SECTION:	Approved:	1		Revised:
COMPLIANCE	07/01/08	07/0	1/08	03/08/12
CHAPTER:	Replaces Po	olicy Rev	ised: 07/	01/08
BILLING:	Retired:			
POLICY:				
MEDICARE ADVANCED BENEFICIARY	PAGE	1	OF	7
NOTICE OF NONCOVERAGE ("ABN")				

## I. PURPOSE

This Policy is to ensure that an appropriate Advance Beneficiary Notice of Noncoverage ("ABN") is obtained from Medicare beneficiaries for laboratory tests, procedures and other medical services that the provider believes Medicare probably or certainly will not pay for because the test, procedure or service has been deemed by Medicare as not reasonable and necessary under the circumstances.

# II. POLICY

An ABN must be obtained from the Medicare patient or his/her authorized representative prior to providing any services that may be denied by Medicare as not "reasonable and necessary." The ABN allows the patient to make an informed consumer decision whether or not to receive the items or services for which he or she may have to pay out of pocket or through other insurance.

Each Department is responsible for knowing the current Medicare rules for services that may be denied by Medicare as not reasonable and necessary. Medicare coverage rules can be found in federal statutes and regulations, the Medicare Benefits Policy Manual, the Medicare National Coverage Determinations Manual (together with the Benefits Policy Manual, the "Manuals"), the J5 MAC B Local Coverage Determinations ("LCDs") and in any notices provided to an individual Creighton provider.

## III. SCOPE

This policy only applies to services provided to Medicare beneficiaries. This policy does not apply to Medicare General Program Exclusion services (i.e., services that are never covered by Medicare, such as preventative annual examinations, cosmetic surgery, etc.).

This policy applies to all employees and agents of Creighton Medical Associates, Creighton Medical Laboratories and the School of Medicine.

SECTION:	Approved:	1		Revised:
COMPLIANCE	07/01/08	07/01/08	-	03/08/12
CHAPTER:	Replaces Po	olicy Revised:	07/0	1/08
BILLING:	Retired:			
POLICY:				
MEDICARE ADVANCED BENEFICIARY	PAGE	2 0	F	7
NOTICE OF NONCOVERAGE ("ABN")				

# IV. PROCEDURE

In addition to Medicare rules, the guidelines set forth below must be followed to ensure that an ABN is obtained in accordance with Medicare requirements. Failure to follow these guidelines will result in an inability to bill the patient for any services that Medicare determines are not reasonable and necessary.

- A. Advanced Beneficiary Notice of Noncoverage Required. An Advanced Beneficiary Notice of Noncoverage must be obtained when one or more of the following circumstances exist:
  - The service or test may not or does not meet Medicare's medical necessity requirements as stated by Medicare in federal statute/regulations, the Manuals, LCDs or individual notice to providers.
  - The service or test may only be paid for a limited number of times within a specified time period and this service or test may exceed that limit (e.g., certain preventive screening tests, vaccinations).
  - The service or test is for investigative, research, or experimental use only.
  - The patient requests a more extensive service or test than is deemed to be medically necessary by the provider.

# B. Obtaining an Advanced Beneficiary Notice of Noncoverage.

# 1. Format and Content.

- a. ABNs must be reproduced on a single page. The page may be either letter or legal-size. The ABN must be easy to read using no less than 12-point font with no italics or other hard to recognize type face.
- b. The entries in blanks on the ABN may be typed or handwritten but should be large enough (i.e., approximately 12point font) to allow ease in reading. The following content is required:

SECTION:	Approved:	Effective D		Revised:
COMPLIANCE	07/01/08	07/01/0	8	03/08/12
CHAPTER:	Replaces Po	olicy Revise	d: 07/	01/08
BILLING:	Retired:			
POLICY:				
MEDICARE ADVANCED BENEFICIARY	PAGE	3 (	OF	7
NOTICE OF NONCOVERAGE ("ABN")				

