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1 of 6

April 24, 2007

American
Clinical Laboratory
Association

Centers for Medicare & Medicaid Services ("CMS")
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

RECEIVED
4/24/07

Re: Advance Beneficiary Notice of Noncoverage ("ABN") (CMS-R-131)

Dear Ms. Harkless:

The American Clinical Laboratory Association ("ACLA") is pleased to have this opportunity to submit our comments with regard to the *Agency Information Collection Activities: Proposed Collection; Comment Request (the "Comment Request")* on the new Advance Beneficiary Notice ("ABN") for the noncoverage of certain Medicare services to beneficiaries. 72 Fed. Reg. 8167 (Feb. 23, 2007). ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. ACLA members frequently rely on ABNs, thus, our members are directly affected by the proposed changes. The Comment Request in the Federal Register invites interested persons to submit comments on the burden estimate of the proposed information collection or any other aspect of the collection of information. As a result, reflecting the views of its members, ACLA is taking this opportunity to comment on the various issues created by the new ABN.

I. Introduction

With the standardization of the ABN in 2002, ABNs became a more significant, and common, part of the Medicare billing process. In its materials, CMS estimates that over 40 million ABNs may be delivered annually, and even that number seems conservative. ABNs are particularly important for laboratory services because many laboratory tests are subject to National Coverage Determinations ("NCDs") and Local Coverage Determinations ("LCDs"), which can result in the delivery of an ABN, if the requirements of the NCD or LCD are not met – a not infrequent occurrence. Moreover, laboratories are often in a difficult position with regard to ABNs because they rely on physicians and their staffs to provide notice to Medicare beneficiaries that Medicare is likely to deny payment for a particular service, to obtain the signed ABN, and to forward it to the laboratory. Given these circumstances, the ABN must be structured to ensure that it can be easily understood by beneficiaries and completed appropriately by physicians.

ACLA is concerned that the new form will be less clear to beneficiaries, more vulnerable to physician error, and the source of increased confusion and costs for all those involved. As explained more fully below, laboratories worked extensively with CMS in 2002 to develop a form that would be clear to all. CMS has provided no reasons why that form, which was

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specifically developed to meet the needs of laboratories, physicians, and patients, is no longer appropriate.

II. General Concerns

In 2000-02, ACLA member laboratories worked extensively with CMS staff to create a clear, concise, and beneficiary-friendly ABN for laboratory testing. This ABN (Form No. CMS-R-131-L June 2002 or the "June 2002 ABN") was created with the benefit of beneficiary focus groups to ensure Medicare beneficiaries' understanding of the form. As a result, specific language, font size, and formats were considered before the June 2002 ABN for laboratories was approved. The value of having had beneficiaries and the laboratory industry involved in the development of the June 2002 ABN for laboratories is evidenced by its practicality, clarity, and effectiveness.

The effectiveness of the ABN is of particular importance to laboratories because often a laboratory will have no direct contact with the beneficiary. Consequently, laboratories are extremely dependent on the language of the ABN for beneficiaries' understanding of their financial responsibilities and the convenience of the ABN to ensure physicians' proper completion of the form. The June 2002 ABN for laboratories was designed to specifically meet these needs. It recognized that there were only three reasons that a lab test is denied by Medicare – medical necessity, frequency, and investigational/experimental. Thus, the ABN permits laboratories to list the tests that could be denied, and to specify the possible reasons for such denial. This allowed laboratories to print them in advance, based on the particular LCDs in effect in a geographic area, and to ensure that the reasons for the potential denial would be ones that Medicare would recognize. As noted, this process has worked quite well.

We see no reason to eliminate the June 2002 ABN for laboratories given its success, and CMS has provided no rationale for the consolidation of the laboratory-specific ABN with other versions of the form. We recognize that by consolidating the ABNs as the agency proposes, CMS is trying to incorporate some of the features of the laboratory-specific ABN in the other general use ABN. However, while improving the general use ABN with some features of the laboratory-specific ABN may be appropriate, it is neither necessary nor reasonable to accomplish that objective by eliminating a laboratory-specific ABN that has worked effectively. There should continue to be a separate laboratory ABN that specifically recognizes and allows for the unique situation that laboratories find themselves in. As we will discuss in further detail below, the consolidation of these forms will result in unnecessary burden and confusion to beneficiaries, physicians, and laboratories.

III. Comments Regarding the Burden of the New ABN

As mentioned above, we find no rationale for revising the June 2002 ABN for laboratories, which is working quite effectively, by creating a single general ABN for all physicians, practitioners, and suppliers. In fact, as part of the Comment Request and supporting documents, CMS has not even attempted to provide a rationale for eliminating the June 2002 ABN for laboratories. Because we see no valid reason for CMS to go forward with this effort,

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we can foresee no benefit that would outweigh the burdens that we discuss below. Moreover, the burdens associated with this new ABN are significant.

