PROSTHETICS & ORTHOTICS
Hanger Inc

ABN

#10

VIA FACSIMILE (202) 395-6974

June 21, 2007

OMB Human Resources and Housing Branch
Attn: Carolyn Lovett
New Executive Office Building
Room 10235
Washington, DC 20503

RE: Advance Beneficiary Notice
Document Identifier: CMS-R-131
OMB Approval Number: 0938-0566

Dear Ms. Lovett:

I am writing to you to provide comment on the proposed Advance Beneficiary Notice (ABN), Document Identifier CMS-R-131. While, generally speaking, we are pleased with the changes made to the form and find it to be more user-friendly for both the provider and beneficiary, one particular item has raised concerns.

Section (G), Option 1 states, in part, "I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less any co-pays or deductibles."

The statement "If Medicare does pay, you will refund any payments I made to you, less any co-pays or deductibles" holds true only if the provider has accepted assignment on the claim. A problem arises wth the fact that the ABN can apply to both assigned and nonassigned claims. Under Medicare's rules of assignment, payment for covered services is made directly to the provider; the provider may collect only the coinsurance and deductible amounts from the beneficiary. When assignment is not accepted, Medicare payment is made to the beneficiary; the provider may collect their actual charge for the covered service from the patient. When assignment is not accepted, the statement "If Medicare does pay, you will refund any payments I made to you, less any co-pays or deductibles" can not apply.

ABN

#11

AMERICAN SOCIETY FOR MICROBIOLOGY

Public and Scientific Affairs Board

June 25, 2007

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building
Room 10235
Washington, DC 20503

Dear Ms. Lovett:

The American Society for Microbiology (ASM) appreciates the opportunity to review and comment on CMS-R-131, Centers for Medicare and Medicaid Services; Agency Information Collection Activities. Submission for OMB Review; Comment Request published Friday May 25, 2007 in the Federal Register, Volume 72, Number 101, pages 29322 - 29323. The ASM opposes the implementation of a generic, all-purpose Advanced Beneficiary Notice (ABN) which would replace the laboratory specific ABN (CMS-R-131-L) implemented in June 2002.

The ASM is the largest, single life sciences society dedicated to the advancement of the microbiological sciences and their application for the common good. The Society represents approximately 42,000 microbiologists, including scientists and science administrators working in a variety of areas, including biomedical, environmental, and clinical laboratory fields. Many of our members have primary involvement in clinical laboratory medicine including individuals directing clinical microbiology or immunology laboratories, individuals licensed or accredited to perform such testing, industry representatives marketing products for use, and researchers involved in developing and evaluating the performance of new technologies. Our clinical laboratory members are involved on a day-to-day basis with testing procedures for many infectious and immunologic diseases, including procedures based on molecular diagnostic techniques. Many of these procedures are covered in existing National and Local Coverage Decisions. Therefore, ASM members have a significant interest in ensuring that any revisions to current ABNs be necessary, reasonable, and convenient for use in a variety of laboratory settings. Further, the complexity of laboratory medicine renders it extremely important that ABNs for laboratory services be designed to enhance beneficiary understanding of reasons for denial of payment for services.

The ASM does not believe that the elimination of the laboratory specific ABN will serve beneficiary interests. For complex infectious and immunologic diseases, it is not the laboratory which notifies the beneficiary about the medical rationale for tests, test procedures, and potential reasons for non-coverage of tests. Instead the ordering

247

physician or other authorized provider is responsible for this notification. The current laboratory specific form clearly identifies the reasons for the denial of laboratory tests as one of three categories: medical necessity, frequency, and investigational/experimental status. This allows an important distinction to be made between laboratory services and other medical services that is more understandable to beneficiaries.

Further, the ASM has other questions and concerns regarding the generic ABN proposal. First, it is unclear whether there is a new requirement that laboratories acquire an ABN when services are never covered due to regulatory interpretations of Medicare statute. Second, CMS has failed to give any reason why it has been deemed necessary to eliminate the laboratory specific ABN which was discussed and agreed upon by stakeholders in 2002. Third, laboratories that have implemented the laboratory specific ABN (Form CMS-131-R-L) will be required to make expensive and time consuming adjustments to information technology systems, as well as invest significant time and effort in educating both laboratorians and ordering providers about the changes in the ABN process, should the general, all-purpose ABN be implemented.

In conclusion, the ASM sees no benefit to the elimination of the laboratory specific ABN, and in fact, foresees significant issues with the removal of this ABN and its replacement with a generic ABN.

Thank you for the opportunity to provide comments.

Sincerely,

Vickie S Baselski

Vickie S. Baselski, Ph.D.
Chair, Committee on Professional Affairs
Public and Scientific Affairs Board

ABN

AMERICAN ASSOCIATION OF BIOANALYSTS
906 Olive Street, Suite 1200 • Saint Louis, Missouri 63101-1434 • Phone: (314)241-1445
Fax: (314)241-1449 • E-mail: aab@aab.org • Web: www.aab.org

(12) 17

June 25, 2007

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

Faxed to: Carolyn Lovett (302) 395-6974

RE: Comments on Revised CMS Advance Beneficiary Notice (ABN)

Dear Ms. Harkless:

The American Association of Bioanalysts (AAB) – a national professional association whose members are directors, owners, managers, supervisors, technologists, and technicians in community clinical laboratories – respectfully submits the following comments relating to the May 25, 2007 notice for additional public comment on the revised Advance Beneficiary Notice (ABN) (CMS-R-131). We welcome the opportunity to partner with the Centers for Medicare & Medicaid Services (CMS), other laboratorians, providers, and Medicare carriers in seeking to develop and implement the most effective ABN and associated instructions for all relevant stakeholders.

Proper instructions for ABN use are essential in order to communicate the possible denial of Medicare coverage to beneficiaries in the most clear and concise fashion possible. Beneficiaries also need and deserve significant advance notice about Medicare coverage to allow them to make an informed decision about whether to proceed with a particular course of medical care.

We are pleased that CMS decided to keep a specific ABN for clinical laboratory services. However, we continue to have other specific concerns about the notice.

First, AAB would like to express concern with the addition of another ABN, bringing the total number of options to three. AAB's laboratories often serve patients who have their blood drawn at another outpatient laboratory. It is possible another laboratory might use a different version of the ABN. This already has caused confusion among beneficiaries who do not understand why they are signing a new and different ABN. By adding a third ABN, a second "generic" one, there is the possibility of even further confusion.

Second, the new laboratory and generic ABN forms do not provide sufficient space for a laboratory to list all of the tests that are subject to National Coverage Determinations ("NCDs")

and Local Coverage Determinations ("LCDs"). The current laboratory ABN provides enough space for a laboratory to list all of the NCD or LCD tests. Having them listed allows staff to simply circle the NCD and/or LCD test when the medical necessity does not support the test being ordered. Filling in each of the tests, however, will create an unnecessary and time-consuming step. Adding more space to the form to allow for all NCD and LCD tests to be listed would be a major improvement to the new laboratory and generic ABN forms. We believe that this is an important point due to the fact that coverage determinations affect the results of an ABN.

Third, AAB recommends that CMS restore the heading for the NCD tests that have frequency parameters in the laboratory ABN form and add it to the new generic ABN form. The old laboratory ABN included the heading "Medicare does not pay for these tests as often as this (denied as too frequent)." Certain tests, such as the Hemoglobin A1C, are considered medically necessary by Medicare to be performed only once every three months. In many cases, a laboratory has no way of knowing how many times the patient has received the test in the past. Since the patient may have already met the frequency parameters without the laboratory's knowledge, the laboratory may not have him or her sign an ABN and will end up paying for the test. The heading for the NCD tests provides a simple explanation to the Medicare beneficiary that this test has frequency parameters that might not have been met yet but if they have, the beneficiary will be responsible for payment.

Fourth, though CMS claims that there will not be a cost associated with both new ABN forms, there will be a cost associated with training staff to understand and sufficiently explain the new ABN forms to Medicare beneficiaries. While AAB appreciates CMS' willingness to ensure that the concerns of the clinical laboratory community are met, we are not convinced that there will be a significant positive outcome for patients by creating either of the new ABN forms.

Finally, AAB believes that there should be an exception for clinical laboratories from the ABN requirement. Clinical laboratories are unique from other providers because they do not order any tests – they must be ordered by the treating physician. Therefore, the laboratory has no access to additional information at the time of service. While AAB appreciates CMS' recognition of this with a lab-only ABN, the fact that laboratories are not in the same category as physicians or other providers remains unaddressed.

AAB stands ready to work with CMS and other stakeholders to ensure that both the clinical laboratory ABN and its associated instructions meet the needs of Medicare beneficiaries, providers, carriers, and laboratorians. If you have any questions about our comments, please do not hesitate to contact us.

Sincerely yours,

Mark S. Birenbaum

Mark S. Birenbaum, PhD
Administrator

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

June 22, 2007

Connie Lovett
OMB Human Resources and Housing Branch
New Executive Office Building
Washington, D.C. 20503

Attention: CMS R-131, Room 10235

Dear Ms. Lovett:

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 May 25, 2007 Federal Register. The CAP is a national medical specialty society representing more than 16,000 physicians who practice anatomic and/or clinical pathology. CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

The Centers for Medicare & Medicaid Services (CMS) is proposing a number of revisions to the content of and instructions for the ABN form. In the supporting statement CMS clarified some uncertainties regarding the use of the new form; however, CMS failed to address the effect of the new mandate to include a cost estimate for physician-ordered laboratory tests. The CAP is concerned that the new form mandates inclusion of an estimated cost instead of making the information optional, as is the current rule for laboratory tests. The CAP asks CMS to 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.

On the current ABN-L there is no column for Estimated Cost, rather, there is line further down on the form for estimated costs. 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]

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

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). The instructions to the new form clearly make the cost estimate a mandate; however, CMS 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 laboratory testing. 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.

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 Soderman MD FCAP

Thomas M. Soderman, MD, FCAP
President

CLMA
THE RESOURCE FOR LABORATORY PROFESSIONALS

989 Old Eagle School Rd., Suite 815
Wayne, PA 19087-1701
tel 610 995 9500
fax 610 995 9568
www.clma.org

ABN

(14)

1147

OMB Desk Officer
OMB Human Resources and Housing Branch
Attention: Carol Lovett
New Executive Office Building
Room 10235
Washington, DC 20503

Dear Ms. Lovett,

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 May 25th, 2007 *Federal Register* notice, "Agency Information Collection Activities: Submission for OMB Review; Comment Request," regarding the Advance Beneficiary Notice of Noncoverage (ABN) (CMS-R 131, OMB:0938-0566).

CLMA appreciates the inclusion of the summary of changes document in the packet attached to the *Federal Register* notice. It was very useful in determining where we needed to focus our attention when reviewing the revised forms and instructions.

CLMA does not have any additional comments on the forms and instructions themselves at this time, except to point out a typographical error in the second line of Option 1. The sentence currently reads "You may collect money from me now, but I also I want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN)."

CLMA would like to comment on the burden associated with this change. As stated in our first set of comments, currently many laboratories and hospitals use automated information systems to detect when an ABN is necessary and then will print the form with automatically inserted information. Since these systems are set up using the format of the previous ABN form, changes will need to be made in order to accommodate the new forms.

