CMS Response to PRA Comments:
Advance Beneficiary Notice (ABN)
May 2007

Summary

Under the limitation of liability provisions set forth in section 1879 of the Act, Medicare beneficiaries may not be held financially responsible for items or services that may be covered under Medicare, but are denied in an individual case, unless the beneficiary is informed prior to receiving the items or services that Medicare is likely to deny payment. Absent such "advance beneficiary notice" (ABN), the provider or supplier may not bill the beneficiary if it furnishes a service that is subsequently denied by Medicare. Thus, the primary use of the ABN is to inform beneficiaries of their potential liability in these situations. The ABN is now approved by OMB under the Paperwork Reduction Act (PRA) of 1995.

When required, the ABN is delivered by Part B paid physicians, providers (including institutional providers like outpatient hospitals) practitioners (such as chiropractors), and suppliers. It is also used by hospice providers, and now may also be used by Religious Non-medical Health Care Institutions (RNHCIs), paid under Part A.

In February, 2007, CMS published a revised version of the existing ABN for public review and comment. Key changes in the form included:

- Changing the official title of to "Advance Beneficiary Notice of Noncoverage" in order to more clearly convey the purpose of the notice
- Merging the very similar ABN-G and ABN-L (previously, PRA approval for the ABN collection 0938-0566 was for two versions of the ABN, the General Use ABN, form CMS-R-131-G, and CMS-R-131-L, specifically for physician-ordered laboratory tests).
- Allowing the ABN to be used for voluntary as well as mandatory liability notification, in place of the voluntary form known as the Notice of Exclusion from Medicare Benefits (NEMB).
- Introducing a mandatory field for cost estimates.
- Adding an additional beneficiary option, under which an individual may choose to receive a service, but pay for it on her own, as opposed to having a bill submitted to Medicare.
- Incorporating a number of "plain language" changes to reflect suggestions made by notifiers based on their experience with use of the current ABN over the past 3 years of use of the ABN, as well refinements made to similar liability notices in the same period through based on consumer testing

In addition to changes to the form itself, our February PRA package also reflected an increase in the burden estimate associated with delivery of the ABN. This increase took into account not only volume increases (commensurate with program growth in the number of beneficiaries, providers, suppliers and claims) but also changes in our

assumptions and estimation methodology. For example, we allowed more time to deliver each ABN, increased our estimate of the frequency of ABN delivery, and provided for increases in personnel-related costs of delivering notices.

Comments on the ABN

The 60-day public comment period on the revised ABN ended April 24, 2007. We received 43 comments, including comments from beneficiary advocacy groups, various national health care industry groups, software and compliance system vendors/consultants, individual provider/supplier notifiers required to issue ABNs, and others. Commenters addressed the wording and organizational structure of notice, the instructions for its use, and the burden estimates associated with ABN delivery.

Wording of ABN and Revised Title

Comment: A large majority of commenters supported the effort to incorporate more plain language into the ABN, and many offered additional suggestions. Among the suggestions for wording changes were requests that the ABN include additional language pertinent to particular providers and suppliers, or that they be permitted to pre-print frequently occurring information. Several commenters requested sizing or spacing adjustments in the proposed notice, including requests that CMS allow more flexibility in formatting for those wishing to reproduce the ABN through automated means. The only two commenters that addressed the new title opposed the change, stating that the ABN had nothing to do with noncoverage.

Response: We thoroughly considered all of the many suggestions for wording changes, many of which addressed the same language in conflicting way. We generally adopted those changes that were in keeping with the goal of using more beneficiary-friendly language in the ABN, such as changing the word "beneficiary" to "patient", and using simper concepts, such as "payment" as opposed to "coverage". We also simplified and shortened the statement that Medicare does not pay for all services, even if recommended by a health care provider. Note that some commenter favor more formal usage and style; however, we did not adopt these comments, based on CMS' extensive experience with tailoring Medicare publications to the beneficiary population and experience gained in beneficiary-oriented consumer testing of notices.

