CMS Response to 30-Day PRA Comments:
Advance Beneficiary Notice of Noncoverage (ABN)

Comment: CMS needs to clarify instructions to providers on how to proceed when Option 1 is selected by the beneficiary for items supplied by an unenrolled supplier or on an unassigned basis.
Response: When ABNs are issued for items/services provided on an unassigned basis, the provider must explain to the beneficiary that if Option 1 is chosen, s/he will be responsible for submitting the claim to Medicare and that Medicare, not the provider will refund any funds that have been collected if Medicare later decides to make payment on the claim.

Comment: CMS should address the burden imposed on the lab industry by use of the new form, which will require costly software upgrades.
Response: The costs borne by the implementation of the revised ABN are not limited to providers of laboratory services. In an effort to streamline the notice process and make liability notices more user friendly for both providers and beneficiaries, CMS has revised all of its financial liability notices across provider settings. The costs that will be incurred by the implementation of the revised ABN will be the only costs that will be incurred for the next three years. In addition, in an effort to minimize costs CMS will allow a longer than usual transition period where needed thereby allowing providers to use up all of their old forms before use of the new forms is required.

Comment: CMS should clarify the rationale for eliminating the separate, lab-specific ABN.
Response: CMS combined the ABN-G and ABN-L in response to issues raised in consumer testing of liability notices across provider settings and in an effort to streamline the notice process by reducing the number of notices being issued. The combined notices will enable CMS to capture the overall improvements incorporated into the revised ABN while still permitting pre-printing of key laboratory-specific information, such as the denial reasons used in the current ABN-L.

Comment: CMS should clarify in instructions whether or not the lack of a cost estimate will invalidate the ABN.
Response: The instructions will state that the ABN will be considered invalid absent a good faith attempt to provide a cost estimate. An actual cost is not required.

Comment: Choosing Option 2 will preclude a beneficiary from getting a Medicare denial, which is needed in order to bill a secondary payer.
Response: Option 2 is a self-pay option for beneficiaries who do not want a claim submitted to Medicare. This option was included on the notice in response to concerns raised by beneficiaries and advocacy groups. Beneficiaries who select Option 2 may later elect to have a claim submitted or submit a claim, on their own to Medicare.

Comment: The delegation of the notifier role could lead to unanswered beneficiary questions, as this role could be delegated to a staff member.
Response: The notice directs the beneficiary to call 1-800- MEDICARE if s/he has questions that the notifier cannot answer.

Comment: CMS should recognize alternate delivery methods of the ABN, such as click-through internet notifications.
Response: ABNs were intended to be given as hard copy notices during in-person patient encounters so that notifiers can ensure beneficiary comprehension. This goal cannot be accomplished by delivering the notice via the internet. However, in an effort to make the delivery process less cumbersome, CMS does allow incorporation of ABNs into other automated business processes as well as some flexibility in formatting the notice as discussed in the form instructions. As an added convenience, notifiers may choose to store the required signed copy of the ABN electronically.

Comment: Option 1 will result in a costly increase in claims submitted to Medicare.
Response: Beneficiaries have always had the right to have a claim submitted to Medicare for an official payment decision. Beneficiaries have been informed of this right through our notices since as early as 2002. Since this language is not new, but is simply being carried over from our current form, there should not be a significant increase of claims submitted to Medicare.

Comment: Option 2 is problematic in that the beneficiary's representative may not be responsible for payment.
Response: The representative acts as an agent of the beneficiary when signing the ABN on his/her behalf. As such, the representative is agreeing to bind the beneficiary, not himself. In other words, the representative, by signing the ABN is certifying that the beneficiary will be responsible for payment in the event that the items/services s/he received are ultimately denied by Medicare.

Comment: Option 2 forces beneficiaries to forfeit their appeal rights regardless of claims processing instructions.
Response: Option 2 is a self-pay option listed on the ABN for beneficiaries who do not want a claim submitted to Medicare. Since a claim will not be submitted, there will be no appeal rights in accordance with claims processing instructions. If a beneficiary wishes to maintain his/her appeal rights, Option 1 must be chosen.

Comment: Ambulance providers should not be responsible for issuing ABNs.
Response: Ambulance providers have always been required to issue ABNs where appropriate because they are the entities responsible for billing. These providers should be familiar with Medicare's coverage guidelines. The release of these revised ABNs does not change this longstanding policy.