CLMA
THE RESOURCE FOR LABORATORY PROFESSIONALS

989 Old Eagle School Rd., Suite 815
Wayne, PA 19087 1704
tel 610 995 9580
fax 610 995 9568
www.clma.org

Although the revised forms based on the first round of public comments will make this transition easier, the industry will still require a grace or transition period of sufficient length in order to make changes in these automated systems, and/or for computer vendors to make these changes. From our members' experience, changes of this nature require significant resources and extended timeframes to implement. Laboratory information systems are so diverse that we cannot suggest to CMS a specific timeframe, but urge the agency to seek input from the industry on this issue and set an implementation timeframe that is reasonable based on the information provided.

In closing, CLMA appreciates the opportunity to comment on the new ABN form. In addition, we very much appreciate the efforts of CMS and its staff in accommodating our suggestions and recommendations for the forms and instructions. 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
President

COUNTY OF SUFFOLK

ABN

#15

DUP

STEVE LEVY
SUFFOLK COUNTY EXECUTIVE

DEPARTMENT OF HEALTH SERVICES

HUMAYUN J. CHAUDHRY, D.O., M.S.
Commissioner

June 14, 2007

CMS, Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development C
Attention: Bonnie L. Harkless
Room C4 26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Ref: CMS-R-131 ABN

Dear Ms. Harkless:

I would like to take this opportunity to make the following comments about the newly drafted Advance Beneficiary Notice of Noncoverage (ABN), of which comments are being accepted until June 24, 2007:

1. We would like to see one (1) form with Laboratory and General combined, specifically Laboratory and Services as for Physician Services.
2. The Spanish versions should come out simultaneously with the English versions.
3. The User-Customizable Sections on page 7 of the Part I – Instructions for Carriers, Physicians and Suppliers in Section E. number 3 should have a clearer description of what can be customized by the physician in reference to the newest drafts.
4. We would recommend the Confidential Statement language be put back in as in the older forms.
5. We would like to know the date or timeframe of when the forms will be approved and ready for use.

Thank you, and if you would like to contact me, I can be reached by email at Shellie.Dworkin@suffolkcountyny.gov or by telephone at 631 853-9084.

Sincerely,

Shellie Dworkin

Shellie Dworkin, MPS,RHIA,CPHQ
Medical Records Administrator

Cc:
OMB Human Resources and Housing Branch
Attention Carolyn Lovett
New Executive Office Building, Room 10235
Washington, DC 20503
Fax# (202) 395-6974

ABN

#1497

FAIRVIEW
Fairview Health Services
Patient Financial Services
P.O. Box 147
Minneapolis MN 55440-0147
(612) 672-6724 Fax: (612)-672-6727

June 21, 2007

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building
Room 10235
Washington, DC

Re: Federal Register Notice (72 FR , No 101, pp 29322-29323 May 25, 2007 Centers for Medicare and Medicaid Services, Department of Health and Human Services; Revision of Advance Beneficiary Notice of Noncoverage (ABN); Document Identifier CMS-R-131 OMB 0938-0566

Dear Ms. Lovett;

Fairview Health Services, which has seven hospitals in Minnesota, wishes to thank you for the opportunity to comment on the proposed changes to the Advance Beneficiary Notice. Our comments are as follows:

Sample L/ Lab ABN:
Lab personnel prefer the current Lab ABN format as it allows for more customization. It is felt that the proposed format does not allow sufficient space to customize for all of the various tests for which there is a Medicare coverage issue, even if there is a font change. Without having this pre-printed, there will be more exception data for lab techs and personnel to look up, which is a training issue and which lends itself to the possibility of errors. The proposed format will mean more up front work. The existing format allows lab to be more time efficient, while still ensuring that the patient gets the correct information.

Sample G:
The consensus of most of the people responding is that this is the preferred format for services other than lab. The other form is too busy and cluttered, and the statement "items or services" describes what will appear in item "D". They would prefer not to have other items to fill in.

General Comments:
Option 2, if selected, tells us not to bill Medicare. In many instances, a secondary payer – whether the provider bills or lets the patient bill the payer – will require that there be a denial from Medicare before they will consider the claim. We could put a notice in "additional information" that speaks to this, however the concern is that it would appear that we are leading the patient to choose option 1, and it has already been stated that "we

Comments to CMS
Changes to the Advance Beneficiary Notice

cannot choose a box for you". Since some providers do not, not are they required to bill the secondary payer, CMS could still add language regarding this requirement, such as " Note: if you have another insurance, you should check to see if they require a denial from Medicare before considering your claim". Then when the patient reviews the 3 options, he or she will know that if they choose option 2, they may not be able to get paid for the service by the secondary payer.

We would also like to point out that should the patient choose option 2, if this is one non-covered item among many other tests, particularly in a large hospital-based setting or large clinic setting, it will be difficult to pull out one test to not bill to Medicare. Also, if we are able to do this, it has been our experience that the patient will compare the hospital or clinic bill to the MSN, and then it will generate calls that we billed incorrectly. They do not remember that they said they did not want something billed.

Notifier: In the instructions, CMS indicates that employees or subcontractors of the notifier may deliver the ABN. The concern is that some notifiers may delegate this function to someone who is not qualified to answer patient questions. Not all employees or subcontractors are clinical staff. We believe that if the notifier delegates the delivery of the ABN, it must be delegated to other staff qualified to answer a patient's questions, or that such qualified staff or the notifier be available in the event that there are questions

Other: We like the plain language and the statement "we cannot choose a box for you".

Thank you for the opportunity to comment.

Sincerely,

Stephanie McDonald
Compliance Specialist
Fairview Health Services
Corporate Office
400 Stinson Blvd NE
Minneapolis, MN 55413

University of Minnesota Medical Center, Fairview
Fairview Southdale Hospital
Fairview Ridges Hospital
Fairview Northland Regional Hospital
Fairview Lakes Regional Medical Center
Fairview Red Wing Hospital
University Medical Center, Mesabi

Janelle A. Montemayor
Contract & Research Specialist

DIRECT SUPPLY

6767 N. Industrial Road
Milwaukee, WI 53223
Phone 414-760-5895
Fax 414-358-7411
jmontemayor@directs.com

ABN #17

June 22, 2007

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulation Development – C
Attention: Bonnie L Harkless
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Information Collection Request – Advance Beneficiary Notice of Noncoverage (ABN)

In response to the call for comments published in the Federal Register on May 25, 2007, we are respectfully submitting remarks regarding proposed changes to the Advanced Beneficiary Notice of Noncoverage (ABN). We encourage CMS to clarify that when an ABN is provided under an exception to the prohibition of routine ABNs, the claim need not be submitted to CMS, and to recognize alternative delivery means for ABNs.

Direct Supply Equipment is the nation's largest supplier of durable medical equipment to the US long term care profession. Our core business is providing equipment to skilled nursing facilities, assisted living centers, and continuing care retirement communities for their use in providing care to their patients and residents. Occasionally, often at the request of our long term care provider customers, we also sell products to consumers through strictly private-pay transactions. We are a virtual distributor of equipment and we neither own nor operate any store fronts, warehouses or manufacturing facilities. When a customer orders a product, we contact the manufacturer who then drop-ships the item to our customer.

The purpose of the Advanced Beneficiary Notice of Noncoverage is to inform the consumer that products or services they are about to receive may not or will not be paid for by Medicare. This allows the consumer to make an educated decision about whether or not they want to receive the item, since they will or may be financially responsible for the cost. There are several instances when an ABN may be used, including cases in which the supplier does not have a valid Medicare supplier number.

Not all sales of products or supplies that are potentially Medicare reimbursable are directed at Medicare beneficiaries. Further, many purchases of potentially Medicare reimbursable products and supplies that are made by Medicare beneficiaries are not intended by the buyer or his or her family members to become the subject of a Medicare claim. In other words, many sales and purchases of potentially Medicare reimbursable products and supplies are intended by the buyers and the sellers to be strictly private pay transactions.

Companies with businesses that consist of conducting private pay transactions have no reason to enroll in Medicare and receive a supplier number. Such companies, when making the sale of a potentially Medicare reimbursable product to a Medicare beneficiary, would utilize the ABN form.

> Given that Medicare denials of payment on the basis of a supplier's lack of a supplier number apply to all varieties of medical equipment and supplies and to all Medicare beneficiaries equally, the usual prohibition on provision of routine notices to all beneficiaries does not apply in these cases.

2014

However, on the proposed new ABN form the first option for the customer says (in part), "*I want the items or services listed above. You may collect money from me now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN).*"

Given the fact that there is no possibility for an item sold by a party with no supplier number to be paid for by Medicare, the requirement that the non-enrolled supplier nonetheless submit claims to Medicare is burdensome and unreasonable for both the supplier and for those processing the claim requests on behalf of CMS. Further, appearing to give the buyer this choice is confusing to Medicare beneficiaries.

To resolve these problems, we propose either that guidance be developed to clarify that ABNs do not need to be submitted if they are being supplied based on one of the routine ABN exceptions, or that another option for the consumer be added on the ABN form. This option would be mandatory if the reason the item will not be paid for by Medicare is because the supplier does not have supplier number and could state the following: "*I want the _____ listed above. I understand this item will NOT be paid for by Medicare because the supplier does not meet basic Medicare supplier requirements. I agree to be responsible for payment and do not want Medicare billed.*"

In addition to the clarification that Medicare not be billed if the ABN is being provided under one of the routine prohibition exceptions, we also encourage CMS to continue to recognize alternative methods of supplying the ABN form. In the "Supporting Statement for the Advanced Beneficiary Notice on Noncoverage (ABN) Contained in 42 CFR 411.404 and 411.408," Section 3 (Improved Information Technology) it is stated:

> ABNs are usually given as hard copy notices during in-person patient encounters. In some cases, notification may be done by telephone with a follow-up notice mailed. There is no provision for alternative uses of information technology to deliver ABNs, though incorporation of ABNs into other automated business processes is permitted, and some limited flexibility in formatting the notice in such cases is allowed, as discussed in the form instructions.

We encourage CMS to recognize alternative delivery methods for ABNs, including but not limited to telephone and "click-through" Internet notifications. The realities of a high-tech national business world have allowed efficient and responsible suppliers to create business models that conveniently provide high quality equipment to consumers at lower prices than traditional suppliers. This savings can be passed on to the consumer, however, capable suppliers (such as Internet, national and mail order suppliers) are continually slowed down and weighed down by the need to supply paper ABNs to consumers.

30/41

Unlike other situations when the ABN is used because Medicare **may not pay** for a particular service or item, Section 1834(j)(1) of the Social Security Act clearly establishes that Medicare payments **will always be denied** if the supplier does not have a valid Medicare supplier number. Section 40.3.6.4 (D) of Medicare Claims Processing Manual (MCPM) (Chapter 30 - Financial Liability Protections) allows for the use of routine ABNs in these instances:

> Given that Medicare denials of payment on the basis of a supplier's lack of a supplier number apply to all varieties of medical equipment and supplies and to all Medicare

In summary, we encourage CMS to recognize instances when it is inefficient to submit claims to Medicare - and confusing to suggest that such claims be filed - because the claims are guaranteed to be denied. In addition, we support any efforts by CMS to recognize alternative methods for ABN delivery. We believe each of these enhancements to the ABN process would provide benefits to both Medicare beneficiaries and the system as a whole.

Respectfully,

Janelle A. Montemayor

Janelle A. Montemayor
Contracts & Research Specialist
Direct Supply, Inc.

ABN

EPOCH SENIOR LIVING
51 Sawyer Road Suite 500
Waltham, MA 02453
T (781) 891-0777
F (781) 891-0774

June 22, 2007

OMB desk officer
OMB Human Resources and Housing Branch,
Attention: Carolyn Lovett
New Executive Office Building, Room 10235
Washington, DC 20503

VIA FAX: (202) 395-6974

RE: Centers for Medicare & Medicaid Services
Document Identifier: CMS-R-131
Agency Information CollectionActivities: Submission for OMBReview; Comment Request

Dear Ms. Lovett:

I have reviewed the revision to the ABN and supporting documents.

