CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1587	**Date: September 5, 2008**
	Change Request 6136

SUBJECT: Revised Form CMS-R-131 Advance Beneficiary Notice of Noncoverage

I. SUMMARY OF CHANGES: Prior to March 3, 2008, providers, practitioners, and suppliers paid under Part B as well as hospice providers and religious non-medical health care institutions paid under Part A were instructed to use the general Advance Beneficiary Notice (ABN-G) or laboratory Advance Beneficiary Notice (ABN-L) to inform beneficiaries of their potential liability in accordance with the limitation on liability provisions set forth in Section 1879 of the Social Security Act. Beginning on March 3, 2008, CMS implemented use of the revised Advance Beneficiary Notice of Noncoverage (ABN). The revised ABN combines the ABN-G and the ABN-L into a single notice, with the same form number (CMS R-131).

NEW / REVISED MATERIAL
EFFECTIVE DATE: *March 3, 2008
IMPLEMENTATION DATE: March 1, 2009

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
R	30/Table of Contents
R	30/50/Form CMS-R-131 Advanced Beneficiary Notice of Noncoverage (ABN)
R	30/50.1/Introduction-General Information
D	30/50.1.1/Approved Standard Forms
D	30/50.1.2/User-Customizable Sections
D	30/50.1.3/Where to Obtain the ABN Forms
D	30/50.1.4/OMB Burden Notice for CMS-R-131
R	30/50.2/General Statutory Authority – Financial Liability Protections Provisions (FLP) of Title XVIII
R	30/50.2.1/Applicability to Limitation On Liability (LOL)

R	30/50.2.2/Compliance with Limitation on Liability Provisions
D	30/50.2.2.1/Non-Qualifying Categorical Exclusions
D	30/50.2.2.2/Non-Qualifying Technical Exclusions
D	30/50.2.2.3/When Services Will Not Be Furnished
D	30/50.2.2.4/M+C Enrollees and Non-Medicare Patients
D	30/50.2.3/Qualifying Categorical Exclusions
D	30/50.2.4/Qualifying Technical Exclusions
D	30/50.2.5/Routine ABNs
D	30/50.2.6/Qualified Recipients
R	30/50.3/ABN Scope
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N	30/50.3.2/Voluntary ABN Uses
R	30/50.4/Issuance of the ABN
N	30/50.4.1/Issuers of ABNs (Notifiers)
N	30/50.4.2/Recipients of the ABN
N	30/50.4.3/Representatives of Beneficiaries
R	30/50.5/ABN Triggering Events
D	30/50.5.1/ Format of Insertions on ABN
D	30/50.5.2/Guidelines for Customizing the ABN Header
D	30/50.5.3/Patient Name Line
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N	30/50.6.4/Retention
N	30/50.6.5/Other Considerations During ABN Completion
R	30/50.7/ABN Delivery Requirements

R	30/50.7.1/Effective Delivery
R	30/50.7.2/Options for Delivery Other than In Person
R	30/50.7.3/Effects of Lack of Notification, Medicare Review and Claim Adjudication
D	30/50.7.3.4/ABNs for Unassigned Claims for Medical Equipment and Supplies Which Are Denied on the Basis of §1862(a)(1) of the Act, as Not Reasonable and Necessary
D	30/50.7.4/ABN Standards for Partial Denials on the Basis of Medical Necessity
D	30/50.7.5/ABN Standards for Upgraded Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
D	30/50.7.6/ABN Standards for Services in Skilled Nursing Facilities (SNFs)
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N	30/50.12.1/Physicians' Services Refund Requirements
N	30/50.12.2/DMEPOS Refund Requirements (RR) Provision for Claims for Medical Equipment and Supplies
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N	30/50.12.4/Supplier's Right to Recover Resalable Items for Which Refund Has Been Made
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N	30/50.14.2/ Emergencies or Urgent Situations
N	30/50.14.3/ Repetitive or Continuous Noncovered Care
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R	30/150.12/Supplier Fails to Make Refund
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III. FUNDING:
SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1587	Date: September 5, 2008	Change Request: 6136

SUBJECT: Revised Form CMS R-131 Advance Beneficiary Notice of Noncoverage

EFFECTIVE DATE: March 3, 2008

IMPLEMENTATION DATE: March 1, 2009

I. GENERAL INFORMATION

A. Background:

Prior to March 3, 2008, providers, practitioners, and suppliers paid under Part B as well as hospice providers and religious non-medical health care institutions paid under Part A were instructed to use the general Advance Beneficiary Notice (ABN-G) or laboratory Advance Beneficiary Notice (ABN-L) to inform beneficiaries of their potential liability in accordance with the limitation on liability provisions set forth in Section 1879 of the Social Security Act. Beginning on March 3, 2008, CMS implemented use of the revised Advance Beneficiary Notice of Noncoverage (ABN). The revised ABN combines the ABN-G and the ABN-L into a single notice, with the same form number (CMS R-131).

The revised notice incorporates suggestions for changes made by users of the ABN and by beneficiary advocates based on experience with the current form, refinements made to similar liability notices through consumer testing and other means, as well as related Medicare policy changes and clarifications occurring in the same interval. Additional changes made to the form were based on comments and suggestions made during the recent public comment period.

B. Policy: The authorization for these requirements are Sections 1879, 1834(a)(18), 1834(j)(4), 1842(l) of the Social Security Act, as well as 42 CFR 411.404(b) and (c), and 411.408(d)(2) and (f), which specify written notice requirements. These requirements are fulfilled by the ABN and subject to the Paperwork Reduction Act of 1995.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6136.1	Beginning March 3, 2008 and prior to March 1, 2009	X	X	X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	Contractors shall accept the current ABN-G and ABN-L or the revised ABN as valid notification.										
6136.2	Beginning March 1, 2009, Contractors shall accept only a properly executed revised ABN (CMS R-131) as valid notification.	X	X	X	X						
6136.3	Contractors shall review the process associated with the revised ABN as indicated in the manual: 100-04/30.	X	X	X	X						
6136.4	Contractors shall perform additional individual provider education if alerted that a notifier is not complying with these instructions.	X	X	X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6136.5	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X	X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Charlayne Van, charlayne.van@cms.hhs.gov , 410-786-8659/Evelyn Blaemire, evelyn.blaemire@cms.hhs.gov , 410-786-1803

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VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Intermediaries (RHHIs):*

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Claims Processing Manual
Chapter 30 - Financial Liability Protections

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(Rev. 1587, 09-05-08)

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50 - Form CMS-R-131 Advance Beneficiary Notice of Noncoverage (ABN)
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

50.1 - Introduction - General Information

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Section 50 of the Medicare Claims Processing Manual establishes the standards for use by providers, practitioners, suppliers, and laboratories in implementing the revised Advance Beneficiary Notice of Noncoverage (ABN) (Form CMS-R-131), formerly the "Advance Beneficiary Notice". This section provides instructions regarding the notice that these providers issue to beneficiaries in advance of initiating, reducing, or terminating what they believe to be noncovered items or services. The ABN must meet all of the standards found in Chapter 30. Beginning March 1, 2009, the ABN-G and ABN-L will no longer be valid; and notifiers must begin using the revised Advance Beneficiary Notice of Noncoverage (CMS-R-131).

50.2 - General Statutory Authority - Financial Liability Protection Provisions (FLP) of Title XVIII
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

The Financial Liability Protection provisions (FLP) of the Social Security Act (the Act) protect beneficiaries and health care providers (physicians, practitioners, and suppliers) under certain circumstances from unexpected liability for charges associated with claims that Medicare does not pay. The FLP provisions include:

- *Limitation On Liability (LOL) under §1879(a)-(g) of the Act;*
- *Refund Requirements (RR) for Non-assigned Claims for Physicians Services under §1842(l) of the Act; and*
- *Refund Requirements (RR) for Assigned and Non-assigned Claims for Medical Equipment and Supplies under §§1834(a)(18), 1834(j)(4), and 1879(h) of the Act.*

50.2.1 - Applicability to Limitation On Liability (LOL)
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

The Limitation On Liability (LOL) protections of §1879 of the Act apply only when a provider believes that an otherwise covered item or service may be denied either as not reasonable and necessary under §1862(a)(1) of the Act or because the item or service constitutes custodial care under §1862(a)(9) of the Act. § 1879 of the Act requires a provider to notify a beneficiary in advance when he or she believes that items or services will likely be denied either as not reasonable and necessary or as constituting custodial care. If such notice is not given, providers may not shift financial liability for such items or services to beneficiaries should a claim for such items or services be denied by Medicare. Note that beneficiaries are not afforded LOL protection when items or services are denied for reasons other than those listed in the Financial Liability Protection Provisions of Title XVIII, which are listed in § 50.3.1.

50.2.2 - Compliance with Limitation On Liability Provisions
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A healthcare provider (herein referred to as a "notifier") who fails to comply with the ABN instructions risks financial liability and/or sanctions. LOL provisions shall apply as required by law, regulations, rulings and program instructions. Additionally, when authorized by law and regulations, sanctions under the Conditions of Participation (COPs) may be imposed.

The Medicare contractor will hold any provider who either failed to give notice when required or gave defective notice financially liable. A notifier who can demonstrate that he or she did not know and could not reasonably have been expected to know that Medicare would not make payment will not be held financially liable for failing to give notice. However, a notifier who gave defective notice may not claim that he or she did not know or could not reasonably have been expected to know that Medicare would not make payment as the issuance of defective notice is clear evidence of knowledge. The beneficiary is not protected from liability if there is clear evidence that he or she knew that Medicare would not make payment. See § 50.12 for Refund Requirements.

50.3 - ABN Scope
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

The revised ABN is the new CMS-approved written notice that is issued by providers, practitioners, suppliers, and laboratories for items and services provided under Medicare Part A (hospice and regional non-medical healthcare institutes only) and Part B and given to beneficiaries enrolled in the Medicare Fee-For-Service (FFS) program. The revised ABN may not be used for items or services provided under the Medicare Advantage (MA) Program or for prescription drugs provided under the Medicare Prescription Drug Program (Part D). The revised ABN will now be used to fulfill both mandatory and voluntary notice functions.