Comment: The new form title, "Advance Beneficiary Notice of Noncoverage" is misleading and confusing.

Response: Since the purpose of the notice is to inform beneficiaries of potential noncoverage, CMS believes that the new title more accurately communicates the purpose of the notice to beneficiaries.

Comment: Use of the term, "notifier" instead of "provider" or "supplier" is confusing.
Response: ABNs are delivered by a variety of providers, including physicians, durable medical equipment suppliers, and other healthcare personnel. Therefore, to reduce beneficiary and provider confusion, we use the general title, "Notifier" to include all provider types.

Comment: The data used by CMS to calculate the burden does not accurately reflect current ABN usage.
Response: Although the process for calculating the burden estimate is not without its shortcomings, we strongly believe it produced a realistic approximation. We appreciate the concern and are exploring other methods to improve how ABN usage is evaluated.

Comment: We believe that if the patient option area remains as drafted this would create operational issues for front desk personnel. It would require cash flow in clinical designated areas where the ABN is most likely obtained. (**Mayo Clinic)**
Response: Providers are not required to collect payments from beneficiaries at the time services are delivered. The language is included on the ABN to allow providers to collect payment up front if they so choose.

Comment: We are also seeking guidance when multiple tests/procedures are needed and the patient would like to have one test performed but not others. (**Mayo Clinc**)
Response: 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 listed under 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 solely to that care. If this cannot be done clearly, a new ABN must be prepared.

Comment: Too many different versions of the ABN will cause confusion for providers.
Response: CMS eliminated one ABN. The two additional versions that were posted were only examples of how the form could be used in different provider settings and are not additional ABNs.

Comment: There will be a cost associated w/the new ABN. (Biological Technology Labs)
Response: The costs that will be incurred by the implementation of the new ABN will be the only costs that will be incurred for the next three years. In addition, in an effort to minimize costs CMS will allow a longer than usual transition period where needed thereby allowing providers to use up all of their old forms before use of the new forms is required.

Comment: We believe there should be an exception to the ABN requirement. Clinical labs are unique from other providers because we do not order any tests-they must be ordered by the treating physician. (Biological Technology Labs)
Response: The ABN has always been required for laboratory tests by any user furnishing such tests. Since laboratory facilities bill Medicare directly for payment, they must issue ABNs for certain noncovered tests in order to assign liability to the beneficiary.

Comment: CMS should involve the provider community when developing the detailed instructions regarding use of the new ABN form. By doing so, CMS would be able to address provider questions and areas of confusion within the instructions versus leaving these areas open to provider interpretation. (Federation of American Hospitals)
Response: While the process for developing manual instructions doesn't involve the provider community, CMS has extensively involved the provider community in the both the revised ABN and its form instructions through the PRA process. Draft versions of the notice and instructions were posted in the Fededral Register for a 60-day comment period in February, 2007.The notice and instructions were subseuqently posted again in the Federal Register for a 30-day comment period in May of 2007.

Comment: The ABN is not appropriate for partial observation hours.
Response: An ABN should not be issued for reasonable and necessary observation services, whether packaged or paid separately. Hospitals should not confuse packaged payment with noncoverage. The only time a hospital would issue an ABN specifically for observation care is when the care provided would meet the definition of observation services, but the hospital thinks it's not reasonable and necessary for the patient at that particular time. CMS plans to clarify the policy regarding observation services in forthcoming revisions to the Claims Processing Manual.

Comment: Listing multiple providers in the header may confuse beneficiaries. (Fed. of American Hospitals)
Response: If appropriate, the name of more than one entity may be given in the "Notifier" area, such as when the ordering and rendering providers differ, as long as this is clearly conveyed to the beneficiary for purposes of responding to questions.

Comment: Is provider required to list other insurance in Blank H. (Carteret Gen. Hospital)
Response: Providing information on other insurance coverage for beneficiaries needing immediate reassurance of additional coverage is an optional use for the space provided for additional information and is not required.

Comment: The Spanish and English versions should be issued together. (County of Suffolk)
Response: The Spanish and English versions will be made available. CMS will make every effort to issue both versions as close in time as possible.

Comment: User-Customizable Sections should have a clearer description of what can be customized by the physician. (County of Suffolk)
Response: CMS will consider amending either the form instructions or the manual instructions to give more information on customizing the ABN.