Of utmost concern is that I do not feel that the "OPTIONS" are clear for beneficiaries, providers and responsible parties acting on behalf of a beneficiary to receive this notice

Issues:

OPTION 1. *"but I also I want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN."*

Checking OPTION 1 suggests if this box is checked EVERY claim must be submitted for medical review. Unless claims processing instructions are very clear, the paperwork and labor burden would increase astronomically if OPTION 1 is routinely checked. It also implies that payment may be collected immediately from the beneficiary regardless of whether or not an appeal is pending which is contrary to current regulations.

OPTION 2. *"You may ask to be paid now as I am responsible for payment. I cannot* ***appeal if Medicare is not billed."***

Checking OPTION 2 is confusing and problematic for the following reasons:

- The individual responsible for making health care decisions about the provision of "reasonable and necessary" clinical services for the beneficiary may NOT be responsible for the payment.
- A beneficiary may still be responsible for their own financial affairs, yet it may be the decision of the clinical staff that this beneficiary is not "capable" of understanding the contents of the notice – especially an issue in a Skilled Nursing Facility [SNF] setting where cognitive impairments and dementia are common.
- Also, it appears that by checking this box, the beneficiary or responsible party forfeits any and all appeal rights regardless of any claims processing instructions.

OPTION 3. *I don't want the _____ listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay."*

Checking OPTION 3 is a problem in a SNF setting. Experience has shown that a beneficiary or responsible party may decide that they do not want to continue to receive services but do not agree to discharge. This leaves the SNF in an untenable position where the beneficiary remains in the SNF without a source of payment because the beneficiary has told us that they are "not responsible for payment". Additionally, as with OPTION 2, it appears that by checking this box, the responsible party forfeits any and all appeal rights regardless of any regulatory requirements or claims processing instructions.

As a practical matter, and in consideration of the time involved in the delivery of the notice as currently proposed, I believe that this notice could not be delivered as promptly and efficiently as indicated. I believe that a significant amount of time would need to be spent explaining the reason for, content of and OPTIONs listed in this notice and their implications both clinical and financial.

It would also be useful to provide specific examples of this notice for a SNF setting. In particular, I would appreciate examples of "Reasons Medicare May Not Pay", and suggested guidelines for completing the "Estimated Cost" section for a SNF.

Finally, this format, rationale and delivery requirements are not clearly integrated with the Generic Notice of Non-coverage requirements and I believe that this has still not been adequately addressed with this version of the ABN for the SNF setting.

Thank you for your consideration.

Sincerely,

Alice Smith
Medicare Specialist

Notifier(s):
Patient Name: **Identification Number:**

ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

NOTE: If Medicare doesn't pay for items or services below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the items or services below.

Items or Services	Reason Medicare May Not Pay	Estimated Cost

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the items or services listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

OPTIONS: **Check only one box. We cannot choose a box for you.**

☐ **OPTION 1.** I want the items or services listed above. You may collect money from me now, but I also I want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

☐ **OPTION 2.** I want the items or services listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**

☐ **OPTION 3.** I don't want the items or services listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

Signature:	**Date:**

Notifier(s):

KDM

#9
1 of 2

June 22, 2007

228 Seventh Street, SE
Washington, DC
20003-4306
202/546-4759
Fax 202/547-9559

Susan Goldwater Levine
Chair

Janet E. Neigh
Executive Director

OMB Human Resources and Housing Branch
Attn: Carolyn Lovett
New Executive Office Building
Room 10235
Washington, DC 20503

Re: CMS-R-131

The Hospice Association of America (HAA) is a national organization representing hospices and their thousands of caregivers from across the country. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed Information Collection: Advance Beneficiary Notice of Noncoverage (ABN). Under CFR 411.404(b) and (c) and 411.408(d)(2) and (f) a written notice is required to be provided to inform beneficiaries in advance of potential liability for payment.

Under Section 1879 of the Social Security Act, a physician, provider, practitioner or supplier of items or services participating in the Medicare Program, may bill a Medicare beneficiary for items or services usually covered under Medicare, but denied in an individual case under specific statutory exclusions, if they inform the beneficiary, prior to furnishing the service, that Medicare is likely to deny payment.

HAA wishes to thank CMS and OMB for their efforts to make the new form easier to understand. We also appreciate the planned transition period. The official title change to "Advance Beneficiary Notice of Noncoverage" is helpful in conveying the purpose of the notice. It is anticipated that Hospices will infrequently have the need to use the ABN. However, we believe the burden for hospices is greater than estimated.

As noted in the Justification, "3. Improved Information Technology, ABNs are usually given as hard copy notices during in-person patient encounters." For inpatient settings, hospices almost always must explain coverage issues to recipients of the Medicare hospice benefit and their family/primary caregiver. The estimated time for this is about 20 minutes to explain why the service requested would not be covered by Medicare, the purpose of the ABN and their

options. More than 90 percent of hospice care is furnished in the patient's place of residence so there are occasions when the hospice must make a home visit to discuss the ABN. This then adds travel time of approximately 45 minutes to the process. For these reasons, we believe the estimated seven minutes to deliver an ABN is underestimated.

Recommendation:

HAA requests that CMS/OMB revaluate the burden estimate for hospice providers, taking into consideration the uniqueness of hospice services, both inpatient and residential and the need for family caregivers to be more involved than in other types of Medicare services.

Again, we thank you for the opportunity to comment.

Sincerely,

Janet E. Neigh
Executive Director

Cc: 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

GREATER LAFAYETTE HEALTH SERVICES

Home Hospital Home Health Care
St. Clare Home Health Care

#20

June 22, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1541-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: CMS-1541-P Medicare Program; Home Health Prospective Payment System Refinement and Rate Update for Calendar Year 2008

I appreciate the opportunity provide comments on the proposed rule for refinement of the Home Health Prospective Payment System (PPS) and the rate update for 2008 that was published on May 4, 2007.

Decrease in Standard Rate:

My first concern is the assumption that the observed increase in case mix weight is due to behavioral changes by Home Health agencies and not to an increase in patient acuity. The Home Care industry has spent many hours and resources developing a better understanding of the OASIS tool and the expectations of the OASIS authors and of CMS in completing the tool. The resulting increase in case mix is a result of improved education resulting in improved accuracy combined with an increase in acuity of home care patients evidenced by decreased hospital length of stay for many common home care diagnosis, an increase in numbers of patients seen in home care with surgical wounds and an increase in patients requiring rehabilitative therapy services. CMS has implicitly acknowledged this fact in finding it necessary to penalize hospitals for early dismissal to home care in their DRG payment for selected diagnosis. Additionally, the time period used as the basis for comparison did not take into account that prior to the implementation of the Balanced Budget Act of 1997, venipuncture was a qualifying skill for home health care and many patients who qualified for home care under the venipuncture benefit received home health aide services as the most intense service in their home care delivery. The decrease in home health aide services that is cited as one justification for the finding that the case mix weight increase is not clinically driven is a result of the venipuncture exclusion and not "gaming". The "finding" that the majority of the increase in case mix weight is due to home health agencies "gaming" the system is capricious and punitive to an industry that has taken great pains to learn what CMS expects of it and to comply. This judgment is not consistent with the accompanying

Home Hospital Home Health Care
1415 Salem Street, Suite 202W
Lafayette, IN 47904
(765) 449-5046
Fax (765) 449-5192

St. Clare Home Health Care
1630 Lafayette Rd., Suite 100
Crawfordsville, IN 47933
(765) 362-5114
Fax (765) 364-8779

ABN

DUP #21

BIOLOGICAL TECHNOLOGY LABORATORY, INC.
10114 Woodfield Lane • St. Louis, MO 63132
(314) 432-5030 • (800) 737-5030

June 22, 2007

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

Faxed to: Carolyn Lovett (202) 395-6974

RE: Comments on Revised CMS Advance Beneficiary Notice (ABN)

Dear Ms. Harkless:

Our company, Biological Technology Laboratory, Inc., (BioTech Lab) is a regional laboratory serving over 300 nursing facilities as well as many physicians and out-patients. We respectfully submit the following comments relating to the Notice dated May 25, 2007 for additional public comment on the revised Advance Beneficiary Notice (ABN) (CMS-R-131). We welcome the opportunity to partner with the Centers for Medicare & Medicaid Services (CMS), other laboratories, providers, and Medicare carriers in seeking to develop and implement the most effective ABN and associated instructions for all relevant stakeholders.

Proper instructions for ABN use are essential in order to communicate the possible denial of Medicare coverage to beneficiaries in the most clear and concise fashion possible. Beneficiaries also need and deserve significant advance notice about Medicare coverage to allow them to make an informed decision about whether to

#22

Taney County Ambulance District

2003 Missouri State EMS Service of the Year

Mailing: P.O. Box 460 Branson, MO 65615-0460
Shipping: 106 Industrial Park Drive Hollister, MO 65672
Business: (417) 334-6586 Fax: (417) 337-5519
EMERGENCY: 9-1-1

ABN

May 31, 2007

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building
Room 10235
Washington, DC 20503

Re: Advance Beneficiary Notice of Noncoverage comments
OMB#: 0938-0566
Document Identifier: CMS-R-131

As an ambulance service provider the Advanced Beneficiary Notice (ABN), creates 2 great burdens on our ambulance service. The first being that the ambulance crew is expected to know billing practices. The second being the form is in paper format and the signature cannot be captured electronically.

Our patients do not come into an office to seek treatment where the business office personnel can discuss covered a non-covered treatment. Our crews are trained on patient care and have a great responsibility for providing that patient care. They should not be required to also know what is covered and not covered based on each patient's insurance coverage. Furthermore, often times the ambulance crew does not know who the patient's primary insurance is until after the transport has ended as they are focused on patient care and not billing. Often times they do not ever know what insurance the patient has. This information is frequently obtained after the transport. EMTALA laws require treatment in the emergency room before knowing patient insurance information. Why should the patient care before their arrival at the ER differ? It should not also be the ambulance crews' responsibility to be able to figure out base rates and mileage charges that a patient would be liable for if they choose the treatment. The crew should not be delayed on scene explaining Medicare's billing practices as this could delay emergency ambulance services to another patient. These patients don't always call for that unreasonable ambulance service during regular business hours. When their catheter is dislodged at midnight or on Saturday, they call then for the service. Beneficiaries should be provided with a policy manual that explains insurance coverage and exclusions regardless of the type of insurance. Then if the insurance denies, the patient is responsible.

Our regional CMS office has indicated that the ABN cannot be part of our electronic software system. I was advised by CMS that "There has never been policy to accept electronic signatures on ABNs, nor would we have such a policy unless beneficiaries requested it." As we now have an electronic patient care reporting system, it would be practical for our forms and signatures to be part of the system, rather than stored somewhere separately.

Sincerely,

Melissa Stiffler
Office Manager
Taney County Ambulance District

ABN

#23

AACC
improving healthcare through laboratory medicine

June 4, 2007

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building
Room 10235
Washington, DC 20503

Dear Ms. Lovett:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to provide input to the Office of Management and Budget (OMB) regarding the Centers for Medicare and Medicaid Services (CMS) revised Advance Beneficiary Notice (ABN). In general, we oppose the adoption of this new form and suggest that the current laboratory-specific ABN remain in place.