Another important consideration was the need to limit the ABN to one page; thus we generally were limited in our ability to add much language to the notice, particularly when the requested language was pertinent to only a particular type of notifier. Instead, we took several measures to make the form more easily customizable for different users. For example, we replaced the term "items/services" with a customizable blank, so that users can insert a description most appropriate to their specific businesses. For example, laboratories can insert "tests" rather than "items/services." The revised form instructions include a list of options to fill in this blank. Similarly, as is done currently with the laboratory ABN (ABN-L), we have clarified that it is permissible to pre-print information like high-volume items and services and common expected reasons for denial/non-

coverage on the form. We have also included an explicit section for "Additional Information", such as context on Medicare payment policy applicable to a specific benefit or information on other insurance coverage.

We have maintained the new title, as we continue to believe that revised title is needed to improve understanding of the purpose of the ABN. This belief is only reinforced by the mistaken belief of the two commenters that the notice has nothing to do with non-coverage.

Beneficiary Options

Comment: Comments were mixed on the need to add a new "self-payment" option to the form. Some commenters asked whether beneficiaries could be permitted to select more than one option, while others recommended that the need to select only one option be made clearer. Two commenters representing beneficiaries recommended that the option to receive services and have a claim submitted to Medicare be the first option, believing that this sequence would be more likely to ensure that beneficiaries were aware of their appeal rights under this option. Commenters also offered suggestions on how to make this option more clear and beneficiary friendly.

Response: The ability to pay for a service without having Medicare billed has always been an option, although it was not clearly enunciated on the previous ABN. This can be an important personal privacy protection, for example in situations where an individual would prefer that entities other than their physician not be made aware of their illness or course of treatment. We have received many comments to this effect during the last three years. Therefore, although some commenters did not appear to understand the need for this option, we have maintained this new choice on this version of the ABN. We made several changes to emphasize that an individual may select only one option, and that the choice is up to the individual, including the addition of a prominent direction stating: "**Check only one box. We cannot choose a box for you."**

As suggested, we have re-ordered the options, so that the first option is to receive services and appeal to Medicare. Other changes made to this option include:

- Making more explicit that beneficiaries are still responsible for payment if Medicare does not pay.
- Providing information on the Medicare Summary Notice (MSN) as the vehicle informing beneficiaries of official payment decisions and appeal rights.
- Clarifying that if Medicare does pay for a service, the beneficiary is still responsible for applicable co-payments or deductibles.

Merger of ABN-G and ABN-L

Comment: We received conflicting comments on this issue. One laboratory group indicated that laboratories were pleased with the current, separate laboratory ABN, while other commenters supported the need for a single cross-cutting notice and opposed a more segmented approach. Commenters in favor of retaining the existing ABN-L cited

the time and resource requirements that would be associated with adopting a new form. Even the commenters that supported the change to a single ABN indicated that certain positive elements of the laboratory-specific ABN needed to be built into the general ABN, such as the ability to pre-print frequently occurring services or denial reasons on the form, or to include other language specific to a particular supplier or practitioner type.

Response: We continue to believe that a single ABN used by all parties will be less confusing for beneficiaries, providers and contractors alike. We also feel strongly that the new general ABN offers significant improvements in terms of clarity, comprehension, and formatting. However, as noted above, we have introduced more flexibility into the ABN, so that it can be tailored for use by a given industry, as opposed to necessitating totally different forms for various practitioner or supplier types. For laboratories, this means that the three standard reasons now used to explain why Medicare is not expected to pay laboratory tests, can continue to be pre-printed on the new notice and matched in automated systems with the applicable tests expected to be denied for these reasons based on Medicare local and national coverage determinations. We believe this addresses the primary concern of the laboratory industry. Note that even if we were to maintain a separate ABN-L, which we do not believe it appropriate or necessary, wording and formatting changes consistent with the PRA process would still be needed. Thus, continued use of the exact same form would not have been possible under any circumstances.

