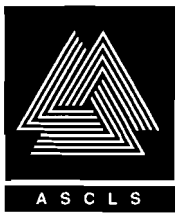

AMERICAN SOCIETY FOR CLINICAL LABORATORY SCIENCE

(39) 1 of 2

April 24, 2007

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4/25/07

post marked
4/24/07

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

Dear Sir or Madam:

The American Society for Clinical Laboratory Science (ASCLS) is writing in response to the proposed revisions of the Medicare Part B Advance Beneficiary Notice CMS-R-131 as published in the Federal Register Vol. 72, No. 36. ASCLS is the nation's oldest and largest non-registry professional association for non-physician clinical laboratory professionals. The Society's mission includes promoting high standards of practice in the workplace and ensuring professional competence, while its ultimate goal is to ensure excellent, cost-effective laboratory services for consumers of health care. Our membership of nearly 12,000 includes clinical laboratory directors, managers, administrators, supervisors, and staff at all levels of practice.

ASCLS questions the need to consolidate the general and laboratory versions of this form. We ask CMS to explain the problem that is being addressed with this consolidation. The current form for laboratory services has eliminated much confusion on the part of the beneficiary and the physician office staff concerning why Medicare might not pay for a laboratory test. The reasons were clearly represented by each column on the form and it was simple to place the name of the test in the appropriate column. The proposed form now asks the physician office staff to write not only the test but the reason, which they usually do not remember. The net result of this change is that laboratories will receive specimens with incorrectly executed ABN forms after the close of the physician's office. Clinical laboratory professionals will be unable contact anyone and face the ethical dilemma of performing a test that may not be billable to either the patient or Medicare.

We would like to raise some additional concerns:

- **(G)Option** - #3 does not clearly state that the beneficiary agrees to be financially responsible for the testing if Medicare does not pay for the test. While financial liability may be implied in option #3, it is not clearly stated as it is in option #2.

6701 Democracy Boulevard, Suite 300 Bethesda, Maryland 20817 301.657.2768 301.657.2909 *fax*

2 of 2

- We believe option #3 should clearly state that the patient is agreeing to be financially responsible for payment if Medicare does not pay and their appeal is not successful.

- **Section H** – We question the necessity for the collection of information about other insurance on an ABN form. Complete billing information should be submitted with the requisition and having other insurance listed on the form does not seem to add any little value to the purpose of the form.

ASCLS is pleased that the ABN lists the charge information for each specific procedure. If a patient has more than one procedure ordered that is not medically necessary, it is currently difficult for the beneficiary to determine the cost of each procedure in order to make a decision as to whether he or she is willing to pay for each procedure.

ASCLS and its members thank you for your attention to these concerns and suggestions and reaffirm our willingness to work with you and your colleagues to ensure that the changes to this form are of benefit to the beneficiary and not burdensome to the providers.

Sincerely,

Shirlyn B. McKenzie

Shirlyn McKenzie, President
American Society for Clinical Laboratory Science

6701 Democracy Boulevard, Suite 300 Bethesda, Maryland 20817 301.657.2768 301.657.2909 *fax*

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4/24/07

By Electronic Transmission

April 24, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Norwalk:

On behalf of the American Association for Homecare (AAHomecare), we are pleased to provide comments on the proposed Advance Beneficiary Notice of Non-Coverage (ABN) notice. Our comments incorporate the expert views of home medical equipment providers and association who utilize this form for individuals seeking health care items, services and therapies under the Medicare program.

AAHomecare is the largest national professional association representing the homecare community. AAHomecare represents health care providers and manufacturers that serve the medical needs of Americans who require oxygen equipment and therapy, sleep therapy technologies and services, mobility assistive technologies, medical supplies, inhalation drug therapy, home infusion, and other home medical equipment, therapies, services and supplies in their homes. Our membership reflects a broad cross-section of the homecare community, including national, regional and local providers operating in approximately 3,000 locations in all 50 states. AAHomecare and its members are committed to advancing the value and practice of quality health care services in the home.

The Association's comments include both clarifications to the proposed ABN and accompanying instructions and recommendations to facilitate a clear understanding of the requirements and facilitate ease of use by providers and Medicare beneficiaries.