First, CMS provides in the Supporting Statement for the ABN that an average of 31.7 ABNs will be delivered each year per physician, practitioner, or supplier. CMS arrived at this number by determining the total universe of ABNs and then dividing that number by the total number of physicians and practitioners. However, this process is clearly flawed. The use of ABNs will vary significantly by the specialty of the physician. For example, in the laboratory context, many types of physicians will never utilize an ABN because they do not order testing services. Thus, the use of ABNs is likely concentrated among only a few specialties. As a result, the 31.7 figure given by CMS fails to account for the disparities in its use. While some physicians probably give out a few ABNs, other physicians will likely give out hundreds a year. Thus, the burden of moving to a new form will be far greater for these physicians. Specifically, adopting a new ABN will result in unnecessary administrative and implementation costs for both physicians and laboratories on a far greater scale than has been envisioned by CMS.

Second, in order to effectively implement a new ABN, physicians and their staffs will need to be educated with respect to the new requirements of the form. For laboratory services, it will be up to laboratories themselves to explain to physicians and their staffs how to fill out the new ABN and how it has changed from the old form. This educational effort will not only require a significant amount of time, but it will also impose a significant financial burden on laboratories. It will also impose additional costs to physicians and their practices, who will now struggle with understanding the new form. CMS does not account for these costs in the burden estimate included in its Supporting Statement.

Third, the changes will result in an increase in forms being completed incorrectly or not being completed at all. The June 2002 ABN for laboratories included the three reasons for why Medicare would deny payment for a beneficiary's service – medical necessity, frequency, and investigational/experimental. This helped to ensure that the reasons submitted by the physician were explanations that were both understandable by beneficiaries and acceptable to Medicare and, thus, ensured that the ABN received was valid. In addition, the June 2002 ABN form was standardized to a sufficient degree that laboratories could automate its use, so that a blank ABN was triggered whenever there was a valid basis for concluding that Medicare might deny payment.

The new ABN, however, would require the physician to complete the reason section of the form even though the Form Instructions state that the reasons from the June 2002 ABN are still valid. This will be more burdensome and time consuming on physicians and their staffs, who will now have to fill out the form by hand. This, of course, will also result in physicians or their staffs not completing forms in their entirety or completing forms incorrectly based on invalid reasons. Not only does this preclude the laboratory from billing Medicare for the noncovered item or service, where appropriate, but it will also increase the questions and inquiries that will result. The laboratory will have to spend time trying to contact the physician or the patient to resolve such questions. In addition, it is likely that contractors will end up having to mediate disputes, as they did before the ABN was standardized in 2002, concerning whether or not an ABN is valid.

Fourth, beneficiaries are likely to be confused by these changes and by the new language. As we have mentioned, the June 2002 ABN for laboratories was developed with the valuable assistance and input of beneficiaries. Through the use of beneficiary focus groups, the June 2002 ABN was crafted to ensure that beneficiaries are adequately notified of any potential financial obligations to Medicare for a noncovered item or service. To this end, the June 2002 ABN took into account appropriate font style and size, formatting structure, and provided the three clear, concise and standard reasons for noncoverage. The new ABN, however, has a smaller font size, a different format, and deletes the standard reasons for likely noncoverage, with the hope that each health care worker completing each ABN will manually describe these reasons with sufficient clarity. As a result, the physician or practitioner will need to take extra time to explain the new ABN to beneficiaries and beneficiaries may have difficulty understanding the new provisions. Further, beneficiaries will likely inquire as to why the ABN has changed and may be reluctant to sign the form altogether.

Lastly, the adoption of a new ABN will impose significant financial burden on laboratories, particularly during the initial stages of implementation. This is true because once laboratories receive a test specimen and valid request, laboratories typically run the test. Even if the laboratory realized that the ABN was invalid at that point, the laboratory would not usually refrain from running the test, both because of the potential liability if the patient later suffered injury and the laboratory had failed to run the test, and because, ethically, most laboratories believe the test must be run once the laboratory has received the order and the specimen, even if it may not ultimately be billable. Moreover, usually, the ABN is not actually reviewed for correctness until the billing process, which occurs after the test has been run. Thus, each time the new ABN is not properly completed or not submitted at all, laboratories will be forced to absorb the cost of the noncovered laboratory service. Further, the Comment Request and its supporting documents fail to account for the significant costs that laboratories would need to incur to change their ABN forms, which would include reprogramming of software and systems, printing costs, and lost investments in existing inventories of paper June 2002 ABNs.

IV. Comments on Specific Aspects of the New ABN

We have outlined our concerns with respect to specific aspects of the new ABN below.

A. Cost Estimates

The new ABN includes a separate column for *"Estimated Cost."* According to the Form Instructions, *"[n]otifiers must enter a cost estimate in this blank for items or services described..."* on the form. This requirement is different from the June 2002 ABN for laboratories, because although there is a designated space on the form for estimated cost, CMS had stated that this was not a requirement in its response to comments to the proposed June 2002 ABN. In response to a comment requesting that CMS delete the "cost estimate" requirement, CMS stated that "[t]he lack of an amount on this line, or an amount which is different from the final actual cost, does not invalidate the ABN; an ABN should not be considered to be defective on that basis."[1] In many cases, as CMS recognized, physicians are simply not aware of what the

[1] CMS, Comments and Responses, Paperwork Reduction Package CMS-R-131 Advance Beneficiary Notice (ABN).

cost may be and, thus, cannot fill in that space. Inclusion of this information as a required item will increase questions about the validity of many ABNs. Thus, it should not be required that physicians determine the cost of the noncovered items or services included on the ABN and this column should be removed from the ABN form. If there is, however, such a space on the form for estimated cost, CMS should make clear, at least for laboratory tests, that a physician would only need to complete this section of the form if the physician is aware of such costs.