The revised ABN replaces the following notices:

- *ABN-G (CMS-R-131-G)*
- *ABN-L (CMS-R-131-L)*
- *NEMB (CMS-20007)*

Note to Skilled Nursing Facilities (SNFs): *Once the revised SNFABN is implemented, SNFs must use the revised SNFABN for all items and services billed to Part A and Part B.*

50.3.1 - Mandatory ABN Uses
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

The following are statutory provisions requiring delivery of the ABN:
- *§1862(a)(1) of the Act (not reasonable and necessary);*
- *§1834(a)(17)(B) of the Act (violation of the prohibition on unsolicited telephone contacts);*
- *§1834(j)(1) of the Act (medical equipment and supplies supplier number requirements not met);*

- *§1834(a)(15) of the Act (medical equipment and/or supplies denied in advance).*
- *§1862(a)(9) of the Act (custodial care);*
- *§1879(g)(2) of the Act (hospice patient who is not terminally ill).*

50.3.2 - Voluntary ABN Uses
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

ABNs are not required for care that is either statutorily excluded from coverage under Medicare (i.e. care that is never covered) or fails to meet a technical benefit requirement (i.e. lacks required certification). However, the ABN can be issued voluntarily in place of the Notice of Exclusion from Medicare Benefits (NEMB) for care that is never covered such as:

- *Care that fails to meet the definition of a Medicare benefit as defined in §1861 of the Social Security Act;*
- *Care that is explicitly excluded from coverage under §1862 of the Social Security Act. Examples include:*
    - *Services for which there is no legal obligation to pay;*
    - *Services paid for by a government entity other than Medicare (this exclusion does not include services paid for by Medicaid on behalf of dual-eligibles);*
    - *Services required as a result of war;*
    - *Personal comfort items;*
    - *Routine physicals and most screening tests;*
    - *Routine eye care;*
    - *Dental care; and*
    - *Routine foot care.*

50.4 - Issuance of the ABN
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

50.4.1 - Issuers of ABNs (Notifiers)
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

*Entities who issue ABNs are collectively known as "**notifiers**". These entities can include physicians, practitioners, providers (including laboratories), suppliers, Medicare contractors, or utilization review committees for the care provider.*

The notifier may direct an employee or a subcontractor to deliver an ABN. However, the notifier is ultimately responsible for effective delivery of the ABN.

When multiple entities are involved in rendering care, it is not necessary to give separate ABNs. Either party involved in the delivery of care can be the notifier when:

- *There are separate "ordering" and "rendering" providers (e.g. a physician orders a lab test and an independent laboratory delivers the ordered tests);*
- *One provider delivers the "technical" and the other the "professional" component of the same service (e.g. a radiological test that an independent diagnostic testing facility renders and a physician interprets); or*

- *The entity that obtains the signature on the ABN is different from the entity that bills for services (e.g. when one laboratory refers a specimen to another laboratory which then bills Medicare for the test).*

Regardless of who gives the notice, the billing entity will always be held responsible for effective delivery. When the notifier is not the billing entity, the notifier must know how to direct the beneficiary who received the ABN to the billing entity itself for questions and should annotate the Additional Information section of the ABN with this information. It is permissible to enter the names of more than one entity in the header of the notice.

50.4.2.-Recipients of the ABN

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Notifiers are required to give an ABN to FFS Medicare beneficiaries or their representatives. Recipients of ABNs include beneficiaries who have Medicaid coverage in addition to Medicare (i.e. dual-eligible). A notifier's inability to give notice to a beneficiary or his or her representative does not allow the notifier to shift financial liability to the beneficiary, unless he or she has exhausted all attempts to issue the notice and such attempts are clearly documented in the patient's record and undisputed by the beneficiary.

50.4.3 - Representatives of Beneficiaries

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Notifiers are responsible for determining who may act as a beneficiary's representative under applicable State or other law. A representative is an individual who may make health care and financial decisions on a beneficiary's behalf (e.g. the beneficiary's legal guardian or someone appointed according to a properly executed "durable medical power of attorney").

If the beneficiary wishes to appoint a representative to file an appeal on his or her behalf, a valid Form CMS-1696 or a conforming written instrument must be signed by both the beneficiary and the prospective representative and filed with the appeal request. See Chapter 29, § 270 for specific instructions related to the use of Form CMS-1696 and the appointment of representatives.

50.5 - ABN Triggering Events

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

*Notifiers are required to issue ABNs whenever limitation on liability applies. This typically occurs at three points during a course of treatment which are initiation, reduction, and termination, also known as "**triggering events**".*

A. Initiations

An initiation is the beginning of a new patient encounter, start of a plan of care, or beginning of treatment. If a notifier believes that certain otherwise covered items or services will be noncovered (e.g. not reasonable and necessary) at initiation, an ABN must be issued prior to the beneficiary receiving the non-covered care.

B. Reductions

A reduction occurs when there is a decrease in a component of care (i.e. frequency, duration, etc.). For example, a beneficiary is receiving outpatient physical therapy five days a week and wishes to continue therapy five days; however, the notifier believes that the beneficiary's therapy goals can be met with only three days of therapy weekly. This reduction in treatment would trigger the requirement for an ABN.

C. Terminations

Termination is the discontinuation of certain items or services. An example would be when a physical therapist no longer considers outpatient speech therapy described in a plan of care reasonable and necessary. An ABN would have to be issued prior to the termination of the speech therapy. If the beneficiary wishes to continue receiving noncovered speech therapy treatments upon receiving the ABN, he or she must select Option 1 or 2 on the ABN stating that he or she wants to receive the services and agrees to be financially responsible if Medicare does not pay.

Note to Hospice and CORF Providers: *In cases where there is a complete cessation of all Medicare covered services, the Expedited Determination notice must be issued by hospice and CORF providers. See §50.14.5 for detailed instructions on issuing Expedited Determination notices.*

50.6 - ABN Standards
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

50.6.1 - Proper Notice Documents
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

The ABN, Form CMS-R-131, is the Office of Management and Budget (OMB) approved standard notice. Failure to use this notice as mandated could result in the notice being invalidated and/or the notifier being held liable for the items or services in question.

Replicable copies of the OMB approved ABN (CMS-R-131) can be found in Appendices A and B of this section.

A. Language Choice

The ABN is available in English and Spanish under a dedicated link on the top left-hand margin of the web page given above: "FFS ABN". Notifiers should choose the appropriate version of the ABN based on the language the beneficiary best understands. Insertions must be in English when the English-language ABN is used. Similarly, when a Spanish-language ABN is used, the notifier should make insertions on the notice in Spanish if applicable. In addition, verbal assistance in other languages may be provided to assist beneficiaries in understanding the document. However, the printed document is limited to the OMB-approved English and Spanish versions. Notifiers should document any types of translation assistance that are used in the

"Additional Information" section of the notice. The notifier must retain either the English or Spanish ABN as signed by the beneficiary.

B. Effective Versions

ABNs are effective as of the OMB approval date given at the bottom of each notice. The routine approval is for 3-year use. Notifiers are expected to exclusively employ the effective version of the ABN. CMS will allow a 6-month transition period from the date of issuance of these instructions for mandatory use of the revised ABN. Thus, notifiers will be required to begin using the revised ABN beginning [insert date 6 months from issuance of these instructions].

50.6.2 - General Notice Preparation Requirements

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

The following are the general instructions notifiers must follow in preparing an ABN for mandatory use:

A. Number of Copies: *A minimum of two copies, including the original, must be made so the beneficiary and notifier each have one. The notifier should retain the original whenever possible.*

B. Reproduction*: Notifiers may reproduce the ABN by using self-carbonizing paper, photocopying, digitized technology, or another appropriate method. All reproductions must conform to applicable form and manual instructions.*

C. Length and Size of Page: *The ABN form must not exceed one page in length; however, attachments are permitted for listing additional items and services. If an attachment sheet is used, a notation such as "See Attached Page" must be inserted in the items/services (D) area of the ABN notice. Attachment pages must include the following:*

- *Beneficiary's name;*
- *Identification number (optional);*
- *Date of issuance;*
- *Table listing the additional items and/or services (D), the reasons Medicare may not pay (E), and the estimated costs (F); and*
- *A space underneath the table designated for Blanks (D)-(F), in which the beneficiary inserts his or her initials to acknowledge receipt of the attachment page.*

The attachment page must present a clear matching of each item or service in question with the reason and cost estimate information. Insertion of unrelated wording or information on the attachment is not permitted.

D. Contrast of Paper and Print: *A visually high-contrast combination of dark ink on a pale background must be used. Do not use reversed print (i.e. white print on black paper), or block-shaded (highlighted) text.*

E. Font: *To the extent practicable, the fonts as they appear in the ABN downloaded from the CMS web site should be used. Any changes in the font type must be based solely on limitations of the notifier's software and/or hardware. In such cases, notifiers should use alternative fonts that*

are easily readable, such as Arial, Arial Narrow, Times New Roman, and Courier. Font style and formatting must be maintained regardless of font type used.

Any other changes to the font, such as italics, embossing, bold, etc., should not be used since they can make the ABN more difficult to read. The font size generally should be 12-point. Titles should be 14 to16-point, but insertions in blanks of the ABN can be as small as 10-point if needed.
Information inserted by notifiers in the blank spaces on the ABN may be typed or legibly hand-written.