In 2002, CMS and the laboratory community worked closely to develop a laboratory-specific ABN, which was acceptable to all parties—CMS, clinical laboratories, physicians and beneficiaries alike. We believe our joint efforts were very successful. The final document was concise, flexible and easily understood by patients. Thus, we are perplexed by CMS's current plan to eliminate the laboratory ABN now that it has been successfully implemented and is widely in use.

To date, CMS has not provided a rationale for creating a single ABN. AACC is concerned that the introduction of this generic form would increase the administrative burdens and costs to laboratories, which would need to re-educate physicians and patients, as well as make additional changes to their computer systems. In addition, we believe the new form would confuse patients without providing any appreciable improvement in health administration. AACC urges OMB to oppose the revised ABN and urge CMS to withdraw it.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (504) 568-4281, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Larry Broussard

Larry Broussard, PhD
President-Elect, AACC

April 11, 2007

ABN

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – C
Attention: Bonnie L. Harkless
Room C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Dear Ms. Harkless

The Centers for Medicare & Medicaid Services (CMS) published a notice in the February 23, 2007 Federal Register on page 8167 indicating CMS is combining CMS-R-131-G with the CMS-R-131-L. These are the Advanced Beneficiary Notice (ABN) forms. Medicare designates form CMS-R-131-G for general use and form CMS-R-131-L is specific to clinical laboratory services. Providers would only use one of these forms if the designated service were an otherwise covered service by Medicare but in this instance, the provider believes the patient's specific situation does not meet Medicare requirements. The ABN allows the patient to make an informed consumer decision whether or not to receive the items or services when notified he or she may be responsible for payment.

In an e-mail notification through a Congressional ListServ, we received a draft of the revised form. CMS indicated they would consider public comments as part of finalizing the revised ABN. I am a Senior Analyst with the Provider Outreach & Education department of Wisconsin Physicians Service (WPS) Medicare. We process claims for Wisconsin, Illinois, Michigan, and Minnesota. I believe the revised version of the form will cause additional confusion within the provider and beneficiary community. Here are my comments:

The CMS Internet Only Manual (IOM) 100-04, Claims Processing, Chapter 30, Financial Liability Protections, Section 20.1 provides detailed information on when it is and is not appropriate to provide this form to the patient. Providing this form to the patient for items or services a provider expects Medicare to deny equates to patient responsibility for the charges. Providers are often confused between the differences in a denial based on medical necessity and a denial for non-coverage.

1. The title of the form indicates "non-coverage." This title is inaccurate. This language is too close to the Notice of Exclusion of Medicare Benefits (NEMB) (CMS-20007). The services described on the ABN are covered services under Medicare. In the patient's specific circumstances, the provider is anticipating denial based on medical necessity, not a statutory or technical coverage issue.

2. There is a statement on the form "We must bill Medicare when you ask us to." Providers are required to submit claims to Medicare for covered services per Sec. 1848 (g) (4) of the Social

MGMA

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

#24 12/7

June 21, 2007

Center for Medicare & Medicaid Services
OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building
Room 10235
Washington, DC 20503

Re: Agency Information Collection Activities: Submission for OMB Review Comment Request (CMS-R-131)

Dear Ms. Lovett:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the Agency Information Collection Activities: Submission for OMB Review Comment Request (CMS-R-131), published in the May 25, 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, 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 offers the following critiques and recommendations related to these proposed revisions.

MGMA applauds CMS' attempt to simplify the administrative process by combining the existing ABNs; however, there are elements of the proposed version that further complicate the process. In addition, the overall revisions to the forms will increase the administrative burden and cost for providers.

MGMA appreciates CMS' acceptance of MGMA's previous recommendations in comments submitted on April 23, 2007 regarding the first series of proposed revision to the ABN. Overall, the font on the ABN has increased to make the form readable for both physician practices and patients. Also, the proposed revised ABN does not include the itemizing of services, which is a significant benefit to the administrative process. This will allow practices to bill services as bundles, thus enabling practices to combine the cost of services and items for procedures. By bundling, patients will be able to view the total cost of procedures which will facilitate their decision regarding whether or not to receive services.
MGMA is pleased that CMS added the word "option" next to the three choices

HEADQUARTERS
104 Inverness Terrace East
Englewood, CO 80112-5306
phone: 303.799.1111
fax: 303.643.4439

GOVERNMENT AFFAIRS
1717 Pennsylvania Avenue
North West, Suite 600
Washington, DC 20006
phone: 202.293.3450
fax: 202.293.2787

www.mgma.com

that beneficiaries are offered. This additional language will positively impact patient care by clearly outlining the beneficiaries' core options. While there is a benefit to the proposed language revisions, the proposed form continues to contain an excessive amount of information and instruction for all populations. The simple "yes" or "no" options provided on the current forms are easier for practices to explain and for beneficiaries to understand.

MGMA values CMS elimination of Section H entitled "Other Insurance to consider for billing." The proposed revision of "Additional Information" in Section H is a positive change that will allow providers and beneficiaries the ability to include the necessary information required for the billing process on one form. We applaud CMS for following MGMA's recommendation to maintain the wording in the note section regarding CMS' willingness to pay for item(s)/service(s)/laboratory test(s).

MGMA commends CMS for the information added within the Section G title box. This information will help clarify financial procedures for beneficiaries. MGMA suggests that CMS change the wording in this section from "we" to "the provider" to allow for greater clarity. Additionally, MGMA appreciates the notice to patients stating that this is just an opinion and not an official decision. This verbiage provides beneficiaries with clarity on the legality of the ABN.

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."

MGMA has several other concerns with the proposed ABN revision, including:

- In Section A, CMS changed the wording from "supplier/provider" to "notifier," which may cause some confusion. MGMA requests that CMS maintain the original wording.

- In Section C, the language continues to lack clarity on whether Section C is for the National Provider Identifier (NPI) or the beneficiary's identification number. Supporting documents state that it is for the beneficiary; however, it needs to be clearly stated that the section is seeking information for beneficiaries on the ABN.

- MGMA understands CMS' goal in combining the forms; however, the purpose is lost if Section D is left for practices to complete or filled in with either "Item(s)/Service(s)" or "laboratory service(s)", which then provides for three versions of the ABN, thus diminishing the intent of the revision. MGMA request replacing the phrase "Item(s)/Service(s)" where it appears in the document with "Item(s)/Service(s)/Test(s)".

- CMS attempted to simplify the wording above the box which explains sections D, E and F. MGMA is concerned that the wording is too simple. MGMA recommends removing the last sentence which reads "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."
- Because multiple items, services and procedures may be included on one

June 11, 2007

ABN

OMB Human Resources and Housing Branch,
Attention: Carol Lovett
New Executive Office Building
Room 10235
Washington, DC 20503

Dear Ms. Lovett

Thank you for taking comments on the proposed revisions for the Advance Beneficiary Notice (ABN). Enclosed please find a letter detailing comments we made previously.

I suggest removing Option 2 from the finalized ABN form. I believe allowing this option could lead to abuses by the provider community and could cause beneficiaries to pay more for medical services than is required by Medicare rules and regulations. In addition, the inclusion of Option 2 takes away from the original intent of the form. The provider should use the form to notify patients on a case-by-case basis when they anticipate Medicare will deny items and services based on the patient's specific condition.

The combination of the ABN and Notice of Exclusion of Medicare Benefits (NEBM) is not beneficial to the beneficiary community. The design and intent of the forms are for two completely different types of denials. The NEMB is simply a reminder for the beneficiary that Medicare statutorily excludes a service. There are publications specific to the beneficiary community, such as the Medicare.gov website and the "Medicare and You" handbook to indicate the non-covered status of these services. Since this is information the beneficiary should know, the form is voluntary for the provider.

Beneficiaries trust the staff in their doctor's offices and are dependent upon them for their medical care. A beneficiary is reluctant to report a provider office for any type of possible violation fearing the provider will be angry and will not continue to treat them. A provider office can present the information in a myriad of ways that would encourage the patient to choose Option 2. This possible manipulation of the discussion could cause a patient to pay the physician office for services in which the patient does not have responsibility.

Based on my experience as a Medicare Provider Outreach and Education (POE) analyst, I believe that providers could use Option 2 to collect inappropriate amounts from beneficiaries. These items and services could include denials based on the Correct Coding Initiative, Skilled Nursing Facility (SNF) Consolidated billing, or items or services

considered bundled. Some provider offices have stated in education forums that they provide an ABN to all patients as a protection for their office. We continue to provide education to stop this abuse. Option 2 indicates the provider does not have to submit the claim to Medicare. Option 2 does not allow a beneficiary many options in addressing any abusive situation.

Section 1879 of the Social Security Act provides protection for the beneficiary. A provider is responsible for knowing the rules and regulations for Medicare items and services. Therefore, a provider should know whether to anticipate payment from Medicare.

Both the ABN and the NEMB provide information to the beneficiary community on possible denials by Medicare. The ABN is specific for otherwise covered items and services that Medicare will not allow for this patient's specific situation. The NEMB is a simple reminder for patients of never covered services.

Thank you for your time in considering my comments. If you have any questions or concerns, please do not hesitate to contact me.

Ellen Berra

Ellen Berra
Senior Analyst
Provider Outreach & Education
Wisconsin Physicians Service (WPS) Medicare
(618) 998-5247
ellen.berra@wpsic.com

ABN

American Academy of Family Physicians

24 197

June 19, 2007

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building, Room 10235
Washington, DC 20503

Re: CMS-R-131

Dear Ms. Lovett,

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents nearly 94,000 family physicians and medical students nationwide. Specifically, I am writing to offer our comments in response to the request for information on the Advance Beneficiary Notice of Noncoverage (ABN) as published in the *Federal Register* on May 25, 2007.

Estimated Burden

As we noted in the previous comment period, the estimated burden appears to be seriously underestimated. The Centers for Medicare and Medicaid Services (CMS) noted that comments to this effect were anecdotal only. This is true because it is CMS which has the data to substantiate a better estimate of this burden. CMS has in the past indicated the ability to track modifier usage from claims data when investigating the use of modifiers such as 25 and 59. This same data should be available to indicate the number of claims by unique physician and provider identifier which contained the GA modifier indicating that an ABN was on file. This number of claims should then be increased by approximately one-third to account for those beneficiaries who elect to not receive the service or to not have a claim filed. Division of this number by the number of unique physician and provider identifiers should provide a better estimate of the burden per notifier. Family physicians, of whom over 90% provide in-office laboratory services, will provide far more ABN's than, for example, surgical specialists who do not have in-office lab at all. Thus, the AAFP continues to maintain that the estimated burden for many family physicians is underestimated by 50 to 150 times.

We also again note that the total cost per notifier of $69.39 does not agree with the statistics provided and significantly underestimates the burden. If the estimated total cost of delivering the ABN's is $326,255,502.00 and notifiers will deliver 40,302,506

11400 Tomahawk Creek Parkway
Leawood, KS 66211-2672
(800) 274-2237
(913) 906-6000
Fax: (913) 906-6075
E-mail: fp@aafp.org
http://www.aafp.org

247

ABN's each year (or 31.7 ABN's per notifier per year) as indicated in number 2 of the supporting statement, then the burden would be $256.62 per notifier.

Further, CMS noted that the work of activities such as researching coverage policies that are not solely required by the ABN are not always part of preparing and delivering the notice, and moreover, are general responsibilities of those participating in Medicare. This may be true. However, some portion of these general responsibilities of participating in Medicare should be attributed to the burden associated with delivering the notice. If not, where is the burden of these activities accounted for?