- i. At a minimum, the name, address and telephone number (including TTY when appropriate) of the provider giving the notice. This information may be contained in a logo.
- ii. Patient name. The patient's name should include the middle initial if used on the patient's Medicare card. Providers should also include an identification number that helps to link the ABN with the related claim; however, the patient's Medicare number will no longer be used on the CMS-R-131 form.
- iii. The items or services that may be denied.
- iv. The reason for noncoverage. There must be at least one reason applicable to each item or service, although, the same reason can apply to multiple items or services. Possible reasons include:
  - Medicare does not pay for these services for your condition.
  - Medicare does not pay for these services as often as this (denied as too frequent).
  - 3) Medicare does not pay for experimental or research use services.
- v. Estimated cost. Providers must enter a good faith cost estimate for any items or services included on the ABN.
- vi. The option box that the patient or authorized representative must complete.
- vi. Patient (or authorized representative) signature and date.
- 2. <u>ABN Form.</u> Use the Advance Beneficiary Notice of Noncoverage (ABN) (CMS-R-131) (03/11) form. A copy of the form with annotations and instructions is attached hereto as Exhibit A (annotations should be removed from the form prior to use). The ABN form (in English and Spanish) and instructions are posted on

SECTION:	Approved:	Effectiv		Revised:
COMPLIANCE	07/01/08	07/0	1/08	03/08/12
CHAPTER:	Replaces Policy Revised: 07/01/08			01/08
BILLING:	Retired:			
POLICY:				
MEDICARE ADVANCED BENEFICIARY	PAGE	4	OF	7
NOTICE OF NONCOVERAGE ("ABN")				

the Centers for Medicare and Medicaid Services ("CMS")
Beneficiary Notice Initiative web page (www.cms.hhs.gov\bni).

3. Process. The ABN must be explained and delivered to the patient (or his/her authorized representative) by knowledgeable staff (i.e., physician, resident, nurse, medical assistant) prior to beginning the service or procedure. Staff must answer any patient questions prior to signature. The ABN must be delivered far enough in advance that the patient or authorized representative has time to consider options and make an informed choice. Registration personnel should not obtain the ABN. The ABN form must be completed and signed by the patient (or his/her authorized representative) AT OR BEFORE THE START OF CARE. The patient shall not be asked to sign an ABN until all information on the form is completed.

An "authorized representative" is a person who is acting on the patient's behalf and in the patient's best interests, and who does not have a conflict of interest with the patient, when the patient is temporarily or permanently unable to act for himself or herself. An individual authorized under state law to make health care decisions (e.g., a legally appointed representative or guardian of the patient (if, for example, the patient has been legally declared incompetent by a court)), or an individual exercising explicit legal authority on the patient's behalf (e.g., in accordance with a properly executed "durable medical power of attorney" statement or similar document), may be the authorized representative of the patient with respect to receiving notice. A person (typically, a family member or close friend) whom the patient has indicated may act for him or her, but who has not been named in any legally binding document conveying such a role to that person may be an authorized representative. In the absence of some more compelling consideration, the order of priority of authorized representatives is:

- a. The spouse, unless legally separated.
- b. An adult child.
- c. A parent.
- d. An adult sibling.

SECTION:	Approved:	1	ve Date:	Revised:
COMPLIANCE	07/01/08	07/0	)1/08	03/08/12
CHAPTER:	Replaces Po	olicy Rev	rised: 07/	01/08
BILLING:	Retired:			
POLICY:				
MEDICARE ADVANCED BENEFICIARY	PAGE	5	OF	7
NOTICE OF NONCOVERAGE ("ABN")				

- e. A close friend (defined as "an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, and who is reasonably available").
- 4. <u>Patient Signature.</u> The patient has two choices when services may not be considered reasonable and necessary and therefore may not be covered by Medicare:
  - Agree to obtain the service(s) and be responsible for payment should Medicare deny payment, or
  - Refuse to be responsible for payment and not obtain the service(s).

The patient or his/her authorized representative must select one of the above options on the form and then sign the ABN **BEFORE** services/items are provided.

- 5. Patient Demands Service but Refuses to Sign. If the patient demands the service(s) and refuses to pay or sign the ABN form, then two witnesses should sign the ABN form and a note should be made that the patient refused to sign. In this case, the service(s) may be provided and if Medicare payment is denied, the patient can be billed for payment.
- 6. Routine Use of ABNs. Routine use of the ABN is **prohibited**. There must be a specific reason to believe Medicare will determine that the service(s) ordered may not be considered **reasonable and necessary**.
- 7. <u>Delivery of signed ABN.</u> The completed and signed ABN should be distributed as follows:
  - Original to the patient's medical record.
  - b. One copy to the patient.
  - If tests are ordered off site, one copy to the entity providing the testing services (i.e., laboratory, radiology, cardiology, etc.).