F. Customization: *Notifiers are permitted to do some customization of ABNs, such as pre-printing information in certain blanks to promote efficiency and to ensure clarity for beneficiaries. Notifiers may develop multiple versions of the ABN specialized to common treatment scenarios, using the required language and general formatting of the ABN. Blanks (G)-(I) must be completed by the beneficiary or his or her representative when the ABN is issued and may **never** be pre-filled. Lettering of the blanks (A-J) should be removed prior to issuance of an ABN.*

If pre-printed information is used to describe items/services and/or common reasons for noncoverage, the notifier must clearly indicate on the ABN which portions of the pre-printed information are applicable to the beneficiary. For example, pre-printed items or services that are inapplicable may be crossed out, or applicable items/services may be checked off.

Providers may pre-print a menu of items or services in Blank (D) and include a cost estimate alongside each item or service. For example, notifiers may merge the items/service section (Blank D) with the estimated cost section (Blank F), as long as the beneficiary can clearly identify the services and related costs that may not be covered by Medicare.

G. Modification*: The ABN may not be modified except as specifically allowed by these instructions and approved by the appropriate CMS Regional Office.*

Notifiers must exercise caution before adding any customizations beyond these guidelines, since such alterations could result in the ABN being invalidated and make the provider liable for noncovered charges. In general, Medicare contractors are responsible for determining whether an ABN is valid, and usually this determination is made as part of their review of ABN-related claims,; however, any complaints received regarding delivery of/failure to deliver an ABN may be investigated by the Medicare contractors and/or CMS' central or regional office staffs.

See appendix B for an example of an approved customization of the ABN which can be used by providers of laboratory services.

50.6.3 - Completing the ABN

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

The ABN is composed of five sections and ten blanks which must appear in the following order from top to bottom on the notice:

- *Header (Blanks A-C)*

- *Body (Blanks D-F)*
- *Option Box (Blank G)*
- *Additional Information (Blank H)*
- *Signature Box (Blanks I-J)*

A. Header

Blanks A-C, the header of the notice, must be completed by the notifier prior to delivering the ABN.

Blank (A) Notifier(s): *Notifiers must place their name, address, and telephone number (including TTY number when needed) at the top of the notice. This information may be incorporated into a notifier's logo at the top of the notice by typing, hand-writing, pre-printing, using a label or other means.*

If the billing and notifying entities are not the same, the name of more than one entity may be given in the notifier area as long as it is specified in the Additional Information (H) section who should be contacted for questions.

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

Blank (C) Identification Number: *Use of this field is optional. Notifiers may enter an identification number for the beneficiary that helps to link the notice with a related claim. The absence of an identification number does not invalidate the ABN. An internal filing number created by the notifier, such as a medical record number, may be used. Medicare numbers (HICNs) or Social Security numbers* ***must not*** *appear on the notice.*

B. Body

Blank (D)*: The following descriptors may be used in the header of Blank (D):*

  - *Item*
  - *Service*
  - *Laboratory test*
  - *Test*
  - *Procedure*
  - *Care*
  - *Equipment*

- *The notifier must list the specific items or services believed to be noncovered under the header of Blank (D).*
- *In the case of partial denials, notifiers must list in Blank (D) the excess component(s) of the item or service for which denial is expected.*

- *For repetitive or continuous noncovered care, notifiers must specify the frequency and/or duration of the item or service. See § 50.14.3 for additional information.*
- *General descriptions of specifically grouped supplies are permitted. For example, "wound care supplies" would be a sufficient description of a group of items used to provide this care. An itemized list of each supply is generally not required.*
- *When a reduction in service occurs, notifiers must provide enough additional information so that the beneficiary understands the nature of the reduction. For example, entering "wound care supplies decreased from weekly to monthly" would be appropriate to describe a decrease in frequency for this category of supplies; just writing "wound care supplies decreased" is insufficient.*

Blank (E) Reason Medicare May Not Pay: *In this blank, notifiers must explain, in beneficiary friendly language, why they believe the items or services described in Blank (D) may not be covered by Medicare. Three commonly used reasons for noncoverage are:*

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

To be a valid ABN, there must be at least one reason applicable to each item or service listed in Blank (D). The same reason for noncoverage may be applied to multiple items in Blank (D).

Blank (F) Estimated Cost: *Notifiers must complete Blank (F) to ensure the beneficiary has all available information to make an informed decision about whether or not to obtain potentially noncovered services.*

Notifiers must make a good faith effort to insert a reasonable estimate for all of the items or services listed in Blank (D). In general, we would expect that the estimate should be within $100 or 25% of the actual costs, whichever is greater; however, an estimate that exceeds the actual cost substantially would generally still be acceptable, since the beneficiary would not be harmed if the actual costs were less than predicted. Thus, examples of acceptable estimates would include, but not be limited to, the following:

For a service that costs $250:

- *Any dollar estimate equal to or greater than $150*
- *"Between $150-300"*
- *"No more than $500"*

For a service that costs $500:

- *Any dollar estimate equal to or greater than $375*
- *"Between $400-600"*
- *"No more than $700"*

Multiple items or services that are routinely grouped can be bundled into a single cost estimate. For example, a single cost estimate can be given for a group of laboratory tests, such as a basic

metabolic panel (BMP). Average daily cost estimates are also permissible for long term or complex projections. As noted above, providers may also pre-print a menu of items or services in Blank (D) and include a cost estimate alongside each item or service. If a situation involves the possibility of additional tests or procedures (such as in reflex testing), and the costs associated with such tests cannot be reasonably estimated by the notifier at the time of ABN delivery, the notifier may enter the initial cost estimate and indicate the possibility of further testing. Finally, if for some reason the notifier is unable to provide a good faith estimate of projected costs at the time of ABN delivery, the notifier may indicate in the cost estimate area that no cost estimate is available. We would not expect either of these last two scenarios to be routine or frequent practices, but the beneficiary would have the option of signing the ABN and accepting liability in these situations.

CMS will work with its contractors to ensure consistency when evaluating cost estimates and determining validity of the ABN in general. In addition, contractors will provide ongoing education to notifiers as needed to ensure proper notice delivery. Notifiers should contact the appropriate CMS regional office if they believe that a contractor inappropriately invalidated an ABN.

C. Options

Blank (G) Options: *Blank (G) contains the following three options:*

❑ ***OPTION 1.*** *I want the* ***(D)______*** *listed above. You may ask to be paid 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.*

This option allows the beneficiary to receive the items and/or services at issue and requires the notifier to submit a claim to Medicare. This will result in a payment decision that can be appealed.

Note: *Beneficiaries who need to obtain an official Medicare decision in order to file a claim with a secondary insurance should choose Option 1.*

❑ ***OPTION 2.*** *I want the* ***(D)_______*** *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.***

This option allows the beneficiary to receive the noncovered items and/or services and pay for them out of pocket. No claim will be filed and Medicare will not be billed. Thus, there are no appeal rights associated with this option.

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

This option means the beneficiary does not want the care in question. By checking this box, the beneficiary understands that no additional care will be provided and thus, there are no appeal rights associated with this option.

The beneficiary or his or her representative must choose only one of the three options listed in Blank (G). Under no circumstances can the notifier decide for the beneficiary which of the 3 checkboxes to select. Pre-selection of an option by the notifier invalidates the notice. However, at the beneficiary's request, notifiers may enter the beneficiary's selection if he or she is physically unable to do so. In such cases, notifiers must annotate the notice accordingly.

If there are multiple items or services listed in Blank (D) and the beneficiary wants to receive some, but not all of the items or services, the notifier can accommodate this request by using more than one ABN. The notifier can furnish an additional ABN listing the items/services the beneficiary wishes to receive with the corresponding option.

If the beneficiary cannot or will not make a choice, the notice should be annotated, for example: "beneficiary refused to choose an option".

D. Additional Information

Blank (H) Additional Information: *Notifiers may use this space to provide additional clarification that they believe will be of use to beneficiaries. For example, notifiers may use this space to include:*

- *A statement advising the beneficiary to notify his or her provider about certain tests that were ordered, but not received;*
- *Information on other insurance coverage for beneficiaries, such as a Medigap policy, if applicable ;*
- *An additional dated witness signature; or*
- *Other necessary annotations.*

Annotations will be assumed to have been made on the same date as that appearing in Blank J, accompanying the signature. If annotations are made on different dates, those dates should be part of the annotations.

E. Signature Box

Once the beneficiary reviews and understands the information contained in the ABN, the Signature Box is to be completed by the beneficiary (or representative). This box cannot be completed in advance of the rest of the notice.

Blank (I) Signature: *The beneficiary (or representative) must sign the notice to indicate that he or she has received the notice and understands its contents. If a representative signs on behalf of a beneficiary, he or she should write out "representative" in parentheses after his or her signature. The representative's name should be clearly legible or noted in print.*

Blank (J) Date: *The beneficiary (or representative) must write the date he or she signed the ABN. If the beneficiary has physical difficulty with writing and requests assistance in completing this blank, the date may be inserted by the notifier.*

Disclosure Statement: *The disclosure statement in the footer of the notice is required to be included on the document.*

50.6.4 - Retention

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Retention Requirements

The ABN must be prepared with an original and at least one copy. The beneficiary is given his or her copy of the signed and dated ABN immediately, and the notifier should retain the original ABN in the beneficiary's record. In certain situations, such as delivery by fax, the notifier may not have access to the original document upon signing. Retention of a copy of the signed document would be acceptable in specific cases such as this.

In a case where the notifier that gives an ABN is not the entity that ultimately bills Medicare for the item or service (e.g. when a physician issues an ABN, draws a test specimen, and sends it to a laboratory for testing), the notifier must give a copy of the signed ABN to the billing entity. The copy provided must be legible and may be a carbon, fax, electronically scanned, or photo reproduction copy.

Applicable retention periods for the ABN are discussed in Chapter 1 of this manual, §110. In general, it is 5 years from discharge/completion of delivery of care when there are no other applicable requirements under State law. Retention is required in all cases, including those cases in which the beneficiary declined the care, refused to choose an option, or refused to sign the notice.

