
Program Memorandum Intermediaries/Carriers

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal AB-02-114

Date: JULY 31, 2002

**THIS PROGRAM MEMORANDUM REPLACES PROGRAM MEMORANDUM
A-01-77, CHANGE REQUEST 1192 DATED JUNE 27, 2001.**

CHANGE REQUEST 2219

**SUBJECT: ABNs and DMEPOS Refund Requirements - Implementation of
Form CMS-R-131, Advance Beneficiary Notice (ABN), and of Limits
on Beneficiary Liability for Medical Equipment and Supplies.**

Attached to this Program Memorandum (PM) are instructions with four exhibits for carriers, intermediaries, physicians, suppliers, and providers.

Part I - Instructions for Carriers, Physicians and Suppliers on Limitations of Beneficiaries' Liability for Claims for Physician and Supplier Services – Advance Beneficiary Notice (ABN) Standards

Part I of this PM instructs physicians, suppliers, and carriers: (1) Regarding the advance beneficiary notices (ABNs) that they must provide to beneficiaries in advance of furnishing what they believe to be non-covered items and services, and (2) The process required for submitting demand bills. Additionally, this PM discusses the approved standard government forms (CMS-R-131) that may be used to provide notice to beneficiaries. Also, this PM provides specific instructions regarding demand billing and demand bills claims processing.

Part II - Instructions for Carriers and Suppliers on Limits on Beneficiary Liability for Medical Equipment and Supplies

Under §1834(a)(18), §1834(j)(4), and §1879(h) (collectively, the “DMEPOS Refund Requirements”) of the Social Security Act (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 these Refund Requirements. Beneficiaries’ liability for payment for covered medical equipment and supplies which are furnished on or after January 1, 1995, and for which Medicare payment is denied for one of several reasons specified herein, may be limited. The Refund Requirements do not provide for either program payment or indemnification, but do provide that suppliers, if held liable, must make refunds to beneficiaries of any amounts collected. For both assigned and unassigned claims, for which the supplier is held to be liable and for which it is held that the beneficiary did not know, the beneficiary has no financial responsibility and the Refund Requirements provisions of the Act apply in virtually all cases.

Part III - Instructions for Fiscal Intermediaries and Providers on ABN Standards for Items and Services for Which Institutional Part B Claims Will Be Processed by Fiscal Intermediaries and on Limits on Beneficiary Liability for Medical Equipment and Supplies

Part III of this PM instructs fiscal intermediaries, suppliers, and providers: (1) Regarding the standards for use by fiscal intermediaries, suppliers, and providers in implementing the Advance Beneficiary Notice (ABN) requirements of the Refund Requirements (RR) and the Limitation On Liability (LOL) provisions of the Act; (2) Regarding limits on beneficiary liability for medical equipment and supplies (the DMEPOS Refund

CMS Pub. 60AB

Requirements provisions of the Act); and (3) Regarding demand billing and demand bills claims processing. These instructions on the use of ABNs apply to all claims for Part B services furnished by institutional providers and/or processed by fiscal intermediaries.

Part IV - Instructions for Regional Home Health Intermediaries (RHHs) and Hospices on Advance Beneficiary Notice (ABN) Standards for Certain Hospice Claims

Part IV of this PM instructs hospices and RHHs with respect to the requirements for ABNs enunciated in Part I of this PM and demand billing, as they are specifically applicable to two types of potential hospice Part A claims denials.

Actions

The instructions in this PM provide guidance with respect to the requirements for ABNs and demand bill processing. These instructions supersede any conflicting current instructions in the Medicare Carriers Manual §§7300-7300.10 & §7330; the Medicare Intermediary Manual §§3430-3445 and §§3719-3730.2; the Hospital Manual §§291-297.1, §406, §414ff.; the Skilled Nursing Facility Manual §§350-362.3; the Hospice Manual §§270-276; and the Medicare Program Integrity Manual, Chapter 5; and supersede the obsolete instructions in PM A-01-77. Sections 7300.5.A & 7330.D of the Medicare Carriers Manual are deleted and replaced by Part I of these instructions.

This PM requires carriers and intermediaries to publish verbatim on their websites the instructions set forth in this PM for the information of physicians, suppliers, and/or providers, no later than September 1, 2002.

Attachments

The *effective date* of this PM is October 1, 2002.

The *implementation date* of this PM is October 1, 2002.

This PM may be discarded October 1, 2003.

These instructions should be implemented within your current operating budget.

Questions related to this request should be addressed to Raymond Boyd, RBoyd@cms.hhs.gov, telephone 410-786-4544.

**Part I - Instructions for Carriers, Physicians, and Suppliers on
Limitations of Beneficiaries' Liability for Claims for Physician and Supplier
Services – Advance Beneficiary Notice (ABN) Standards**

Following are the standards for use by carriers, physicians, and suppliers in implementing the Advance Beneficiary Notice (ABN) requirements of several statutory provisions which limit beneficiaries' financial liability for certain denied claims, which currently include the Refund Requirements (RR) provisions in §§1834(a)(18), 1834(j)(4), 1842(l), and 1879(h) of the Social Security Act (the Act) and the Limitation On Liability (LOL) provisions in §1879(a)-(c) of the Act. References to manual sections are references to the Medicare Carriers Manual (MCM), Part 3. References to “you” and “your” refer to the Medicare carrier. The instructions contained here in Part I will be manualized in the MCM under a new section 7310. Following are several frequently asked questions (FAQs) about different ABN implications of Limitation On Liability and the Refund Requirements.