SECTION:	Approved:	Effective	Date:	Revised:
COMPLIANCE	07/01/08	07/01	/08	03/08/12
CHAPTER:	Replaces Policy Revised: 07/01/08			01/08
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MEDICARE ADVANCED BENEFICIARY	PAGE	6	OF	7
NOTICE OF NONCOVERAGE ("ABN")				

# C. Billing Modifiers.

- 1. Medicare modifiers should be used as follows:
  - GA Modifier. Use this modifier when the ABN was signed and is on file. You should also use this modifier when the patient refuses to sign the ABN but still demands the service if two witnesses have signed the ABN form noting the patient's refusal to sign. For services provided by the laboratory and billed to the contractor on UB-92 forms, utilize occurrence code "32" when there is a signed ABN on file.
  - **GZ Modifier**. Use this modifier when the claim is expected to be denied as "not reasonable and necessary" but no ABN was obtained. Beneficiaries may not be billed for any claim to which the "GZ" modifier is appended.
  - GY Modifier. Use this modifier when the claim is expected to be denied as "noncovered". ABNs are not required when these types of services are provided (i.e., routine physicals). This modifier is for informational use by the Carrier and does not prevent directly billing the patient for the service. The "GY" modifier should be used when the patient refuses to pay until Medicare denies the claim.

# D. Implementation

- 1. It is the responsibility of each Department, and Creighton Medical Associates (CMA) to educate staff (i.e., physicians, nurses, coding/billing staff and front-end staff) on the contents of this policy and Medicare's requirements and to designate staff who are responsible for obtaining the ABN.
- In general the ABN should be kept for five years from the date of care delivery. Health care providers/suppliers are required to keep a record of the ABN in all cases, including those cases in which the beneficiary declined care, refused to choose an option, or refused to sign the notice.

SECTION:	Approved:	Effective Da	
COMPLIANCE	07/01/08	07/01/08	03/08/12
CHAPTER:	Replaces Po	olicy Revised:	07/01/08
BILLING:	Retired:		
POLICY:			
MEDICARE ADVANCED BENEFICIARY	PAGE	7 O	F 7
NOTICE OF NONCOVERAGE ("ABN")			

# V. <u>ADMINISTRATION AND INTERPRETATIONS</u>

Questions regarding this policy may be addressed to your Department Administrator, Service Line Director, Clinic Manager or the Billing Compliance Director.

# VI. AMENDMENTS OR TERMNATION OF THIS POLICY

This policy may be amended or terminated at any time.

# VII. REFERENCES

42 U.S.C. §1395pp, Medicare Claims Processing Manual, Chapter 30, and CMS' website: http://www.cms.hhs.gov/bni

B. Patient Name:		C. Identification Number:	
Advanc	e Beneficia	ary Notice of Noncoverage	(ABN)
ledicare does not pay fo	r everything, ev	below, you may have twen some care that you or your health ect Medicare may not pay for the <b>D.</b>	care provider have
<b>D.</b>		E. Reason Medicare May Not Pay:	
<ul> <li>Ask us any ques</li> <li>Choose an option</li> <li>Note: If you choose that you me</li> </ul>	so you can ma tions that you n n below about v ose Option 1 o night have, but	ake an informed decision about your can have after you finish reading.  whether to receive the <b>D.</b> or 2, we may help you to use any other Medicare cannot require us to do this.	listed above. insurance
		x. We cannot choose a box for you.	
also want Medicare bille Summary Notice (MSN) payment, but I can app does pay, you will refun I OPTION 2. I want task to be paid now as I OPTION 3. I don't was	ed for an officia  I understand  eal to Medicar  d any payment  he D  am responsible  ant the D  payment, and I	listed above. You may ask to be decision on payment, which is sent to that if Medicare doesn't pay, I am respect by following the directions on the MS ts I made to you, less co-pays or deduce listed above, but do not bill Me for payment. I cannot appeal if Medicare well cannot appeal to see if Medicare well	o me on a Medicare consible for SN. If Medicare ctibles. dicare. You may icare is not billed with this choice I
his notice gives our o	oinion, not an Iling, call 1-800	official Medicare decision. If you ha D-MEDICARE (1-800-633-4227/TTY: 1	-877-486-2048).
I. Signature:	t you have rece	eived and understand this notice. You a	aiso receive a copy