50.6.5 - Other Considerations During ABN Completion

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A. Beneficiary Changes His or her Mind

If after completing and signing the ABN, a beneficiary changes his or her mind, the notifier should present the previously completed ABN to the beneficiary and request that the beneficiary annotate the original ABN. The annotation must include a clear indication of his or her new option selection along with the beneficiary's signature and date of annotation. In situations where the notifier is unable to present the ABN to the beneficiary in person, the notifier may annotate the form to reflect the beneficiary's new choice and immediately forward a copy of the annotated notice to the beneficiary to sign, date, and return.

In both situations, a copy of the annotated ABN must be provided to the beneficiary as soon as possible. If a related claim has been filed, it should be revised or cancelled if necessary to reflect the beneficiary's new choice.

B. Beneficiary Refuses to Complete or Sign the Notice

If the beneficiary refuses to choose an option and/or refuses to sign the ABN when required, the notifier should annotate the original copy of the ABN indicating the refusal to sign and may list witness(es) to the refusal on the notice although this is not required. If a beneficiary refuses to sign a properly delivered ABN, the notifier should consider not furnishing the item/service, unless the consequences (health and safety of the patient, or civil liability in case of harm) are such that this is not an option.

In any case, the notifier must provide a copy of the annotated ABN to the beneficiary, and keep the original version of the annotated notice in the patient's file.

C. Routine Notice Prohibition

Notifiers are prohibited from issuing ABNs on a routine basis (i.e., where there is no reasonable expectation of noncoverage). Notifiers will not violate the routine notice prohibition solely on the basis of the number of ABNs issued, so long as there is a reasonable basis for issuing an ABN.
(See §40.3.6.4, "Routine ABN Prohibition Exceptions")

50.7 - ABN Delivery Requirements
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

50.7.1 - Effective Delivery
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A. Delivery Requirements

ABN delivery is considered to be effective when the notice is:

1. *Delivered by a suitable notifier to a capable recipient and comprehended by that recipient.*

2. *Provided using the correct OMB approved notice with all required blanks completed.*

    - *Failure to use the correct notice may lead to notifiers being found liable since the burden of proof is on the notifier to show knowledge was conveyed to the beneficiary according to CMS instructions.*

3. *Delivered to the beneficiary in person if possible.*

4. *Provided far enough in advance of delivering potentially noncovered items or services to allow sufficient time for the beneficiary to consider all available options.*

5. *Explained in its entirety, and all of the beneficiary's related questions are answered timely, accurately, and completely to the best of the notifier's ability.*

    - *The notifier should direct the beneficiary to call 1-800-MEDICARE if the beneficiary has questions he or she cannot answer. If a Medicare contractor finds that the notifier refused to answer a beneficiary's inquiries or direct them to 1-800-MEDICARE, the*

notice delivery will be considered defective, and the notifier will be held financially liable for noncovered care.

6. *Signed by the beneficiary or his or her representative.*

B. Period of Effectiveness

An ABN can remain effective for up to one year. ABNs may describe treatment of up to a year's duration, as long as no other triggering event occurs. If a new triggering event occurs within the 1-year period, a new ABN must be given. *See § 50.5 – Triggering Events.*

C. Incomplete ABNs

Allegations of improper or incomplete notices will be investigated by Medicare contractors. If the notifier is found to have given improper or incomplete written notice, the applicable Medicare contractor will not hold the beneficiary liable in the individual case.

50.7.2 - Options for Delivery Other than In-Person

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

ABNs should be delivered in-person and prior to the delivery of medical care which is presumed to be noncovered. In circumstances when in-person delivery is not possible, notifiers may deliver an ABN through one of the following means:

- *Telephone contact;*
- *Mail;*
- *Secure fax machine; or*
- *Internet e-mail*

All methods of delivery require adherence to all statutory privacy requirements under HIPAA. The notifier must receive a response from the beneficiary or his or her representative in order to validate delivery.

When delivery is not in-person, the notifier must verify that contact was made in his or her records. In order to be considered effective, the beneficiary cannot dispute such contact. Telephone contacts must be followed immediately by either a hand-delivered, mailed, emailed, or faxed notice. The beneficiary or representative must sign and retain the notice and send a copy of this signed notice to the notifier for retention in the patient's record.

The notifier must keep a copy of the unsigned notice on file while awaiting receipt of the signed notice. If the beneficiary does not return a signed copy. the notifier must document the initial contact and subsequent attempts to obtain a signature in appropriate records or on the notice itself.

50.7.3 - Effects of Lack of Notification, Medicare Review and Claim Adjudication
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A. Beneficiary Liability

A beneficiary who has been given a properly written and delivered ABN and agrees to pay may be held liable. The beneficiary is relieved from liability if he or she does not receive proper notice when required.

Notifiers may not issue ABNs to shift financial liability to a beneficiary when full payment is made through bundled payments. In general, ABNs cannot be used where the beneficiary would otherwise not be financially liable for payment for the service because Medicare made full payment.

B. Provider Liability

A notifier will likely have financial liability for items or services if he or she knew or should have known that Medicare would not pay and fails to issue an ABN when required, or issues a defective ABN. In these cases, the notifier is precluded from collecting funds from the beneficiary and is required to make prompt refunds if funds were previously collected. Failure to issue a timely refund to the beneficiary may result in sanctions.

A notifier may be protected from financial liability when an ABN is required if he or she is able to demonstrate that he or she did not know or could not reasonably have been expected to know that Medicare would not make payment. Issuance of a defective notice establishes the notifier's knowledge of potential noncoverage.

50.8 - ABN Standards for Upgraded Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Notifiers must give an ABN when they expect Medicare to reduce the level of payment for an item or service because part of the item or service is not reasonable and necessary. For example, an ABN must be issued when a notifier expects a partial denial of a more extensive part of a usually covered item or service because that part is not reasonable and necessary.

Examples of excess parts include increased charges attributable to furnishing something that is more in number, more frequent, given for a longer period of time, or that has added features or specific additional uses that are not medically necessary.

ABNs cannot be used to charge beneficiaries for premium quality services described as "excess components." Similarly, ABNs cannot be used to shift liability for an item or service that is described on the ABN as being "better" or "higher quality" on an ABN.

50.9 - ABNs for Denials Under §1834(a)(17)(B) of the Act (Prohibition Against Unsolicited Telephone Contacts)

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A refund is required under §1834(a)(18) or §1879(h)(3) of the Act for both assigned and unassigned claims unless prior to furnishing the item, a valid ABN was issued notifying the beneficiary of potential nonpayment because the supplier violated the prohibition against unsolicited telephone contacts. The supplier must obtain a signed ABN before furnishing the item to the beneficiary.

Giving advance beneficiary notice by telephone does not qualify as notice in this case and is not permissible. The supplier must either hand deliver or mail a written ABN and obtain the beneficiary's signature prior to making the unsolicited telephone contact.

There is presumption of provider knowledge of the prohibition on unsolicited telephone contacts. To rebut this presumption, the supplier must submit convincing evidence showing ignorance of the prohibition. A previous denial of a claim for any item furnished by a particular supplier on the basis of this prohibition is considered actual notice to that supplier. Such a denial shall be construed as actual knowledge on all future claims.

50.10 - ABNs for Claims Denied Under §1834(j)(1) of the Act (Supplier Did Not Meet Supplier Number Requirements)

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

§§s 1834(j)(4)(A) and 1879(h)(1) of the Act require issuance of a valid ABN notifying the beneficiary of potential nonpayment because a supplier did not meet the supplier number requirement. These provisions apply to both assigned and unassigned claims.

A supplier can qualify for a waiver of the refund requirements if adequate public notice is given to beneficiaries informing them of the supplier's failure to meet Medicare's supplier number requirements. An example of adequate public notice would include clearly visible signs posted at the suppliers place of business. If a supplier only conducts business via the internet, a clearly visible notice on the supplier's internet business site is acceptable as long as such notice is also available in printed materials, such as a supplier's catalog. These public notices must be readily visible, in easily readable plain language, in large print, and must be provided in the language(s) commonly used in the locality. The supplier will qualify for a waiver of the Refund Requirements as long as the adequacy of such public notice is not disputed by the beneficiary,

In the event that the beneficiary disputes receipt of public notice, there is a presumption that the supplier did not properly notify the beneficiary unless the supplier can provide evidence to the contrary. Medicare contractors will not hold a beneficiary who cannot read any such public notice liable.

If a supplier can show that he or she did not know that a purchase was being made either by or for a Medicare beneficiary, he or she may seek protection from the refund requirements under §1834(j)(4) of the Act.

Medicare contractors presume that suppliers know that a supplier number is required in order for Medicare to make payment. Thus, a supplier would have to submit evidence to the contrary to rebut this presumption. However, this presumption is not rebuttable if a supplier has previously received a claim denial §1834(j)(1).

50.11 - ABNs for Claims Denied in Advance Under §1834(a)(15) of the Act (When a Request for an Advance Determination of Coverage Is Mandatory)

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

50.11.1 - Situations In Which Advance Coverage Determinations Are Mandatory

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A request for an advance determination of coverage of medical equipment and supplies is mandatory under §1834(a)(15)(C)(i) & (ii) of the Act when:

- *The item is listed by the Secretary as being subject to unnecessary utilization in your carrier service area under §1834(a)(15)(A); or*
- *The supplier is listed by the Secretary under §1834(a)(15)(B) of the Act as a supplier who has submitted a substantial number of claims, which have been denied as not medically reasonable and necessary under §1862(a)(1) of the Act or the Secretary has identified a pattern of over utilization.*

In cases in which an advance coverage determination is mandatory, an ABN must be issued to the beneficiary prior to furnishing the item. If the advance coverage determination has not been received or if the determination is that Medicare will not pay for the care, an ABN is required prior to furnishing the requested item.

50.11.2 - Situations In Which Advance Coverage Determinations Are Optional

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A request for an advance determination of coverage of medical equipment and supplies is optional under §1834(a)(15)(C)(iii) of the Act when the item is customized and either the patient or the supplier requests an advance determination. In cases where an advance coverage determination is optional and the beneficiary requests such a determination, an ABN must be furnished prior to furnishing the requested item.

