

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 10862</b>	<b>Date: July 14, 2021</b>
	<b>Change Request 12242</b>

**SUBJECT: Section 50 in Chapter 30 of Publication (Pub.) 100-04 Manual Updates**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to reorganize, make edits, and changes to the Advance Beneficiary Notice of Non-coverage (ABN) section 50 in chapter 30 of Pub. 100-04, Medicare Claims Processing Manual.

**EFFECTIVE DATE: October 14, 2021**

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

**IMPLEMENTATION DATE: October 14, 2021**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	30/Table of Contents
R	30/50/Advance Beneficiary Notice of Non-coverage (ABN)
R	30/50/50.1/ABN Scope
R	30/50/50.2/ABN Uses
R	30/50/50.2.1/Optional ABN Uses
D	30/50/50.2.2/Compliance with Limitation On Liability Provisions
R	30/50/50.3/Issuance of the ABN
D	30/50/50.3.1/Mandatory ABN Uses
D	30/50/50.3.2/Voluntary ABN Users
R	30/50/50.4/ABN Triggering Events
D	30/50/50.4.1/Issuers of ABNs (Notifiers)
D	30/50/50.4.2/Recipients of the ABN
D	30/50/50.4.3/Representatives of Beneficiaries
R	30/50/50.5/ABN Standards
R	30/50/50.6/Completing the ABN
D	30/50/50.6.1/Proper Notice Documents
D	30/50/50.6.2/General Notice Preparation Requirements
D	30/50/50.6.3/Completing the ABN
D	30/50/50.6.4/Retention Requirements
D	30/50/50.6.5/Other Considerations During ABN Completion
R	30/50/50.7/Retention Requirements
D	30/50/50.7.1/Effective Delivery
D	30/50/50.7.2/Options for Delivery Other Than In Person
D	30/50/50.7.3/Effects of Lack of Notification, Medicare Review and Claim Adjudication
D	30/50/50.7.3.1/Using ABNs for Medical Equipment and Supplies Claims When Denials Under &sect.,1834(a)(17)(B) of the Act (Prohibition Against Unsolicited Telephone Contacts) Are Expected
D	30/50/50.7.3.2/ABNs for Medical Equipment and Supplies Claims Denied Under &sect,1834(j)(1) of the Act (Because the Supplier Did Not Meet Supplier Number Requirements)
D	30/50/50.7.3.3/ABNs for Medical Equipment and Supplies Claims Denied in Advance Under &sect,1834(a)(15) of the Act - Prior Authorization Procedures

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	30/50/50.8/ABN Delivery Requirements
N	30/50/50.8.1/Options for Delivery Other than In-Person
R	30/50/50.9/Effects of Lack of Notification, Medicare Review and Claim Adjudication
R	30/50/50.10/Using ABNs for Medical Equipment and Supplies Claims When Denials Under §1834(a)(17)(B) of the Act (Prohibition Against Unsolicited Telephone Contacts) Are Expected
R	30/50/50.11/ABNs for Medical Equipment and Supplies Claims Denied Under §1834(j)(1) of the Act (Because the Supplier Did Not Meet Supplier Number Requirements)
D	30/50/50.11.1/Situations In Which Advance Coverage Determinations Are Mandatory
D	30/50/50.11.2/Situations In Which Advance Coverage Determinations Are Optional
R	30/50/50.12/ABNs for Claims Denied in Advance Under §1834(a)(15) of the Act
R	30/50/50.13/ABN Standards for Upgraded Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
D	30/50/50.13.1/Physicians' Services Refund Requirements
D	30/50/50.13.2/DMEPOS Refund Requirements (RR) Provision for Claims for Medical Equipment and Supplies
D	30/50/50.13.3/Time Limits and Penalties for Physicians and Suppliers in Making Refunds
D	30/50/50.13.4/Supplier's Right to Recover Resalable Items for Which Refund Has Been Made
R	30/50/50.14/ABNs for items listed in a DMEPOS Competitive Bidding Program (CBP)
R	30/50/50.15/Collection of Funds and Refunds
R	30/50/50.15.1/Physicians' Services RR
R	30/50/50.15.2/DMEPOS RR Provision for Claims for Medical Equipment and Supplies
R	30/50/50.15.3/Time Limits and Penalties for Healthcare Providers and Suppliers in Making Refunds
D	30/50/50.15.3.1/Special Issues Associated with the ABN for Hospice Providers
D	30/50/50.15.3.2/Special Issues Associated with the ABN for CORFs

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	30/50/50.15.4/Supplier's Right to Recover Resalable Items for Which Refund Has Been Made
D	30/50/50.15.5/Outpatient Therapy Services
N	30/50/50.16/CMS Regional Office (RO) Referral Procedures
N	30/50/50.17/ABN Special Considerations
R	30/500/Glossary

### **III. FUNDING:**

#### **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**

# Attachment - Business Requirements

Pub. 100-04	Transmittal: 10862	Date: July 14, 2021	Change Request: 12242
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**SUBJECT: Section 50 in Chapter 30 of Publication (Pub.) 100-04 Manual Updates**

**EFFECTIVE DATE: October 14, 2021**

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## I. GENERAL INFORMATION

**A. Background:** The Financial Liability Protections (FLP) provisions of the Social Security Act (the Act) protect beneficiaries, healthcare providers, and suppliers under certain circumstances from unexpected liability for charges associated with claims that Medicare does not pay. The FLP provisions apply after an item or service's coverage determination is made. The following are outlined in the FLP provisions:

- 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.
- 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.

In most cases, the FLP provisions apply only to beneficiaries enrolled in the Original Medicare Fee-For-Service program Parts A and B.

The FLP provisions apply only when both of the following conditions are met:

- Items and/or services are denied on the basis of specific statutory provisions; and
- Involve determinations about knowledge of whether Medicare was likely to deny payment for the items and/or services.

The LOL provisions, §1879(a)-(g) of the Act, fall under the FLP provisions and provide financial relief and protection to beneficiaries, healthcare providers, and suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain items and/or services for which Medicare payment would otherwise be denied.

When it is determined that a review falls under the LOL provisions, evidence must show that either a healthcare provider, supplier or the beneficiary knew or should have known that Medicare was going to deny payment on the item or service.

42 CFR 411.404 provides criteria for beneficiary knowledge based on written notice, however, §1879(a)(2) of the Act specifies only that knowledge must not exist in order to apply the LOL provision. Beneficiary knowledge is established when the healthcare provider/supplier gives a valid written notice (i.e., issuing an Advance Beneficiary Notice of Non-coverage (ABN), Form CMS-R-131) but can also be established when the beneficiary receives notice of a recent claim denial for the same item or service.