Q.1. What are the main differences between “Limitation On Liability” (LOL) and the “Refund Requirements” (RR)?

A.1. LOL and RR are both financial liability provisions of the Medicare law. LOL is provided under §1879(a)-(c) of the Social Security Act (the Act) for all Part A services and all assigned claims for Part B services. RR is provided under §1879(h) of the Act for assigned claims for medical equipment and supplies. RR is also provided for unassigned claims for medical equipment and supplies under §§ 1834(a)(18) and 1834(j)(4) of the Act and for unassigned claims for physicians' services under §1842(l) of the Act. LOL provides for program payment for denied claims in certain circumstances, and for beneficiary indemnification in certain circumstances. RR does not provide for either program payment or indemnification, but does provide that physicians and suppliers, if held liable under RR provisions, must make refunds to beneficiaries of any amounts collected.

Q.2. So, ABNs are used under both LOL and RR? The same ABNs?

A.2. Yes, CMS-R-131 forms may be used under both LOL and RR. An ABN-G would be the appropriate ABN for all RR situations as well as for all LOL situations. ABN-L may be used where LOL applies in a claim for laboratory tests. There should be no occasion when using an ABN-L would be appropriate under RR since payment for laboratory tests is claimed on an assigned basis, meaning that only LOL might apply.

Q.3. Is there some difference in the significance of the beneficiary's signature on an ABN depending on whether LOL or RR applies?

A.3. Yes. In order for a beneficiary to be held liable under RR, that is, under §§ 1834(a)(18), 1834(j)(4), 1842(l), or 1879(h) of the Act, it is necessary that the beneficiary sign the ABN. All the RR provisions require, not only that the beneficiary be notified, but also that the beneficiary agree to pay in order for the beneficiary to be held liable. Thus, an unsigned ABN cannot be used to shift liability to a beneficiary when RR applies. Under LOL, a beneficiary signature is not an absolute requirement. The LOL provision requires only that the beneficiary be properly notified; there is no explicit requirement for an agreement to pay. Therefore, our instructions provide for the situation in which a beneficiary receives an ABN, refuses to sign it, but still demands to receive the services specified on the ABN. In that case, the physician or supplier can annotate the form, with the signature of a witness, that the beneficiary received notice but refused to sign the form, and can submit the claim with a GA modifier indicating that an ABN was given (Section I.3.F.2).

Q.4. The ABN forms include these sentences in Option 1: “If Medicare denies payment, I agree to be personally and fully responsible for payment. That is, I will pay personally, either out of pocket or through any other insurance that I have.” If LOL does not require the beneficiary to agree to make payment, why are these sentences included?

A.4. The LOL provisions require only that the beneficiary be notified (i.e., agreement to pay is not a requirement); nevertheless, since the beneficiary's signature on an ABN indicating receipt can, and very likely will, result in his or her financial liability under the LOL provisions, the approved ABN form includes agreement to pay language in all cases, as a matter of full disclosure. Consumer testing indicated that beneficiaries appreciated this information and considered it important and necessary for making an informed consumer decision. Furthermore, not including this information on ABNs given in LOL applicable situations could easily mislead beneficiaries to think that they have a third option, i.e., to receive the services and not accept liability; which is not a genuine option under LOL. Under LOL, a beneficiary who is properly notified and who receives a service which is subsequently denied payment for the reasons cited on the ABN can be held liable, whether or not the beneficiary agreed to make payment. This fact is a significant difference between LOL and RR.

Section I.1 -- General

A. Basic Requirements for ABNs.--An ABN is a written notice a physician or supplier gives to a Medicare beneficiary before items or services are furnished when the physician or supplier believes that Medicare probably or certainly will not pay for some or all of the items or services on the basis of one of the following statutory exclusions.

- §1862(a)(1) of the Act, for example:
 - medical reasonableness and necessity;
 - custodial care;
 - mammography;
 - pap smear;
 - pelvic exam;
 - glaucoma;
 - prostate cancer; and
 - colorectal cancer screening tests.
- §1834(a)(17)(B) of the Act, violation of the prohibition on unsolicited telephone contacts for medical equipment and supplies;
- §1834(j)(1) of the Act, medical equipment and supplies supplier number requirements not met; and
- §1834(a)(15) of the Act, medical equipment and/or supplies is denied in advance.

The only other applicable bases of denial for which ABNs are applicable, i.e.,

- §1862(a)(9) of the Act, custodial care;
- §1879(g)(1) of the Act, homebound and intermittent denials for home health care; and
- §1879(g)(2) of the Act, hospice patient is not terminally ill, are unlikely to apply in a Part B situation.

