to support the functional level for prosthetics billed to Medicare. You assert that Jurisdiction B is "staking out dangerous new policies" and urge CMS to improve its oversight and management of this contractor. CMS monitors the medical review activities of review contractors and it is our opinion that Jurisdiction B is making appropriate decisions in accordance with the LCD and CMS policy.

As noted in previous correspondences with your organization, 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." The DME MACs recognize this statutory requirement, as well as the unique skill set and training that certified orthotists and prosthetists have in the Local Coverage Determination (LCD) for Lower Limb Prosthetics in the passage that sets out the requirement for making a functional level determination. The LCD states:

> A determination of the medical necessity for certain components/additions to the prosthesis is based on the beneficiary's potential functional abilities. Potential functional ability is based on the **reasonable expectations of the prosthetist, and treating physician**, considering factors including, but not limited to:
> - The beneficiary's past history (including prior prosthetic use if applicable); and
> - The beneficiary's current condition including the status of the residual limb and the nature of other medical problems; and
> - The beneficiary's desire to ambulate.
>
> (Emphasis added).

As noted above, the prosthetist's assessment does play a part in the selection of the functional (K) level; however, the prosthetist's assessment must be consistent with information in the

medical record from the treating physician's assessment and prognosis of overall health status. This corroboration of the prosthetic functional determination with the independent medical record information is essential to assure that the item(s) provided are appropriate for the beneficiary and eligible for reimbursement.

As we have discussed previously, 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. The prosthetic record provides key supplemental information as described by the policy provision noted above and consistent with the provisions set out in CMS' Program Integrity Manual Chapter 5, Section 5.7.

You agree with this position in your letter. You acknowledge that the physician must make a prognosis "based on science and principles of medicine" and that it amount to "that physician's prognosis of the likelihood of the patient's ability to become a community ambulator, able to discharge the activities of daily living most fully, with the mobility assistance provided by a specific advanced technology incorporated into a prosthetic limb." CMS agrees.

Your letter then contends that the contractor should not be taking overall health status into consideration as they evaluate medical record information. While you previously agreed that the physician must use all of his or her diagnostic skill and medical training that would, by necessity, include the beneficiary's past medical history and illnesses, you then criticize Jurisdiction B medical review staff for attempting to conduct claim review in a similar manner. Your letter states:

"Specifically, we are aware of claims in which Jurisdiction B claims reviewers have been using details of the patient's health that are unrelated to their amputation or limb loss. These factors include the use of hypertensive medications to treat blood pressure, history of cancer treatment, history of peripheral vascular disease, body weight conclusions derived from scrutiny of every factor in the patient's medical record."

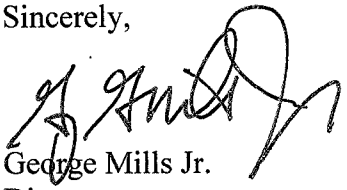
As you know, there are many factors other than the physical loss of a limb that impact a beneficiary's ability to function. It is entirely appropriate for medical claim reviewers to evaluate documentation concerning-morbid conditions when such conditions could reasonably be expected to impact a beneficiary's overall functional ability when making reasonable and necessary determinations. For example, a beneficiary with Class IV heart failure as a result of their hypertension is not likely to improve with a limb amputation such that they are now a K-3 level ambulator. The ordering physician's medical documentation must support the K-level determination they themselves make. Reviewers are neither altering these determinations nor affecting the standard of care in any way. Reviewers only confirm whether or not submitted documentation is sufficiently supportive.

To provide an example of the relevance of this approach, CMS staff conducted data analyses on claims paid for K-3 and K-4 level prosthetic feet. Using Medicare paid claims data, CMS discovered illogical claim groupings. For example, CMS found that over ten percent of beneficiaries receiving K-3 and K-4 feet received a Power Mobility Device to assist them in activities of daily living within the home (close in time to their receipt of a prosthesis) or had an

illness so severe that they required oxygen in the home. Therefore, these claim payments appear to be potentially contradictory to a high functional level assessment. While an individual claim determination cannot be made based upon data suggesting that these claims for prosthetics were all incorrect, these findings would suggest further review is required. Similar claim reviews performed by the contractors have identified an unexpectedly high level of disconnect between the prosthetic functional assessment and the information contained in the medical record.

To summarize, the material published by Jurisdiction B simply restates existing requirements in order to encourage suppliers to adhere to Medicare's existing payment rules. This article does not create new policy. I hope you find this information useful. In addition, CMS looks forward to working with your organization to develop an electronic clinical template. If you have any additional questions, please do not hesitate to contact me at George.Mills@cms.hhs.gov.