Use of ABN for Voluntary Notification

Comment: Several commenters opposed the use of the ABN in situations where they now provide the Notice of Exclusion from Medicare Benefits (NEMB). Their comments reflected an apparent mistaken belief that use of the ABN would become mandatory in situations where it was previously voluntary, such as where Medicare never covers a given service. Other commenters supported this change.

Response: The purpose of this change was to streamline the current notice process and to reduce or eliminate any widespread need for a separate notice such as the NEMB in voluntary notification situations. There is no additional mandate for use of the ABN.

Need for a Cost Estimate

Comment: Several commenters objected to the mandatory inclusion of a cost estimate for the services in question, and raised questions about various ways in which they could provide this information. Previously, the ABN included a space for a cost estimate but it was not mandatory.

Response: We believe, as a matter of law and of common sense, that a cost estimate must be provided in order for a beneficiary to give truly informed consent with respect to the decision on whether to obtain services. Thus, notices must contain a reasonable cost estimate, and an ABN will not be considered valid absent a legitimate attempt to estimate cost. However, we are willing to consider various approaches to providing this estimate,

such as (1) indicating that total costs will not exceed a certain dollar threshold, especially in situations where the notifier is not fully aware of the precise costs of the service (such as in the case of an ordering physician and independent laboratory subsequently performing tests); or (2) permitting multiple items or services that cannot be itemized to be bundled under one cost. It is important to note that the costs listed on the ABN are estimates, and that reasonable variation is to be expected and will not alone invalidate the notice.

Burden Estimate

Comment: Many commenters expressed an opinion on the burden associated with the ABN. Some commenters argued that creating changes in the ABN or its instructions would increase burden. A few commenters specifically stated the ABN required more time to complete, in the range of 10-15 minutes. In most cases, however, the commenters included activities in their estimates that are general responsibilities of Medicare providers, such as understanding Medicare coverage rules. Another commenter said that the time required to give the ABN was overestimated, and should be no more than 3 minutes.

Response: As discussed above, we believe that there are significant advantages in terms of beneficiary understanding that are associated with changes to the notice, and that we have an obligation to do so based on experience with the existing form. Thus we believe any one-time burden associated with changing the notice once every three years is unavoidable and an appropriate objective of the PRA process. Based on this experience, we had already raised the burden estimate from 5 to 7 minutes per form, as well as re-estimating the volume of forms to be delivered. We received no comments that persuaded us that any further increase was necessary in the burden estimate.

Transition Period for New ABN

Comment: Three commenters raised transition concerns. All asked for a reasonable transition period to change from use of the current to the newly approved ABN.

Response: We believe there is a legitimate need for a reasonable period to permit notifiers to adopt the revised ABN, and would appreciate the opportunity to work with OMB to establish a phase-in approach to use of the new form, once it is approved in final.

PRA Disclosure Statement

Comment: Several commenters suggested that this statement be eliminated or abbreviated.

Response: The disclosure statement is not specific to the ABN but is an OMB requirement for all applicable information collections. Thus, we made no changes to this statement.

Other Comments

Comment: In addition to the comments discussed above, we also received many comments addressing issues related to general CMS notice policy that are also relevant to ABN delivery. These questions involved issues such as:

- Definition of (authorized) representative
- What Medicare participation agreements require for billing and collection of funds
- Refund requirements for non-participating providers
- Other questions on billing and coding of claims
- CMS coverage policies

Response: Although we are interested in commenters' views on these areas, they are not directly pertinent to the changes in the ABN form and instructions and thus are not addressed here. In some cases, we made minor changes to the ABN to clarify language related to these issues. For example, we strengthened Option 1 to make it more explicit that a notifier must bill Medicare when requested to do so by a beneficiary, even though providers and suppliers do not normally submit a bill for what they believe to be non-covered services. Again, coding practices associated with such billing are addressed through CMS' guidance in this regard.