If the healthcare provider/supplier had actual knowledge of the non-coverage of item and/or service in a particular case, could reasonably have been expected to have such knowledge or

the beneficiary was shown not to have knowledge (found not liable), the Medicare program shall not make a payment to the healthcare provider/supplier.

Generally, Medicare provides forms (i.e., the ABN, Form CMS-R-131, Skilled Nursing Facility ABN, Form CMS-10055, etc.) for healthcare providers and suppliers to use as a way to provide written notice to beneficiaries. The healthcare provider/supplier should issue the applicable written notice each time, and as soon as, it makes the assessment that Medicare payment certainly or probably will not be made in order to transfer potential financial liability to the beneficiary. The written notice allows the beneficiary to:

- Make an informed decision whether or not to receive the item and/or service; and
- Better participate in his/her own health care treatment decisions.

A healthcare provider/supplier should follow specific written notice standards when issuing the written notice as evidence of the beneficiary’s knowledge for the purposes of the FLP provisions.

**B. Policy:** Section 1879 of the Act and 42 CFR 411.404

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12242.1	Contractors shall review the process associated with the revised language as indicated in Chapter 30 of Pub. 100-04.	X	X	X	X					
12242.2	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				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12242.3	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X	X	X	

#### IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements:** N/A

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: All other recommendations and supporting information:** N/A

#### V. CONTACTS

**Pre-Implementation Contact(s):** Jennifer McCormick, 410-786-2852 or Jennifer.McCormick1@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

#### VI. FUNDING

**Section A: 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.

**ATTACHMENTS: 0**



# Medicare Claims Processing Manual

## Chapter 30 - Financial Liability Protections

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**50 - Advance Beneficiary Notice of Non-coverage (ABN)**  
*(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)*

**A. General Statutory Authority - Applicability to Limitation on Liability (LOL)**

Section 1879 of the Act (*where the LOL provisions are located*) requires a *healthcare provider or supplier (i.e. notifier)* to notify a beneficiary in advance of furnishing an item or service when s/he believes that items or services will likely be denied *by Medicare for any of the reasons specified in the statutory provision in order to shift financial liability to the beneficiary for the denial*. For example, advance notice is required if the item or service may be denied 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. Notice (e.g., the ABN) is *a way for healthcare providers or suppliers* to establish beneficiary knowledge of non-coverage and therefore, shift financial liability for these items or services if Medicare denies the claim.

**B. Compliance with Limitation on Liability Provisions**

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 *may* hold any *healthcare provider or supplier* who either failed to give notice when required, or gave defective notice, financially liable. A notifier who can demonstrate that s/he 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 s/he did not know or could not reasonably have been expected to know that Medicare would not make payment, as the issuance of the *notice* is clear evidence of knowledge. A notifier who cannot demonstrate that adequate advance notice was furnished to the beneficiary will not be able to use the provisions in section 1879 of the Act to transfer financial liability to the beneficiary.

ABN - Quick Glance Guide <sup>3</sup>			
<b>Notice Name:</b> Advance Beneficiary Notice of <i>Non-coverage</i> (ABN)			
<b>Notice Number:</b> Form CMS-R-131			
<b>Issued by:</b> <i>Healthcare</i> providers and suppliers of Medicare Part B items and services; Hospice and Religious Non-medical HealthCare Institute (RNHCI) providing Medicare Part A items and services; and home health agencies(HHAs) for Part A and Part B items and services			
<b>Recipient:</b> Original Medicare FFS (fee for service) beneficiary;			
<b>Type of notice:</b>	<b>Must be issued:</b>	<b>Timing of notice:</b>	<b>Optional use:</b>

Financial liability notice	<p>Prior to providing an item or service that is usually paid for by Medicare under Part B (or under Part A for hospice, HHA, and RNHCI providers only) but may not be paid for in this particular case because it is not considered medically reasonable and necessary</p> <p>Prior to providing custodial care</p> <p>For hospice providers, prior to caring for a patient who is not terminally ill</p> <p>For <i>Durable Medicare Equipment (DME)</i> suppliers</p> <p>For HHA providers, prior to providing care when the individual is not confined to the home or does not need intermittent skilled nursing care.</p>	<p>Prior to delivery of the item or service in question.</p> <p>Provide enough time for the beneficiary to make an informed decision on whether or not to receive the service or item in question and accept potential financial liability.</p>	<p>Yes. Prior to providing an item or service that is never covered by Medicare (i.e. not a Medicare benefit).</p>
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<sup>3</sup> This is an abbreviated reference tool and is not meant to replace or supersede any of the directives contained in Section 50.

### **50.1- *ABN Scope***

***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

The ABN is an Office of Management and Budget (OMB)-approved written notice issued by *healthcare* providers and suppliers for items and services provided under Medicare Part B. With the exception of DME suppliers, *only healthcare* providers and suppliers who are enrolled in Medicare can issue the ABN to beneficiaries.

The ABN is given to beneficiaries enrolled in the Medicare FFS program. It is not 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).

Skilled Nursing Facilities (SNFs) issue the ABN for Part B services only. The Skilled Nursing Facility Advance Beneficiary Notice of Non-coverage (SNF ABN), CMS Form 10055, is issued for Part A SNF items and services. Section 70 of this chapter contains information on SNFABN issuance

### **50.2 - *ABN Uses***

***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

The following provisions necessitate 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);
- §1879(g)(1) of the Act (home health services requirements are not met – not confined to the home or no need for intermittent skilled nursing care);

- §1862(a)(1)(P) of the Act, Medicare covered personalized prevention plan services (as defined in §1861(hhh)(1)) that are performed more frequently than indicated per coverage guidelines are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member);
- Under 42 CFR §414.408(e)(3)(ii) when a noncontract supplier furnishes an item included in the Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) for a Competitive Bidding Area (CBA). Although all other denial reasons triggering mandatory use of the ABN are found in §1879 of the Act, in this situation, §1847(b)(5)(D) of the Act permits use of the ABN with respect to these items and services; *or*
- When Medicare considers an item or service experimental (e.g., a “Research Use Only” or “Investigational Use Only” laboratory test), payment for the experimental item or service is denied under §1862(a)(1) of the Act as not reasonable and necessary. In circumstances such as this, the beneficiary must be given an ABN.