ABNs are designed for use with Medicare beneficiaries only, including those who are dually-eligible for Medicare and Medicaid. ABNs are not for use with patients who are not Medicare beneficiaries. The purpose of the ABN is to inform a Medicare beneficiary, before he or she receives specified items or services that otherwise might be paid for, that Medicare probably will not pay for them on that particular occasion. The ABN, also, allows the beneficiary to make an informed consumer decision whether or not to receive the items or services for which he or she may have to pay out of pocket or through other insurance. In addition, the ABN allows the beneficiary to better participate in his/her own health care treatment decisions by making informed consumer decisions. If the physician or supplier expects payment for the items or services to be denied by Medicare, the physician or supplier must advise the beneficiary before items or services are furnished that in their opinion the beneficiary will be personally and fully responsible for payment. To be "personally and fully responsible for payment" means that the beneficiary will be liable to make payment "out-of-pocket," through other insurance coverage (e.g., employer group health plan coverage), or through Medicaid or other Federal or non-Federal payment source. The physician or supplier must issue notices each time, and as soon as, they make the assessment that Medicare payment probably or certainly will not be made. If a physician or supplier fails to provide a proper ABN in situations where one is required, you may find the physician or supplier to be liable under the provisions of LOL or RR, where such provisions apply, unless the physician or

supplier can show that they did not know and could not reasonably have been expected to know that Medicare would deny payment. To be acceptable, an ABN must be on the approved Form CMS-R-131, must clearly identify the particular item or service, must state that the physician or supplier believes Medicare is likely (or certain) to deny payment for the particular item or service, and must give the physician's or supplier's reason(s) for their belief that Medicare is likely (or certain) to deny payment for the item or service.

1. Reason for Predicting Denial.--Statements of reasons for predicting Medicare denial of payment at a level of detail similar to those in the Medicare Carriers Manual, Part 3 §7012, Item 15.0.ff., "Medical Necessity" are acceptable for ABN purposes. Simply stating "medically unnecessary" or the equivalent is not an acceptable reason, insofar as it does not at all explain why the physician or supplier believes the items or services will be denied as not reasonable and necessary. To be acceptable, the ABN must give the beneficiary a reasonable idea of why the physician or supplier is predicting the likelihood of Medicare denial so that the beneficiary can make an informed consumer decision whether or not to receive the service and pay for it personally. The use on the ABN-G, in the customizable "Because:" box, of lists of reasons for denial which the particular physician or supplier has found are frequently applicable, with check-off boxes or some similar method of indicating the selection of the reason(s), is an acceptable practice. For example, the three reasons included on the ABN-L form may be used, with slight modification, on the ABN-G form: "Medicare does not pay for this item or service for your condition"; "Medicare does not pay for this item or service more often than frequency limit"; and "Medicare does not pay for services which it considers to be experimental or for research use". Listing several reasons which apply in different situations without indicating which reason is applicable in the beneficiary's particular situation generally is not an acceptable practice, and such an ABN may be defective and may not protect the physician or supplier from liability. However, if more than one reason for denial could apply (e.g., exceeding a frequency limit and "same day" duplication; cases where the reason for denial could depend upon the result of a test; etc.), do not invalidate an ABN on the basis of citing more than one reason for denial. See Section I.2.D.4.b with respect to citing the lack of a Certificate of Medical Need (CMN) as a reason for expecting a medical necessity denial.

2. Routine Notices Prohibition - Generic and Blanket Notices.--In general, the "routine" use of ABNs is not effective. By "routine" use, we mean giving ABNs to beneficiaries where there is no specific, identifiable reason to believe Medicare will not pay. Physicians and suppliers should not give ABNs to beneficiaries unless the physician or supplier has some genuine doubt that Medicare will make payment as evidenced by their stated reasons. Giving routine notices for all claims or services is not an acceptable practice. If you identify a pattern of routine notices in situations where such notices clearly are not effective, write to the physician or supplier and remind them of these standards. In general, routinely given ABNs are defective notices and will not protect the physician or supplier from liability. However, in certain circumstances, ABNs may be routinely given to beneficiaries because all or virtually all beneficiaries may be at risk of having their claims denied in those circumstances. Section I.1.A.2.d. ff specify those circumstances in which ABNs may be routinely given.

a. Generic ABNs: "Generic ABNs" are routine ABNs to beneficiaries which do no more than state that Medicare denial of payment is possible, or that the physician never knows whether Medicare will deny payment. Such "generic ABNs" are not considered to be acceptable evidence of advance beneficiary notice. The ABN must specify the service and a genuine reason that denial by Medicare is expected. ABN standards likewise are not satisfied by a generic document that is little more than a signed statement by the beneficiary to the effect that, should Medicare deny payment for anything, the beneficiary agrees to pay for the service. "Generic ABNs" are defective notices and will not protect the physician or supplier from liability.

b. Blanket ABNs: A physician or supplier should not give an ABN to a beneficiary unless the physician or supplier has some genuine doubt regarding the likelihood of Medicare payment as evidenced by its stated reasons. Giving ABNs for all claims or items or services (i.e., "blanket ABNs") is not an acceptable practice. Notice must be given to a beneficiary on the basis of a genuine judgment about the likelihood of Medicare payment for that individual's claim.

c. Signed Blank ABNs: A physician or supplier is prohibited from obtaining beneficiary signatures on blank ABNs and then completing the ABNs later. An ABN, to be effective, must be completed before delivery to the beneficiary. Hold any ABN that was blank when it was signed to be defective notice that will not protect the physician or supplier from liability.