B. Options

The June 2002 ABN for laboratories includes the following two options for beneficiaries to select –

(1) Yes. I want to receive these laboratory tests.

(2) No. I have decided not to receive these laboratory tests.

As part of these options, there is also a detailed explanation of what is meant by these options to a beneficiary. In contrast, the new ABN does not include the explanatory details that are included in the June 2002 ABN for laboratories, which have been helpful to beneficiaries' understanding of the ABN form and its consequences.

Further, the new ABN includes an additional option – *"2. Provide me with what is listed above. I do not want Medicare billed. I agree to be responsible for payment."* We find this option to be both unnecessary and confusing to beneficiaries. That is, it is unlikely that a beneficiary would not want Medicare to make a determination as to whether the item or service was covered by Medicare. The inclusion of this option may mislead beneficiaries into paying for an item or service without realizing that Medicare would not be billed for the item or service and be required to make a determination of coverage. This option allows Medicare to not pay for a service that may, in fact, be covered, but that the beneficiary misguidedly decided to pay for himself/herself. As such, we strongly encourage that CMS eliminate option 2 on the new ABN. In addition, we encourage CMS to include more details under each option on the form to better explain to the beneficiary the consequences of each choice, and strongly suggest further beneficiary focus group studies regarding any change to this effect.

C. Other Insurance

Unlike the June 2002 ABN, the new ABN includes a section (H) for *"other insurance to consider for billing."* Again, we find this section to be unnecessary and confusing to beneficiaries, as well as beyond the scope of the ABN's intended purpose. In addition, its inclusion will only increase the number of questionable ABNs that are received. According to our member laboratories, information relating to other insurance is already included in test request forms, where there is sufficient space to collect all of the data needed if the information is to be useful, such as address of the secondary insurer, group numbers, beneficiary numbers, limitations, and deductibles. Inclusion of this line in the ABN will not garner useful information and will only raise questions about the validity of the form. Further, beneficiaries may think that by indicating an "other" insurer on the ABN, the "other" insurer will pay for their item or

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service, which may not be the case. Thus, we encourage CMS to eliminate this section from the ABN form to minimize beneficiary confusion, avoid questions of ABN validity, and maintain the focus of the ABN's intended purpose of providing documented notice to beneficiaries.

D. Customization of ABN

Finally, it is general practice that laboratories customize the June 2002 ABN to meet their needs by, for example, placing bar codes on the top of the form or preparing the ABN in duplicate. These customizations of the June 2002 ABN have made it easier for laboratories to track beneficiaries and their respective tests, input ABNs into laboratory databases, and coordinate specimens and test results with requisition forms. For these reasons, it is important that laboratories are permitted equal flexibility with the new ABN. CMS should consider these uses in designing the form and in writing its instructions.

V. Conclusion

In closing, although ACLA does not agree that a new ABN is needed for laboratory tests, if such a form is to be developed, we strongly believe that CMS should first seek additional input from the laboratory industry and Medicare beneficiaries before consolidating the general ABN and laboratory-specific ABN forms into a new ABN, and we urge CMS to conduct beneficiary focus group studies to ensure that significant changes will be understood by beneficiaries, as this was a critical component to the successful design of the June 2002 laboratory-specific ABN. The importance of maintaining a concise, clear, and understandable ABN specific to laboratory services cannot be overemphasized. We worked closely with CMS in the past to develop an effective laboratory-specific ABN, and we would welcome the opportunity to meet with CMS again to ensure that any future ABN is effective for physicians, beneficiaries, and laboratories. If you have any further questions or comments, do not hesitate to contact us.

Sincerely,

Alan Mertz
President

McKesson Corporation
One Post Street
San Francisco, CA 94104

Ann Richardson Berkey
Senior Vice President
Public Affairs

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McKESSON

April 24, 2007

Ms. Bonnie L. Harkless
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8014

Re: CMS-R-131: Advance Beneficiary Notice of Noncoverage (ABN), (OMB: 0938-0566)

Dear Ms. Harkless:

On behalf of McKesson Corporation (hereinafter "McKesson"), I am pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed revisions to the Advance Beneficiary Notice of Noncoverage (CMS-R-131) form.

For nearly 175 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 18 corporation, we deliver vital medicines, medical supplies, care management services, automation, and health information technology solutions that touch the lives of over 100 million patients in healthcare settings that include more than 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, and 25,000 retail pharmacies. Through our recent acquisition of Per-Se Technologies, McKesson is now connected to more than 90% of U.S. pharmacies, and we process approximately 70% of all electronic pharmacy transactions. In that capacity, we also serve as the CMS contractor of TrOOP administration for the Medicare Part D prescription drug benefit.