Clarifications and Recommendations

1) Proposed ABN form instructions contain a field for the beneficiary's name (Blank B). Notice instructions indicate that, "Notifiers must enter the first and last name of the

beneficiary receiving the notice and the middle/initial also if used on the beneficiary's Medicare card. The Association requests guidance from CMS that a provider makes the best intent to accurately reflect the beneficiary's name, however since other identifying information is included on the ABN, a missing middle initial or misspelled name should not invalidate the ABN.

2) ABN form instructions contain a field for the beneficiary's identification number. The instructions state, "notifier should enter an identification number for the beneficiary that helps to link the notice with a related claim when applicable. When a number such as a Medicare number of HICN is used the notice must be delivered in a secure manner consistent with federal privacy requirements." The association requests that an identifying number be optional to help better identify a patient to a database, however it does not invalidate an ABN if left blank. The Association recommends that the requirement for an HICN be eliminated from the notice. Medicare beneficiaries are becoming increasingly concerned with providing personal identification information.

3) Field F on the proposed form requires the "notifier must enter a cost estimate in this blank for items or services described in Blank (D)" This requirement is a departure from the previous ABN form, which indicates that, "You may provide the patient with an estimated cost of the items and/or services." The Association's recommendation is to continue the requirement that a provider may provide a cost estimate. Since services provided by DME suppliers may have monthly, daily, per dosage charges, it is impossible to accurately reflect all potential charges for a course of therapy.

4) The Association is fully supportive of the wording of Blank (G) option 2. We recommend that CMS include additional information in the instructions that provide an example of its application. For instance, an example could be, "Patient wishes to purchase a wheelchair rather than rent or the patient wants to purchase additional diabetic supplies beyond those covered in the medical policy."

5) Under Blank (G) options, the instructions indicate "If a beneficiary cannot or will not make a choice, the notice should be annotated." We request that CMS provide an acceptable example of an appropriate annotation. Our recommendation for an example is; patient not available to sign, family member requested purchase of wheelchair on patients behalf. Also, if no choice is made but an annotation is made it is deemed a valid ABN.

6) The current ABN allows for cases when the patient refuses to sign the ABN. In these circumstances, suppliers can have a witness sign and date the form, noting that the ABN was given to the patient who refused to sign the notice. Will this policy still be permissible under the proposed ABN?

7) Will the proposed ABN be needed for a DMEPOS item or service that is not covered or simply for medical necessity denials?

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8) We would like guidance from CMS indicating the effective period of an ABN. There has been inconsistent guidance from the DME MACs on this issue. We would recommend that an ABN is valid for the full period of medical necessity. This would allow suppliers to get only one document per therapy.

9) The Association strongly recommends that CMS provide for a sufficient transition to the use of the new form. The proposed form is dated "June 2007." We want to be sure that older forms are not considered invalid, and therefore, the ABN is invalid because an old version of the form was used. There should be a grace period of at least 90 days when either form may be used and considered valid.

10) We recommend revising the wording in number 3 under option G. The wording in the second sentence of the proposed notice states, "I want you to bill Medicare for an official decision of payment." We propose revising this sentence to, "I want the provider or supplier to bill Medicare for an official decision on payment." We also would recommend that sentence 3 in Option G number 3 be eliminated. This sentence is confusing and does not take into consideration non-assigned claims.

We appreciate your consideration of the Association's comments and recommendations on the proposed Advance Beneficiary Notice of Non-Coverage notice. We hope to work closely with CMS on the proposed form and may provide additional comments that we receive from our members. If you have any questions about the recommendations and clarifications contained in our comments, please contact Walter Gorski at (703) 535-1894.

Sincerely,

Tyler J. Wilson

Tyler Wilson
President
American Association for Homecare

Federation of American Hospitals®

Charles N. Kahn III
President

(39)

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April 23, 2007

BY OVERNIGHT MAIL

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

RE: ***CMS–R-131 (OMB#: 0938–0566); Agency Information Collection Activities: Proposed Collection; "Comment Request – Advance Beneficiary Notice of Noncoverage (ABN)"***

Dear Ms. Harkless:

The Federation of American Hospitals ("FAH") is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural parts of the United States. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Notice, issued in accordance with the Paperwork Reduction Act of 1995, regarding agency information collection activities involving the Medicare Advance Beneficiary Notice of Noncoverage ("ABN"). (*See* 72 *Fed. Reg.* 8167 (Feb. 23, 2007).)