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

B. Nombre del paciente:	<u> </u>	Número de identificación	* *
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		o solamente. No pode	mos escoger un
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también deseo que se co	bre a Medicare a fin de d	que se expida una decisión	oficial sobre el pago,
la cual se me enviará en	el Resumen de Medicare	e (MSN). Entiendo que si M	edicare no paga, soy
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En esta notificación se o	da a conocer nuestra or	oinión, no la de Medicare.	Si tiene otras
preguntas sobre la presen	nte notificación o el cobro	a Medicare, llame al 1-800	-MEDICARE (1-800-
633-4227/ <b>TTY</b> : 1-877-486	i-2048).		•
entrega una copia.	ca que na recibido y cor	nprende la presente notifica	ación. También se le
I. Firma:		J. Fecha:	
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existentes, recabar los datos necesarios y lic	enar v revisar los datos recogidos. Si tien	puesta, incluido el tiempo para revisar las in e comentarios sobre la precisión del cálculo d	el tiempo o cugaranciae nara maiora
presente formulario, sírvase escribir a: CM	S, 7500 Security Boulevard, Attn: PRA F	teports Clearance Officer, Baltimore, Marylan	nd 21244-1850.

Formulario CMS-R-131 (03/11)

# Form Instructions Advance Beneficiary Notice of Noncoverage (ABN) OMB Approval Number: 0938-0566

## **Overview**

The ABN is a notice given to beneficiaries in Original Medicare to convey that Medicare is not likely to provide coverage in a specific case. "Notifiers" include physicians, providers (including institutional providers like outpatient hospitals), practitioners and suppliers paid under Part B, as well as hospice providers and religious non-medical health care institutions (RNHCIs) paid exclusively under Part A. They must complete the ABN as described below, and deliver the notice to affected beneficiaries or their representative before providing the items or services that are the subject of the notice. (Note that Medicare inpatient hospitals, skilled nursing facilities (SNFs), and home health agencies (HHAs) use other approved notices for this purpose.)

The ABN must be verbally reviewed with the beneficiary or his/her representative and any questions raise during that review must be answered before it is signed. The ABN must be delivered far enough in advance that the beneficiary or representative has time to consider the options and make an informed choice. Employees or subcontractors of the notifier may deliver the ABN. ABNs are never required in emergency or urgent care situations. Once all blanks are completed and the form is signed, a copy is given to the beneficiary or representative. In all cases, the notifier must retain the original notice on file.

#### **ABN Changes**

The ABN is a formal information collection subject to approval by the Executive Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). As part of this process, the notice is subject to public comment and re-approval every 3 years. The revised ABN included in this package incorporates: suggestions for changes made by notifiers over the past 3 years of use, refinements made to similar liability notices in the same period based on consumer testing and other means, as well as related Medicare policy changes and clarifications occurring in the same interval. We have made additional changes based on suggestions received during the recent public comment period.

This version of the ABN continues to combine the general ABN (ABN-G) and the laboratory ABN (ABN-L) into a single notice, with an identical OMB form number. As combined, however, the new notice will capture the overall improvements incorporated into the revised ABN while still permitting pre-printing of the lab-specific key information and denial reasons used in the current ABN-L.

Also, note that while previously the ABN was only required for denial reasons recognized under section 1879 of the Act, the revised version of the ABN may also be used to provide voluntary notification of financial liability. Thus, this version of the ABN should eliminate any widespread need for the Notice of Exclusion from Medicare Benefits (NEMB) in voluntary notification situations.

Instructions for completion of the form are set forth below. Once the new ABN approval process is completed, CMS will issue detailed instructions on the use of the ABN in its on-line Medicare Claims Processing Manual, Publication 100-04, Chapter 30. Related policy on billing and coding of claims, and as well as coverage determinations, is found elsewhere in the CMS manual system or website (www.cms.hhs.gov).