### ***50.2.1– Optional ABN Uses***

***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

ABNs are not required for care that is either statutorily excluded from coverage under Medicare (i.e. care that is never covered) or most care that fails to meet a technical benefit requirement (i.e. lacks required certification). However, *CMS strongly encourage healthcare providers and suppliers to issue* the ABN 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 eye care;
  - Dental care; and
  - Routine foot care.

*When the ABN is used in this way it* serves as a courtesy to the beneficiary in forewarning him/her of impending financial obligation. *The* beneficiary should not be asked to choose an option box or sign the notice. The *healthcare* provider or supplier is not required to adhere to the issuance guidelines for the ABN.

**NOTE:** Certain DME items/services that fail to meet a technical requirement may require an ABN as outlined in the mandatory use section above.

### ***50.3 - Issuance of the ABN***

***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

<p><b>Notifiers</b></p>	<p>May direct an employee or a subcontractor to deliver an ABN. The billing entity will always be held responsible for effective delivery regardless of who gives the <i>notice</i>.</p> <p>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:</p> <ul style="list-style-type: none"> <li>• There are separate “ordering” and “rendering” <i>healthcare</i> providers <i>or supplier</i> (e.g. a physician orders a lab test and an independent laboratory delivers the ordered tests);</li> <li>• One <i>healthcare</i> provider <i>or supplier</i> 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</li> <li>• 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).</li> </ul> <p>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 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.</p>
<p><b>Representatives of Beneficiaries</b></p>	<p>If the beneficiary has a known, legally authorized representative, the ABN must be issued to the existing representative. If a beneficiary does not have a representative and one is necessary, a representative may be appointed for purposes of receiving notice following CMS guidelines and as permitted by State and Local law. When a representative is signing the ABN on behalf of a beneficiary, the ABN should be annotated to identify that the signature was penned by the “rep” or “representative”. If the representative’s signature is not clearly legible, the representative’s name should be printed on the ABN. <i>See section 500 of this</i></p>

	<i>manual under “Authorized representative” for more information.</i>
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## 50.4 - *ABN Triggering Events*

*(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)*

<b>Initiations</b>	<b>Reductions</b>	<b>Terminations</b>
The beginning of a new patient encounter, start of a plan of care, or beginning of treatment.	A reduction occurs when there is a decrease in a component of care (i.e. frequency, duration, etc.). The ABN is not issued every time an item or service is reduced. But, if a reduction occurs and the beneficiary wants to receive care that is no longer considered medically reasonable and necessary, the ABN must be issued prior to delivery of this non-covered care.	A termination is the discontinuation of certain items or services. The ABN is only issued at termination if the beneficiary wants to continue receiving care that is no longer medically reasonable and necessary.

## 50.5 - *ABN Standards*

*(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)*

The ABN, Form CMS-R-131, is the OMB approved standard written 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.

The online replicable copies of the OMB approved ABN (CMS-R-131) and instructions for notice completion are available on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html>

### **A. Language Choice**

The ABN is available in English and Spanish under a dedicated link on the web page given above. 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.

### **B. Effective Versions**

ABNs are effective as of the OMB approval or expiration date given at the bottom of each notice. The routine approval is for 3-year use. Notifiers are expected to exclusively use the current version of the ABN. CMS will allow a transition period for *healthcare* providers and suppliers to switch from using expiring notices to newly approved notices.

### **C. General Notice Preparation Requirements**

<b><i>Number of Copies</i></b>	<i>A minimum of two copies, including the original, should be made so the beneficiary and notifier each have one. The notifier should retain the original whenever possible.</i>
<b><i>Reproduction</i></b>	<i>Notifiers may reproduce the ABN by using self-carbonizing paper, photocopying, digitized technology, or another appropriate method. All reproductions should conform to applicable requirements.</i>
<b><i>Length and Size of Page</i></b>	<i>The ABN form must not exceed one page in length; however, attachments are permitted for listing additional items and services. If attachments are used, they should allow for clear matching of the items or services in question with the reason and cost estimate information. The ABN is designed as a letter- sized form. If necessary, it may be expanded to a legal-sized page.</i>
<b><i>Contrast of Paper and Print</i></b>	<i>A visually high-contrast combination of dark ink on a pale background should be used– Do not use reversed print (i.e. white print on black paper), or block-shaded (highlighted) text.</i>
<b><i>Font</i></b>	<i>Fonts as they appear in the ABN downloaded from the CMS web site should be used. In cases where changes need to occur, notifiers should use alternative fonts that are easily readable, such as Arial, Arial Narrow, Times New Roman, and Courier. 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 14-16 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.</i>
<b><i>Customization</i></b>	<i>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</i>

	<p><i>multiple versions of the ABN specialized to common treatment scenarios, using the required language and general formatting of the ABN.</i></p> <p><i>Blanks (G)-(I) must be completed by the beneficiary when the ABN is issued and should not 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 non-coverage, the notifier must clearly indicate on the ABN which portions of the pre-printed information are applicable to the beneficiary</i></p> <p><i>Healthcare providers or suppliers who pre-print a menu of items or services may wish to list a cost estimate alongside each item or service.</i></p>
<p><b>Modification</b></p>	<p><i>The ABN may not be modified except as specifically allowed by these instructions. Notifiers must exercise caution before adding any customizations beyond these guidelines, since changing ABNs too much could result in invalid notice and healthcare provider or supplier liability for non-covered charges. Validity judgments are generally made by Medicare contractors, usually when reviewing ABN-related claims; however, any complaints received may be investigated by contractors and/or CMS central or regional offices.</i></p>

## **50.6 - Completing the ABN**

*(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)*

Step-by-step instructions for notice completion are posted along with the notice on the CMS website and can be downloaded via this link:

<http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html>

### **A. Other Considerations During ABN Completion**

#### **1. Beneficiary Changes His/her Mind**

If after completing and signing the ABN, a beneficiary changes his/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/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 *should* 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.

## ***2. 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 or choose an option 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 *should* provide a copy of the annotated ABN to the beneficiary, and keep the original version of the annotated notice in the patient's file.

### ***50.7 – ABN Retention***

***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

The notifier should retain the ABN delivered to the beneficiary on file should there be any question regarding whether the beneficiary had knowledge of the potential financial liability. 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 *should* give a copy of the signed ABN to the billing entity.

In general, it is 5 years from discharge/completion of delivery of care when there are no other applicable requirements under State law. Electronic retention of the signed paper document is acceptable. Notifiers may scan the signed paper or "wet" version of the ABN for electronic medical record retention and if desired, give the paper copy to the beneficiary.