d. Routine ABN Prohibition Exceptions: ABNs may be routinely given to beneficiaries and considered to be effective notices which will protect physicians and suppliers only in the following exceptional circumstances:

i. Services Which Are Always Denied for Medical Necessity - In any case where a national coverage decision provides that a particular service is never covered, under any circumstances, as not reasonable and necessary under §1862(a)(1) of the Act (e.g., at present, all acupuncture services are denied as not reasonable and necessary), an ABN that states in the "Because:" box that: "Medicare never pays for this *item/service*" may be routinely given to beneficiaries, and no claim need be submitted to Medicare. If the beneficiary demands that a claim be submitted to Medicare, submit the claim as a demand bill in accordance with Section 1.3.G.

ii. Experimental Items and Services - When any item or service which Medicare considers to be experimental (e.g., "Research Use Only" and "Investigational Use Only" laboratory tests) is to be furnished, since all such services are denied as not reasonable and necessary under §1862(a)(1) of the Act because they are not proven safe and effective, the beneficiary may be given an ABN-G that states in the "Because:" box that: "Medicare does not pay for services which it considers to be experimental or for research use" or an ABN-L with a test listed in the third column, "Medicare does not pay for experimental or research use tests". Alternative, more specific, language with respect to Medicare coverage for clinical trials may be substituted as necessary in the ABN-G "Because:" box or as the caption for the right column of the customizable portion of the ABN-L at the user's discretion.

iii. Certain Frequency Limited Items and Services - When any item or service is to be furnished for which Medicare has established a statutory or regulatory frequency limitation on coverage, or a frequency limitation on coverage on the basis of a national coverage decision or on the basis of your local medical review policy (LMRP), because all or virtually all beneficiaries may be at risk of having their claims denied in those circumstances, the physician or supplier may routinely give ABNs to beneficiaries. In any such routine ABN-G, the physician or supplier must state the frequency limitation in the ABN-G "Because:" box (e.g., "Medicare does not pay for this item or service more often than *frequency limit*").

iv. Medical Equipment and Supplies Denied Because the Supplier Had No Supplier Number or the Supplier Made an Unsolicited Telephone Contact - Given that Medicare denials of payment under §1834(j)(1) of the Act on the basis of a supplier's lack of a supplier number, and under §1834(a)(17)(B) of the Act, the prohibition on unsolicited telephone contacts, apply to all varieties of medical equipment and supplies and to all Medicare beneficiaries equally, the usual prohibition on provision of routine notices to all beneficiaries does not apply in these cases. See Section 1.2.D.1 & 2.

B. Determining Whether or Not the Beneficiary is Liable--In deciding whether the beneficiary or his/her authorized representative knew, or could reasonably have been expected to know, that payment would not be made for items or services s/he received, the beneficiary's allegation that s/he did not know, in the absence of evidence to the contrary, will be acceptable evidence for LOL purposes. However, there may be evidence that will rebut such an allegation. For example, within the previous twelve months a beneficiary received a denial notice stating that a service was excluded from coverage, that previous denial notice, if it pertains to a similar or reasonably comparable service, would constitute evidence that the beneficiary did have knowledge of exclusion. While evidence of beneficiary knowledge generally must be based on written notice, §1879(a)(2) of the Act specifies only that knowledge must not exist in order to apply the LOL protection. If it is clear and obvious that a beneficiary in fact did know, prior to receiving a service or item, that Medicare payment for that service or item would be

denied, the administrative presumption favorable to the beneficiary is rebutted. For example, if a beneficiary admits he or she had prior knowledge that payment would be denied, no further evidence is required; the absence of a written notice is moot. The failure of any physician or supplier to furnish an ABN to a beneficiary is not sufficient to afford the beneficiary the protection of the LOL provision if you have proof that the beneficiary, nonetheless, had the requisite knowledge that payment would be denied. In any case in which you have such evidence of prior knowledge on the beneficiary's part, old the beneficiary liable under the LOL provision. The most likely reason to find that the beneficiary knew or could reasonably have been expected to know that Medicare would not pay is where, before the item or service was furnished, the physician or supplier notified the beneficiary by properly delivering the approved Form CMS-R-131, of the likelihood that Medicare would not pay for the specific service. In a case where a beneficiary received an ABN and, upon initial determination, the claim was paid as covered, that original ABN cannot be used as evidence of knowledge to hold the beneficiary liable in a later case relating to a similar or reasonably comparable service in which the same reason for denial applies, since the original ABN was relied by the favorable payment decision. In a case where RR applies, in order for the beneficiary to be held liable, it is necessary that after being informed, the beneficiary agreed to pay the physician or supplier for the service personally or through other insurance, as evidenced by a signed agreement to pay. (See §7300.5 of the MCM for instructions on determining liability for assigned claims for physician and supplier services for which payment is denied as "not reasonable and necessary.") Do not accept generic ABNs or blanket ABNs as effective notice to beneficiaries for either LOL or RR purposes.

C. Delivery of ABN.--Delivery of an ABN occurs when the beneficiary or authorized representative (i.e., the person acting on the beneficiary's behalf) both has received the notice and can comprehend its contents. All notices must include an explanation written in lay language of the physician's or supplier's reason for believing the items or services will be denied payment. Do not accept an incomprehensible notice or any notice which the individual beneficiary or his/her authorized representative is incapable of understanding due to the particular circumstances (even if others may understand).