#### Completing the Notice

OMB-approved ABNs are placed on the CMS website at: <a href="http://www.cms.hhs.gov/BNI">http://www.cms.hhs.gov/BNI</a>. Notices placed on this site can be downloaded and should be used as is, as the ABN is a standardized OMB-approved notice. However, some allowance for customization of format is allowed as mentioned for those choosing to integrate the ABN into other automated business processes. In addition to the generic ABN, CMS will also provide alternate versions with certain blanks completed for those not wishing to do additional customization as permitted, including a version illustrating laboratory-specific use of the notice.

ABNs must be reproduced on a single page. The page may be either letter or legal-size, with additional space allowed for each blank needing completion when a legal-size page is used.

#### Sections and Blanks:

There are 10 blanks for completion in this notice, labeled from (A) through (J), with accompanying instructions for each blank below. We recommend that the labels for the blanks be removed before use. Blanks (A)-(F) and blank (H) may be completed prior to delivering the notice, as appropriate. Entries in the blanks may be typed or hand-written, but should be large enough (i.e., approximately 12-point font) to allow ease in reading. (Note that 10 point font can be used in blanks when detailed information must be given and is otherwise difficult to fit in the allowed space.) The Option Box, Blank (G), must be completed by the beneficiary or his/her representative. Blank (I) should be a cursive signature, with printed annotation if needed in order to be understood.

#### Header

#### Blank (A) Notifier:

Notifiers may elect to place their logo at the top of the notice by typing, hand-writing, pre-printing, use of a label or other means. At a minimum, the name, address, and telephone number (including TTY when appropriate) of the notifier must appear, whether incorporated into the logo or not, to ensure the beneficiary's

ability to follow-up with additional questions. The title for Blank (A)—that is, "Notifier", may be completely removed during reproduction to accommodate letterhead type logos that go across the entire page. 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.

#### Blank (B) Patient Name:

Notifiers must enter the first and last name of the beneficiary receiving the notice, and middle initial should also be used if on the beneficiary's Medicare (HICN) card. (Note that the ABN will not be invalidated by a misspelling or missing initial, as long as the beneficiary or representative recognizes the name listed as that of the beneficiary.)

#### Blank (C) Identification Number:

Notifiers should enter an identification number for the beneficiary that helps to link the notice with a related claim when applicable. However, this field is optional, and choosing not to enter a number does not invalidate the ABN. The beneficiary's Medicare number or HICN will no longer be used.

#### **Body**

The body of the notice consists of the text below the header, the box to record the items and services, reasons coverage is not expected and estimated cost, and the remaining text above the options box. Consistent with past policy, ABNs can be used for a single item or service or multiple items or services. However, when there are multiple items or services at issue, the name of each item or service, the reason it is not covered by Medicare and the estimated cost must be presented in a parallel format that enables the beneficiary or representative to match particular items or services with the applicable reason and cost information. Gridlines may be used across the box for this purpose. A standard letter-size downloadable ABN allows for entry of at least 6 lines across the box containing items, reasons and costs at 12 point font.

Note that it is permissible for multiple items or services to all be explained by one reason or bundled under one cost, in which case the same information would not have to be entered multiple times. Itemized costs may be totaled but this is not required.

If more items or services need to be described than fit onto the one-page ABN, use of an attached sheet is permissible. In such cases, the presence of an attachment should be noted in the box on the first page, and the attachment should again allow for clear matching of the items or services in question with the reason and cost information. The attachment should be retained along with the first page of the ABN. Note that common or high-volume items or services, reasons and costs may be pre-printed in the notice, though "blank" ABNs should also be available to allow for less commonly performed procedures.

Note that a box must appear around the items and services, reasons and costs, and that each of these sections must be clearly labeled with the proper heading. However, the shading included in this box is not mandatory. As a general rule, shading and shadowing is not required anywhere on the notice, although it is recommended if possible, since consumer testing has shown such shading to be useful in assuring beneficiaries' attention. Similarly, other limited formatting modifications are permissible to accommodate automated business processes—for example, vertical lines are recommended but do not have to appear between the columns, and the width and length of the entire box can be adjusted on the page.