Every supplier is expected to know whether or not an advance coverage determination is required for Medicare payment. The presumption of that supplier's knowledge becomes non-rebuttable after a single denial under §1834(a)(15) of a claim by a particular supplier.

50.12 - Collection of Funds and Refunds

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A. Collection of Funds

A beneficiary's agreement to be responsible for payment on an ABN means that the beneficiary agrees to pay for expenses out-of-pocket or through any insurance other than Medicare that the

beneficiary may have. The notifier may bill and collect funds from the beneficiary for noncovered items or services immediately after an ABN is signed, unless prohibited from collecting in advance of the Medicare payment determination by other applicable Medicare policy, State or local law.

If Medicare ultimately denies payment of the related claim, the notifier retains the funds collected from the beneficiary. However, if Medicare subsequently pays all or part of the claim for items or services previously paid by the beneficiary to the notifier, or if Medicare finds the notifier liable, the notifier must refund the beneficiary the proper amount in a timely manner.

B. Refund Requirements Requiring Liability Notice

Under the Refund Requirements in §§1842(l) and 1879(h) of the Act, a beneficiary must receive a properly executed ABN so that is "on notice" of liability. By signing the ABN, the beneficiary acknowledges that he or she understands the potential for liability and agrees to pay for the item or service described. The refund requirements requiring ABNs are:

1. *Supplier claims under §1879(h) of the Act, citing three specific requirements when assignment is accepted:*
    a. *§1834(j)(1), when supplier number requirements for medical equipment and supplies are not met;*
    b. *§1834(a)(15), when medical equipment and/or supplies are denied in advance; or*
    c. *§1834(a)(17)(B), when there is a violation of the prohibition on unsolicited telephone contacts for medical equipment and supplies.*
2. *Physician claims under §1842(l) from non-participating physicians when assignment is not accepted for individual items and services that are denied on the basis of §1862(a)(1).*

Physicians must make prompt refunds unless they could not have been expected to know that Medicare would not provide coverage or they notified the beneficiary in advance by issuing the ABN. Refunds are considered prompt when made within 30 days of notice of denial from Medicare or within 15 days after a determination on an appeal if an appeal is made.

50.12.1 - Physicians' Services Refund Requirements
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

The physicians' services refund requirement provision, found in §1842(l) of the Act as amended by the Omnibus Budget Reconciliation Act (OBRA) of 1986, requires timely refunds for certain services. When a reduction in payment, not a full denial, occurs, the physician must refund to the beneficiary any amounts collected which exceed the Medicare payment for the less extensive item or service. These refund requirements apply to both participating and non-participating physicians.

When the beneficiary signs an ABN agreeing to accept responsibility for payment before services are delivered, the collected funds can be retained. A refund is not required if the physician did

not know and could not reasonably have been expected to know that Medicare would not pay for the services because they were not reasonable and necessary.

The Medicare contractor must notify the beneficiary in any case in which the physician requests review of the denial or reduction in payment or asserts that a refund is not required.

Note: Contractors should refer to §140 for detailed instructions on physicians' refund requirements and related appeal rights.

50.12.2 - DMEPOS Refund Requirements (RR) Provision for Claims for Medical Equipment and Supplies

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

All suppliers who sell or rent medical equipment and supplies to Medicare beneficiaries are subject to the refund provisions of §§1834(a)(18), 1834(j)(4) and 1879(h) of the Act, whether accepting assignment or not. Medical equipment and supplies are defined in the following statutes applicable to this section:

- *Durable medical equipment, as defined in §1861(n) of the Act;*
- *Prosthetic devices, as described in §1861(s)(8) of the Act;*
- *Orthotics and prosthetics, as described in §1861(s)(9) of the Act;*
- *Surgical dressings, as described in §1861(s)(5) of the Act;*
- *Home dialysis supplies and equipment, as described in §1861(s)(2)(F) of the Act;*
- *Immunosuppressive drugs, as described in §1861(s)(2)(J) of the Act;*
- *Therapeutic shoes for diabetics, as described in §1861(s)(12) of the Act;*
- *Oral drugs prescribed for use as an anticancer therapeutic agent, as described in §1861(s)(2)(Q) of the Act;*
- *Self-administered erythropoietin, as described in §1861(s)(2)(P) of the Act; and*
- *Other items as determined by the Secretary.*

If a proper ABN is not issued prior to the receipt of one of the preceding items and the above provisions apply, the beneficiary has no financial responsibility. The refund provisions of the Act apply to both assigned and unassigned claims.

In claims for medical equipment and supplies, payment reductions may be based on partial denials of coverage for additional expenses not attributable to medical necessity and/or in excess of the beneficiary's medical needs.

Note: Contractors should refer to §150 for detailed instructions on DMEPOS refund requirements and related appeal rights.

50.12.3 - Time Limits and Penalties for Physicians and Suppliers in Making Refunds

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A required refund must be made within specified time limits:

- *The refund must be made to the beneficiary within 30 days after the date the physician/supplier receives the remittance advice (RA) if the physician/supplier does not request review of an initial full or partial denial; or*
- *The refund must be made to the beneficiary within 15 days after the date the physician/supplier receives the notice of the review determination if the physician/supplier requests review within 30 days of receipt of the notice of the initial determination.*

Physicians/suppliers who knowingly and willfully fail to make a refund where required within these time limits may be subject to civil money penalties and/or exclusion from the Medicare program.

The beneficiary should contact the contractor or CMS when a physician/supplier fails to make a timely refund. If the contractor determines that a physician/supplier failed to make a refund, it will contact the physician/supplier in person or by telephone to discuss the facts of the case. The contractor will attempt to determine why the required refund has not been made and will explain the legal requirements. The contractor will determine whether referral to the Office of Inspector General (OIG) is appropriate and will make the referral to the regional OIG Sanctions Coordinator if necessary. The OIG may impose civil money penalties, assessments, and sanctions if fails to make the required refund. The contractor will retain a detailed written report of contact.

50.12.4 - Supplier's Right to Recover Resalable Items for Which Refund Has Been Made

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

If the Medicare contractor denies Part B payment for an item of medical equipment or supplies on the basis of §1862(a)(1), §1834(a)(17)(B), §1834(j)(1), or §1834(a)(15) of the Act, and the beneficiary is relieved of liability for payment for that item under §1834(a)(18) of the Act, the effect of the denial, subject to State law, cancels the contract for the sale or rental of the item. If the item is resalable or re-rentable, the supplier is permitted to repossess the item. Suppliers are strongly discouraged from recovering items which are consumable or not fit for resale or re-rental.

If a supplier makes proper refund under §1834(a)(18) of the Act, Medicare rules do not prohibit the supplier from recovering from the beneficiary items which are resalable or re-rentable. When the contract of sale or rental is cancelled on the basis described above, the supplier may enter into a new sale or rental transaction with the beneficiary as long as the beneficiary has been informed of their liability. If the circumstances which preclude payment for the item have been removed (e.g. the supplier has now obtained a supplier number when that supplier did not have one before), the supplier may submit to the Medicare contractor a new claim based on the resale or re-rental of the item to the beneficiary. If payment is still precluded, the supplier can issue an ABN.

Under the capped-rental method, if the Medicare contractor determines that the supplier is obligated to make a refund, the supplier must repay Medicare those rental payments that the

supplier has received for the item. However, the Medicare beneficiary must return the item to the supplier.

50.13 - CMS Regional Office (RO) Referral Procedures
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Prior to submitting any materials to the RO, the Medicare contractor will contact the RO to determine how to proceed in referring a potential sanction case. When referring these types of cases to the region, the contractor should include the following:

A. Background of the Subject

The subject's business name, address, Medicare Identification Number, owner's full name and Social Security Number, Tax Identification Number (if different), and a brief description of the subject's special field of medical equipment, supplies, or services.

B. Origin of the Case

A brief description of how the violations were discovered.

C. Statement of Facts

A statement of facts in chronological order describing each failure to comply with the refund requirements.

D. Documentation

Include copies of written correspondence and written summaries of any meetings or telephone contacts with the beneficiary and the supplier regarding the supplier's failure to make a refund. Include a listing of the following for each item or service not refunded to the beneficiary by the supplier (grouped by beneficiary):

- *Beneficiary Name and Health Insurance Claim Number;*
- *Claim Control Number;*
- *Procedure Code (CPT-4 or HCPCS) of nonrefunded item or service;*
- *Procedure Code modifier;*
- *Date of Service;*
- *Place of Service Code;*
- *Submitted Charge;*
- *Units (quantity) of Item or Service; and*
- *Amount Requested to be Refunded.*

Include any additional information that may be of value to the RO.

50.14 - Special Considerations
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

50.14.1 - Obligation to Bill Medicare
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

*Upon receipt of an ABN, a beneficiary who selects Option 1 and receives the items or services described in the notice has the right to ask the notifer to submit a claim to Medicare for an official payment decision on the items or services received. If the items or services in question are furnished on an **assigned** basis, the notifier **must** file the claim with Medicare as requested. However, the notifier may decline to file a claim if the items or services are furnished on an **unassigned** basis.*

Providers should refer to Publication 100-4, Chapter 1, § 60 for instructions on submitting claims for statutorily noncovered items or services.

***Note**: Providers will not violate mandatory claims submission rules under §1848 of the Social Security Act when a claim is not submitted to Medicare at the beneficiary's written request in choosing Option 2 on the revised ABN.*

50.14.2 - Emergencies or Urgent Situations
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

In general, a notifier, may not issue an ABN to a beneficiary who has a medical emergency or is under similar duress. Forcing delivery of an ABN during an emergency may be considered coercive. ABN usage in the ER may be appropriate in some cases where the beneficiary is medically stable with no emergent health issues.