### ***50.8 – Effective ABN Delivery***

***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

ABN delivery is considered to be effective when the ABN 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 the notifier being found liable since the burden of proof is on the notifier to show that 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 non-covered 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 s/he 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 non-covered care.

6. Signed by the beneficiary.

#### ***A. Period of Effectiveness/Repetitive or Continuous Non-covered Care***

*An ABN remains effective after valid delivery so long as there has been no change in:*

- *Care from what is described on the original ABN;*
- *The beneficiary's health status which would require a change in the subsequent treatment for the non-covered condition; and/or*
- *The Medicare coverage guidelines for the items or services in question (i.e., updates or changes to the policy of an item or service).*

***NOTE:*** *If any of the above changes during the course of treatment, a new ABN must be issued.*

*For items or services that are repetitive or continuous in nature, notifiers may issue another ABN to a beneficiary after one year for subsequent treatment for the non-covered condition. However, this is not required unless any of the conditions described above apply to the given situation.*

*Notifiers may give a beneficiary a single ABN describing an extended or repetitive course of non-covered 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 non-covered items or services are needed, the notifier must give the beneficiary another ABN.*

If a beneficiary is receiving repetitive non-covered care, but the **healthcare** provider or supplier failed to issue an ABN before the first or the first few episodes of care were provided, the ABN may be issued at any time during the course of treatment. However, if the ABN is issued after repetitive treatment has been initiated, the ABN cannot be retroactively dated or used to shift liability to the beneficiary for care that had been provided before ABN issuance. In cases such as this, care that was provided before ABN delivery would be the financial responsibility of the **healthcare provider or supplier**.

#### ***B. 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 notice, the applicable Medicare contractor will not hold the beneficiary liable in the individual case.

#### ***C. Electronic Issuance of the ABN***

Electronic issuance of ABNs is not prohibited. If a **healthcare provider or supplier** elects to issue an ABN that is viewed on an electronic screen before signing, the beneficiary **has** the option of requesting paper issuance over electronic if that is what s/he prefers. Also, regardless of whether a paper or electronic version is issued and regardless of whether the

signature is digitally captured or manually penned, the beneficiary *should* be given a paper copy of the signed ABN to keep for his/her own records.

### ***50.8.1- Options for Delivery Other than In-Person (Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

ABNs should be delivered in-person and prior to the delivery of medical care which is presumed to be non-covered. In circumstances when in-person delivery is not possible, notifiers may deliver an ABN *using another method. Examples include:*

- Direct 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/her representative in order to validate delivery.

When delivery is not in-person, the notifier must verify that contact was made in his/her records. In order to be considered effective, the beneficiary should not dispute such contact. Telephone contacts *should* be followed immediately by either a hand-delivered, mailed, emailed, or a faxed notice. The beneficiary *should* 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 should document the initial contact and subsequent attempts to obtain a signature in appropriate records or on the notice itself.

## ***50.9 - Effects of Lack of Notification, Medicare Review and Claim Adjudication (Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

### ***A. Beneficiary Liability***

A beneficiary who has been given a properly delivered ABN and agrees to pay may be held liable. The charge may be the *healthcare provider or supplier's* usual and customary fee for that item or service and is not limited to the Medicare fee schedule. If the beneficiary does not receive proper notice when required, s/he is relieved from liability.

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. Healthcare Provider or Supplier Liability***

A notifier will likely have financial liability for items or services if s/he 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 s/he is able to

demonstrate that s/he did not know or could not reasonably have been expected to know that Medicare would not make payment.

**50.10 - *Using ABNs for Medical Equipment and Supplies Claims When Denials Under §1834(a)(17)(B) of the Act (Prohibition Against Unsolicited Telephone Contacts) Are Expected***  
***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

To qualify for waiver of the *Refund Requirements (RR) provision* under §1834(a)(18) or §1879(h)(3) of the Act (unassigned and assigned claims, respectively), an ABN must clearly identify the particular item or service and state that the supplier expects that Medicare will deny payment for that particular medical equipment or supplies because the supplier violated the prohibition on unsolicited telephone contacts. Since it is the unsolicited telephone contact which is prohibited by law, giving notice by telephone does not qualify as notice and is not permissible. Telephone notice may not be used in this case.

Since giving or mailing an ABN and obtaining the beneficiary's agreement to pay before telephoning is equivalent to obtaining the beneficiary's written permission for the supplier to telephone under §1834(a)(17)(A)(i) of the Act, a supplier has little to gain from using the ABN process instead of simply seeking the beneficiary's written permission to contact him or her. If a supplier does use an ABN prior to calling, the beneficiary's agreement to pay is essential under the Refund Requirements in order for the supplier to collect from the beneficiary. Medicare denial of payment because of the prohibition on unsolicited telephone contacts applies to all varieties of medical equipment and supplies and to all Medicare beneficiaries equally. Therefore, the usual restriction on routine notices to all beneficiaries does not apply in this case.

Since unsolicited telephone contacts are expressly prohibited by statute, there is presumption of supplier knowledge of this provision. 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.

**50.11 - *ABNs for Medical Equipment and Supplies Claims Denied Under §1834(j)(1) of the Act (Because the Supplier Did Not Meet Supplier Number Requirements)***  
***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

To qualify for waiver of the RR under §1834(j)(4)(A) and §1879(h)(1) of the Act (unassigned and assigned claims, respectively) for medical equipment and supplies for which payment will be denied due to failure to meet supplier number requirements under §1834(j)(1) of the Act, the ABN must state that Medicare will deny payment for any medical equipment or supplies because the supplier does not have a supplier number. *The supplier should keep the ABN on file for documentation that the beneficiary has knowledge of this particular denial and that the beneficiary accepts financial liability.* This relieves the supplier, which has duly notified a beneficiary of its lack of a supplier number and the fact that Medicare will not pay, from the necessity of obtaining a signed agreement from the beneficiary every time the beneficiary does business with the supplier.

**Exception to ABN Requirement**

A supplier which can show that it did not know and could not reasonably have been expected to know that a customer was a Medicare beneficiary, or that a customer was making a

purchase for a Medicare beneficiary, can seek protection under the LOL provision or, in the case of unassigned claims, under the applicable RR provision, §1834(j)(4) of the Act. *Below are situations where the supplier may seek protection under the LOL provision or the RR provision:*

- If the supplier can show that a person who is not a Medicare beneficiary made a purchase on behalf of a person who is a Medicare beneficiary and did not apprise the supplier of the fact that the purchase was being made on behalf of a Medicare beneficiary, the supplier may be protected.
- If the supplier can show that a Medicare beneficiary who made a purchase did not identify himself or herself as a Medicare beneficiary and that the person's age or appearance was such that the supplier could not reasonably have been expected to know or surmise that the person was a Medicare beneficiary, the supplier may be protected. These protections are meant for an honest supplier in the rare case where a Medicare beneficiary who is relatively youthful, healthy and able in appearance does not identify himself or herself as a beneficiary and the supplier understandably does not surmise that he or she might be a Medicare beneficiary.