1. The physician or supplier should hand-deliver the ABN to the beneficiary or authorized representative. Delivery is the physician's or supplier's responsibility. (Consider delivery of an ABN by a physician's or supplier's staff or employees to be delivery by the physician or supplier.) If the beneficiary alleges non-receipt of notice and the physician cannot show that notice was received by the beneficiary, do not find that the beneficiary knew or could reasonably have been expected to know that Medicare would not pay; i.e., hold the physician or supplier liable and the beneficiary not liable. The ABN must be prepared with an original and at least one copy. The physician or supplier must retain the original and give the copy to the beneficiary or authorized representative. (In a case where the physician or supplier that gives an ABN is not the entity which ultimately bills Medicare for the item or service, e.g., when a physician draws a test specimen and sends it to a laboratory for testing, the physician or supplier should give a copy of the signed ABN to the entity which ultimately bills Medicare.) The copy is given to the beneficiary immediately after the beneficiary signs it. Legible duplicates (carbons, etc.), fax copies, electronically scanned copies, or photocopies will suffice. This is a fraud and abuse prevention measure. If a beneficiary is not given a copy of the ABN and if the beneficiary later alleges that the ABN presented to the carrier by the physician or supplier is different in any material respect from the ABN he/she signed, give credence to the beneficiary's allegations.

2. Do not consider a telephone notice to a beneficiary, or authorized representative, to be sufficient evidence of proper notice for limiting any potential liability, unless the content of the telephone contact can be verified and is not disputed by the beneficiary. If a telephone notice was followed up immediately with a mailed notice or a personal visit at which written notice was delivered in person and the beneficiary signed the written notice accepting responsibility for payment, accept the time of the telephone notice as the time of ABN delivery.

3. Do not consider delivery of a notice to be properly done unless the beneficiary, or authorized representative, was able to comprehend the notice (i.e., they were capable of receiving notice). A comatose person, a confused person (e.g., someone

who is experiencing confusion due to senility, dementia, Alzheimer's disease), a legally incompetent person, a person under great duress (for example, in a medical emergency) is not able to understand and act on his/her rights, therefore necessitating the presence of an authorized representative for purposes of notice. A person who does not read the language in which the notice is written, a person who is not able to read at all or who is functionally illiterate to read any notice, a blind person or otherwise visually impaired person who cannot see the words on the printed page, or a deaf person who cannot hear an oral notice being given by phone, or could not ask questions about the printed word without aid of a translator, is a person for whom receipt of the usual written notice in English may not constitute having received notice at all (this is not an exclusive list). This may be remedied when an authorized representative has no such barrier to receiving notice. However, in the absence of an authorized representative, the physician or supplier must take other steps to overcome the difficulty of notification. These may include providing notice in the language of the beneficiary (or authorized representative), in Braille, in extra large print, or by getting an interpreter to translate the notice, in accordance with the needs of the beneficiary or authorized representative to act in an informed manner. If the beneficiary was not capable of receiving the notice, hold that the beneficiary did not receive proper notice, hold that the beneficiary is not liable, and hold the physician or supplier liable.

4. Hold that a beneficiary did not receive proper notice in any case where you find that the physician or supplier refused to answer inquiries from a beneficiary, or authorized representative, who requested further information and/or assistance in understanding and responding to the notice, including the basis for his/her/its assessment that items or services may not be covered. In the case of a beneficiary complaint about not receiving sufficient information about the cost of a service or item for which an ABN was given, follow the guidance in Section I.3.E.1.b.vi in determining whether the physician or supplier was sufficiently responsive.

5. a. A patient must be notified far enough in advance of receiving a medical service so that the patient can make a rational, informed consumer decision without undue pressure. The purpose of this timely delivery rule is to avoid putting the beneficiary into a position in which she/he is already committed to receiving the item or service before receiving notice of the likelihood of denial of payment by Medicare.

b. As a general rule, ABN delivery should take place before a procedure is initiated and before physical preparation of the patient (e.g., disrobing, placement in or attachment of diagnostic or treatment equipment) begins. This criterion does not constitute a blanket prohibition on giving an ABN to a beneficiary after she/he has entered an examination room, a draw station, a DMEPOS sales room, etc., and is ready to receive services or items. We recognize, for example, that situations may arise during an encounter when a physician (or supplier) sees a need for a previously unforeseen service, expects that Medicare will not pay for it, and wishes to give an ABN. This is permissible, provided that the beneficiary is capable of receiving notice in accordance with paragraph 3 above, and has a meaningful opportunity to act on it (e.g., the beneficiary is not under general anesthesia). Where it is foreseeable that the need for service for which Medicare likely would not pay may arise during the course of an encounter, and the beneficiary is either certain or likely not to be capable of receiving notice during the initial service (e.g., the beneficiary will be under anesthesia), it is permissible to give an ABN before any service is initiated; such an ABN would not violate the general prohibition of routine ABNs in Section I.1.A.2. Also, in a case where a physician draws a test specimen and sends it to a laboratory for testing, and did not give the beneficiary an ABN, the laboratory may contact the beneficiary and give him/her an ABN without violating this timely delivery rule, so long as testing of the specimen has not begun.

c. If a beneficiary alleges she/he was coerced into accepting medical items or services by receiving the ABN at the last moment, investigate the facts. If the physician or supplier clearly and obviously violated this timely delivery rule, hold that the notice was not properly delivered in advance of furnishing the item or service and that the beneficiary therefore is not liable.