Transition Burden

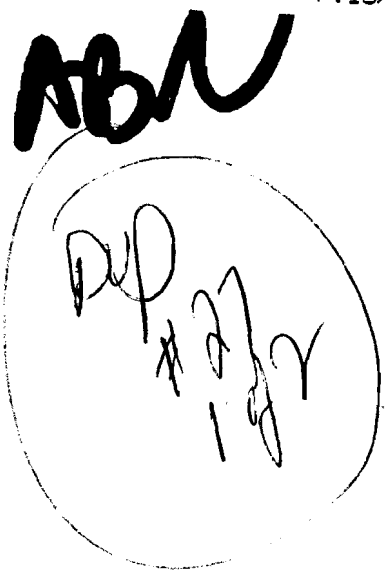
We agree with commenters who noted other concurrent CMS initiatives involving physicians that require significant operational resources (e.g., the National Provider Identifier (NPI) initiative), and asked for a reasonable period of time in which to transition from the current ABN to the new notice. We note that the NPI initiative is one of several initiatives faced by physicians in 2007 including transition to the new CMS 1500 form and preparation for the Physician Quality Reporting Initiative. We appreciate CMS's agreement that a reasonable transition period is necessary and that this issue will be addressed prior to final approval of the new ABN.

Use of Single ABN

We note that the simplification of one ABN form has been lost to the creation of one form with three versions. There are, in essence, three forms with minor differences. The generic version of the form which leaves field D blank should meet the needs of all physicians and providers and avoid confusion. However, the reasons Medicare may not pay which are included on the laboratory version of the ABN might be included on the generic version in lieu of a separate form. The three reasons given could be modified as follows to be inclusive of services other than laboratory tests:

- Medicare does not pay for these (D) _____ for your condition.
- Medicare does not pay for these (D) _____ as often as ordered for you.
- Medicare does not pay for experimental or research use (D) _____.

This would allow for one version of the ABN form which could be used for many purposes as was indicated in the original request for comments.



FAIRVIEW
Fairview Health Services
Patient Financial Services
P.O. Box 147
Minneapolis MN 55440-0147
(612) 672-6724 Fax: (612)-672-6727

June 21, 2007

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building
Room 10235
Washington, DC

Re: Federal Register Notice (72 FR , No 101, pp 29322-29323 May 25, 2007 Centers for Medicare and Medicaid Services, Department of Health and Human Services; Revision of Advance Beneficiary Notice of Noncoverage (ABN); Document Identifier CMS-R-131 OMB 0938-0566

Dear Ms. Lovett;

Fairview Health Services, which has seven hospitals in Minnesota, wishes to thank you for the opportunity to comment on the proposed changes to the Advance Beneficiary Notice. Our comments are as follows:

Sample L/ Lab ABN:
Lab personnel prefer the current Lab ABN format as it allows for more customization. It is felt that the proposed format does not allow sufficient space to customize for all of the various tests for which there is a Medicare coverage issue, even if there is a font change. Without having this pre-printed, there will be more exception data for lab techs and personnel to look up, which is a training issue and which lends itself to the possibility of errors. The proposed format will mean more up front work. The existing format allows lab to be more time efficient, while still ensuring that the patient gets the correct information.

Sample G:
The consensus of most of the people responding is that this is the preferred format for services other than lab. The other form is too busy and cluttered, and the statement "items or services" describes what will appear in item "D". They would prefer not to have other items to fill in.

General Comments:
Option 2, if selected, tells us not to bill Medicare. In many instances, a secondary payer – whether the provider bills or lets the patient bill the payer – will require that there be a denial from Medicare before they will consider the claim. We could put a notice in "additional information" that speaks to this, however the concern is that it would appear that we are leading the patient to choose option 1, and it has already been stated that "we

Comments to CMS
Changes to the Advance Beneficiary Notice

cannot choose a box for you". Since some providers do not, not are they required to bill the secondary payer, CMS could still add language regarding this requirement, such as " Note: if you have another insurance, you should check to see if they require a denial from Medicare before considering your claim".. Then when the patient reviews the 3 options, he or she will know that if they choose option 2, they may not be able to get paid for the service by the secondary payer.

We would also like to point out that should the patient choose option 2, if this is one non-covered item among many other tests, particularly in a large hospital-based setting or large clinic setting, it will be difficult to pull out one test to not bill to Medicare. Also, if we are able to do this, it has been our experience that the patient will compare the hospital or clinic bill to the MSN, and then it will generate calls that we billed incorrectly. They do not remember that they said they did not want something billed.

Notifier: In the instructions, CMS indicates that employees or subcontractors of the notifier may deliver the ABN. The concern is that some notifiers may delegate this function to someone who is not qualified to answer patient questions. Not all employees or subcontractors are clinical staff. We believe that if the notifier delegates the delivery of the ABN, it must be delegated to other staff qualified to answer a patient's questions, or that such qualified staff or the notifier be available in the event that there are questions.

Other: We like the plain language and the statement "we cannot choose a box for you".

Thank you for the opportunity to comment.

Sincerely,

Stephanie McDonald
Compliance Specialist
Fairview Health Services
Corporate Office
400 Stinson Blvd NE
Minneapolis, MN 55413

University of Minnesota Medical Center, Fairview
Fairview Southdale Hospital
Fairview Ridges Hospital
Fairview Northland Regional Hospital
Fairview Lakes Regional Medical Center
Fairview Red Wing Hospital
University Medical Center, Mesabi

RDI

www.acr.org

#28

June 22, 2007

OMB Human Resources and Housing Brach
Attention: Carolyn Lovett
New Executive Office Building, Room 10235
Washington, DC 20503

Re: Advance Beneficiary Notice, Form Number CMS-R-131 (OMB: 0938-0566)

Dear Ms. Lovett:

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 a second comment on the proposed revision to the Medicare Advanced Beneficiary Notice of Non-coverage (ABN) in response to the request for comments, initially published in the Federal Register on February 23, 2007 and for the second time on May 25th, 2007.

The ACR is pleased to see that CMS is working on the ACR's recommended changes on the ABN. We would like to reiterate a recommendation made in our first comment letter about the ABN.

In our first comment letter, we suggested the inclusion of language directing patients to their referring physician before making their final decision. In particular, this would encourage the patient to discuss the treatment options with his/her referring physician before declining the treatment. Language such as "If you are not clear as to 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" can encourage the patient to obtain further information from the referring physician.

The ACR is concerned about the implication of potential liability of radiologists not providing the ordered exam because the patient selects option 3, which enables the patient to opt out from receiving care. When the patient selects option 3, it also leaves radiologists with the responsibility of informing the referring physician that the patient has selected option 3. This can be burdensome. Therefore, the ACR recommends adding language on the ABN that directs patients to the referring physician to discuss treatment options.

We appreciate the second opportunity to comment on the revised ABN. 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

Harvey L. Neiman, MD, FACR
Executive Director

cc: Michelle Shortt, CMS
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 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
1818 Market St, Suite 1600
Philadelphia, PA 19103
(215) 574-3150

American Academy of Dermatology
and AAD Association
Physicians Dedicated to Excellence in Dermatology

Correspondence
PO Box 4014
Schaumburg, IL 60168-4014

Location
930 N Meacham Rd
Schaumburg, IL 60173-4965

Phone (847) 330-0230
Fax (847) 330-0050

AAD Web Site
www.aad.org

C. William Hanke, MD, FAAD
President

Henry W. Lim, MD, FAAD
Vice President

James S. Taylor, MD, FAAD
Vice President-Elect

Diane R. Sailer, MD, FAAD
Secretary

Mary E. Maloney, MD, FAAD
Secretary-Treasurer

Hubert T. Greenway, Jr., MD, FAAD
Assistant Secretary-Treasurer

Ronald A. Hennessy, CAE
Executive Director & CEO

Friday, June 22, 2007

OMB Desk Officer
OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building Room 10235
Washington, DC 20503

FAX Number 202 395 6974

Re: CMS R 131 Proposed Revision to Advance Beneficiary Notice

Dear Ms. Lovett:

The American Academy of Dermatology is requesting that the comment period for this document revision be extended at least another 30 days or a new comment period of 60 days be provided. We are deeply concerned that any revision to form CMS-R-131 Advance Beneficiary Notice succeed in making it simpler and easier for Medicare beneficiaries to understand the care and billing options that are being presented to them.

While we believe that the current ABN and Lab ABNs can be effectively combined, we are very concerned that the sequence and text of the information being presented on this form are not being provided in an easily understood fashion. We believe that the instructions to the beneficiary as well as the choices being presented could be clearer. Certain parts of the text continue to be redundant and/or unnecessary. We do not support the current draft revised Advance Beneficiary Notice forms.

Consideration should also be given to providing this form to a beneficiary on a per service basis rather than a potential list of up to six services and a form that does not support the beneficiaries' ability to choose/select services to receive and services to reject. If six services are listed, how does a beneficiary indicate that he or she wishes to receive three and reject three? How would they indicate the application of the three Options(G) to one or more of the services listed?

We are also concerned with the proposal to eliminate the Notice of Exclusions From Medicare Benefits. We believe this form has proven to be an effective and frank method of explaining that Medicare does not pay for everything and that specific items and services, especially those that are clearly cosmetic in nature, are not billable to Medicare. We strongly recommend that this form be retained.

Thank you in advance for your consideration. If you have questions regarding this request, please contact Norma L. Border at 847 240 1814, nborder@aad.org.

Respectfully,

Brett Coldiron MD

Brett Coldiron, MD, FAAD, FACP
Chair/AAD Health Care Finance Committee

ABN

DUP #30 1/4

Federation of American Hospitals•

Charles N. Kahn III
President

June 25, 2007

SENT VIA FACSIMILE AND U.S. MAIL

Ms. Carolyn Lovett
OMB Human Resources and Housing Branch
New Executive Office Building
Room 10235
Washington, DC 20503

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

Dear Ms. Lovett:

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 the renewal of an agency information collection activity involving the Medicare Advance Beneficiary Notice of Noncoverage ("ABN"). (*See* 72 *Fed. Reg.* 29,322 (May 25, 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 voluntarynotification 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 notifiers "must complete the ABN as described below, and deliver the notice to the affected beneficiary..." 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.

Accordingly, we believe that Option 2 should be removed from Section G of the proposed ABN form because it appears to apply 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.

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

[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.

DUP 3/16

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. Interpretive Rules To Implement the New ABN

The proposed Form Instructions for the Advance Beneficiary Notice of Noncoverage (ABN) state that:

> *[O]nce the new ABN approval process is completed, CMS will issue more detailed instructions on the use of the ABN in its on-line Medicare Claims Processing Manual, Publication 100-04, Chapter 30. In addition, note that related policy on billing and coding of claims, and as well as coverage determinations, is found elsewhere in the CMS manual system or website.*

We request that CMS 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.

We request that as CMS is developing the detailed instructions, that they also review the policies regarding billing and coding of claims that are found elsewhere in CMS materials to ensure that no conflicting information is disseminated.

For example, the following information is found in various material published by CMS regarding non-covered observation services:

> *ABNs may not be used to shift liability to a beneficiary in the case of services or items for which full payment is bundled into other payments; that is, where the beneficiary would otherwise not be liable for payment for the service or item because bundled payment is made by Medicare. Using an ABN to collect from a beneficiary where full payment is made on a bundled basis would constitute double billing. An ABN may be used to shift liability to a beneficiary in the case of services or items for which partial payment is bundled into other payments; that is, where part of the cost is not included in the bundled payment made by Medicare.* (Medicare Claims Processing Manual, Chapter 30, Section 50.7.7.6 - ABNs and Bundled Payment)

Because observation is normally packaged and the additional hours over eight are packaged for separately payable observation, the above statements indicate that it would not be appropriate to obtain an ABN or NEMB and bill the beneficiary for the non-covered hours.