Sincerely,



George Mills Jr.
Director
Provider Compliance Group

March 8, 2013

George G. Mills, Jr., Director, Provider Compliance Group
Centers for Medicare and Medicaid Services
Office of Financial Management
Mail Stop C3-09-27; Room C3-09-17
7500 Security Boulevard
Baltimore, MD 21244

Subject: Prosthetist Notes in Medical Record

Dear Mr. Mills:

I am writing to inform you of, and to request your action to ameliorate, a recent inappropriate action undertaken by one of the Medicare contractors. This relates to whether the prosthetist's notes of visits with a Medicare amputee beneficiary patient become a legitimate part of the patient's medical record when those notes are received by, reviewed by, and entered by the patient's physician into their file, whether hard copy or electronic, which the physician maintains on the past, current and future health care of that patient.

Specifically, I am referring to the attached announcement issued by Jurisdiction B, which is attached and which stated:

Note: *Suppliers are reminded per the Centers for Medicare & Medicaid Services (CMS) Internet-Only Manual (IOM) Publication 100-08, Program Integrity Manual, Chapter 5, Section 5.7-5.9, supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.*

In May, I was among a small contingent of individuals representing the Orthotic and Prosthetic Alliance who met with you, Ms. Melanie Coombs-Dyer, Dr. James Rollins and Dr. Susan Miller. At that meeting we had raised the question of the medical record because there had been an oral statement by a specific DME MAC Medical Director at an earlier public meeting that the prosthetist's notes would not be considered a legitimate part of the patient's medical record. We had also reported that a contrary position had been announced subsequently by one of the CMS internal employee Medical Directors who had participated in a meeting the O&P Alliance had arranged with Mr. Laurence Wilson.

Dr. Miller had stated during our May meeting that in the circumstances outlined above the prosthetist's notes do indeed become part of the patient's medical record. Dr. Miller

indicated that there must have been some confusion or misunderstanding on the part of the contracted DME MAC Medical Director who had made a statement to the contrary. Dr. Miller promised that she would assure that all DME MAC contractor personnel were timely apprised of that determination by CMS relating to the prosthetist's notes. We were reassured by Dr. Miller's commitment, and looked forward to that issue being clarified at last.

Given Dr. Miller's statements, we were very surprised when we saw the Jurisdiction B announcement within the past six weeks advising that the prosthetist's notes are not part of the patient's medical record. We are not sure what may have gone awry—whether the notification promised by Dr. Miller was either not received or not understood by the Medicare DME MAC contractors, but it is clear that this 'confusion' continues. The purported basis for the 'exclusion' of the prosthetist's notes is that since the prosthetist is a provider and the amount of Medicare payment he/she receives may be affected by the observations made and notations he/she records from one or more examinations and clinical visits with the patient, that the notes' legitimacy is somehow compromised. The fundamental flaw in that logic is that the same is true of most health care encounters and professionals with whom Medicare beneficiaries/patients have contact. The prosthetist's notes are just as legitimate a part of the medical record as the surgeon's report on a pre-surgical consultation, the subspecialist's report, and the radiologist's notes on an x-ray report (which if inconclusive might require more advanced imaging studies).

AOPA believes that this errant contractor activity/interpretation needs to be quickly and decisively corrected. We therefore request that you immediately reverse this recent Jurisdiction B policy statement and instruct the Jurisdiction B contractor to cease and desist from such statements and practices that are contrary to CMS policy. We also request that you notify the remaining Jurisdictions to refrain from any similar policies that could operate to the detriment of disabled individuals, in this case Medicare amputees. Amounts already withheld from providers as a result of any cases in which a claims review has been based on any patient record/physician file which has not included the prosthetist's notes should be returned conclusively and in full with interest to the prosthetic providers.

Fairness in the Medicare system demands strong and effective oversight and of Medicare contractors. This represents an instance in which we believe that oversight and management has been lacking, and needs to be remedied immediately to avoid further severe and potentially irreparable damage to Medicare disabled beneficiaries.

We would be pleased to discuss directly, on an expedited basis, any questions relating to this requested action. We believe immediate Medicare intervention is required.

Very truly yours,

Thomas F. Fise, J.D.

Executive Director

cc: Marilyn Tavenner, CMS Administrator
James Rollins, M.D.
Susan Miller, M.D.
Melanie Combs-Dyer
The Honorable L.F. Payne, MaguireWoods
Thomas A. Scully, Esquire, Alston & Bird
Thomas Mills, Esquire, Winston & Strawn

National Government Services

Jurisdiction B Daily News

Documentation for K Levels for Prosthetics

National Government Services, the Jurisdiction B Durable Medical Equipment Medicare Administrative Contractor (DME MAC) has received several inquiries in regards to what documentation must appear in the medical record to support the K level for prosthetics.

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 information must be documented by the **treating physician and the prosthetist**.