6. In the case of an ABN on which the physician's or supplier's identifying information in the header of the ABN form identifies the physician or supplier that obtained the ABN, rather than the physician or supplier that is billing for the services (e.g., when one laboratory refers a specimen to another laboratory which then bills Medicare for the test; when a physician executes an ABN with his or her own identifying information in the header in conjunction with ordering a laboratory test for which the testing laboratory will submit the claim to Medicare), consider the ABN form to be valid so long as it was otherwise properly executed.

D. Effect of Furnishing ABNs and Collection from Beneficiary.--

1. When ABNs are properly used by physicians and suppliers, the ABNs also protect them from liability under the several statutory provisions which limit beneficiaries' liability. A beneficiary who has been given a proper written ABN, before an item or service was furnished, giving notice of the likelihood (or certainty) that Medicare would not pay for the specific item or service and of the reason therefore and who, after being so informed, has agreed to pay the physician or supplier for the item or service, will be held liable. That is, that beneficiary will be found to have known in advance that Medicare would not pay, and the physician or supplier will be free to bill and collect the related charges from the beneficiary. A beneficiary who has been given such a proper ABN and who, after being so informed, refused to sign the ABN at all but demanded and received the item or service, may be held liable under LOL, but not under RR (see Section I.1.B, above).

2. Failure to meet the ABN standards and procedures will expose a physician or supplier to the risk of potential financial liability for denied items or services in cases where, in the absence of a proper ABN, the beneficiary would be held not to have known, nor to reasonably have been expected to have known, that his/her claims for the denied items and services he/she received were likely to be denied by Medicare. A physician or supplier held liable for such denied charges will be precluded from collecting from the beneficiary and may be required to make refunds to the beneficiary, or face possible sanctions for failure to do so. If you suspect that a physician or supplier is not furnishing ABNs with the intent to induce or coerce referrals for other items and/or services paid for by Medicare whereby anti-kickback statutes could be implicated, or if you suspect that a physician or supplier is doing so for any fraudulent, abusive, or otherwise illegal purposes, refer the case to the CMS regional office. In the case of a physician or supplier that does not obtain an ABN, when giving an ABN would have been appropriate, because the physician or supplier had no opportunity to do so (e.g., when a laboratory receives a specimen for testing, does not see the patient, and the specimen's testing is time-sensitive, such that the patient cannot be contacted about an ABN before the test is performed), do not consider the physician's or supplier's failure to obtain an ABN under such circumstances as indicative of fraud or abuse on that sole basis.

3. A physician or supplier who supplies a defective ABN (one which does not meet the standards in Section I.1.f) will not be protected from liability. A beneficiary who received a defective ABN should not be liable and the physician or supplier who/which gave the defective ABN should be held liable. Certain ABN standards may vary on the basis of the particular type of denial (e.g., as not reasonable and necessary, as violating the prohibition on unsolicited telephone contacts) and on the basis of whether the claim is assigned or unassigned. Section I.2 provides particular standards which apply to specific types of denials.

4. When an ABN was properly executed and given timely to a beneficiary (who, if RR applies, agreed to pay in the event of denial by Medicare) and, in fact, Medicare denies payment on the related claim (whether assigned or unassigned), the physician or supplier may bill and collect from the beneficiary for that service (see MCM §3045.2, Physician's Right to Collect from Enrollee on Assigned Claim). Medicare does not limit the amount which the physician or supplier, participating or nonparticipating, may collect from the beneficiary in such a situation. Medicare charge limits do not apply to either assigned or unassigned claims when collection from the beneficiary is permitted on the basis of an ABN. A beneficiary's agreement to "be personally and fully responsible for payment" means that the beneficiary agrees to pay out-of-pocket or

through any other insurance that the beneficiary may have, e.g., through employer group health plan coverage, Medicaid or other Federal or non-Federal payment source.

5. When an ABN was given to a beneficiary for a service for which Medicare pays in more than one part to different entities, e.g., for a radiological test with a technical component and a professional component, if the specification of the service on the ABN reasonably includes both components, that ABN, from either party, will serve as evidence of knowledge for LOL and RR. It is not necessary that both parties to the service give separate ABNs. If the beneficiary asks for a cost estimate, the estimate should include both parts of the service.

6. ABNs may not be used to shift liability to a beneficiary in the case of services or items for which full payment is bundled into other payments; that is, where the beneficiary would otherwise not be liable for payment for the service or item because bundled payment is made by Medicare. Using an ABN to collect from a beneficiary where full payment is made on a bundled basis would constitute double billing. An ABN may be used to shift liability to a beneficiary in the case of services or items for which partial payment is bundled into other payments; that is, where part of the cost is not included in the bundled payment made by Medicare.