> *If a hospital intends to place or retain a beneficiary in observation for a noncovered service, it must give the beneficiary proper written advance notice of noncoverage under limitation on liability procedures (see Pub. 100-04, Medicare Claims Processing Manual; Chapter 30, "Financial Liability Protections," §20, at http://www.cms.hhs.gov/manuals/downloads/clm104c30.pdf for information regarding Limitation On Liability (LOL) Under §1879 Where Medicare Claims Are Disallowed).* (Medicare Benefit Policy Manual, Chapter 6, Section 20.5 - Outpatient Observation Services)

The above guidelines suggest that we should be obtaining ABNs and billing the patient for noncovered observation.

In addition, current instructions in the Medicare Claims Processing Manual, Chapter 4, Section 290.5 - Services Not Covered as Observation Services state:

> *The hospital should bill for the period of medically necessary observation and should also submit non-covered services according to billing instructions in the Medicare Claims Processing Manual, Pub 100-04, Chapter 1, §60.1.2. Hospitals should submit a non-covered charge amount equal to the total charge for each service and should use modifier -GY or condition code 21 as appropriate.*

These differing statements have resulted in various provider interpretations regarding the appropriateness of the use of ABNs for observation services.

III. Header

Regarding completion of the Header of the new ABN form, the instructions state: "*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.*"

Since the rendering provider is ultimately responsible for obtaining ABNs and billing Medicare for such services, we do not recommend that both the ordering and rendering providers be listed in the Header section. Listing both providers may be confusing to the beneficiary.

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. We also ask that CMS provide additional guidance regarding what constitutes a "good faith estimate."

V. Options 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.

a. Option 1

We request that CMS clarify their intent regarding the use of Option 1. If this is an option that the beneficiary can choose for statutorily excluded services, how would providers bill for a coverage decision? Currently statutorily excluded services are reported as non-covered and Medicare Contractors do not review these services to determine coverage. If providers were to report statutorily excluded services as covered, how would Medicare Contractors know that the provider recognizes these services as non-covered and is not seeking reimbursement from the Medicare program?

b. Option 2

We request that CMS clarify their intent regarding use of Option 2. Can beneficiaries choose this option for statutorily excluded services and also those services that are not medically necessary according to a local coverage decision or national coverage decision? If a beneficiary chooses Option 2 for a service that is not covered according to a local coverage decision or national coverage decisions, the provider would be making the ultimate coverage decision as no claim would be submitted to the Medicare contractor.

From an editorial consistency perspective, we suggest changing the statement, "You may ask to be paid now as I am responsible for payment" to "I understand that I may be asked to pay now as I am responsible for payment."

c. Option 3

In order to provide clear guidance to the beneficiary, we suggest that the statement "I understand with this choice I am not responsible for payment," be revised to read "I understand that with this choice I will not receive the service, I am not responsible for payment . . . "

VI. Additional Information

To clarify the Medicare coverage decision process, we suggest changing the language in the Additional Information section from "This notice gives our opinion, not an official Medicare decision" to "Based on Medicare coverage guidelines, this notice gives our opinion and is not an official Medicare decision. Please note that Medicare does not make pre-service coverage decisions."

VII. 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,

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

ABN

June 25, 2007

American Clinical Laboratory Association

Office of Management and Budget ("OMB")
Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building
Room 10235
Washington, DC 20503

Re: Advance Beneficiary Notice of Noncoverage ("ABN") (CMS-R-31)

Dear Ms. Lovett:

The American Clinical Laboratory Association ("ACLA") is pleased to have this opportunity to submit our comments with regard to the *Agency Information Collection Activities: Submission for OMB Review; Comment Request (the "Comment Request")* on the new Advance Beneficiary Notice of Noncoverage ("ABN") for the noncoverage of certain Medicare services to beneficiaries. 72 Fed. Reg. 29322 (May 25, 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 this 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.

ACLA expressed its views to the Centers for Medicare & Medicaid Services ("CMS") regarding the *Agency Information Collection Activities: Proposed Collection; Comment Request.* 72 Fed. Reg. 8167 (Feb. 23, 2007). While CMS has made some of the requested changes based on the initial comment period, the revisions still do not address many of our questions and concerns. Accordingly, we are again submitting comments regarding the new ABN form, many of which reiterate our earlier comments to CMS, as well as emphasizing our goal to maintain the existing laboratory-specific ABN ("ABN-L").

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.

2/17

While ACLA members appreciate CMS' effort to accommodate the need for a laboratory-specific ABN by including in the information collection paperwork a version of the ABN for laboratory-specific use ("Sample L"), we still see no reason to eliminate the existing ABN-L, which has worked successfully for beneficiaries, physicians and laboratories. Further because the Sample L form is not an improvement on the existing ABN-L for the reasons we describe below, it is now even more unclear as to CMS' purpose for replacing the existing ABN-L with another ABN form for laboratory-specific use. Thus, in spite of CMS' effort to create a version of the ABN form that is specific for laboratory services, ACLA is still concerned that the Sample L 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 reason why that form, which was specifically developed to meet the needs of beneficiaries, laboratories, and physicians, 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-L to be used by physicians for laboratory-specific testing in lieu of the ABN form for general use ("ABN-G"). The ABN-L 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 ABN-L was approved. The value of having had beneficiaries and the laboratory industry involved in the development of the ABN-L is evidenced by its practicality, clarity, and effectiveness.

The effectiveness of the ABN-L 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 ABNs for beneficiaries' understanding of their financial responsibilities and the convenience of ABNs to ensure physicians' proper completion of the form. The ABN-L 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-L permits laboratories to list the tests that could be denied, and to specify the possible reasons for such denial. This allowed laboratories to print the ABN-L forms in advance, customized to 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 current ABN-L given its success, and CMS has provided no rationale for creating the new Sample L form to be used for laboratory services. While we are aware that under the Paperwork Reduction Act of 1995 ("PRA") CMS is required to re-approve the ABN with a notice and public comment period, there is no requirement that a new ABN form be created. Although CMS has indicated that many of its changes are based on comments and suggestions from both notifiers and beneficiaries, we find it difficult to believe that this is the form that notifiers or beneficiaries had envisioned for laboratory services, and CMS has failed to articulate the specific reasons why such comments and suggestions justify the specific changes proposed.

3 of 12

As we will discuss in further detail below, the Sample L form will resul in unnecessary burden and confusion to beneficiaries, physicians, and laboratories. Thus, it is neither necessary nor reasonable to replace the existing ABN-L with the Sample L form, which has w rked effectively.

III. Comments Regarding the Burden of the Sample L Form

As mentioned above, we find no rationale for revising the ABN-L, which is working quite effectively, by creating a version of the new ABN form specific for laboratories. In fact, as part of the Comment Request and supporting documents, CMS has not even attempted to provide a rationale for eliminating the existing ABN-L. Because we see no valid reason for CMS t go forward with this effort, we can foresee no benefit that would outweigh the significant burdens tha t we discuss below.

First, CMS provides in the Supporting Statement for the new ABN form that an average of 31.7 ABNs will be delivered each year per notifier. CMS arrived at this number b determining the total universe of ABNs and then dividing that number by the total number of physi ians and practitioners. However, this process is clearly flawed. The use of ABNs will vary significa tly by the specialty of the physician. For example, in the laboratory context, many types of physicia ns 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 accou nt for the disparities in its use. While some physicians probably give out a few ABNs, other physici ns will likely give out hundreds a year. Thus, the burden of moving to a new ABN form will b far greater for these physicians. Specifically, adopting the new Sample L form will result in unn cessary administrative and implementation costs for both physicians and laboratories on a far great r scale than has been envisioned by CMS.

Second, in order to effectively implement the Sample L form, physicia ns and their staffs will need to be educated with respect to the new requirements of the form. For lab ratory services, it will be up to laboratories themselves to explain to physicians and their staffs how t fill out the Sample L form and how it has changed from the existing ABN-L. 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 wi l now struggle with understanding the Sample L form, and how it applies to laboratory services. CM S does not account for these costs in the burden estimate included in its Supporting Statement.

Third, because the new format will make completing the form unne cessarily difficult and burdensome and will make it far more complicated to create a software progr m that will create the appropriate form when necessary, the changes will result in an increase in n mber of forms being completed incorrectly or not being completed at all.

The ABN-L was standardized to a sufficient degree so that laborato ies could automate its use, triggering a blank ABN whenever there was a valid basis for concluding tha t Medicare might deny payment.[1] The current ABN-L was formatted vertically so that each laboratory test could be listed in the applicable reason column. That format allowed different laboratory test to be arrayed in the proper column according to the reason applicable to the specific test. For spacin g reasons, this allowed several tests to be included in an orderly fashion without any confusion. Indee l, if a laboratory knew

[1] We have enclosed two sample ABN-L forms from member laboratories at the end of our comm nts to illustrate this point.

4 of 12

that the carrier had LCDs for 10 laboratory tests that required diagnosis codes, then the laboratory could list those 10 tests under the column for "Not Medically Necessary." Then the physician could simply check off the appropriate test when he or she believed that Medicare would not pay for the test with that information.

The Sample L form, however, makes that simple procedure far more difficult because it is set up differently, and requires that all of the tests be listed in one column. Then, the reason for each test must be set up on that same line horizontally. As a result, notifiers will be required to ensure that tests match up horizontally with the corresponding reason codes and estimated costs. The horizontal nature of the box will be problematic because not only does that limit the number of tests that can be included in the box, but tests that could be denied for more than one reason (e.g., frequency and medical necessity) will need to be repeated in the first column for each reason of non-coverage. In addition, ensuring that the tests are lined up appropriately will place additional burdens for automation purposes and pre-printed forms. Although it is possible that the tests could be listed, it will then be up to the physicians and their staffs to complete the reason column across from each test, which will have to be completed by hand, and, therefore will be prone to manual error. Even with the use of gridlines, the formatting of the new Sample L form presents a number of logistical issues.

Further, a typical existing ABN-L includes, on average, 3 tests for each ABN. But, the ABN-L is designed to accommodate more than the average number of tests, which occurs frequently. Typically, these tests are denied for reasons of frequency and/or medical necessity. Depending on the carrier, there can be as many as 50 types of tests that are denied for these reasons. Most often, these tests include, for example, pap screening, lipid panels, and colorectal cancer screening. The layout of the ABN-L – which allowed numerous tests to be included in each column, under the appropriate reason – made it easy to fit all of the information in a clear fashion on a single page. This will be difficult to do with the Sample L and, as a result, additional pages will be required. As such, additional formatting changes will be required to ensure that the attached sheets model the Sample L form, which will increase the costs of production, transmittal, and storage. Although CMS has indicated that the Sample L form can be customized into legal size and the use of attachments is permitted to allow for additional space, this additional burden on notifiers is unnecessary, considering that the existing ABN-L is more than effective.

Because of the way the form is organized, it will be far more difficult for laboratories to establish software programs that will automatically create the appropriate form for the physician to present to the patient. As a result, physicians or their staffs may not complete forms in their entirety or may complete forms incorrectly. 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 the changes to the new Sample L form, including the new language. As we have mentioned, the existing ABN-L was developed with the valuable assistance and input of beneficiaries. Through the use of beneficiary focus groups, the ABN-L was crafted to ensure that beneficiaries are adequately notified of any potential financial obligations for a noncovered item or service. To this end, the ABN-L took into account appropriate font style and

size, formatting structure, and provided the three clear, concise and standard reasons for noncoverage. The new Sample L form, however, has a different format and font style, as well as the options from which the beneficiary must select. As a result of these changes, the physician or practitioner will need to take extra time to explain the Sample L form 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.

