RBMA
Building the Business of Radiology

RADIOLOGY BUSINESS MANAGEMENT ASSOCIATION

10300 Eaton Place
Suite 460
Fairfax, VA 22030

703-621-3355 Direct
888-224-7262 Toll Free
703-621-3356 Fax

www.rbma.org

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February 23, 2007

Rec'd 4/24/07

Michelle Shortt
Director, Regulations Development Group
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services
Attn: Bonnie L Harkless, Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Ms. Shortt:

The Radiology Business Management Association (RBMA) appreciates the opportunity to comment on the Advance Beneficiary Notice of Noncoverage (ABN) pursuant to the agency's Comment Request as published in the February 13, 2007 *Federal Register*.

Founded in 1968, the RBMA represents over 2,000 radiology practice managers and other radiology business professionals. RBMA is the leading professional organization for radiology business management, offering quality education, resources and solutions for its members and the healthcare community, and helping shape the profession's future.

In general, RBMA commends CMS' efforts to improve the user-friendliness of the ABN. Many of the proposed revisions are a step in the right direction. For example, adding "1-800-MEDICARE" is a welcomed improvement. RBMA also supports proposed ABN revisions including more payment options, space for other insurance information, and a description of the significance of the signature.

However, RBMA has a fundamental concern about the ABN process in the hospital radiology environment. Hospital-based radiology is a fast-paced, fluid environment with an emphasis on speed and efficiency – essential elements in good radiological patient care. As such, hospital-based radiologists depend on the patient-specific information provided to them by the hospital and/or the referring physician. Since time is of the essence and medical necessity decisions are made elsewhere in the patient care continuum, it is unreasonable to deny payment to hospital-based radiologists when ABNs are not obtained. Additionally, given this high patient volume through hospital radiology departments, the ABN requirement imposes a significant administrative burden on radiology department staff. **RBMA, therefore, recommends that a hospital's notice of non-coverage (either an ABN or Hospital Issued Notice of Noncoverage) provide "umbrella" notification to the Medicare beneficiary of any and all financial liability stemming from in-hospital Medicare noncovered services during his/her hospital encounter.**

RBMA offers the following specific comments on the revised ABN:

- Estimated Cost (Item F) is ill-defined, as the term can have multiple meanings, and is potentially confusing to patients, physicians, and administrative staff. **RBMA recommends that CMS clarify what the phrase means.**

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- With respect to (Item G) Options, the current "provide me with" language reads awkwardly. RBMA suggests rewording the first sentence (to be printed in bold) as follows:

  1. I do not wish to have the item(s)/service(s) listed above.
  2. I do wish to have the item(s)/service(s) listed above.
  3. I do wish to have the item(s)/service(s) listed above.

  We believe the proposed revision conveys the intent of the ABNs language while making the options more readable and understandable.

- RBMA also would favor adding more information why Medicare does not cover the service in question. Language such as, "**the service(s)/item(s) listed below may not be covered by Medicare because these services/items do not meet Medicare's reasonability and necessity criteria for coverage**" could be helpful to patients.

The RBMA appreciates the opportunity to comment on CMS' revised ABN. If questions arise or additional information is needed, please feel free to contact RBMA's Executive Director Michael R. Mabry at 703.621.3363 or mike.mabry@rbma.org.

Sincerely,

Gregory M. Kusiak

Gregory M. Kusiak, MBA
President, RBMA Board of Directors

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

Direct Response To:
DIVISION OF GOVERNMENT AND PROFESSIONAL AFFAIRS
1350 I Street, NW, Suite 590
Washington, DC 20005-3305
202-354-7100 Fax: 202-354-7155
800-392-9994 • http://www.cap.org

April 23, 2007

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

Attention: CMS-R-131, Room C4-26-05

Dear Ms. Harkless:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed changes to the Advance Beneficiary Notice of Noncoverage (ABN) published in the February 23, 2007 Federal Register. The CAP is a national medical specialty society representing more than 16,000 physicians who practice anatomic and/or clinical pathology. College members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

CMS is proposing a number of changes to the format and content of the ABN form, including combining two existing ABN forms – the ABN-G for general use and the ABN-L for physician-ordered laboratory tests – into a single form. The CAP believes that many of the proposed changes will make the ABN more usable for providers and beneficiaries alike; however, the CAP is concerned with several aspects of the new combined form. First, the CAP is concerned that new combined form will not allow the necessary flexibility to address laboratory testing issues. Second, the CAP is concerned that the new form mandates inclusion of an estimated cost instead of making the information optional. Lastly, the CAP is concerned with financial liability under the new beneficiary payment option and collection of upfront payment by a different entity than the supplier of a laboratory testing service. To respond to these concerns the CAP asks CMS to:

1. Confirm that the new combined form can be customized for laboratory testing, as is permitted for the current ABN-L;

2. Confirm that the inclusion of an estimated cost for laboratory testing is optional and that the lack of an estimated cost amount will not invalidate the ABN; and

3. Confirm that selection of the new beneficiary payment option and collection of upfront payment will not make a supplier of any portion of the laboratory testing service financially liable or responsible for a refund to the beneficiary if a different entity executes the ABN for laboratory testing services.

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1. Confirmation that the New Combined Form can be Customized

On the current ABN-L, providers can customize the columns for "Items/Service" and "Because" for their specific needs. Customization of these columns is addressed in the Medicare Claims Processing Manual, CMS Pub. 100-04, Chapter 30, Section 50.5.6. The CAP asks CMS to clarify the ability to customize the new combined form. Specifically, the CAP asks CMS to confirm that on the columns on the new combined form to identify the "Item/Service" and "Reasons" can be customized in a similar manner as the ABN-L, including the use of check off boxes and a preprinted list of tests linked to captioned reasons for denial. Without the ability to customize the form, the form cannot meet the needs for laboratory testing.

Because customization with lists of laboratory testing can be lengthy, CMS has been flexible in the font size and format of the ABN-L. The Form Instructions released with the new combined form recommend a font size of 12-point. The CAP asks CMS to verify that it will continue to allow a font size range of 10 to 12 point and will remain flexible with the formatting of customized forms for laboratory testing services.

2. Confirmation that Lack of an Estimated Cost Will Not Invalidate the New Combined Form

On the current ABN-L there is no column for Estimated Cost, rather, there is line for estimated costs and completion of this line is optional. For the current ABN-L form CMS provides the following instructions:

> "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***."[1]

The Form Instructions released with the new combined form state for the column for Estimated Cost that users "***must*** enter a cost estimate in this blank" (emphasis added). This language infers a mandate to include an estimated cost and fails to address the implication of a blank line or a discrepancy between the estimated and actual cost.

There are legitimate reasons why a provider may not be able to include an estimated cost. For example, an ordering clinician may not have readily available a current or complete clinical laboratory fee schedule. Moreover, the cost elements of complex non-routine testing may be difficult to estimate. The CAP asks CMS to make column for the estimated costs optional for laboratory testing services and to confirm that the lack of an estimated cost amount or a discrepancy between the estimated and actual costs will not invalidate the new combined form.

3. Confirmation that Laboratory Testing Service Supplier is Not Financially Liable or Responsible for Refund for Upfront Payments Collected by a Different Entity

The new combined form offers three beneficiary options that affect the financial liability and refund responsibility. The third option grants a beneficiary an official decision on payment, but also allows collection of upfront payment from the beneficiary, to be refunded in the event Medicare pays for the item or service. It is likely that a physician will execute the new combined ABN for multiple items and services, including ordered laboratory tests. It is also likely that if the beneficiary selects the third option on the form that the physician will collect upfront payment for some of the items and services. The

[1] Medicare Claims Processing Manual, CMS Pub. 100-04, Chapter 30, Section 50.5.7 (emphasis added).

collection of upfront payment can create confusion for beneficiaries regarding their financial liability and the refund responsibilities, if any, of the ordering physician and the supplier of the laboratory tests.

In particular, if Medicare denies payment for the laboratory tests and the supplier of the testing services bills the beneficiary for the uncovered services, the beneficiary may refuse to pay and challenge their financial liability because of a mistaken belief that the upfront payment satisfied their payment obligations for all described services. This situation may be further exacerbated if the ordering physician provided inaccurate cost estimates of the services. Conversely, if Medicare pays for the laboratory tests the beneficiary may demand a refund from the supplier of the testing service even though the upfront payment was made to a different entity.

The CAP asks CMS to clarify that the supplier of the laboratory testing services will not be held financially liable or responsible for refund if a different entity executes the ABN and collects upfront payment from the beneficiary. The CAP asks CMS to further clarify that the supplier of the laboratory testing services will not be financially liable or responsible for refund if a different entity executes the ABN with inaccurate cost estimates, resulting in a higher financial responsibility to the beneficiary than described in the ABN.