7. Health Insurance Portability & Accountability Act of 1996 (HIPAA) Sanctions and the Use of ABNs.--Section 231(e)(4) of HIPAA adds to the Social Security Act a new §1128A(a)(1)(E) which provides for civil monetary penalties when claims are submitted "for a pattern of medical or other items or services that a person knows or should know are not medically necessary". This HIPAA sanction provision and the ABN provisions are not related and should not be confused with one another, but also are not mutually exclusive. Concerns have been raised by the physician and supplier communities that the use of ABNs could be construed by CMS or another agency pursuing enforcement activities as documenting such a pattern of medically unnecessary care. You may assure physicians and suppliers inquiring about this matter that the use of ABNs will not run them afoul of the HIPAA sanctions. The HIPAA sanctions are meant to deal with fraudulent claims for patently unnecessary medical care. The LOL and RR ABN provisions are meant to deal with giving beneficiaries proper advance notice of the likelihood of Medicare denial of payment for medical care that may be medically unnecessary, under Medicare coverage standards, for the individual beneficiary on a specific occasion. These are entirely different provisions and should not be confused, as indicated in the Conference Report accompanying HIPAA §231 ("*the conferees intend that a penalty will be imposed on presentation of a claim that is false or fraudulent. No sanction is intended for providers who simply inform beneficiaries that a particular service is not covered by Medicare. Moreover, nothing in this section is intended to supersede the limitation on liability provisions established under Section 1879 of the Social Security Act.*"). The use of ABNs, in and of itself, is not evidence of any HIPAA sanctionable violation. At the same time, the use of an ABN does not provide any protection against the HIPAA sanctions to any physician, supplier or provider that does file a fraudulent claim. Do not hold any beneficiary who received an ABN in the case of a fraudulent claim to be properly notified under either LOL or RR; do hold the physician or supplier liable in such a case.

E. Approved Notice Language.--The OMB-approved ABNs for use with Part B items and services (viz., OMB Approval No. 0938-0566, Form No. CMS-R-131) satisfy the requirements under both LOL and RR for the physician's or supplier's advance beneficiary notice and the beneficiary's agreement to pay. The use of any other ABNs or modified ABNs may be ineffective in protecting physicians and suppliers from liability.

1. OMB Notice.--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 5 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 any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850.

2. ABN-G & ABN-L--Forms attached to these instructions, CMS-R-131-G and CMS-R-131-L (Exhibits 1 and 2, respectively, and Spanish versions in Exhibits 1S and 2S, respectively), represent the OMB-approved ABNs for use with Part B items and services. The ABN-G and the ABN-L must be prepared with an original and at least one patient copy. The Exhibits are not replicable copies, due to formatting for these instructions. For the replicable copies of the approved forms CMS-R-131 (G & L) in PDF format, go to the CMS Beneficiary Notices Initiative (BNI) webpage at <http://cms.hhs.gov/medicare/bni/>. Physicians and suppliers must use approved ABN forms. The ABN-G may be used for all situations, including laboratory tests. The ABN-L may be used for physician-ordered laboratory tests. Laboratories are permitted to reproduce the ABN on the back of their laboratory test requisition forms. ABNs may be produced using self-carboning paper and other methods of producing copies, including photocopying, printing, and electronic generation.

3. User-Customizable Sections--Physicians and suppliers are permitted to customize the header, the "Items or Services" and "Because" box area on the CMS-R-131-G, the header, the reasons, and tests 3-column box area on the CMS-R-131-L form. The box containing three columns for laboratory tests and reasons for expecting denial on the ABN-L is customizable by the physician or supplier, except that the captions (reasons) for the left and center columns may not be revised while the right column (experimental and research use exclusion) may be revised or deleted at the discretion of the physician or supplier. Do not invalidate an ABN solely on the basis that the physician or supplier included in a customizable area some item(s) of information (e.g., information about the ABN's implications for the beneficiary's other insurers) which is/are not explicitly required by these instructions. The specified box areas are customizable and are scalable (that is, they may be lengthened). The ABN is designed as a letter-size form; nevertheless, it may be expanded to a legal size form by a user, to allow increasing the size of the customizable box areas, to suit the physician's or supplier's particular needs. In any case, the ABN must be only one page in length and may be modified only in the specified user-customizable sections. The standard sections of the forms (those sections which are not specified as user-customizable) may not be modified in any respect; they must be identical to the replicable PDF forms files at the website address provided in subparagraph 2. above. The use of improperly modified ABNs may be ineffective in protecting physicians and suppliers from liability.

F. Definition of Authorized Representative-- An authorized representative is a person who is acting on the beneficiary's behalf and in the beneficiary's best interests, and who does not have a conflict of interests with the beneficiary, when the beneficiary is temporarily or permanently unable to act for himself or herself. If you receive an allegation that the person (not the beneficiary) who signed an ABN was not a properly authorized representative, use the following guidance in deciding if the beneficiary can be held liable. Ultimately, if a situation arises in which a beneficiary simply cannot receive an ABN and notice cannot be given to an authorized representative, the beneficiary is protected by not having received an ABN. A physician's or supplier's inability to give notice to a beneficiary directly or through an authorized representative does not allow the physician or supplier to shift liability to the beneficiary.

1. The first consideration with respect to an "authorized representative" is the most important. An individual authorized under state law to make health care decisions, e.g., a legally appointed representative or guardian of the beneficiary (if, for example, the beneficiary has been legally declared incompetent by a court), or an individual exercising explicit legal authority on the beneficiary's behalf (e.g., in accordance with a properly executed "durable medical power of attorney" statement or similar document), may be the authorized representative of the beneficiary with respect to receiving ABNs.