If the involved Medicare beneficiary is found to be obviously aged and/or disabled, such that any adult person working for a supplier would reasonably surmise that he or she could be a Medicare beneficiary, the supplier's allegation may not be accepted. If the beneficiary purchased an item which would strongly suggest to any reasonable adult person working for a supplier that the beneficiary is aged and/or disabled, the supplier's allegation may not be accepted.

- If a supplier can show that a customer, who is a Medicare beneficiary or was making a purchase for a Medicare beneficiary and did not identify him/herself accordingly to the supplier, was on notice of the necessity to so self-identify, the beneficiary may be held *liable*, in which case the supplier could collect from the beneficiary.

Given the possible difficulty of showing conclusively that it did not know and could not reasonably have been expected to know that a customer was a Medicare beneficiary, or that a customer was making a purchase for a Medicare beneficiary, a supplier would be well advised to consider using signage, giving public notice alerting customers that they need to inform the supplier if they are a Medicare beneficiary or are making a purchase for a Medicare beneficiary. If a supplier which does not have a supplier number provides adequate public notice to a Medicare beneficiary before medical equipment or supplies are furnished (e.g., by means of clearly visible signs, and if the adequacy of such public notice is not disputed by the beneficiary) the supplier can qualify for waiver of the Refund Requirements. Such public notices must be such that Medicare beneficiaries:

1. Are virtually certain to see them before purchasing or renting Medicare-covered medical equipment or supplies from the supplier (that is, they are posted in places where they are most likely to be seen by the target audience), and
2. May reasonably be expected to be able to read them and understand them.

Therefore, such public notices must be readily visible, in easily readable plain language, in large print, and would have to be provided in the language(s) commonly used in the locality.

Do not hold any beneficiary who cannot read any such public notice of a supplier to be properly notified in advance by the supplier that Medicare will not pay. If a supplier alleges

that it provided adequate public notice to Medicare beneficiaries but a beneficiary disputes the allegation, in the absence of conclusive evidence in favor of the supplier, do not hold the beneficiary to be properly notified in advance by the supplier that Medicare will not pay; hold the supplier liable. The RR provision that the beneficiary must agree to pay for the item or service makes the use of signage without an ABN a risk for the supplier. It would be in a supplier's best interest to issue ABNs advising beneficiaries that they will have to pay for supplies and to post public notices in its store(s) which inform beneficiaries of the fact that it is not a Medicare enrolled supplier, and that claims for supplies purchased from that supplier will be denied payment by Medicare. The use of notices in conjunction with public notices will provide maximum protection to suppliers as well as more surely providing proper notice to beneficiaries so that they can make informed consumer decisions.

Medicare denial of payment on the basis of a supplier's lack of a supplier number applies to all varieties of medical equipment and supplies and to all Medicare beneficiaries equally. Therefore, the usual restriction on routine notices to all beneficiaries does not apply in this case.

### ***50.12- ABNs for Claims Denied in Advance Under §1834(a)(15) of the Act (Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

#### ***A. Mandatory***

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 contractor's 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 overutilization.

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.

#### ***B. Optional***

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 beneficiary 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.

### ***50.13 - ABN Standards for Upgraded Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

Notifiers must give an ABN before a beneficiary receives a Medicare covered item

containing upgrade components that are not medically reasonable and necessary and not paid for by the supplier. DME upgrades involve situations in which the upgraded item or component has a different Health Insurance Common Procedure Coding System (HCPCS) code than the item that will be covered by Medicare. Please refer to Chapter 20, Section 120 in this manual for information on billing procedures for ABN upgrades.

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 but do not exceed the HCPCS code description.

#### **50.14 - *ABNs for items listed in a DMEPOS Competitive Bidding Program (CBP)***

***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

Section 1862 (a)(17) of the Act excludes Medicare payment for CBP items/ services that are provided by a non-contract supplier in a Competitive Bidding Area (CBA) except in special circumstances. A non-contracted supplier is permitted to provide a beneficiary with an item or service listed in the CBP when the supplier properly issues an ABN prior to delivery of the item or service per 42 CFR §414.408(e)(3)(ii). In order for the ABN to be considered valid when issued under these circumstances, the reason that Medicare may not pay must be clearly and fully explained on the ABN that is signed by the beneficiary.

To be a valid ABN, the beneficiary must understand the meaning of the notice. Suppliers must explain to the beneficiary that Medicare will pay for the item if it is obtained from a different supplier in the area. While some suppliers may be reluctant to direct beneficiaries to a specific contracted supplier, the non-contracted supplier should at least direct the beneficiary to 1-800 –MEDICARE to find a local contracted supplier at the beneficiary’s request.

#### **50.15 - *Collection of Funds and Refunds***

***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

##### **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 non-covered 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. Regardless of whether they accept assignment or not, *healthcare* providers and suppliers are permitted to charge and collect the usual and customary fees; therefore, funds collected are not limited to the Medicare allowed amounts.

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

##### **50.15.1 - *Physicians’ Services RR***

***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

The physicians' services *RR* 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 amounts collected which exceed the Medicare payment for the less extensive item or service. These *RR* 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.

### ***50.15.2 - DMEPOS RR Provision for Claims for Medical Equipment and Supplies*** ***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

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.

### ***50.15.3 - Time Limits and Penalties for Healthcare providers and Suppliers in Making Refunds*** ***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

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 *healthcare provider or* supplier receives the remittance advice (RA) if the *healthcare provider or*/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 *healthcare provider or* supplier receives the notice of the review determination if the *healthcare provider or* supplier requests review within 30 days of receipt of the notice of the initial determination.

*Healthcare provider or* 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 *healthcare provider or* supplier fails to make a timely refund. If the contractor determines that a *healthcare provider or* supplier failed to make a refund, it will contact the *healthcare provider or* 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) or CMS is appropriate and will make appropriate referrals to the OIG if necessary. The OIG or CMS may impose civil money penalties, assessments, and sanctions if he or she fails to make the required refund. The contractor will retain a detailed written report of contact.