McKesson is the largest pharmaceutical supply management company in North America. We are also the nation's leading health information technology (IT) company, with software and hardware technology installed in over half of the nation's hospitals with more than 200 beds. Our health IT solutions provide decision support software to help determine clinical diagnosis and treatment plans for patients, electronic systems that eliminate the need for paper prescriptions and paper medical records, secure online access to patient information for physicians, and bar-code scanning technology to prevent more than 96,000 medication errors every week. Additionally, McKesson is the nation's largest provider of disease management services to state Medicaid programs to reduce the

cost and improve the quality of care for patients with chronic diseases. We also provide technology to support insurers' efforts to capture and utilize information that will improve patient care and expedite reimbursement.

We are drawing on our extensive experience in health information technology to provide comments on the proposed revisions to the Advance Beneficiary Notice of Noncoverage (ABN) form.

McKesson commends CMS for striving to improve the Advance Beneficiary Notice of Noncoverage. We support the agency's intent to combine the CMS-R-131-G and CMS-R-131-L versions and adopt more user-friendly language on the form.

We would like to comment in greater detail on two areas of the proposed rule: (1) the significance of the structure and format of the form for information technology systems, and (2) the implementation schedule of the proposed changes. In addition, we offer suggestions for CMS to consider before the final revision is issued.

Structure and Format of the Revised Form

In the proposed new format, the table style, which lists "*(D) Items/Services, (E) Reason and (F) Estimated Cost*", has gridlines which will significantly limit the description field when the user's computerized system attempts to print onto a pre-formatted form. We recommend that CMS consider a block format for this table, similar to the block format in the current ABN, to alleviate any potential difficulties in printing this form.

Additionally, the proposed '(G) Options' header/box will present printing problems when used with line-printers, which are commonly used today in many hospitals and laboratories and cannot accommodate this type of print formatting. Since shadowed checkboxes in the '(G) Options' box of the proposed form will be problematic for some report writing tools, we recommend the use of a centered title within the 'Options' box and the use of simple checkboxes.

Several additional recommendations on these sections include:

1. Provide an estimated cost for each service so patients can better understand the financial liability for each service;
2. When Medicare will not cover a particular service, state the agency's rationale for each non-reimbursable service;
3. Include a total cost in Section F so that patients can better assess their alternatives when presented with this form at the time of service; and
4. Simplify the form to accommodate commonly used printers within healthcare settings.

Implementation Schedule

The proposed new ABN form displays the date of "June 2007" at the bottom of the form. A June 2007 implementation date would provide an extremely limited time frame for multiple information systems to be updated, tested and released to accommodate the new ABN format. Although the ABN form may be created in one module of an information

system, changes to the ABN form will require integration across several programs within a hospital organization's information system.

Due to these concerns, we strongly urge CMS to delay the implementation date for the new form until January 2008 or later. This proposed implementation schedule will provide the additional time required for vendors to adequately test these form revisions across their systems and install system upgrades. Providers will also need to implement the UB04, the new CMS-1500 and the NPI; therefore, we recommend a 90-day transition period to allow users enough time to educate their staff and address operational issues subsequent to the implementation date of this initiative.

Other Recommendations

We recommend that CMS include a field, header, note and/or line to accommodate the signature of a witness when a patient will not or cannot sign the ABN form.

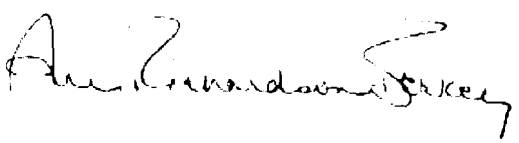
Conclusion

In summary, McKesson recommends that CMS:

- Provide an estimated cost for each service, an associated rationale for non-payment of any service and the total costs in Sections E and F of the ABN form;
- Accommodate format and printing specifications for healthcare provider information systems;
- Establish an implementation date of January 2008 or later; and
- Include a witness signature line in the revisions to the ABN form.

Thank you for the opportunity to share our comments on Proposed Rule CMS-R-131. We hope these comments provide constructive recommendations for the revisions to the ABN form. Should you have questions or need further information, please contact me at (415) 983-8494 or ann.berkey@mckesson.com.

Sincerely,



Ann Richardson Berkey

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MGMA

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

April 23, 2007

Center for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attention: Bonnie L. Harkless
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7500 Security Boulevard
Baltimore, Maryland 21244-1850

RECEIVED
4/24/07

Re: Proposed Revised Version of the General Advanced Beneficiary Notice of Noncoverage (ABN) (CMS-R-131)

Dear Ms. Harkless:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the Proposed Revised Version of the General Advance Beneficiary Notice (ABN) (CMS-R-131), published in the February 23, 2007 *Federal Register*. We appreciate the Centers for Medicare & Medicaid Services' (CMS) outreach to the provider community and the willingness to participate in constructive dialogue to improve this particular administrative aspect of the Medicare program. We look forward to continuing our collaborative work on this and other administrative simplification issues. MGMA offers the following critiques and recommendations related to these proposed revisions.