50.14.3 - Repetitive or Continuous Noncovered Care
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

*Notifiers may give a beneficiary a single ABN describing an extended or repetitive course of noncovered treatment provided that the ABN lists all items and services that the notifier believes Medicare will not cover. If applicable, the ABN must also specify the duration of the period of treatment. If during the course of treatment additional noncovered items or services are needed, the notifier must give the beneficiary another ABN. **The limit for use of a single ABN for an extended course of treatment is one year.** A new ABN is required when the specified treatment extends beyond one year.*

50.14.4 - Hospice and CORF
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

50.14.4.1 - Special Issues Associated with the Advance Beneficiary Notice (ABN) Issued to Hospice Patients
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A. General Use

Notifiers issue the ABN to hospice patients (Form CMS-R-131), according to the instructions given in this section. The ABN will likely be given less frequently for the hospice benefit than in other settings.

The three situations that would require issuance of the ABN to a hospice patient are:

- *Ineligibility because the beneficiary is not "terminally ill" as defined in §1879(g)(2) of the Act;*
- *Specific items or services that are billed separately from the hospice payment, such as physician services, are not reasonable and necessary as defined in either §1862(a)(1)(A) or §1862(a)(1)(C); or*
- *The level of hospice care is determined to be not reasonable or medically necessary as defined in §1862(a)(1)(A) or §1862(a)(1)(C), specifically for the management of the terminal illness and/or related conditions.*

Examples of common denial reasons that the notifier may list in Blank (E) on the ABN include:

- *Ineligibility for the Hospice Benefit;*
- *The documentation submitted does not support that your illness is terminal;*
- *According to Medicare hospice requirements, this service is not covered because it was provided by a non-attending physician;*
- *Surgical removal of a cataract is not a hospice covered benefit; and*
- *This service is not covered because you are enrolled in a hospice.*

B. Hospice Care Delivered by Non-Hospice Providers

It is the notifier's responsibility to issue an ABN when a beneficiary who has elected the hospice benefit chooses to receive care in a hospital that is not under contract with the hospice or if the beneficiary continues an inpatient hospital stay, which is no longer deemed medically necessary by the hospice. The hospice may delegate delivery of the ABN to the hospital in these cases.

C. When ABNs Are Not Required for Hospice Services

1. ***Revocations***
   Hospice beneficiaries or their representatives can revoke the hospice benefit. Revocations are not considered terminations under liability notice policy since the beneficiary is exercising his or her own freedom of choice. Therefore no ABN is required.
2. ***Respite Care Beyond Five Consecutive Days***
   Mandatory notification is not required when respite care exceeds five consecutive days, because payment for respite care is limited to this time period under the Act. Respite care on the sixth consecutive day is therefore considered outside the definition of the hospice benefit, and the hospice provider is not required to issue an ABN. However, CMS encourages hospice providers to give the ABN as a voluntary notice to inform patients of possible financial liability in such cases.
3. ***Transfers***

Beneficiaries are allowed one transfer to another hospice during a benefit period. However, subsequent transfers within the same benefit period are not permitted. In either case, an ABN is not required.

50.14.5 - Expedited Determination Notices
(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

*Hospice and CORF providers must use expedited determination ("Generic") notices in accordance with §1869 of the Act when required. Expedited determination notices are given to beneficiaries when **all** Medicare covered services are being terminated for coverage reasons, so beneficiaries are alerted to their right to obtain an independent, immediate Quality Improvement Organization (QIO) review of the decision to end coverage.*

The expedited determination notice and the ABN must be issued together only when all covered care is being terminated for coverage reasons and the beneficiary is expected to continue receiving noncovered care. No ABN is required if no further services will be provided.

For detailed instructions regarding the delivery of the expedited determination notice, see Transmittal 594, Change Request 3903, dated June 24, 2005 and the subsequent Questions and Answers on www.cms.hhs.gov/BNI.

(A) Notifier(s):
(B) Patient Name: **(C) Identification Number:**

ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

NOTE: *If Medicare doesn't pay for* ***(D)***______________ *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 ***(D)***_____________ *below.*

(D)	(E) Reason Medicare May Not Pay:	(F) 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* ***(D)***_____________*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.*

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

❑ **OPTION 1.** *I want the* ***(D)***___________ *listed above. You may ask to be paid 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.*

❑ **OPTION 2.** *I want the* ***(D)***___________ *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* ***(D)***___________*listed above. I understand with this choice I am* ***not*** *responsible for payment, and* ***I cannot appeal to see if Medicare would pay.***

(H) 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.

(I) Signature:	(J) Date:

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

50 - APPENDIX B

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Approved Customized ABN (CMS-R-131) for Providers of Laboratory Services

(A) Notifier(s):

(B) Patient Name: ***(C) Identification Number:***

ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

NOTE: *If Medicare doesn't pay for items checked or listed in box **(D)** 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 listed or checked in box **(D)** below.*

(D) Listed or Checked Items Only:			
(E) Reason Medicare May Not Pay:			
(F) 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 checked items in **(D)** 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.*

(G) Options: ***Check only one box. We cannot choose a box for you.***

❑ ***OPTION 1.*** *I want the **(D)** ______listed above. You may ask to be paid 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.*

❑ ***OPTION 2.*** *I want the **(D)** ______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 **(D)** ______ 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.

(I) Signature:	***(J) Date:***

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.

Form CMS-R-131 (03/08) ***Form Approved OMB No. 0938-0566***

140 - Physician Refund Requirements (RR) Provision for Nonassigned Claims for Physicians Services Under §1842(l) - Instructions for Contractors

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Following are the procedures for implementing §1842(l) of the Act. Under §9332(c) of OBRA 1986 (P.L. 99-509), which added §1842(l) to the Act, new liability protections for Medicare beneficiaries affect nonparticipating physicians.

150 - DMEPOS Refund Requirements (RR) Provision for Claims for Medical Equipment and Supplies under §§1834(a)(18), 1834(j)(4), and 1879(h) - Instructions for Contractors

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Following are the procedures for implementing §§1834(a)(18), 1834(j)(4) and 1879(h) of the Act. Under §132 of SSAA-1994 (Social Security Act Amendments of 1994, P.L. 103-432) which adds §1834(a)(18) to the Act, and under §133 of SSAA-1994 which adds §1834(j)(4) and §1879(h) to the Act, new liability protections for Medicare beneficiaries affect suppliers of medical equipment and supplies. All suppliers who sell or rent medical equipment and supplies to Medicare beneficiaries are subject to the refund provisions of §§1834(a)(18), 1834(j)(4) and 1879(h) of the Act. Beneficiaries' liability for payment for certain items and services, that is, for otherwise covered medical equipment and supplies as defined in §150.10 , which are furnished on or after January 1, 1995, and for which Medicare payment is denied for one of several reasons specified below, may be limited as follows. For both assigned and unassigned claims, for which the supplier knew or should have known of the likelihood that payment would be denied (that is, the supplier is held to be liable) and for which the beneficiary did not know, the beneficiary has no financial responsibility and the refund provisions of the Act apply in virtually all cases. The single exception to this rule of applicability is that, with respect to medical equipment and supplies for which the supplier accepted assignment and for which payment is denied because the item or service is not medically reasonable and necessary under §1862(a)(1) of the Act, the §1879 Limitation on Liability provisions which applied to such denials prior to January 1, 1995, still apply. The refund provisions do not apply to these denials.

In claims for medical equipment and supplies, payment reductions may be based on partial denials of coverage for additional expenses not attributable to medical necessity. A medical necessity "partial denial" is the denial of coverage for the unnecessary component of a covered item or service, when that component is in excess of the beneficiary's medical needs. Any such excess component is not medically reasonable and necessary and therefore, under §1862(a)(1) of the Act, it is not covered. A partial denial may be used to base payment on the least costly, medically appropriate, alternative. The beneficiary liability protections of §1879 and of §1834(j)(4) of the Act apply to any payment reductions due to partial denials of coverage for medical equipment or supplies on the basis of medical necessity under §1862(a)(1) of the Act. (See §140 for its similar provision for the applicability of the refund requirements under §1842(l) of the Act to partial denials of coverage for physicians' services.)

When the refund provisions of §§1834(a)(18), 1834(j)(4) and 1879(h) of the Act apply and the supplier is held to be liable, a required refund must be made on a timely basis. Suppliers which knowingly and willfully fail to make refund within specified time limits may be subject to civil money penalties and/or exclusion from the Medicare program.

Refund is not required if the supplier is held not to be liable, that is, if it is held that the supplier did not know and could not reasonably have been expected to know that Medicare would not pay on the basis of §1834(a)(17)(B), §1834(j)(1), §1834(a)(15), or §1862(a)(1) of the Act, or if it is held that, before the item or

service was furnished, the beneficiary was informed by the supplier that Medicare would not pay and the beneficiary agreed to pay for the item or service. In any case where the supplier is held not to be liable, the beneficiary is liable for payment.

150.5.2.1 - Denial of Payment in Advance

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Denial of payment in advance under §1834(a)(15) of the Act refers both to cases in which the supplier requested an advance determination and the *contractor* determined that the item would not be covered, and to cases in which the supplier failed to request an advance determination when such a request is mandatory.

150.5.2.4 - Presumption for Constructive Notice

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

In determining whether the supplier knew, or could reasonably have been expected to know, that Medicare would deny payment in advance under §1834(a)(15) of the Act, presume that the supplier knew that Medicare would not pay in all cases in which the supplier failed to request a mandatory advance determination, on the basis of constructive notice of the lists of items and of suppliers to the supplier through the *contractor*'s regular newsletter/bulletin publication. The supplier would have to submit convincing evidence to the contrary to rebut this presumption.

150.5.2.5 - Presumption When Advance Determination was Requested

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

In determining whether the supplier knew, or could reasonably have been expected to know, before furnishing the item, that Medicare would deny payment in advance under §1834(a)(15) of the Act, presume that the supplier knew that Medicare would not pay in all those cases in which a request for advance determination was made, and the *contractor* denied payment in advance on the basis that the item is not reasonable and necessary under §1862(a)(1) of the Act or that the item is not covered. This is a nonrebuttable presumption.