I. Combination of the Advance Beneficiary Notice and the Notice of Exclusion from Medicare Benefits

The proposed revisions to the ABN include combining the current General Use ABN (Form CMS-R-131-G) and the Laboratory Use ABN (Form CMS-R-131-L) into a single notice, called the Advance Beneficiary Notice of Noncoverage. In addition, according to the proposed form's instructions, this single general notice would be used in place of the Notice of Exclusion from Medicare Benefits (NEMB) to provide voluntary

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notification of financial liability.[1] The FAH supports combining the Forms CMS-R-131-G and CMS-R-131-L, and appreciates the agency's action to streamline the ABN process to use one form.

However, for several reasons discussed below, we do not believe the ABN and NEMB forms and related processes should be combined. First, the instructions for the revised form state that "Physicians, providers.... must complete the ABN as described below, and deliver the notice to the affected beneficiary..." Form instructions at p. 1. This means that a completed ABN form is mandatory if a provider wishes to bill Medicare and hold the beneficiary liable should Medicare deny payment. Conversely, completion of the NEMB form for statutorily excluded services or services that do not meet the definition of a Medicare benefit is optional, and the provider may bill the beneficiary for such services even if an NEMB is not completed.

Also, the billing rules for statutorily excluded services (NEMB) and non-medically necessary services (ABN) are not equivalent. When an ABN is obtained for services that the provider does not believe are medically necessary, the provider must bill the services to Medicare in order for the Medicare Contractor to make a coverage determination. When reporting ABN services to Medicare, the services are listed as covered with occurrence code 32 and/or the GA modifier present on the claim. Medicare Claims Processing Manual (CMS Pub. 100-04), Chapter 1, §§ 60.1.2 and 60.4.1.

If a provider decides to obtain an NEMB for statutorily excluded services and the provider submits a claim to Medicare, the services are reported as non-covered with the GY modifier. The Medicare administrative contractor always will deny these services. Medicare Claims Processing Manual (CMS Pub. 100-04), Chapter 1, § 60.3.1.

If the forms are combined and both non-medically necessary and statutorily excluded services are included on the same ABN, the provider billing process would be more difficult, *e.g.*, determining which services require the GA modifier versus the GY modifier when both were on the same ABN. In addition, CMS billing rules state that ABN and demand billing should not be on the same claim. Medicare Claims Processing Manual (CMS Pub. 100-04), Chapter 1, § 60.3.1.

As a result, because the specific requirements for obtaining the two forms differ, we believe it is not reasonable to combine the forms and related billing processes, and doing so is likely to create confusion in the provider and beneficiary communities.

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[1] It is also not clear from the proposed form and accompanying instructions whether the single general notice would replace the American Dental Association NEMB used for dental exclusions and the American Podiatric Medical Association NEMB used for foot care exclusions under Medicare. While these forms are not published by CMS, they are reviewed and approved by the agency and are used as part of the NEMB process.

Accordingly, we believe that Option 2 should be removed from Section G of the proposed ABN form because it applies only to statutorily excluded services.

If CMS decided to continue with its plan to combine the ABN and NEMB forms, the billing instructions for these two distinct types of items or services in the Medicare Claims Processing Manual, Chapter 1, Section 60 and Chapter 30, Section 90 will need to be revised. In accordance with revisions to these rules, Medicare claims processing systems also would need to be evaluated and potentially modified to process and adjudicate claims appropriately. Also, providers would need to implement system changes, develop new processes, and furnish extensive education. [2]

The amount of time needed to publish new rules, update claims processing systems and conduct provider education should be considered when determining an effective date of the new ABN form. At a minimum, we estimate that this is likely to take as long as six months to accomplish. Therefore, if CMS decides to move forward with this proposal, we request a significant transition period to allow both providers and Medicare Contractors to modify their operations to implement these changes.