MGMA, founded in 1926, is the nation's principal voice for medical group practice. MGMA's nearly 21,000 members manage and lead some 12,500 organizations in which almost 270,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently, so physician time and resources can be focused on patient care.

MGMA applauds CMS for attempting to simplify the administrative process by combining the existing ABNs; however, there are elements of the proposed version that further complicate the process. The overall revisions to the forms will add additional time and money.

Expanding the information request has benefit to the patient, but may hinder the administrative process for practices. The space allocated to provide additional information has decreased. Even though lines are provided to clearly itemize services, practices will have to decrease their handwriting to include all required information, which will compromise the readability for Medicare patients.

The expansion of Section D through F is a positive mechanism for providing beneficiaries with the requested breakdown of cost of services; however, not all services can be itemized. Providing beneficiaries with a breakdown of service costs can also affect patient care. Some beneficiaries may base their decision on out-of-pocket considerations and not

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medical necessity. The proposed revisions will lump expensive and inexpensive services together, adding to the beneficiary's confusion. Additionally, problems will result if practices include services that they typically do not bill. The expansion of information complicates the administrative process by not clearly addressing how to determine the beneficiary's decision per service on ABNs that include multiple services.

Providing additional payment options to a patient population that has difficulty understanding current options will further confuse them. Previously, the word "option" was directly next to the choices that beneficiaries were offered. On the revised proposal, the word "option" is buried in the center of the form, therefore requiring the administrative staff to increase the time necessary to inform beneficiaries of their choices. Also, the proposed form contains excessive information and instructions. The simple "yes" or "no" options provided on the existing forms are easier to explain to beneficiaries.

Stylistically, the proposed ABN does simplify the administrative process; however there are elements of the form, listed below, that will add complexity to the process.

- Adding section identifiers (A through J) is a positive change because it clearly identifies the sections, but the section identifiers do not assist the beneficiary or the practice in completing the form.

- The proposed form omits the phrase "signature of patient or person acting on patient's behalf." This is valuable wording because often beneficiaries have a caretaker or family member overseeing their medical care.

- On the existing form there is no Section H. If CMS wishes to include this section, MGMA recommends that CMS expand it to include the following information: beneficiary's plan, eligibility dates and identification number.

- The privacy notice on the proposed form is too small to read and too lengthy. MGMA request that CMS replace it with the wording from the existing ABNs that states that the information provided will be kept confidential.

- MGMA recommends that CMS keep the same title "Advanced Beneficiary Notice" as opposed to changing it to the proposed title, "Advanced Beneficiary Notice of Noncoverage." The proposed title implies that the service in question is not a covered service.

MGMA supports CMS' decision to change the phrasing of the note from "You need to make a choice about receiving these laboratory test or health care items or services" to "If Medicare does not pay for things listed below, you may have to pay."

Beyond adjustments and modifications to the ABN, CMS needs to clarify policies and procedures encompassing ABNs. CMS needs to clearly identify when a form is considered a valid form and what constitutes a completed form for a beneficiary's receipt. MGMA recommends that CMS develop policy to streamline ABN requirements for dual eligibles by only requiring a beneficiary to complete one form. MGMA also recommends that CMS create policies that would allow beneficiaries to complete ABNs on an annual or procedure basis.

MGMA appreciates your consideration of these comments and looks forward to collaborating to educate medical group practices on the proposed Medicare program changes. If you have any questions, please contact Leah S. Cohen in the Government Affairs Department at 202.293.3450.

Sincerely,

William F. Jessee, MD, FACMPE
President and Chief Executive Officer

The SCOOTER Store®

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April 23, 2007

VIA FEDEX

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4/24/07

CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attention: **Bonnie Harkless**
Room C4-26-05
Baltimore, MD 21244-1850

Subject: FR/ Volume 72, Number 36/Februrary 232, 2007, page 8167/ CMS Agency Information Collection Activities; Revision of currently approved Collection; Advance Beneficiary Notice of Noncoverage (ABN)

On behalf of The SCOOTER Store, a nationwide provider of Power Mobility Equipment, I am please to submit the following comments concerning the Advance Beneficiary Notice of Noncoverage (ABN).

- On the form in Box (G) Options reword the third option to read "Provide me with what is listed above. I want you to bill Medicare for an official decision on payment. You can ask for payment now that will be refunded if Medicare pays. I understand if Medicare does not pay I can appeal their decision. *I understand that if Medicare does not pay, I agree to be personally and fully responsible for payment.*

- Please clarify that a representative will be allowed to sign for the beneficiary.

Thank you for this opportunity to comment on the planned information collection.