The medical record should reflect that a comprehensive medical assessment has occurred. The medical record should include, but is not limited to, past history, current functional capabilities and the beneficiary's expected functional potential, including an explanation for the difference, if that is the case. The medical record should establish the severity of the beneficiary's condition and the immediate and long term need for the prosthetic and the therapeutic benefits the beneficiary is expected to realize from its use. An entry in the medical record of therapeutic effectiveness or benefit based on speculation or theory alone cannot be accepted. When restoration of function is cited as a reason for use of the prosthetic, the exact nature of the deformity or medical problem should be clear from the medical evidence submitted. Also, the manner in

which the prosthetic will restore or improve the bodily function should be explained by the treating physician. The K-level selected must be consistent with the overall health status of the beneficiary.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of prosthetic.

Note: Suppliers are reminded per the Centers for Medicare & Medicaid Services (CMS) Internet-Only Manual (IOM) Publication 100-08, *Program Integrity Manual*, Chapter 5, Section 5.7-5.9, supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.

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

March 8, 2013

Mr. George Mills
Director, Compliance Provider Group
Centers for Medicare and Medicaid Services
Room C3-09-17
7500 Security Boulevard
Baltimore, MD 21244

Subject: Calculation methodology used by Performant Recovery

Dear Mr. Mills,

The American Orthotic and Prosthetic Association (AOPA) would like to bring to your attention what we believe to be an error in the calculation methodology used to determine the maximum number of additional documentation requests (ADR) for orthotic and prosthetic claims by Performant Recovery, Inc., the contractor responsible for the Jurisdiction A RAC program.

Based on reports from several AOPA members, it appears that Performant Recovery, Inc. is applying the provider based ADR calculation methodology to DMEPOS suppliers, including suppliers who submit claims to the DME MACs for orthotic and prosthetic services. The documents in the links below, provide detailed information regarding the different methodology that should be used by RAC contractors when requesting additional documentation from providers (except suppliers and physicians) and suppliers.

http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/Providers_ADRLimit_Update-03-12.pdf

http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Recovery-Audit-Program/Downloads/FY2011Limits.pdf

According to the documents in the links above, the maximum number of ADRs for suppliers within a 45 day period is limited to 10% of all claims submitted for the previous full calendar year, divided into eight periods. While the document states that the maximum number of ADRs within a 45 day period for a single Tax ID is 250, the document does not contain any reference to a minimum number of ADRs. In fact, an example is given where the calculated limit is 16 ADRs within a 45 day period.

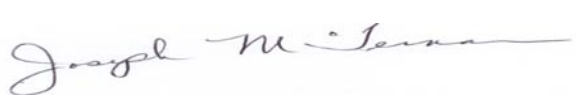
The document that addresses provider ADRs limits the requests to 2% of all claims submitted during the previous full calendar year divided by eight and contains a statement that allows Recovery Auditors to request up to 35 ADRs per 45 days even if the 2% calculation results in fewer than 35 ADRs.

Several AOPA members have received letters from Performant Recovery that uses the provider based calculation as justification for the number of ADRs requested. As providers of orthotics and prosthetics are classified as suppliers under Medicare regulations, AOPA believes that Performant Recovery should be basing its ADR requests on the guidelines established for suppliers rather than providers. Copies of these letters are available upon request.

AOPA respectfully requests that CMS review the calculation methodology that is being used by Performant Recovery, Inc. when requesting additional documentation from suppliers and provide appropriate training as necessary to ensure that it is performing its responsibilities properly.

If you require further information, please contact me at (571) 431-0811 or via e-mail at jmcternan@aopanet.org.

Sincerely,



Joseph McTernan
Director, Coding and Reimbursement Services, Education and Programming

Cc: Marilyn Tavenner, Acting Administrator, CMS

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C3-01-24
Baltimore, Maryland 21244-1850

OFFICE OF FINANCIAL MANAGEMENT

MAR 18 2013

Mr. Joseph McTernan
The American Orthotic & Prosthetic Association
330 John Carlye St
Suite 200
Alexandria, VA 22314

Dear Mr. McTernan:

This is in response to your recent inquiry concerning the calculation methodology for determining the additional documentation limit used by the Region A Recovery Auditor.

The Centers for Medicare & Medicare Services (CMS), Provider Compliance Group (PCG) was previously made aware of this issue in February 2013. PCG investigated and communicated with the Recovery Auditor on the correct methodology to calculate the additional documentation request (ADR) limits. The Recovery Auditor erroneously used the minimum amount for another provider type and applied it to Durable Medical Equipment Prosthetic and Orthotic Suppliers (DMEPOS). This was incorrect and the Recovery Auditor fixed their calculation as soon as CMS made them aware of their mistake. As of February 26, 2013 all suppliers who had received incorrect additional documentation limits were issued revised notices.

CMS is currently in the process of recompeting the Recovery Auditor contracts. As part of the new contract CMS is considering adjusting the additional document request limits for very small DMEPOS suppliers. If you have any comments concerning future ADR limits for small DMEPOS suppliers or issues regarding the Recovery Auditors please send them directly to the Director of the Division of Recovery Audit Operations Connie Leonard at connie.leonard@cms.hhs.gov.

Sincerely,

George Mills
Director
Provider Compliance Group