150.5.2.9 - Presumption About Beneficiary Knowledge

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Presume that a Medicare beneficiary does not know, and cannot reasonably be expected to know, that Medicare will deny, or has denied, payment in advance under §1834(a)(15) of the Act unless and until the beneficiary has received a proper advance beneficiary notice (ABN) to that effect from the supplier before the item is furnished to them.

150.5.3 - Knowledge Standards for §1834(a)(17)(B) Denials

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

In determining whether the supplier knew, or could reasonably have been expected to know, that Medicare would not pay because of the prohibition on unsolicited telephone contacts under §1834(a)(17)(B) of the Act, presume that the supplier knew that Medicare would not pay on the basis of constructive notice to the supplier through publication of the prohibition on such contacts through the *contractor*'s professional relations function, as well as publicity through trade organizations' own publications, professional training, conventions, etc. The supplier would have to submit convincing evidence to the contrary, showing ignorance of the prohibition on the supplier's part, to rebut this presumption. A single denial of a claim for any item furnished by a particular

supplier on the basis of the prohibition on unsolicited telephone contacts shall be held to be actual notice of the prohibition to that supplier; and that supplier shall be considered, on that basis, to have had knowledge that payment would be denied for all such future claims, even those for different items of medical equipment and supplies. That is, after a single denial under §1834(a)(17)(B) of a claim by a particular supplier, the presumption of that supplier's knowledge becomes nonrebuttable.

150.5.4 - Knowledge Standards for §1834(j)(1) Denials

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

In determining whether the supplier knew, or could reasonably have been expected to know, that Medicare would not pay due to failure to meet supplier number requirements under §1834(j)(1) of the Act, presume that the supplier knew that Medicare would not pay. Every supplier is expected to know whether or not it has a supplier number, and to know that Medicare will not make payment for medical equipment and supplies furnished a Medicare beneficiary by a supplier which does not have a supplier number. All suppliers should have this knowledge on the basis of the *contractor*'s professional relations function, as well as publicity through trade organizations' own publications, professional training, conventions, etc. The supplier would have to submit extraordinary evidence to the contrary to rebut this presumption. If a supplier submits evidence the *contractor* finds credible, consult your regional office before rebutting the presumption of supplier knowledge. After a single denial under §1834(j)(1) of a claim by a particular supplier, the presumption of that supplier's knowledge becomes nonrebuttable.

150.5.5 - Additional Knowledge Standards for All Medical Equipment and Supplies Denials

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

The *contractor* may make a determination, as provided for in Section I.2.D.2.b. imputing a lack of knowledge to a supplier, on the basis that the supplier did not know and could not reasonably have been expected to know that Medicare would not pay, if the supplier did not know and could not reasonably have been expected to know that a purchase (or rental) of medical equipment or supplies involved a Medicare beneficiary.

150.7 - Appeal Rights

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Nonparticipating suppliers have the same rights to appeal the *contractor*'s determination in an unassigned claim for medical equipment and supplies if the *contractor* denies payment on the basis of §1862(a)(1) , §1834(a)(17)(B) , §1834(j)(1), or §1834(a)(15) of the Act as they or participating suppliers have in assigned claims. These rights of appeal also extend to determinations that a refund is required either because the supplier knew or should have known that Medicare would not pay for the item or service, or because the beneficiary was not properly informed in writing in advance that Medicare would not pay or was unlikely to pay for the item or service. In addition to the beneficiary's right to appeal the *contractor*'s decision to deny payment on the basis of §1862(a)(1), §1834(a)(17)(B), §1834(j)(1), or §1834(a)(15) of the Act, the beneficiary becomes a party to any appeal request filed by the supplier. Since the beneficiary and the supplier may have adverse interests in a decision regarding refund, it is essential to notify the beneficiary in any case in which the supplier requests an appeal of the denial or asserts that a refund is not required because one of the conditions in §150.5 is met. (See Chapter 29, "Appeals of this Claims Decision," for detailed appeals instructions.)

150.8 - Processing Initial Denials

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

In any unassigned claim for medical equipment and supplies furnished on or after January 1, 1995, in which the *contractor* denies payment on the basis of §1862(a)(1), §1834(a)(17)(B), §1834(j)(1), or §1834(a)(15) of the Act, send separate notices to both the beneficiary (a Medicare Summary Notice (MSN)) and the supplier (a remittance advice (RA)).

NOTE: This instruction to send a remittance advice to the supplier in the case of denial of an unassigned claim is a specific requirement of §1834(a)(18)(C) of the Act, incorporated by reference into §1834(j)(4) and §1879(h) of the Act, applicable to denials of claims for medical equipment and supplies furnished on or after January 1, 1995.

If the beneficiary signed an ABN which satisfies the requirements in subsection II.6 and the supplier included a GA modifier on the Form CMS-1500 to that effect, do not make an automatic finding that the claim should be denied on the basis of §1862(a)(1), §1834(a)(17)(B), §1834(j)(1), or §1834(a)(15) of the Act, merely because the supplier submitted a GA modifier. The fact that an ABN was given to the beneficiary will in no way prejudice the *contractor*'s determination as to whether there is or is not sufficient evidence to justify a denial. In the case where there is an ABN, mail a standard denial MSN notice to the beneficiary. If the beneficiary did not sign an ABN and the supplier included a GZ modifier on the Form CMS-1500 to that effect, include, in addition to one of the denial notices in Chapter 21, "Medicare Summary Notices," the following initial beneficiary notice in the MSN sent to the beneficiary.

A. Initial Beneficiary Notice

> (MSN 8.54)
>
> If the supplier should have known that Medicare would not pay for the denied items or services and did not tell you in writing before providing them that Medicare probably would deny payment, you may be entitled to a refund of any amounts you paid. However, if the supplier requests an appeal of this claim within 30 days, a refund is not required until we complete our appeal. If you paid for this service and do not hear anything about a refund within the next 30 days, contact your supplier.

(MSN 8.54) - In Spanish

> Si el suplidor hubiera sabido que Medicare no pagaría por los artículos o servicios negados y no le informó por escrito, antes de proveerle los artículos o servicios, que Medicare probablemente negaría el pago, usted podría tener derecho a recibir un reembolso por cualquier cantidad que pagó. Sin embargo, si el suplidor pide una revisión de esta reclamación en 30 días, un reembolso no es requerido hasta que completemos nuestra revisión. Si usted pagó por este servicio y no escucha nada sobre un reembolso en 30 días, comuníquese con su suplidor.

B. Initial Supplier Notice

Include in the notice to the supplier the following;

- The patient's name and health insurance claim number;

- A description of the item or service by procedure code, date and place of service, and amount of the charge;
- The same denial notice included on the beneficiary's MSN, (see Chapter 21, "Medicare Summary Notices"); and
- If the supplier submitted a GA modifier (signed ABN obtained), include in the notice to the supplier the following Notice 1. However, if the supplier submitted a "-GZ" modifier (a signed ABN was not obtained), include in the notice to the supplier the following Notice 2.

Notice 1. – Signed Advance Beneficiary Notice Obtained

(Remark Code N124)

> Payment has been (denied for the/made only for a less extensive) service/item because the information furnished does not substantiate the need for the (more extensive) service/item. The patient is liable for the charges for this service/item as you informed the patient in writing before the service/item was furnished that we would not pay for it, and the patient agreed to pay.

Or

Notice 2. – Signed Advance Beneficiary Notice Not Obtained

(Remark Code N125)

> Payment has been (denied for the/made only for a less extensive) service/item because the information furnished does not substantiate the need for the (more extensive) service/item. If you have collected any amount from the patient, you must refund that amount to the patient within 30 days of receiving this notice. The law permits exceptions to this refund requirement in two cases: if you did not know, and could not have reasonably been expected to know, that Medicare would not pay for this service/item; or if you notified the beneficiary in writing before providing it that Medicare likely would deny the service/item, and the beneficiary signed a statement agreeing to pay.
>
> If an exception applies to you, or you believe the *contractor* was wrong in denying payment, you should request an appeal of this determination by the *contractor* within 30 days of receiving this notice. Your request for appeal should include any additional information necessary to support your position. If you request an appeal within 30-days, you may delay refunding to the beneficiary until you receive the results of the appeal. If the appeal determination is favorable to you, you do not have to make any refund. If the appeal is unfavorable, you must make the refund within 15 days of receiving the unfavorable appeal decision.
>
> You may request an appeal of the determination at any time within 120 days of receiving this notice. An appeal requested after the 30-day period does not permit you to delay making the refund. Regardless of when an appeal is requested, the patient will be notified that you have requested one, and will receive a copy of the determination.
>
> The patient has received a separate notice of this denial decision. The notice advises that he or she may be entitled to a refund of any amounts paid, if you should have known that Medicare would not pay and did not tell him or her. It also instructs the patient to contact your office if he or she does not hear anything about a refund within 30 days.

> The requirements for refund are in §1834(a)(18) of the Social Security Act (and in §§1834(j)(4) and 1879(h) by cross-reference to §1834(a)(18)). Section 1834(a)(18)(B) specifies that suppliers which knowingly and willfully fail to make appropriate refunds may be subject to civil money penalties and/or exclusion from the Medicare program. If you have any questions about this notice, please contact (contractor contact, telephone number).

Ensure that the telephone number puts the supplier in touch with a knowledgeable professional who can discuss the basis for the denial or reduction in payment.

NOTE: These procedures do not apply where the contractor automatically denies Part B services related to hospital inpatient services denied by the Quality Improvement Organization (QIO). In those cases, the QIO is responsible for notifying the beneficiary and supplier of the refund requirements of §§1834(a)(18), 1834(j)(4), and 1879(h) of the Act and making the refund determination where appropriate.