Sincerely,

William T. T. Hood, Jr. PAHM, CHC
Vice President for Medicare/DMAC/PSC
Relations, Policy and Corporate Compliance

The POWER MOBILITY Coalition
WORKING TOGETHER for FREEDOM and INDEPENDENCE

The POWER MOBILITY Coalition
WORKING TOGETHER for FREEDOM and INDEPENDENCE

April 23, 2007

Eric W. Sokol
Director

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The Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – C
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Baltimore, MD 21244-1850

RE: CMS-R-131, CMS-10219, CMS-10097, CMS-255 and CMS-437

Dear Ms. Harkless:

On behalf of the Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized wheelchairs and power operated vehicles (POVs), we are submitting the following comments concerning the revised Advanced Beneficiary Notice (ABN) that was published in the Federal Register on February 23, 2007. 72 Fed. Reg. 8,167-8,168. In this revised ABN, CMS incorporated the general use ABN (form CMS-R-131-G) and the physician ordered ABN used for laboratory services (form-R-131-L) into a single notice meeting both needs. In addition, with this revised ABN, CMS also sought to make the ABN "more user friendly," adding the 1-800-MEDICARE number, adding addition beneficiary's right information, and increasing the selection options to allow beneficiaries the right to pay out of pocket. The following are some concerns with the revised ABN form and information collection identified by PMC members:

CMS Should Allow Suppliers to Establish a List of Reasons Why an ABN is Applicable

The instructions for the general use ABN (form CMS-R-131-G) established that the reason(s) for requiring an ABN "be sufficiently specific to allow the patient to understand the basis for the expectation that Medicare will deny payment." CMS further added that the "use of lists of reasons for denial which the particular physician or supplier has found are frequently applicable, with check-off boxes or some similar method of indicating the selection of the reason(s) is an acceptable practice."

The revised ABN instructions state, in part, that "Blanks (A)-(F) may be completed prior to delivering the notice." The instructions further identify three possible reasons for noncoverage taken from the previous version of the ABN (form-R-131-L) that may be pre-printed in Section E. CMS should clarify that Medicare suppliers and physicians may establish a list of reasons that are frequently applicable and can then be placed in Section E of the revised ABN.

We greatly appreciate the opportunity to present our concerns with the revised ABN forms. Further, we look forward to working with CMS to ensure that beneficiaries are fully aware of their liability and that suppliers are not unduly burdened in fulfilling the ABN requirement.

Respectfully Submitted,

Eric W. Sokol
PMC Director

Stephen M. Azia
PMC Counsel

ORTHOREHAB™

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1 of 3

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Division of Regulations Development – C
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Baltimore, Maryland 21244-1850

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4/24/07

April 23, 2007

Dear Ms. Harkless:

On behalf of Otto Bock HealthCare LP dba ORTHOREHAB I am responding to your proposed changes for the Advance Beneficiary Notice of Noncoverage (ABN) form (copy enclosed). This proposed form change may cause even more confusion for beneficiaries. In light of the concern for the patients we serve, please consider the following recommendations for the proposed ABN form.

A. Under the first bulleted section:

- Medicare wants us to be sure you make an informed choice. This is not an official Medicare decision. Ask us for more explanation if you need it. For questions on this notice or on Medicare billing, you can also call 1-800-MEDICARE.
    - **Concerns:**
        1. When I have called this number myself, the wait time is stated as follows: "Your estimated wait time is 15 minutes". Many times it is longer than stated. Keep in mind our patients have just been discharged from the hospital and are generally in either discomfort or pain from their recent surgery.
        2. Medicare patients have told us that it is very frustrating using this toll-free number. They do not usually know what option to select and they get very frustrated with the wait time.
        3. If the patient does choose to wait for a Medicare associate while the HME provider's representative is still in the home with the patient, this is a concern from a provider's point of view. As the expression goes, time is money and undue time delays driving up the cost of health care for the providers.
        4. There have been times when the patients we serve are given incorrect information when they call Medicare. This misinformation confuses the patient and makes it difficult for them to make an informed decision at the time we are delivering the equipment.

Recommendation:
Do not print the toll-free 800 on the ABN form. The patient receives a copy of the 21 Provider Standards and the exact same toll-free 800 number (1-800-MEDICARE) is at the bottom of this form and is pointed out to the patient at the time the equipment is delivered and set up.

B. Under the third bulleted section:

- We must bill Medicare when you ask us to. We may help you with billing other insurance if you choose Option 2 or 3 below, though Medicare cannot require us to do this.
    - **Concerns:**
        1. If Medicare is primary, we as the provider cannot bill another insurance without the EOB from Medicare. So, if the patient chooses Option 2, then we would not be able to bill other insurance(s) since Medicare was not billed first. Even if our equipment

is not covered or medically necessary, some insurance companies will still pay, but they must have an EOB first. Most patients will not know their insurance coverage criteria, so this is not a good choice for patients with either Secondary or Supplemental insurance.

2. This option would be very confusing for the patient and it becomes a challenge for the provider to explain why this is not a good choice for them.
3. This option could also lead to potential fraud and abuse by HME providers, convincing the patient that it is not covered and collecting payment up front leaving no recourse for the patient.

Recommendation:

- Eliminate this choice since it is unfair to and confusing for the patient and could lead to potential abuse by HME providers.

C. Under (G) Option # 2:

- Provide me with what is listed above. I do not want Medicare billed. I agree to be responsible for payment. I understand that I cannot appeal to Medicare when choosing this option.
  - **Concern:**

    Why even have this option, since patients would not have the right to an appeal. This seems in conflict with patient rights, especially under the new CMS accreditation standards for DMEPOS providers. The patient most likely will not choose this option due to the fact that they cannot appeal to Medicare.