Fifth, the adoption of the Sample L form will impose a 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 Sample L form 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 document 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 ABN-Ls.

IV. Comments on Specific Aspects of the Sample L Form

We have outlined our concerns with respect to specific aspects of the new Sample L form below.

A. Cost Estimates

The Sample L form includes a separate column for *"Estimated Cost."* According to the Form Instructions, *"[n]otifiers must enter a cost estimate..."* on the form. This requirement is different from the ABN-L 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 ABN-L. 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."[2] In many cases, as CMS recognized, physicians are simply not aware of what the 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.

As such, it should not be required that physicians determine the cost of the noncovered items or services included on the ABN for the ABN to be valid, and this column should be removed from the Sample L form. If physicians believe that they are required to submit estimated costs for the form to be valid, they may forego completing the form altogether. Further, beneficiaries may be overwhelmed by all of the estimated costs on the form. If beneficiaries are interested in the estimated cost of a

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

6 of 12

laboratory test, he or she may request that information from the physician, which is currently the case. If there is, however, a space on the form for estimated costs, 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.

In addition, CMS should clarify its meaning of a "good faith" estimate of costs. This is important because, as noted above, physicians and their staffs are responsible for completing the ABN form. Accordingly, laboratories do not have the opportunity to complete this portion of the ABN to indicate a good faith estimate of cost and, therefore, laboratories should not be forced to absorb the costs of noncovered tests should physicians and their staffs not complete the section correctly or at all. Moreover, the ABN-L did not request an itemized cost of each laboratory test. The new Sample L form, however, seems to encourage a listing of itemized costs by service, but permits the bundling of costs under certain circumstances. If CMS intends to require estimated costs and permit the bundling of these costs, we strongly encourage that CMS make clear the circumstances, if any, when bundling would be permitted.

B. Options

The ABN-L 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.

The new Sample L form includes an additional option – *"2. I want the laboratory tests listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed."* 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 or herself. We find this to be unacceptable. There should be no option included on the ABN form that attempts to deny beneficiaries the right to payment for services that may be covered by Medicare. As such, we believe that option 2 on the Sample L form should be eliminated.

Further, we find that the discussion with respect to payment may be confusing to beneficiaries who may be expecting to pay the laboratory immediately after testing. For example, in the first option, the description states that *"I want the laboratory tests listed above. You may collect money from me now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles."* Our member laboratories typically do not collect payments from beneficiaries at patient service centers. Thus, we recommend that CMS make clear that payment is to be collected at the time of specimen collection or testing only at the option of the laboratory. This change will ensure that beneficiaries are aware that they will be

required to make a payment only if the laboratory requests such payment. Furt er, any reference to co-pays or deductibles should be deleted from the form, since there are no co- ays or deductibles for Medicare Part B clinical laboratory services.

V. Conclusion

In closing, ACLA does not agree that the new Sample L form is needed for laboratory tests and believes that beneficiaries and physicians are quite satisfied with the existing ABN-L and would find the Sample L form confusing and inadequate. If a new form is to be develope , however, we strongly believe that the OMB should seek additional input from the laboratory ndustry and Medicare beneficiaries before creating a new ABN form specific to laboratories, and ve again 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 th ABN-L. We worked closely with CMS in the past to develop an effective laboratory-specific ABN, nd we would welcome the opportunity to meet with the OMB and/or CMS again, to ensure that any uture ABN is effective for beneficiaries, physicians, and laboratories.

If you have any further questions or comments, do not hesitate to contac us.

Sincerely,

Alan Mertz
President

Enclosures: Sample ABNs

6 of 12

KS Removal Stub Location

Quest Diagnostics

Patient's Name: Medicare # (HICN):

ADVANCE BENEFICIARY NOTICE (ABN)

NOTE: You need to make a choice about receiving these laboratory tests.

We expect that Medicare will not pay for the laboratory test(s) that are described below. Medicare does not pay for all of your health care costs. Medicare only pays for covered items and services when Medicare rules are met. The fact that Medicare may not pay for a particular item or service does not mean that you should not receive it. There may be a good reason your doctor recommended it. Right now, in your case, **Medicare probably will not pay for the laboratory test(s) indicated below for the following reasons:**

Medicare does not pay for these tests for your condition			**Medicare does not pay for these tests as often as this (denied as too frequent)**
6399 ☐ CBC	861 ☐ T-3, Uptake		☐ Occult Blood, Micr Scr or Dx
978 ☐ CEA	867 ☐ T-4 Thyroxine		☐ Pap Smear
418 ☐ Digoxin	866 ☐ T-4 Free		☐ Liquid-Based Pap with or without Reflex
457 ☐ Ferritin	395 ☐ Culture, Urine Routine (incl ID & Susceptibility as when ord)		☐ PSA, Micr Scr or Dx
496 ☐ Hemoglobin A1C			7600 ☐ Lipid Panel
571 ☐ Iron, Total	Other ☐ _____		334 ☐ Cholestro , Total
7573 ☐ Iron (Tot), IBC % Sat	Other ☐ _____		508 ☐ HDL Chol strol
7600 ☐ Lipid Panel	Other ☐ _____		8847 ☐ PT w/INR
5363 ☐ PSA, Dx	Other ☐ _____		☐ Glucose, erum or Plasma
8847 ☐ PT w/INR	Other ☐ _____		496 ☐ Hemoglobin A1C
763 ☐ PTT, Activated	Other ☐ _____		Other ☐ _____
699 ☐ TSH	Other ☐ _____		Other ☐ _____
36127 ☐ TSH w/Reflex T-4 Free	Other ☐ _____		

The purpose of this form is to help you make an informed choice about whether or not you want to receive these laboratory tests, knowing that you might have to pay for them yourself. Before you make a decision about your options, you should **read this entire notice carefully.**

- Ask us to explain, if you don't understand why Medicare probably won't pay.
- Ask us how much these laboratory tests will cost you (**Estimated Cost: $___ ___**), in case you have to pay for them yourself or through other insurance.

PLEASE CHOOSE **ONE** OPTION. CHECK **ONE** BOX. **SIGN & DATE** YOUR CHOICE.

☐ **Option 1. YES. I want to receive these laboratory tests.**
I understand that Medicare will not decide whether to pay unless I receive these laboratory tests. Please submit my claim to Medicare. I understand that you may bill me for laboratory tests and that I may have to pay the bill while Medicare is making its decision.
If Medicare does pay, you will refund to me any payments I made to you that are due to me.
If Medicare denies payment, I agree to be personally and fully responsible for payment. That is, I will pay personally, either out of pocket or through any other insurance that I have.
I understand I can appeal Medicare's decision.

☐ **Option 2. NO. I have decided not to receive these laboratory tests.**
I will not receive these laboratory tests. I understand that you will not be able to submit a claim to Medicare and that I will not be able to appeal your opinion that Medicare won't pay.
I will notify my doctor who ordered these laboratory tests that I did not receive them.

Date **Signature of patient or person acting on patient's behalf**

NOTE: Your health information will be kept confidential. Any information that we collect about you in this form will be kept confidential in our offices. If a claim is submitted to Medicare, your health information on this form may be shared with Medicare. Your health information which Medicare sees will be kept confidential by Medicare.

OMB Approval No.0938-0566 Form No. CMS-R-131-L

Screened Box measures: 2½" X 1.25"

1st Ply - Quest Diagnostics Copy 2nd Ply - Patient Copy 3rd Ply - Physician Copy

KS Removal Stub Location

9 of 12

Quest Diagnostics

Patient's Name: Medicare # (HICN):

ADVANCE BENEFICIARY NOTICE (ABN)

NOTE: You need to make a choice about receiving these laboratory tests.

We expect that Medicare will not pay for the laboratory test(s) that are described below. Medicare does not pay for all of your health care costs. Medicare only pays for covered items and services when Medicare rules are met. The fact that Medicare may not pay for a particular item or service does not mean that you should not receive it. There may be a good reason your doctor recommended it. Right now, in your case, **Medicare probably will not pay for the laboratory test(s) indicated below for the following reasons:**

Medicare does not pay for these tests for your condition			Medicare does not pay for these tests as often as this (denied as too frequent)
6399 ☐ CBC	861 ☐ T-3, Uptake		☐ Occult Blood, Micr Scr or Dx
978 ☐ CEA	867 ☐ T-4 Thyroxine		☐ Pap Smear
418 ☐ Digoxin	866 ☐ T-4 Free		☐ Liquid-Based Pap with or without Reflex
457 ☐ Ferritin	395 ☐ Culture, Urine Routine (inc. ID & Susceptibilities when posi		☐ PSA, Micr Scr or Dx
496 ☐ Hemoglobin A1C			7600 ☐ Lipid Panel
571 ☐ Iron, Total	Other ☐		334 ☐ Cholestrol, Total
7573 ☐ Iron (Tot), IBC % Sat	Other ☐		606 ☐ HDL Cholestrol
7600 ☐ Lipid Panel	Other ☐		8847 ☐ PT w/INR
5353 ☐ PSA, Dx	Other ☐		☐ Glucose, Serum or Plasma
8847 ☐ PT w/INR	Other ☐		496 ☐ Hemoglobin A1C
763 ☐ PTT, Activated	Other ☐		Other ☐
899 ☐ TSH	Other ☐		Other ☐
36127 ☐ TSH w/Reflex T-4 Free	Other ☐		

The purpose of this form is to help you make an informed choice about whether or not you want to receive these laboratory tests, knowing that you might have to pay for them yourself. Before you make a decision about your options, you should **read this entire notice carefully.**

- Ask us to explain, if you don't understand why Medicare probably won't pay.
- Ask us how much these laboratory tests will cost you (**Estimated Cost: $**_____). in case you have to pay for them yourself or through other insurance.

PLEASE CHOOSE **ONE** OPTION. CHECK **ONE** BOX. **SIGN & DATE** YOUR CHOICE.

☐ **Option 1. YES. I want to receive these laboratory tests.**
I understand that Medicare will not decide whether to pay unless I receive these laboratory tests. Please submit my claim to Medicare. I understand that you may bill me for laboratory tests and that I may have to pay the bill while Medicare is making its decision.
If Medicare does pay, you will refund to me any payments I made to you that are due to me.
If Medicare denies payment, I agree to be personally and fully responsible for payment. That is, I will pay personally, either out of pocket or through any other insurance that I have.
I understand I can appeal Medicare's decision.

☐ **Option 2. NO. I have decided not to receive these laboratory tests.**
I will not receive these laboratory tests. I understand that you will not be able to submit a claim to Medicare and that I will not be able to appeal your opinion that Medicare won't pay.
I will notify my doctor who ordered these laboratory tests that I did not receive them.

Date **Signature of patient or person acting on patient's behalf**

NOTE: Your health information will be kept confidential. Any information that we collect about you on this form will be kept confidential in our offices. If a claim is submitted to Medicare, your health information on this form may be shared with Medicare. Your health information which Medicare sees will be kept confidential by Medicare.