150.10.1 - Appeal of the Denial of Payment

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

The first stage of the appeal is a new, independent, and critical reexamination of the facts regarding the denial of payment. If the *contractor* finds that the initial denial of payment was appropriate, go on to §150.10.2.

150.10.2 - Beneficiary Given Advance Beneficiary Notice and Agreed to Pay

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A supplier which has given the beneficiary an ABN and has obtained the beneficiary's signed statement agreeing to pay, is not required to make a refund. If the supplier claims to have given an ABN to the beneficiary, the *contractor* will ask the supplier to furnish a copy of the ABN. Examine the ABN to determine whether it meets the standards in §40.3 and §50. In the absence of acceptable evidence of advance beneficiary notice, go on to §150.10.3.

150.10.3 - Supplier Knowledge

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A supplier which did not know and could not reasonably have been expected to know that Medicare would not pay for the medical equipment or supplies is not required to make a refund. If the supplier claims not to have had any such knowledge, the *contractor* will determine whether the supplier knew, or could reasonably have been expected to know, that Medicare would not pay by applying the knowledge standards provided in §150.5.

150.11 - Guide Paragraphs for Inclusion in Appeal Determination

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Upon completion of the appeal, the *contractor* will send the supplier an appeal notice. Send a copy to the beneficiary. If the initial payment determination is reversed to payment, include in the appeal notice the supplier notice language required in §150.9. Otherwise, include one of the following paragraphs concerning refund.

Paragraph 1. Refund Not Required - Beneficiary Was Given Advance Beneficiary Notice and Agreed to Pay

> Under §1834(a)(18) and under §1834(j)(4) of the Social Security Act, a supplier which does not accept assignment and collects any amounts from a Medicare beneficiary for medical equipment and supplies for which Medicare does not pay on the basis of §1834(a)(17)(B), §1862(a)(1),

§1834(j)(1), or §1834(a)(15) of the Social Security Act, must refund these amounts to the beneficiary. However, a refund is not required if, prior to furnishing the items or services, the supplier notified the beneficiary in writing that Medicare would not pay for the items or services and the beneficiary signed a statement agreeing to pay for them. After reviewing this claim, we have determined that you informed the beneficiary in advance that Medicare does not pay for the above items or services and the beneficiary agreed to pay for them. Therefore, you are not required to make a refund in this case. The beneficiary has been sent a copy of this notice.

Paragraph 2. Refund Not Required - Supplier Did Not Know That Medicare Would Not Pay For the Services

Under §1834(a)(18) and §1834(j)(4) of the Social Security Act, a supplier which does not accept assignment and collects any amounts from a Medicare beneficiary for medical equipment and supplies for which Medicare does not pay on the basis of §1834(a)(17)(B), §1862(a)(1), §1834(j)(1), or §1834(a)(15) of the Social Security Act, must refund these amounts to the beneficiary. However, a refund is not necessary if the supplier did not know, and could not reasonably have been expected to know, that Medicare does not pay for the items or services. After reviewing this claim, we find that you did not know, and could not reasonably have been expected to know, that Medicare would not pay for the above items or services. Therefore, you are not required to make a refund in this case. Upon your receipt of this notice, it is considered that you now have knowledge of the fact that Medicare does not pay for (description of item or service) similar conditions. The beneficiary has been sent a copy of this notice.

Paragraph 3. Adverse Action on Denial - Refund Required

Under §1834(a)(18) and §1834(j)(4) of the Social Security Act, a supplier which does not accept assignment and collects any amounts from a Medicare beneficiary for medical equipment and supplies for which Medicare does not pay on the basis of §1834(a)(17)(B), §1862(a)(1), §1834(j)(1), or §1834(a)(15) of the Social Security Act, must refund these amounts to the beneficiary. A refund is not required if (1) The supplier did not know, and could not reasonably have been expected to know, that Medicare would not pay for the items or services; or (2) The supplier notified the beneficiary in writing before furnishing the items or services that Medicare would not pay for the items or services and the beneficiary signed a statement agreeing to pay for them. After reviewing this claim, we have determined that neither of these conditions is met in this case. You must therefore refund any amount you collected for these items or services within 15 days from the date you receive this notice. A refund must be made within 15 days from receipt of this notice for you to be in compliance with the law. The beneficiary has been sent a copy of this notice.

Suppliers which knowingly and willfully fail to make appropriate refunds may be subject to civil money penalties (up to $10,000 per item or service), assessments (three times the amount of the claim), and exclusion from the Medicare program.

NOTE: For claims presented to the contractor prior to January 1, 1997, the amount of the civil money penalty is up to $2,000 per item or service and the assessment is not more than twice the amount claimed.

150.12 - Supplier Fails to Make Refund

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Under §1834(a)(18)(B) of the Act, a supplier which knowingly and willfully fails to make refund within the time limits in §150.4 may be subject to sanctions under §1128A the Act (i.e., civil money penalties (up to

$10,000 per item or service), assessments (three times the amount of the claim), and exclusion from the Medicare program).

NOTE: For claims presented to the contractor prior to January 1, 1997, the amount of the civil money penalty is up to $2,000 per item or service and the assessment is not more than twice the amount claimed.

Generally, the failure of a supplier to make a refund to a beneficiary comes to the *contractor*'s attention as a result of a beneficiary complaint or a referral from the Social Security Administration (SSA) or the CMS. Document beneficiary complaints and, if necessary, contact the beneficiary to clarify the information in the complaint and determine the amount the beneficiary paid the supplier for the denied items or services. If the *contractor* determines that a supplier failed to make a refund, the *contractor* will contact the supplier in person or by telephone (if that is not feasible, contact the supplier by letter) to discuss the facts of the case. The *contractor* will attempt to determine why the amounts collected have not been refunded. Explain that the law requires that the supplier make a refund to the beneficiary and that if it fails to do so, the Secretary may impose civil money penalties, assessments, and exclusion from the Medicare program. Make a dated report of contact. Include the information relayed to the supplier and the supplier's response. Re-contact the beneficiary in 15 days to determine whether the refund has been made. Do not make any referral to the CMS regional office until the supplier has been formally notified to refund the money and the supplier's appeal rights have been exhausted, or until the time limit for an appeal has passed.

150.13 - CMS Regional Office (RO) Referral Procedures

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

Prior to submitting any materials to the RO, the *contractor* will contact the RO to determine how to proceed in referring a potential sanction case. When referring a sanction case to the region, include in the sanction recommendation (to the extent appropriate) the following:

Background of the Subject

The subject's business name, address, Medicare Identification Number, owner's full name and Social Security Number, Tax Identification Number (if different), and a brief description of the subject's special field of medical equipment and supplies business.

Origin of the Case

A brief description of how the violations were discovered.

Statement of Facts

A statement of facts in chronological order describing each failure to comply with the refund requirements.

Documentation

Include copies of written correspondence and written summaries of any meetings or telephone contacts with the beneficiaries and the supplier regarding the supplier's failure to make refunds. Include a listing of the following for each item or service not refunded to the beneficiary by the supplier (grouped by beneficiary):

- Beneficiary Name and Health Insurance Claim Number;

- Claim Control Number;

- Procedure Code (CPT-4 or HCPCS) of nonrefunded item or service;
- Procedure Code modifier;
- Date of Service;
- Place of Service Code;
- Submitted Charge;
- Units (quantity) of Item or Service; and
- Amount Requested to be Refunded.

Other Significant Issues

Include any information that may be of value to the RO while they review and possibly develop a case to impose sanctions.

150.15 - Supplier's Right to Recover Resaleable Items for Which Refund Has Been Made

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

If the *contractor* denies Part B payment for an item of medical equipment or supplies on the basis of §1862(a)(1), §1834(a)(17)(B), §1834(j)(1), or §1834(a)(15) of the Act, and the beneficiary is relieved of liability for payment for that item under §1834(a)(18) of the Act, the effect of the denial, subject to State law, cancels the contract for the sale or rental of the item and, if the item is resaleable or re-rentable, permits the supplier to repossess that item for resale or re-rental. In the case of consumable items or any other items which are not fit for resale or re-rental and which cannot be made fit for resale or re-rental, suppliers are strongly discouraged from recovering these items since such actions reasonably could be viewed as purely punitive in nature. If a supplier makes proper refund under §1834(a)(18) of the Act, Medicare rules do not prohibit the supplier from recovering from the beneficiary items which are resalable or re-rentable.

Alternatively, when the contract of sale or rental is cancelled on the basis described above, whether or not the supplier physically repossesses the resaleable or re-rentable item, the supplier may enter into a new sale or rental transaction with the beneficiary with respect to that item as long as the beneficiary has been informed of their liability. If the circumstances which preclude payment for the item have been removed, e.g., the supplier has now obtained a supplier number, the supplier may submit to the *contractor* a new Part B claim based on the resale or re-rental of the item to the beneficiary. If Part B payment is still precluded, the supplier can establish the beneficiary's liability for payment for the denied resold or re-rented item by giving the beneficiary an ABN notifying the beneficiary of the likelihood that Medicare will not pay for the item and obtaining the beneficiary's signed agreement to pay for the item. The resale or re-rental of the item to the beneficiary does not change the fact that the beneficiary is relieved of liability in connection with the original transaction.

Under the capped-rental method, if the *contractor* determines that the supplier is obligated to make a refund, the supplier must repay Medicare those rental payments that the supplier has received for the item. However, the Medicare beneficiary must return the item to the supplier.

200.5.3 - Length and Page Size

(Rev.1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

The Important Message from Medicare: The IM must NOT exceed two sides of a page in length. The IM is designed as a letter-sized form. If necessary, it may be expanded to a legal-sized page to accommodate information hospitals insert in the notice.

The Detailed Notice: The Detailed Notice must NOT exceed one side of a page in length. The Detailed Notice is designed as a letter-sized form. If necessary, it may be expanded to a legal-sized page to accommodate information hospitals may insert in the notice. Hospitals may attach applicable Medicare policies to the notice.