Recommendation:

- Eliminate this choice since the patient would not have the option to appeal and violates their rights as a patient/beneficiary.

Form Restrictions:

Unless I misread the section entitled "Completing the Notice" on page one of Form Instructions, it states the form must be used as is. ORTHOREHAB is using digitized technology for patient forms so this form should be able to be reproduced using the exact information, font size, 1-page format and reference the OMB numbers. I would recommend that as long as providers use the exact same format, they should be allowed to reproduce the ABN according to their technological capabilities.

Thank you in advance for considering the ABN form recommendations noted above. Please contact me if you have any questions at 800-711-2205 – extension 2302.

Sincerely,

Sherry Carlson

Sherry Carlson
Compliance Department

Cc: Steve Carr
Compliance Officer

Enclosure: Proposed ABN Form No. CMS-R-131

3/3/7

(A) Supplier/Provider:

(B) Beneficiary Name: _____ (C) Identification Number: _____

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare does not pay for things listed below, you may have to pay.

We think Medicare will not pay for the "**Item(s)/Service(s)**" listed below because of certain rules for coverage described under "**Reason**". You still can receive this care, since you or your health care provider may have good reason to think you need it, but it is likely you or other insurance will have to pay. We have estimated about how much you may have to pay under "**Estimated Cost**" to help you decide whether or not to receive the care listed.

(D) Item(s)/Service(s):	(E) Reason:	(F) Estimated Cost:

- **Medicare wants us to be sure you make an informed choice.** Read this whole notice, which explains our opinion that Medicare won't pay. **This is not an official Medicare decision.** Ask us for more explanation if you need it. For questions on this notice or on Medicare billing, you can also call **1-800-MEDICARE (1-800-633-4227/TTY: 1-877-486-2048).**
- **You need to make a choice about receiving the care listed above.** You must choose **only one** of the three options below. **We cannot choose for you.**
- **We must bill Medicare when you ask us to.** We may help you with billing other insurance if you choose Option 2 or 3 below, though Medicare cannot require us to do this.

(G) OPTIONS

☐ **1. Do not provide me with anything listed above.** With no care provided, there is no billing. I understand that **I cannot appeal** to Medicare when choosing this option.

☐ **2. Provide me with what is listed above. I do not want Medicare billed. I agree to be responsible for payment.** I understand that **I cannot appeal** to Medicare when choosing this option.

☐ **3. Provide me with what is listed above. I want you to bill Medicare for an official decision on payment. You can ask for payment now that will be refunded if Medicare pays.** I understand that if Medicare does not pay, **I can appeal that decision.**

(H) Other insurance to consider for billing: _____

Your signature below means that you have received this notice and understand it. You will also get a copy.

(I) Signature:	(J) Date:

PRIVAY NOTICE: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average (0 hours)(7 minutes) per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

OMB Approval No. 0938-0566 **Form No. CMS-R-131** **(June 2007)**

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

RECEIVED
4/24/07

Dear Ms. Harkless,

On behalf of CLMA, the Clinical Laboratory Management Association, an organization of more than 4,300 clinical laboratory professionals and consultants representing hospitals, independent clinical laboratories, physician office laboratories, skilled nursing facilities, and medical device companies, I am writing in response to the February 23, 2007 *Federal Register* notice, "Agency Information Collection Activities: Proposed Collection; Comment Request," regarding the Advance Beneficiary Notice of Noncoverage (ABN) Advanced Beneficiary Form (CMS-R-131, OMB:0938-0566).

Our comments are organized as follows:

- Comments on the Supporting Statement for the new ABN form
- Comments on the Instructions for the new ABN form
- Comments on the actual content of the new ABN Form

Comments on the Supporting Statement for the New ABN form:

2. Information Users

The Supporting Statement indicates that the new ABN form is also to be used in cases where a service is never covered under Medicare, replacing the voluntary Notice of Exclusion from Medicare Benefits (NEMB). It is not clear if a notice for services that are never covered is now mandatory or if it is still voluntary. The following language in the new instructions is somewhat ambiguous:

> "Previously, the ABN was only required for denial reasons recognized under section 1879 of the Act. This version of the ABN must also be used in place of the Notice of Exclusion from Medicare Benefits (NEMB) to provide voluntarily notification of financial liability."

CLMA requests that CMS clarify whether advanced notice of an excluded benefit is now required or voluntary, and if the new ABN form is required in place of the NEMB. In addition, we ask that CMS clarify which modifier, GA or GY, would be appropriate in this case.

B. Justification

1. Need and Legal Basis

CMS does not provide an explanation as to why the agency is eliminating the ABN-L form. A laboratory-specific ABN was originally created based on CMS recognizing that the laboratory presents a special case regarding medical necessity and the use of the ABN. The reasons have not changed as to why the laboratory presents a special case.