If CMS cannot confirm that the new combined ABN form can be used and construed in a manner consistent with the current ABN-L as described above, then the CAP strongly urges CMS to retain the ABN-L as a separate form for physician-ordered laboratory tests.

The College of American Pathologists is pleased to have the opportunity to comment on these changes and appreciates your consideration of our comments. Any questions regarding the comments should be directed to Donna Meyer at 202-354-7112 (dmeyer@cap.org).

Sincerely,

Thomas Sodeman MD FCAP

Thomas M. Sodeman, MD, FCAP
President

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(29) 1/4

April 23, 2007

Michelle Shortt
Director, Regulations Development Group
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attn: Bonnie L Harkless, Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Advance Beneficiary Notice

Dear Ms. Shortt:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, is pleased to submit comments on the proposed notice, "Agency Information Collection: Proposed Collection," published in the Federal Register on February 23, 2007. We will address the Advanced Beneficiary Notices (ABN) proposal.

The ACR appreciates the Center for Medicare and Medicaid Services' (CMS) effort to develop a a more comprehensible ABN. The new form instructions are an improvement in making the ABN easier to understand and complete. However, the ACR believes the following further clarifications can make the ABN easier for patients to understand and easier to use in the hospital and office settings.

The ACR is aware that in order for physicians to collect payment for non-covered Medicare services, that an advanced beneficiary notice must be signed prior to providing the medical service. Therefore, many patients are asked in the hospital outpatient and office setting to sign one ahead of time, "just in case" the ABN is needed to receive payment after a claim denial. The ACR believes that the ABN form should be worded in such a way that the patient understands why their doctor ordered a procedure or test and that it may or may not be covered. The ACR offers the following suggested changes that make this form more informative, understandable and in compliance with Medicare regulations.

The ACR suggests adding additional clarification to lessen the likelihood of patients not understanding why Medicare does not cover the service. Simplified language and further explanation can help beneficiaries understand why Medicare does not cover a particular service. Adding language, such as "the service(s)/item(s) listed below may not be covered by Medicare because these services/items do not meet the reasonability and necessity criteria for coverage," can clarify the reason why Medicare is not covering the service.

Headquarters
1891 Preston White Dr
Reston, VA 20191
(703) 648-8900

Government Relations
1701 Pennsylvania Ave NW, Suite 610
Washington, DC 20006
(202) 223-1670

Clinical Research
1818 Market St, Suite 1600
Philadelphia, PA 19103
(215) 574-3150

ACR appreciates the fact that a toll-free number will be added on the new notice in order to provide further explanation.

We are very concerned about proposed option 2. As described in the Federal Register notice, this new option is intended "to allow beneficiaries' the right to pay out of pocket when they desire." However, the circumstances under which a beneficiary might select this proposed option are not described. Consequently, we hesitate to endorse this change out of concern that: (1) beneficiaries might select this option and pay out-of-pocket for a service that might have been covered by Medicare; and, (2) physicians might be at risk of civil monetary penalties for failing to submit a claim or for charging more than is allowed under the balance billing requirements of the Medicare fee schedule.

Normally, physicians and practitioners are required to submit claims on behalf of beneficiaries for all items and services they provide for which Medicare payment may be made under Part B. Also, they are not allowed to charge beneficiaries in excess of the limits on charges that apply to the item or service being furnished. In fact, as described in section 40 *Effect of Beneficiary Agreements Not to Use Medicare Coverage* in Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02):

> "*Where a physician/practitioner, or other supplier, fails to submit a claim to Medicare on behalf of a beneficiary for a covered Part B service within one year of providing the service, or knowingly and willfully charges a beneficiary more than the applicable charge limits on a repeated basis, he/she/it may be subject to civil monetary penalties under §§1848(g)(1) and/or 1848(g)(3) of the Act. Congress enacted these requirements for the protection of all Part B beneficiaries. Application of these requirements cannot be negotiated between a physician/practitioner or other supplier and the beneficiary except where a physician/practitioner is eligible to opt out of Medicare under §40.4 and the remaining requirements of §§40.1 - 40.38 are met.*"

We understand that a physician may opt out of Medicare and that a physician who opts out is not required to submit claims on behalf of beneficiaries. In addition, an opt-out physician is not subject to balance billing limits. For physicians who do <u>not</u> opt out of Medicare, the manual section cited above states that:

> *The only situation in which non-opt-out physicians or practitioners, or other suppliers, are not required to submit claims to Medicare for covered services is where a beneficiary or the beneficiary's legal representative refuses, of his/her own free will, to authorize the submission of a bill to Medicare. However, the limits on what the physician, practitioner, or other supplier may collect from the beneficiary continue to apply to charges for the covered service, notwithstanding the absence of a claim to Medicare.*

Headquarters
1891 Preston White Dr
Reston, VA 20191
(703) 648-8900

Government Relations
1701 Pennsylvania Ave NW, Suite 610
Washington, DC 20006
(202) 223-1670

Clinical Research
1818 Market St, Suite 1600
Philadelphia, PA 19103
(215) 574-3150

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Thus, it appears that the proposed option 2 is not consistent with existing Medicare policy. However, we do not believe this policy is well understood by beneficiaries and physicians and we are especially concerned that the proposed ABN does not convey the sense that the beneficiary "refuses, of his/her own free will, to authorize the submission of a bill to Medicare." We believe an example of the circumstances under which option 2 might be selected should be included on the ABN so that beneficiaries will be fully informed.

The ACR recommends rearranging the list of selections in item G (OPTIONS section) in the way that is least alarming to patients. Patients can get alarmed by the perception of a financial burden and decide not to have the needed procedure. If the list is rearranged by placing the least alarming and most conducive to receiving care option first (e.g. Option 3) and the most alarming option last (e.g. Option 1), patients might elect to have needed procedures. Furthermore, the ACR recommends adopting clearer language to describe the options under item G. A language that is similar to the ABN used in home health setting, which is also stated below can clarify beneficiaries' options.

- Option 1. I want the items and/or services listed above, and I agree to pay for the items and/or services myself if Medicare or my other insurance doesn't pay. Send the claim to:

  (Please check one or both boxes):
  □ Medicare
  □ My other insurance. _____

- Option 2. I want the items and/or services listed above, and I agree to pay myself since I don't want a claim submitted to Medicare or any other insurance I have. I understand that I have no appeal rights since a claim won't be submitted to Medicare.

- Option 3. I don't want the items and/or services listed above. I understand that I won't be billed and that I have no appeal rights since I will not receive those items and/or services.

Please note: If you select option 1 and a claim is submitted to Medicare, you will get a Medicare Summary Notice (MSN) showing Medicare's official payment decision. If the MSN indicates that Medicare won't pay all or part of your claim, you may appeal Medicare's decision by following the appeal procedures in the MSN. If you don't receive an MSN for your claim, you can call Medicare at: (___) _____. TTY: (___) _____. You may have to pay the full cost at the time you get the items and/or services. If Medicare or your other insurance decides to pay for all or part of the items and/or services that you have already paid for, you should receive a refund for the appropriate amount.

Headquarters
1891 Preston White Dr
Reston, VA 20191
(703) 648-8900

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1701 Pennsylvania Ave NW, Suite 610
Washington, DC 20006
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The ACR also suggests including language such as "If you are still confused about why your doctor ordered this specific test, if there is an alternative test, or if your doctor knew it may not be covered then please contact your doctor." This will allow the patient to get information from the referring physician.

The supporting statement in section B.12 (Burden Estimate) contains the method of evaluating the cost to the provider for delivering the ABN. The ACR believes this method of evaluating the cost for delivering the notice does not capture all the costs. Providers are the ones that share the burden of educating referring physicians on Local Coverage Determinations (LCDs). The ACR recommends CMS establish a method that factors an education cost into the burden, in addition to the delivery cost.

Thank you for the opportunity to comment on this proposed notice. The ACR looks forward to a continuing dialogue with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter, please contact Helen Olkaba at 800-227-5463 ext 4132 or via email at holkaba@acr.org.

Respectfully Submitted,

Harvey L. Neiman, MD, FACR
Executive Director

cc: Bonnie L Harkless, CMS
John A, Patti, MD, FACR, Chair, ACR Commission on Economics
Bibb Allen, JR., MD, FACR, Vice-Chair, ACR Commission on Economics
Pamela J. Kassing, ACR

Headquarters
1891 Preston White Dr
Reston, VA 20191
(703) 648-8900

Government Relations
1701 Pennsylvania Ave NW, Suite 610
Washington, DC 20006
(202) 223-1670

Clinical Research
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Philadelphia, PA 19103
(215) 574-3150