#### ***50.15.4 - Supplier's Right to Recover Resalable Items for Which Refund Has Been Made*** ***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

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.

#### ***50.16 - CMS Regional Office (RO) Referral Procedure*** ***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

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 for violation of refund requirements. When referring these types of cases to the region, the contractor should include the following:

<b>Background of the Subject</b>	<i>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.</i>
<b>Origin of the Case</b>	<i>A brief description of how the violations were discovered.</i>
<b>Statement of Facts</b>	<i>A statement of facts in chronological order describing each failure to comply with the refund requirements.</i>
<b>Written Correspondence and Written Summaries</b>	<i>Copies of any meetings or telephone contacts with the beneficiary and the supplier regarding the supplier's failure to make a refund.</i>
<i>List of the following for each item or service not refunded to the beneficiary by the supplier (grouped by beneficiary):</i>	<ul style="list-style-type: none"> <li>•Beneficiary Name and Medicare beneficiary identifier;</li> <li>•Claim Control Number;</li> <li>•Procedure Code (CPT-4 or HCPCS) of non-refunded item or service;</li> <li>•Procedure Code modifier;</li> <li>•Date of Service;</li> <li>•Place of Service Code;</li> <li>•Submitted Charge;</li> <li>•Units (quantity) of Item or Service; and</li> <li>•Amount Requested to be refunded.</li> </ul>
<b>Additional Information</b>	<i>Any information that may be of value to the RO.</i>

### **50.17 – ABN Special Considerations**

**(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)**

#### **A. Obligation to Bill Medicare**

Upon receipt of an ABN, beneficiaries always have the right to ask the notifier to submit a claim to Medicare for an official payment decision. A beneficiary must receive the item/service described in the ABN and choose Option 1 in order to request Medicare claim submission.

Healthcare providers or suppliers should refer to Publication 100-4, Chapter 1, Section 60 for instructions on submitting claims for statutorily non-covered items or services.

**Note:** Healthcare providers or suppliers will not violate mandatory claims submission rules under Section 1848 of the Social Security Act when a claim is not submitted to Medicare at

the beneficiary's request by their choice of Option 2 on the ABN.

### **B. Dually Eligible Individuals (Has a Qualified Medicare Beneficiary (QMB) Program and/or Medicaid coverage)**

Dually Eligible beneficiaries must be instructed to check **Option Box 1** on the ABN in order for a claim to be submitted for Medicare adjudication.

The provider must strike through **Option Box 1** as provided below:

**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.~~

These edits are required because the provider cannot bill the dual eligible beneficiary when the ABN is furnished. Providers must refrain from billing the beneficiary pending adjudication by both Medicare and Medicaid in light of federal law affecting coverage and billing of dual eligible beneficiaries. If Medicare denies a claim where an ABN was needed in order to transfer financial liability to the beneficiary, the claim may be crossed over to Medicaid or submitted by the provider for adjudication based on State Medicaid coverage and payment policy. Medicaid will issue a Remittance Advice based on this determination.

Once the claim is adjudicated by both Medicare and Medicaid, providers may only charge the patient in the following circumstances:

- If the beneficiary has QMB coverage without full Medicaid coverage, the ABN could allow the provider to shift financial liability to the beneficiary per Medicare policy.
- If the beneficiary has full Medicaid coverage and Medicaid denies the claim (or will not pay because the provider does not participate in Medicaid), the ABN could allow the provider to shift financial liability to the beneficiary per Medicare policy, subject to any state laws that limit beneficiary liability.

**Note:** These instructions should only be used when the ABN is used to transfer potential financial liability to the beneficiary and not in voluntary instances. More information on dual eligible beneficiaries may be found at: [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare\\_Beneficiaries\\_Dual\\_Eligibles\\_At\\_a\\_Glance.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf)

### **C. Ambulance Transports**

<b>Emergency or urgent situations</b>	<p>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.</p>
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<p><b><i>Non-emergent/urgent ambulance transport</i></b></p>	<p><i>If the provider or supplier wants to transfer liability to the beneficiary, issuance of the ABN is mandatory for ambulance transport services if all of the following 3 criteria are met.:</i></p> <ol style="list-style-type: none"> <li><i>1. The service being provided is a Medicare covered ambulance benefit under §1861(s)(7) of the SSA and regulations under this section as stipulated in 42 CFR §410.40 -.41;</i></li> <li><i>2. The healthcare provider or supplier believes that the service may be denied, in part or in full, as “not reasonable and necessary” under § 1862(a)(1)(A) for the beneficiary on that particular occasion; and</i></li> <li><i>3. The ambulance service is being provided in a non-emergency situation. (The patient is not under duress.)</i></li> </ol>
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*ABN issuance is mandatory only when a beneficiary’s covered ambulance transport is modified to a level that is not medically reasonable and necessary and will incur additional costs. If an ambulance transport is statutorily excluded from coverage because it fails to meet Medicare’s definition of the ambulance benefit, a voluntary ABN may be issued to notify the beneficiary of his/her financial liability as a courtesy.*

#### ***D. Hospice***

*Mandatory use of the ABN is very limited for hospices. Hospice providers are responsible for providing the ABN when required as listed below for items and services billable to hospice. Hospices are not responsible for issuing an ABN when a hospice patient seeks care outside of the hospice’s jurisdiction.*

*The three situations that would require issuance of the ABN by a hospice are:*

- Ineligibility because the beneficiary is not determined to be “terminally ill” as defined in §1879(g)(2) of the Act; or*
- 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.*

***Note:*** *It is the hospice’s responsibility to issue an ABN when a beneficiary who has elected the hospice benefit chooses to receive inpatient hospice care in a hospital that is not under contract with the hospice. The hospice may delegate delivery of the ABN to the hospital in these cases.*

## ***End of all Medicare covered hospice care –***

*When it is determined that a beneficiary who has been receiving hospice care is no longer terminally ill and the beneficiary is going to be discharged from hospice, the hospice may be required to issue the Notice of Medicare Non-coverage (NOMNC), CMS 10123. If upon discharge the patient wants to continue receiving hospice care that will not be covered by Medicare, the hospice would issue an ABN to the beneficiary in order to transfer liability for the non-covered care to the beneficiary. If no further hospice services are provided after discharge, ABN issuance would not be required.*

*ABNs are not required for Hospice Services in these situations:*

- ***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/her own freedom of choice. Therefore, no ABN is required.
- ***Respite Care Beyond Five Consecutive Days*** - Respite care is limited to five consecutive days under the Act. When respite care exceeds five consecutive days, an ABN is not required since additional days of respite care are not part of the hospice benefit. CMS encourages hospice providers to give the ABN as an optional notice to inform patients of financial liability when more than five days of respite care will be provided.
- ***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.
- ***Failure to Meet the Face to Face Requirement*** - The ABN must not be issued when the face to face requirement for hospice recertification is not met within the required timeframe. Failure to meet the face to face requirement for recertification should not be misrepresented as a determination that the beneficiary is no longer terminally ill.
- ***Room and Board Costs for Nursing Facility Residents*** - Since room and board are not part of the hospice benefit, an ABN would not be required when the patient elects hospice and continues to pay out of pocket for long term care room and board.