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There are limited reasons associated with claims denials for laboratory services under the Limitation of Liability regulations. The "reason" boxes on the ABN-L made it easy for laboratory suppliers to complete the form and allowed for automatic printing of the form. Therefore, CLMA believes there will be an additional capital cost associated with eliminating the ABN-L (See comment under "13. Capital Costs").

5. Small Business

CLMA believes the additional choice on the new ABN form related to use with excluded services actually complicates the entire ABN process. Further, the wording in the options section is now likely to generate even more questions from beneficiaries, requiring additional time and effort for personnel to answer. Increasing the number of actual items and services that are covered with this form makes it harder to implement for small businesses and does not reduce their burden. CLMA believes this section incorrectly states the burden not only for small clinical laboratories, but for all small entities notifying beneficiaries about services when they are not the ordering provider.

13. Capital Costs

Currently many laboratories and hospitals use automated information systems to detect when an ABN is necessary and then it will print the form with the information already inserted. For the vast majority of laboratory ABNs, this simply requires placing the test in the correct box on the form. The structure of the new ABN form will no longer allow this, and substantial reprogramming of these systems will be required to accommodate the new form. CLMA believes there will be an additional capital cost associated with reprogramming that is not accounted for in burden estimate in section 13.

Comments on the Instructions for the new ABN form:

CLMA is seeking clarification regarding changes in the instructions for the new ABN form. We assume that the changes in the instructions are a replacement for sections 50.5 through 50.5.9 in Chapter 30 of the Claims Processing Manual only, and that all other instructions, with the exception of references to the old forms, would remain basically unchanged. We respectfully request that CMS clarify which sections of Internet Only Manuals (IOM) are going to be changed.

In the first section of the instructions, there is a statement that CLMA would like to address.

> "The ABN must be verbally reviewed with the beneficiary or their representative and any questions raised during that review must be answered before they sign it."

Laboratories present a unique case regarding this requirement. If the specimen is drawn at the laboratory and not in the physician's office, the laboratory as the "notifier" cannot answer questions about medical necessity or why the physician ordered a test that is not covered. The laboratory employee administering the ABN in many cases is a phlebotomist, and it would not be appropriate for a phlebotomist or any laboratory employee to address these questions. The laboratory could only indicate that no information regarding a diagnosis was provided as a reason why the test would be covered under Medicare. CLMA recommends that CMS include an exception in this section of the instructions for suppliers who are "notifiers," but not ordering providers.

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Comments on the Content of the New ABN Form:

Form Title/NOTE:
The use of the word "things" as a general term to describe the item(s)/service(s) the beneficiary may be receiving is not professional language used in the medical community. CLMA recommends replacing the word "things" with the words "item(s)/service(s)," to describe in a more professional manner what the patient may be receiving.

Blank A – Supplier/Provider

CLMA seeks clarification as to who is the "notifier" in the case where a specimen is drawn for a laboratory test in a physician's office. The ABN would be provided to the beneficiary receiving the services at that time, and the specimen would then be sent to the laboratory for testing,
In order to inform the beneficiary who will be billing them and how to contact the billing entity, in this instance, would the physician's information be included in "Blank A, Supplier/Provider" as the "notifier" or would the laboratory be listed?

Blanks D, E and F (The "table" with gridlines):

CLMA seeks clarification on exactly how much customization of this table is allowable. For instance, will the laboratory be required to maintain six separate lines or, if there is only one item, could the laboratory use a blank box and fill it in? For a programmer writing software to pre-print items that can vary in length or need more than one line, an unlined box is considerably easier to work with.

Will the laboratory be required to use lines, or could items be separated using a space as long as the items, reasons and estimated price are all in a straight line?

Can the laboratory change the width of the boxes? For laboratory services, the item or service description and the cost estimate will be short, while the "reason" for noncoverage will be long. Can laboratories adjust the box widths accordingly?

Can laboratories pre-print any tests or reasons on the form and then check or clearly indicate which are applicable when the form is delivered to the beneficiary? Since the ABN must be verbally reviewed with the beneficiary, laboratories could make clear which services and reasons are applicable during that review.

Blank G Options

CLMA recommends that Option 2 also include the following statement:
"You can ask for payment now."

This is the same statement included in Option 3 but without "that will be refunded if Medicare pays." In the case of Option 2, the laboratory would not bill Medicare.

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Blank I Signature

The new ABN form does not clearly indicate when the beneficiary's representative signs on behalf of the beneficiary. CLMA recommends that box be modified to include a way to indicate when the person signing the form is the beneficiary's representative, not the beneficiary receiving services.

Privacy Notice

The font size at the bottom of the ABN is smaller than the rest of the form (size 8), and appears to be inconsistent with requirements suppliers and providers must meet in other areas of the form. Because the privacy notice is an important part of the ABN, CLMA recommends that it meet a required font size that is easily readable by the beneficiary.

In closing, CLMA appreciates the opportunity to comment on the new ABN form. Our members and staff stand ready to answer any questions or concerns that you may have regarding these comments.

Please contact Katharine I. Ayres, CLMA Director of Legislative and Regulatory Affairs, at kayres@clma.org or 610.995.9580 for further assistance.

Sincerely,

JoAnne Milbourn

JoAnne Milbourn
President