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April 9, 2007

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – C
Attention: Bonnie L. Harkless
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Harkless:

The American Podiatric Medical Association (APMA), the national organization representing more than 11,500 of America's Foot and Ankle Physicians and Surgeons, is pleased to offer comments on recent changes to the Advance Beneficiary Notice of Noncoverage (ABN).

We support the decision to combine the previous two versions of the ABN, form CMS-R-131-G and CMS-R-131-L and believe that one form is better for both beneficiaries and physicians, providers, practitioners and suppliers. We believe that use of a single form will eliminate some of the confusion that occurred previously when a beneficiary was presented with different versions of the ABN.

We believe that it would be useful if the form listed the possible reasons for denial so that the physician could simply check the appropriate item. We recommend revising the form to include the basic reasons why a service would be denied, such as Medicare will not pay for the service or item, or the service or item has not been proven effective, or there are limits on the number of services or items allowed by Medicare. An "other" section could be included but by pre-printing the more common reasons for denial on the form, the beneficiary would generally encounter the same language regarding denials. This would also eliminate the burden on the physician or office staff to recall and write out Medicare's reasons for denial.

Additionally, we are concerned that the revised form may be confusing to beneficiaries and may lead to misunderstandings regarding who is responsible for payment of an item or service. The first paragraph in the ABN states "it is likely you or other insurance will have to pay." In the overwhelming majority of cases, a patient's other insurance acts as a co-insurance to Medicare and does not pay if Medicare does not pay. The language in the new form could lead a beneficiary to assume that someone else will pay for the item or service when, in fact, most of the time the beneficiary will be responsible for payment.

The previous version of the ABN (CMS-R-131-G) specifically said "we expect Medicare will not pay" while the new one states "we think Medicare will not pay." The APMA believes that the original language was more definitive and better communicated to the patient that Medicare would not pay for an item or service. The revised language, which is softer, could result in more misunderstandings between patients and physicians. If a patient believes Medicare might pay,

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they may be more willing to agree to a service or item. If they discover subsequently that Medicare did not pay and they are now responsible for payment, they may argue that the form they signed led them to believe that Medicare would pay. Since the physician provided the form initially, the patient may unfairly assign responsibility for Medicare's decision to the physician.

The new ABN states, "You still can receive this care, since you or your health care provider may have good reason to think you need it..." while the old version stated, "The fact that Medicare may not pay for a particular item or service does not mean that you should not receive it." We believe that the previous language was more respectful of the physician and his or her decision making and encourage CMS to return to the original language.

While the APMA recognizes that the addition of the telephone number is helpful for the beneficiary, we do not believe it is practical to expect that the physician will have time to wait while the beneficiary contacts Medicare in the office setting.

Also, by bolding and underlining the statement, "I can appeal that decision," there is an implication that the patient has a reasonable chance of getting paid by Medicare eventually. The previous version of the form mentioned the possibility of appealing but did not bold the information. We support retaining the sentence but suggest that it does not need to appear in bold print.

Item H of the revised ABN is for "Other insurance to consider for billing." As part of the normal course of business, a doctor's office will obtain insurance information from the patient so it is not necessary to request it on this form. By including the request on the ABN, the patient may again be given the impression that some other entity will pay the claim and the patient will not be responsible. We think this could lead a beneficiary to agree to a service or item that they would not otherwise agree to if they fully understood they would likely be responsible for payment.

We appreciate the opportunity to offer these comments. If you have questions regarding our response, please contact Dr. Nancy L. Parsley, at (301) 581-9233.

Sincerely,



Christian A. Robertozzi, DPM
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RE: Comments on Proposed Revisions on Advanced Beneficiary Notice Form and Use

Dear Ms. Harkless:

I appreciate the opportunity to comment on the revisions to the Advanced Beneficiary Notice (ABN) form and instructions for use outlined in the February 23, 2007 *Federal Register* (8167). I am the compliance director for a multi-specialty practice comprised of 240 providers serving patients at 65 clinic locations in Iowa and western Illinois. Many of our physicians and non-physician practitioners order for patients services with applicable local or national coverage determinations which could limit coverage; our clinics issue ABNs to patients for these services.

I have comments in four general areas. First, the instructions are helpful; however, please add further clarification on identity of the “notifier.” The instructions indicate that this form is to be completed, delivered to the patient, and retained by the “notifier.” In situations when the entity that actually performs and bills for the test (e.g., reference laboratory) has no contact with the patient, who is the “notifier?” In cases when the service is furnished by an entity that is not affiliated with the ordering provider, is the ordering provider ever the “notifier”?

Second, the form should emphasize that the “estimated cost” is just an estimate and actual cost to the beneficiary may vary. For example, the clinic may draw the specimen and send it to the reference lab with orders for a particular lab test that may be denied. If, in this case, the notifier is the clinic that drew the specimen and ordered the test, it may be difficult for the clinic to know with any amount of certainty what the estimated cost will be, especially since the lab submitting the claim will be able to bill the charge (rather than the allowable) if the claim is denied.

Third, since the three reasons for possible denial are defined by Medicare, they should be pre-printed on the form for more efficient completion by the notifier. Print the reasons, each preceded by a checkbox, in the Blank E or assign each a letter (e.g., A = “Medicare does not pay for these tests for your condition”, B = “Medicare does not pay for these tests as often as this ...”, etc.) and allow the notifier to indicate by letter the reason for

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denial in Blank E. I appreciate the clear statement that this form can be used to advise patients about services that are always non-covered and for which the beneficiary will have full financial liability. This being the case, I suggest that an additional reason for possible denial be added for Blank E: "This service is considered noncovered by Medicare."

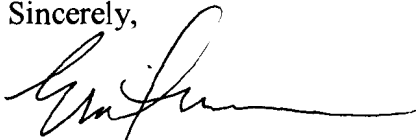
Similarly, the form could be completed more efficiently if we were permitted to pre-populate the form in Blank D with certain high volume services which are frequently non-covered.

Fourth, I would like to see further clarification in the instructions in several other areas:

- Clarify under what circumstances a single ABN can be obtained for a series of services that may be non-covered (e.g., monthly B12 injections).
- **Include specific guidance on the procedure for handling beneficiaries who have been given the notice and who wish to receive the service but refuse to sign the ABN. I do not believe that the proposed changes will fully eliminate this situation.**
- Clarify who can serve as a patient's representative.

In general, this form is simpler and an improvement over the past versions.

Sincerely,



Erika Linden, CHC
Director of Coding and Compliance