## ***E. Comprehensive Outpatient Rehabilitation Facility (CORF)***

*Since Comprehensive Outpatient Rehabilitation Facility (CORF) services are billed under Part B, CORF providers must issue the ABN according to the instructions given in this section. The ABN is issued by CORFs before providing a service that is usually covered by Medicare but may not be paid for in a specific case because it is not medically reasonable and necessary.*

*When all Medicare covered CORF services are going to end, CORF's are required to issue a notice regarding the beneficiary's right to an expedited determination called a NOMNC, CMS 10123. Upon termination of all CORF care, the ABN would be issued only if the beneficiary wants to continue receiving some or all services that will not be covered by Medicare because they are no longer considered medically reasonable and necessary. An ABN would not be issued if no further CORF services are provided.*

## ***F. Home Health Agency (HHA)***

*The following chart summarizes the statutory provisions related to ABN issuance for LOL*

*purposes:*

***Application of LOL for the Home Health Benefit***

<b><i>Citation from the Act</i></b>	<b><i>Brief Description of</i></b>	<b><i>Recommended Explanation</i></b>
<i>§1862(a)(1)(A)</i>	<i>Care is not reasonable and necessary</i>	<i>Medicare does not pay for care that is not medically reasonable and</i>
<i>§1862(a)(9)</i>	<i>Custodial care is the only care delivered</i>	<i>Medicare does not usually pay for custodial care,</i>
<i>§1879(g)(1)(A)</i>	<i>Beneficiary is not homebound</i>	<i>Medicare requires that a beneficiary cannot leave home (with certain exceptions) in order to cover services</i>
<i>§1879(g)(1)(B)</i>	<i>Beneficiary does not need skilled nursing care on an intermittent basis</i>	<i>Medicare requires part-time or intermittent need for skilled nursing care in order to cover</i>

***Triggering Events for ABN issuance by HHAs\****

*HHAs may be required to provide an ABN to an Original Medicare beneficiary when a triggering event occurs.*

<b><i>EVENT</i></b>	<b><i>DESCRIPTION</i></b>	<b><i>EXAMPLE</i></b>
<i>Initiation</i>	<i>An ABN must be issued to the beneficiary prior to receiving care that is usually covered by Medicare, but in this particular instance, it is not covered or may not be covered by Medicare because the care is not medically reasonable and necessary, the beneficiary is not confined to his/her home (considered homebound), or the beneficiary does not need skilled nursing care on an intermittent basis, or the beneficiary is receiving custodial care only.</i>	<i>A beneficiary requires skilled nursing wound care 3 times weekly; however, she is not confined to the home. She wants the care done at her home by the HHA.</i>
<i>Reduction</i>	<i>Reductions involve any decrease in services or supplies, such as frequency, amount, or level of care, provided by the HHA and/or care that is part of the POC. If a reduction occurs for an item or service that will no longer be covered by Medicare</i>	<i>The beneficiary requires physical therapy (PT) for gait retraining 5 times per week for 2 weeks, then reduce to 3 times</i>

	<i>but the beneficiary wants to continue to receive the care and assume the financial charges, the HHA must issue the ABN prior to providing the non-covered items or services.</i>	<i>weekly for 2 weeks. After 2 weeks of PT, the beneficiary wants to continue therapy 5 times a week even though this amount of therapy is no longer medically reasonable and necessary. The HHA would issue an ABN to the beneficiary so that he understands the situation and can consent to financial responsibility for the PT not covered by Medicare.</i>
<i>Termination</i>	<i>When an HHA expects that Medicare coverage will end for all items and services in total.</i>	

*\*If the beneficiary does not want the item or service that is being initiated, reduced, or terminated, no ABN is required.*

*When an HHA performs an initial assessment of a beneficiary prior to admission but does not admit the beneficiary, an ABN is not required if there is no charge for the assessment. However, if an HHA charges for an assessment, the HHA must provide notice to the beneficiary before performing and charging for this service.*

*Since Medicare has specific requirements for payment of home health services, there may be occasions where a payment requirement is not met, and therefore, the HHA expects that Medicare will not pay for the services. The HHA cannot use the ABN to transfer liability to the beneficiary when there is concern that a billing requirement may not be met. For example, a home health agency can't issue an ABN at initiation of home care services in order to charge the beneficiary if the healthcare provider face to face encounter requirement is not met.*

*When all Medicare covered home health care is terminated, HHAs may sometimes be required to deliver the NOMNC, CMS- 10123. The NOMNC informs beneficiaries of the right to an expedited determination by a Quality Improvement Organization (QIO) if they feel that termination of home health services is not appropriate. If a beneficiary requests a QIO review upon receiving a NOMNC, the QIO will make a fast decision on whether covered services should end. If the QIO decides that Medicare covered care should end and the patient wishes to continue receiving care from the HHA even though Medicare will not pay, an ABN must be issued to the beneficiary since this would be an initiation of non-covered care.*

### ***HHA Exceptions to ABN Notification Requirements***

*ABN issuance is NOT required in the following HHA situations:*

- initial assessments (in cases where beneficiaries are not admitted) for which HHAs do not charge;*

- *care that is never covered by Medicare under any circumstances (i.e., an HHA offers complimentary hearing aid cleaning and maintenance);*
- *telehealth monitoring used as an adjunct to regular covered HH care; or*
- *non-covered items/services that are part of care covered in total under a Medicare bundled payment (e.g., HH prospective payment system (PPS) episode payment).*

## **500 - Glossary**

***(Rev. 10862; Issued: 07-14-21; Effective: 10-14-21; Implementation: 10-14-21)***

The following terms are defined only for purposes of this Chapter 30 of the Medicare Claims Processing Manual.