## Blank (D) Title Unfilled:

Though these instructions use the default term "items and services", consistent with the Medicare statute, the label "Blank (D)"—which is used in various parts of the ABN—may vary in its wording. The most appropriate of the following choices can be inserted by the individual notifier in preparing the ABN before it is delivered (i.e., in pre-printing the notice):

- Item(s)
- Service(s)
- Item(s) or service(s)
- Laboratory test(s)
- Test(s)
- Procedure(s)
- Care
- Equipment
- Supply(ies)

Note the variable "s" may or may not appear, or a space can be left so that an "s" can be entered when appropriate, or appear and be crossed out when not appropriate. CMS will also post at least one version of the notice with Blank (D) filled in for those wishing just to download a notice needing only the individual case-specific information to be entered.

In filling in the column under Blank (D) in the body of the ABN, notifiers must enter the name/description of all items or services that are the subject of the notice. The description may include a date, if that is relevant. Whenever possible, language that is easy for beneficiaries to understand should be used. If technical language must be used, it must be explained verbally to the beneficiary or representative. It is never permissible to add items or services to Blank (D) after the beneficiary or representative has signed the notice. The ABN is only effective for items and services clearly described on the notice at the time it is signed by the beneficiary or representative.

#### Blank (E) Reason Medicare May Not Pay:

Under the heading for this blank, notifiers must explain, in beneficiary-friendly language, why they believe the care that is the subject of the notice is not covered

by Medicare. There must be at least one reason applicable to each item or service listed, although, as mentioned above, the same reason can apply to multiple things.

In the previous version of the ABN-L, there were 3 possible reasons for noncoverage pre-printed on the ABN:

- "Medicare does not pay for these tests for your condition"
- "Medicare does not pay for these test as often as this (denied as too frequent)"
- "Medicare does not pay for experimental or research use tests"

These reasons are still appropriate for use in Blank (E) of this ABN. Note there are many other possible valid reasons in addition to the examples given above.

#### Blank (F) Estimated Cost:

Notifiers must enter a cost estimate under the heading for Blank (F) for any items or services described in Blank (D). As noted above, there is flexibility in listing individual or total cost. The revised ABN will not be considered valid absent a good faith attempt to estimate cost. CMS will be flexible in defining what a good faith estimate is, particularly in consideration of cases where the ordering and rendering providers may be different.

# Option Box and Additional Information

#### Blank (G) Options:

The option box now has a title that stretches across the page, which should prove easier for systems formatting purposes. Also, we have included additional guidance within the options to reinforce critical aspects of the choice that a patient has to make. (As noted above shading of the header line and shadowing of the checkboxes in the option box are recommended but not mandatory.)

These 3 checkboxes represent the beneficiary's possible choices regarding the potentially noncovered care described in the body of the ABN. The beneficiary or representative must select only 1 of the 3 checkboxes. Under no circumstances can the notifier decide for the beneficiary or representative which of the 3 checkboxes to select. If the beneficiary cannot or will not make a choice, the notice should be annotated.

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

#### Blank (H) Additional Information:

Space is provided below the Option Boxes for additional information to be inserted on the ABN. Notifiers are permitted to use this space for additional clarification that will be of use to beneficiaries. Possible uses of this space by notifiers include:

- The former ABN-L language, "[You should] notify your doctor who orders these laboratory tests you did not receive them";
- Providing context on Medicare payment policy applicable to a specific benefit;
- Information on other insurance coverage for beneficiaries needing immediate reassurance of additional coverage.

Note that the ABN no longer includes an "Other Insurance" blank. Instead, the body of the notice now indicates that the notifier may help the patient to access any other insurance, although not required by the Medicare program. In addition, as noted above, notifiers may use the "Additional Information" space to record other payer information if they so choose. Under the "Additional Information" section, the ABN now alerts beneficiaries that the ABN conveys the notifier's opinion, not an official Medicare decision, and also that the 1-800-MEDICARE number is available for additional help when needed.

#### Signature Box

### Blank (I) Signature:

The beneficiary or representative must sign the notice, with his or her own name, in this box simply labeled "Signature", to allow maximum space for making the written entry. The signature indicates that he or she has received the notice and understands its contents.

#### Blank (J) Date:

The beneficiary or representative must enter the date he or she signed the ABN.

#### **Disclosure Statement**

The disclosure statement is not specific to the ABN but is required by OMB to appear on applicable information collections. It replaces the previous statement on confidentiality of ABN information.