II. Option Box

The proposed instructions state:

> *If a beneficiary chooses to receive some, but not all of the items or services that are subject of the notice, the items and services in Blank (D) that they do not wish to receive may be crossed out, if this can be done in a way that also clearly strikes the reason(s) and cost information in Blanks (E) and (F) that correspond to that care. If this cannot be done clearly, a new ABN must be prepared.*

We do not feel that it is appropriate to cross out those items that the beneficiary chooses not to receive without further action. This does not allow the beneficiary to choose an option from Section G of the form. In the scenario where there are multiple services listed on the ABN and the beneficiary chooses to receive some but not all of the services, a new ABN should be created; therefore allowing the beneficiary to choose Option 1 on the form for the services that they do not want to receive and either Option 2 or 3 on the other form for those services that they want to receive.

III. Other Insurance

We believe that Section H should be removed from the ABN form as this information already is obtained from the beneficiary during the registration process by

[2] We also assume, although it is not stated in the Notice, that CMS intends to publish an English and Spanish version of the single ABN.

collecting Medicare Secondary Payer data. To ask for this information again would be redundant.

IV. Estimated Cost

Regarding Section F Estimated Cost, the instructions for the revised form state, "Notifiers must enter a cost estimate in this blank for the items or services described in Blank (D)." Form Instructions at p. 3. Current instructions (Medicare Claims Processing Manual, Chapter 30, Section 50.5.7) regarding Estimated Cost state:

> *The user may provide the patient with an estimated cost of the items and/or services. The patient may ask about the cost and jot down an amount in this space. Users should respond to such inquiries to the best of their ability. The 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 will not be considered to be defective on that basis. In the case of an ABN which includes multiple items and/or services, it is permissible for the user to give estimated amounts for the individual items and/or services rather than an aggregate estimate of costs. Amounts may be provided either with the description of items and services or on the "Estimated Cost" line.*

We would ask CMS to clarify whether the Estimated Cost is mandatory. In addition, we request that CMS define if an estimate is different from the actual cost how much variance is allowed before the ABN would be considered defective.

V. Item(s)/Service(s)

The instructions for the revised form state for Section D Item(s)/Service(s):

> *Notifiers must enter the name/description of all item(s) and/or service(s) that are the subject of the notice. Whenever possible, language that is easy for beneficiaries to understand should be used. If technical language must be used, it must be explained verbally to the beneficiary or representative.*

Current instructions (Medicare Claims Processing Manual, Chapter 30, §§ 50.5.5 and 50.5.6) state:

> *...the user specifies the health care items or services for which he/she/it expects Medicare will not pay. The items or services at issue must be described in sufficient detail so that the patient can understand what items or services may not be furnished. HCPCS codes by themselves are not acceptable as descriptions.*

We would request that CMS clarify what degree of specificity is required when completing this section. For example, a physician orders an MRI of the head without contrast to be performed at XYZ Hospital. The patient is registered and an ABN is obtained based on a Local Coverage Determination. The Item listed is "MRI of head

without contrast." Upon consultation with the patient's physician, the radiologist performs an MRI of the head with and without contrast. CMS should define whether the ABN would be valid in this type of scenario.

VI. Burden Estimate

We believe the Burden Estimate is understated in several aspects. While we do not disagree with the seven minutes on average to deliver an ABN, but do not feel that the estimate accurately includes all aspects of the process. In addition to delivering the ABN, there are additional steps during the billing and collection process that are affected by the ABN. We believe that each claim that includes services for which an ABN has been obtained, takes an additional five minutes to process by the provider. Also, if Medicare denies the ABN service, the provider will incur additional costs to collect the funds from the beneficiary, including producing patient billing statements and follow-up phone calls.

Also, the estimated volume of ABNs delivered is based on the current ABN form and does not appear to be inclusive of the volume of NEMBs delivered.

We would request that the Burden Estimate be recalculated taking these points into consideration.

* * * * * *

We appreciate the opportunity to comment on this information collection activity and hope that the agency carefully considers the comments in this letter. If appropriate, we would welcome the opportunity to meet, at your convenience, to discuss our views. If you have any questions, please feel free to contact me or Jeffrey Micklos of my staff at (202) 624-1500.

Respectfully submitted,