**Advance notice of non-coverage**— 42 CFR 418.408(d)(2) states that if Medicare would be likely to deny payment as not medically reasonable and necessary, before the service was provided, the physician informed the beneficiary, or someone acting on the beneficiary's behalf, in writing that the physician believed Medicare was likely to deny payment for the specific service and that the beneficiary signed a statement agreeing to pay for that service. This statement may appear as the notice of non-coverage (e.g. Advance Beneficiary Notice of Non-coverage (ABN), Form CMS-R-131, Skilled Nursing Facility *Advance* Beneficiary Notice of Non-Coverage (SNF ABN), Form CMS-10055, Home Health Change of Care Notice (HHCCN), Form CMS-10280), as defined in 42 CFR 411.404.)

**Advance Beneficiary Notice of Non-coverage (ABN, Form CMS-R-131)** - Issued by healthcare providers and suppliers to Original Medicare (fee for service) beneficiaries in situations where Medicare payment is expected to be denied.

**Authorized representative** – An individual authorized under State or other applicable law, e.g., a legally appointed representative or guardian of the beneficiary (if, for example, the beneficiary has been legally declared incompetent by a court) to act on behalf of a beneficiary when the beneficiary is temporarily or permanently unable to act for himself or herself. The authorized representative will have all of the rights and responsibility of a beneficiary or party, as applicable. In states which have health care consent statutes providing for health care decision making by surrogates on behalf of patients who lack advance directives and guardians, reliance upon individuals appointed or designated under such statutes to act as authorized representatives is permissible. The **Appointment of Representative**, Form CMS-1696 is available for the convenience of the beneficiary or any other individual to use when appointing a representative.

For purposes of this chapter, when the term beneficiary is used, for legal purposes, and the beneficiary has an authorized representative, the use of either beneficiary or authorized representative are exchangeable of each other, unless otherwise indicated.

**Beneficiary** – Individual who is enrolled to receive benefits under Medicare Part A and/or Part B.

**Detailed Explanation of Non-Coverage (DENC, Form CMS-10124)** – Medicare Fee-For-Service (FFS) Expedited Determination Notice given only if a beneficiary requests an expedited determination. The DENC explains the specific reasons for the end of services.

**Detailed Notice of Discharge (DND, Form CMS-10066)** – Hospital Discharge Appeal Notice given to beneficiaries who choose to appeal a discharge decision from the hospital or their Medicare Advantage plan, if applicable.



**Financial Liability Protections (FLP) Provisions** – The FLP provisions of the Social Security Act protect beneficiaries, healthcare providers, and suppliers under certain circumstances from unexpected liability for charges associated with claims that Medicare does not pay. The FLP provisions apply after an item or service’s coverage determination is made.

**Healthcare provider** – Healthcare provider means a “provider of services” (or provider) (as defined under Section 1861(u) of the Social Security Act), a hospital, a critical access hospital (CAH), a skilled nursing facility (SNF), a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services).

**Home Health Change of Care Notice (HHCCN, Form CMS-10280)** - Used by Home Health Agencies (HHAs) to notify Original Medicare beneficiaries receiving home health care benefits of plan of care changes. HHAs are required to provide notification to beneficiaries before reducing or terminating an item and/or service.

**Hospital-Issued Notices of Non-coverage (HINNs)** - Hospitals provide to beneficiaries prior to admission, at admission, or at any point during an inpatient stay if the hospital determines that the care the beneficiary is receiving, or is about to receive, is not covered by Medicare.

**Important Message from Medicare (IM, Form CMS-R-193)** – Hospital Discharge Appeal Notice delivered to all Medicare beneficiaries (Original Medicare beneficiaries and Medicare Advantage plan enrollees) who are hospital inpatients. The IM informs hospitalized inpatient beneficiaries of their hospital discharge appeal rights.

**Limitation on Liability (LOL) Provision**– The LOL provisions, §1879(a)-(g) of the Social Security Act, fall under the FLP provisions and provide financial relief and protection to beneficiaries, healthcare providers, and suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain items and/or services for which Medicare payment would otherwise be denied.

**Limitation on Recoupment** – The requirement that (in certain cases) Medicare must cease or delay recovery of an overpayment when a valid first or second level appeal request is received from a provider on an overpayment, in accordance with Section 1893 of the Social Security Act. For more information, see 100-06 Medicare Financial Management Manual, Chapter 3, Overpayments.

*Medicare Beneficiary Identifier (MBI) - is a general term describing a beneficiary's Medicare identification number. Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

**Medicare Contractor** - An entity that contracts with the Federal government to review and/or adjudicate claims, determinations and/or decisions.

**Medicare Outpatient Observation Notice (MOON, Form CMS-10611)** - A standardized notice to inform Medicare beneficiaries (including health plan enrollees) that they are outpatients receiving observation services and are not inpatients of a hospital or CAH.

**Notice of Medicare Non-Coverage (NOMNC, Form CMS-10123)** - FFS Expedited Determination Notices that informs beneficiaries on how to request an expedited determination from their Quality Improvement Organization (QIO) and gives beneficiaries the opportunity to request an expedited determination from a QIO.

**Overpayment Recovery Waiver** – An allowance providing that beneficiaries, healthcare providers, and suppliers can keep Medicare overpayments (in certain circumstances) if they are determined to be “without fault” for causing the overpayment, in accordance with Section 1870 of the Social Security Act. For more information, see 100-06 Medicare Financial Management Manual, Chapter 3, Overpayments.

**Refund Requirements (RR) for Non-assigned Claims for Physicians Services** - Under §9332(c) of OBRA 1986 (P.L. 99-509), which added §1842(l) to the Social Security Act, new liability protections for Medicare beneficiaries affect nonparticipating physicians.

**Refund Requirements (RR) for Assigned and Non-assigned Claims for Medical Equipment and Supplies** – Under §132 of SSAA-1994 (Social Security Act Amendments of 1994, P.L. 103-432) which adds §1834(a)(18) to the Social Security Act, and under §133 of SSAA-1994 which adds §1834(j)(4) and §1879(h) to the Social Security 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 Social Security Act.

**Skilled Nursing Facility *Advance* Notice of Non-coverage (SNF ABN, Form CMS-10055)** – Issued in order for a Skilled Nursing Facility (SNF) to transfer financial liability to an Original Medicare beneficiary for items or services, *paid under the SNF PPS*, that Medicare is expected to deny payment (entirely or in part).

**Supplier** – Unless the context otherwise requires, a physician or other practitioner, a facility, or entity (other than a provider of services) that furnishes health services covered by Medicare.