OMB Approval No.0938-0566 Form No. CMS-R-131-L

1st Ply - Quest Diagnostics Copy 2nd Ply - Patient Copy 3rd Ply - Physician Copy

10 of 12

SAME AS 2

P.O. Box 2240 Burlington, NC 27215 Phone: (800) 222-7566 / Fax: (8[illegible]6) 827-8047

LabCorp

LabCorp Use Only

Patient's Name: Medicare # (HICN):

ADVANCE BENEFICIARY NOTICE (ABN)

NOTE: You need to make a choice about receiving these laboratory tests.

We expect that Medicare will not pay for the laboratory test(s) that are described below. Medicare does not pay for all of your health care costs. Medicare only pays for covered items and services when Medicare rules are met. The fact that Medicare may not pay for a particular item or service does not mean that you should not receive it. There may be a good reason your doctor recommended it. Right now, in your case, **Medicare probably will not pay for the laboratory test(s) indicated below for the following reasons:**

Medicare does not pay for These tests for your condition		Medicare does not pay for these tests as often as this (denied as too frequent)	Medicare does not pay for experimental or research use tests
☐ AFP: 82105	☐ IBC: 83550	☐ Cardiovascular Dis Scr: 80061, 82465, 83718, 84478	☐ 878844 Acetylcholine Recept Pnl
☐ CA 15-3 & CA 27.29: 86300	☐ Immuno. Testing: 87536, 87539	☐ Colorectal Cancer Screen: 82270, G0328	☐ 085926 AChR Blocking Ab, Ser.
☐ CA 19-9: 86301	☐ Iron: 83540	☐ Diabetes Scr. Tests: 82947, 82950, 82951	☐ 138315 Babesia Microti Ant. Pnl
☐ CA 125: 86304	☐ LDL Cholesterol DM: 83721	☐ Digoxin: 80162	☐ 140848 Chromogranin A
☐ CBC: 85004, 85007, 85008, 85013-85032, 85048, 85049	☐ Lead: 83655	☐ GGT: 82977	☐ 511121 CMV DNA Detect/Quant
☐ CEA: 82378	☐ Lipid Panel: 80061	☐ Glucose: 82947, 82948, 82962	☐ 138610 Cytomegalovirus Quant.
☐ Cholesterol: 82465	☐ Lipoprotein: 83700, 83701, 83704	☐ HGB A1C: 83036	☐ 164722 Ehrlichia Ab Panel
☐ Collagen Cross Links: 82523	☐ Lithium, Assay: 80178	☐ Pap Screen: G0123, G0124, G0141-G0148, P3000-P3001	☐ 163583 H. Pylori Antibodies
☐ Cytogenetic: 88230-88299	☐ Occult Blood: 82272, G0394	☐ Prothrombin Time: 85610	☐ 480038 hCG, Beta Subunit, Qn
☐ Digoxin: 80162	☐ Prothrombin Time: 85610	☐ PSA Screen: G0103	☐ 163204 Helicobacter Pylori
☐ Ferritin: 82728	☐ PSA Total: 84153	☐ PSA Total: 84153	☐ 505026 HNK1 (CD57) Panel
☐ Flow Cytometry: 88182, 88184-88189	☐ PTT: 85730	☐ T3 Uptake: 84479	☐ 138293 JC/BK Virus DNA PCR
☐ Fructosamine: 82985	☐ T3 Uptake: 84479	☐ T4 Free: 84439	☐ 505321 Lymphocyte Act. Profile
☐ GGT: 82977	☐ T4 Free: 84439	☐ T4 Total: 84436	☐ 511238 MTHFR
☐ Glucose: 82947, 82948, 82962	☐ T4 Total: 84436	☐ TSH: 84443	☐ 512094 PreGen-Plus™
☐ Hepatitis Panel: 80074	☐ Transferrin: 84466	☐ Other _____	☐ 140194 PTH-Related Peptide
☐ hcG: 84702, 84703	☐ Triglycerides: 84478	☐ Other _____	☐ 505750 T-Cell Activation
☐ HDL Cholesterol: 83718	☐ TSH: 84443	☐ Other _____	☐ 163253 Tetanus/Diphtheria Ab
☐ HGB A1C: 83036	☐ Urine Culture: 87086, 87088		☐ 826008 Tryptase
☐ HIV Tests: 86689, 86701-86703, 87390, 87391, 87534, 87535	☐ Other _____		☐ Other _____
	☐ Other _____		☐ Other _____
	☐ Other _____		☐ Other _____
	☐ Other _____		☐ Other _____

The purpose of this form is to help you make an informed choice about whether or not you want to receive these laboratory tests, knowing that you might have to pay for them yourself. Before you make a decision about your options, you should **read this entire notice carefully**.

- Ask us to explain, if you don't understand why Medicare probably won't pay.
- Ask us how much these laboratory tests will cost you (**Estimated Cost: $_____ _____**), in case you have to pay for them yourself or through other insurance.

PLEASE CHOOSE **ONE** OPTION. CHECK **ONE** BOX. **SIGN & DATE** YOUR CHOICE.

☐ **Option 1. YES. I want to receive these laboratory tests.**
I understand that Medicare will not decide whether to pay unless I receive these laboratory tests. Please submit my claim to Medicare. I understand that you may bill me for laboratory tests and that I may have to pay the bill while Medicare is making its decision. If Medicare does pay, you will refund to me any payments I made to you that are due to me. If Medicare denies payment, I agree to be personally and fully responsible for payment. That is, I will pay personally, either out of pocket or through any other insurance that I have. I understand I can appeal Medicare's decision.

☐ **Option 2. NO. I have decided not to receive these laboratory tests.**
I will not receive these laboratory tests. I understand that you will not be able to submit a claim to Medicare and that I will not be able to appeal your opinion that Medicare won't pay. I will notify my doctor who ordered these laboratory tests that I did not receive them.

_____ _____

Date **Signature of patient or person acting on patient's behalf**

NOTE: Your health information will be kept confidential. Any information that we collect about you on this form will be kept confidential in our offices. If a claim is submitted to Medicare, your health information on this form may be shared with Medicare. Your health information which Medicare sees will be kept confidential by Medicare.

List of Medicare Limited Coverage Tests for North Carolina as of 04/01/2007:

*AFP (Alpha-Fetoprotein): 82105
Aluminum: 82108
Ambulatory Blood Pressure Monitoring (ABPM): 93784, 93786, 93788, 93790
Arsenic, Blood or Urine: 82175
*CA 15-3 & CA 27.29 (Tumor Antigen by Immunoassay): 86300
*CA 19-9 (Tumor Antigen by Immunoassay): 86301
*CA 125 (Tumor Antigen by Immunoassay): 86304
Cadmium, Urine: 82300
*Cardiovascular Disease Screening: 80061, 82465, 83718, 84478
*CBC (Blood Counts): 85004, 85007, 85008, 85013-85018, 85025, 85027, 85032, 85048, 85049
*CEA (Carcinoembryonic Antigen): 82378
*Cholesterol (Lipids): 82465
Chromium: 82495
*Collagen Cross Links, Any Method: 82523
*Colorectal Cancer Screen: 82270, G0328
Copper: 82525
*Cytogenetic Studies: 88230-88299, 88367, 88368
*Diabetes Screening Tests: 82947, 82950, 82951
*Digoxin (Digoxin Therapeutic Assay): 80162
Event Monitoring (Patient Demand Cardiac Event Recording): 93012, 93014, 93235-93237, 93268, 93270-93272
*Ferritin (Serum Iron Studies): 82728
Flow Cytometry: 88182, 88184-88189
*Fructosamine (Glycated Protein): 82985
*GGT (Gamma Glutamytransferase GGT): 82977
*Glucose (Blood Glucose Testing): 82947, 82948, 82962
*Gonadotropin, Qualitative (Human Chorionic Gonadotropin): 84703
*Gonadotropin, Quantitative (Human Chorionic Gonadotropin): 84702
*Hepatitis Panel: 80074
*HDL Cholesterol (Lipids): 83718
Heavy Metal (Antimony, Arsenic, Barium, Beryllium, Bismuth, Mercury): Screen: 83015
*HGB A1C (Glycated Hemoglogin): 83036
*Human Immunodeficiency Virus Testing: 86689, 86701-86703, 87390, 87391, 87534, 87535, 87537, 87538
*IBC (Serum Iron Studies): 83550
*Immunodeficiency Virus Testing (Prognosis Including Monitoring): 87536, 87539
*Iron (Serum Iron Studies): 83540
*LDL Cholesterol DM (Lipids): 83721
Lead: 83655
*Lipid Panel (Lipids): 80061
*Lipoproteins (Lipids): 83700, 83701, 83704
Lithium Assay: 80178
Mammography, Diagnostic: 77051, 77055, 77056, G0204, G0206
Mammography, Screening: 77052, 77057, G0202
Manganese: 83785
Mercury, Quantitative: 83825
Nickel: 83885
*Occult Blood (Fecal Occult Blood): 82272, G0394
*Pap Screen: G0123, G0124, G0141-G0148, P3000, P3001
*Pap Smears: 88141, 88150
*Prothrombin Time: 85610
*PSA Screen (Prostate Cancer Screening): G0103
*PSA Total (Prostate Specific Antigen (PSA)): 84153
*PTT (Partial Thromboplastin Time): 85730
Selenium: 84255
Silica: 84285
*T3 Uptake (Thyroid Testing): 84479
*T4 Free (Thyroid Testing): 84439
*T4 Total (Thyroid Testing): 84436
*Transferrin (Serum Iron Studies): 84466
*Triglycerides (Lipids): 84478
*TSH (Thyroid Testing): 84443
Unlisted Chemistry Procedure: 84999
*Urine Culture (Urine Bacterial Culture): 87088, 87086
Zinc: 84630

List of Tests Subject to Frequency Limitations for North Carolina as of 04/01/2007:

*CA 125 (Tumor Antigen by Immunoassay): 86304
*Cardiovascular Disease Screening: 80061, 82465, 83718, 84478
*CEA (Carcinoembryonic Antigen): 82378
*Cholesterol (Lipids): 82465
*Collagen Cross Links, Any Method: 82523
*Colorectal Cancer Screening: 82270, G0328
*Diabetes Screening Tests: 82947, 82950, 82951
*Digoxin (Digoxin Therapeutic Assay): 80162
*Ferritin (Serum Iron Studies): 82728
*Fructosamine (Glycated Protein): 82985
*GGT (Gamma Glutamytransferase GGT): 82977
*Glucose (Blood Glucose Testing): 82947, 82948, 82962
*Gonadotropin, Quantitative (Human Chorionic Gonadotropin): 84702
*HDL Cholesterol (Lipids): 83718
*HGB A1C (Hemoglobin; Glycated): 83036
*Human Immunodeficiency Virus Testing: 86689, 86701-86703, 87390, 87391, 87534, 87535, 87537, 87538
*LDL Cholesterol DM (Lipids): 83721
*Lipid Panel (Lipids): 80061
*Occult Blood (Fecal Occult Blood): 82272, G0394
*Pap Screen: G0123, G0124, G0141-G0148, P3000, P3001
*Prothrombin Time: 85610
*PSA Screen (Prostate Cancer Screening): G0103
*PSA Total (Prostate Specific Antigen (PSA)): 84153
*T3 Uptake (Thyroid Testing): 84479
*T4 Free (Thyroid Testing): 84439
*T4 Total (Thyroid Testing): 84436
*Triglycerides (Lipids): 84478
*TSH (Thyroid Testing): 84443

Tests highlighted in bold are not preprinted on the front of this form. If ordered and applicable, please write these tests in the 'Other' blank below the appropriate reason(s).

*National Policy.

There can be no representation or warranty as to the accuracy or completeness of this information. To ensure accurate information, please contact the CIGNA Medicare Part B office at 866-238-9651.