2. The second consideration with respect to an authorized representative is that she/he should have the beneficiary's best interests at heart. That is, the authorized representative should be reasonably expected to act in a manner which is protective of the rights of the beneficiary, and is protective of the beneficiary himself or herself. In the absence of some more compelling consideration, the order of priority of authorized representatives should be: The spouse, unless legally separated; An adult child; A parent; An adult sibling; and, if none of these are available, A close friend

(defined as “an adult who has exhibited special care and concern for the patient, who is familiar with the patient’s personal values, and who is reasonably available”).

3. The third consideration for an authorized representative is that she/he should have no relevant conflict of interests with the beneficiary. That is, even though a particular individual may sincerely like a beneficiary and wish him or her well, if that individual is an employee of a physician or supplier that is notifying the beneficiary about the likelihood of noncoverage by Medicare and has a competing/conflicting financial interest (such as shifting liability for a service to the beneficiary), that individual is not qualified to be an authorized representative.

4. Another possible consideration with respect to an authorized representative is whether the person is someone (typically, a family member or close friend) whom the beneficiary has indicated may act for him or her, but who has not been named in any legally binding document conveying such a role to that person. Presently, a majority of states have health care consent statutes providing for health care decision-making by surrogates on behalf of patients who lack advance directives and guardians. In such states, reliance upon individual’s appointed/designated under such statutes to act as authorized representatives may be necessary. In this last case, such a person may well be a more appropriate authorized representative (in terms of having the best interests of the beneficiary at heart) than some other person with some official standing short of actually being legally appointed representative or guardian of the beneficiary (e.g., an ombudsman).

5. Finally, another possible consideration with respect to an authorized representative is a disinterested third party. While a beneficiary who is temporarily unable to act for himself or herself should have an authorized representative who can make decisions and receive notices for him or her, it is entirely possible that, in any particular case, especially where the beneficiary’s inability to act has arisen suddenly (e.g., a medical emergency, a traumatic accident, an emotionally traumatic incident, disabling drug interaction, stroke, etc.), there may be no one who can be genuinely considered to be the beneficiary’s choice as his or her authorized representative. In such a case, recourse may be made to a disinterested third party, such as a public guardianship agency, taking care to avoid any conflicts of interest.

Section I.2 Special Rules.--

A. Exception for Repetitive Notices.--A single ABN covering an extended course of treatment is acceptable provided the ABN identifies all items and services for which the physician or supplier believes Medicare will not pay. If, as the extended course of treatment progresses, additional items or services are to be furnished for which the physician or supplier believes Medicare will not pay, the physician or supplier must separately notify the patient in writing (i.e., give the beneficiary another ABN) that Medicare is not likely to pay for the additional items or services and obtain the beneficiary’s signature on the ABN. Items or services (e.g., laboratory tests) provided on a regularly scheduled basis under a “standing order” may be considered, for these beneficiary notice purposes only, as an extended course of treatment; and a single ABN may suffice (e.g., for all the tests furnished the beneficiary which are contemplated by that order), as described above, with a new ABN being required only when additional items or services, which are not specified by the initial course of treatment ABN and for which noncoverage is expected, are to be furnished to the beneficiary. When an ABN is to be given for a “standing order” the physician or supplier must specify in the “Items or Services:” box of the ABN-G, or in the appropriate column of the customizable box beginning “Medicare probably will not pay...” on the ABN-L, the pertinent facts (e.g., frequency and duration) of the standing order (see Section I.3.E.1.b.v.). One year is the limit for use of a single ABN for an extended course of treatment; if the course of treatment extends beyond one year, a new ABN is required for the remainder of the course of treatment. An ABN, once signed by the beneficiary, may not be modified or revised. When a beneficiary must be notified of new information, a new ABN must be given.

B. Guidelines for Situations Where the Beneficiary is in a Medical Emergency or Is Otherwise Under Great Duress.--An ABN-G or ABN-L should not be obtained from a beneficiary in a medical emergency or otherwise under great duress (i.e.,

when circumstances are compelling and coercive) since that individual cannot be expected to make a reasoned informed consumer decision. In genuine emergencies, the beneficiary/victim and his or her family/friends (authorized representative) are under great duress by the emergency circumstances, to sign anything in order to obtain help. On the other hand, there is a risk that beneficiaries might actually forego needed emergency services if faced with a financial burden which they believe they cannot bear. A requirement for delivery of a notice is that the beneficiary, or authorized representative, must be able to comprehend the notice, i.e., they must be capable of receiving notice (see Section I.1.C.3). A person under great duress is not able to understand and act on his or her rights. If the beneficiary is not capable of receiving the notice, then the beneficiary has not received proper notice and cannot be held liable where the LOL or RR provisions apply, and the physician or supplier may be held liable.

1. Emergency Medical Treatment and Active Labor Act (EMTALA) Situations.--An ABN should not be given to a beneficiary in any case in which EMTALA (§1876 of the Act) applies, until the hospital has met its obligations under EMTALA, which includes completion of a medical screening examination (MSE) to determine the presence or absence of an emergency medical condition, or until an emergency medical condition has been stabilized. CMS published this policy in the November 10, 1999 OIG/HCFR Special Advisory Bulletin on the Patient Anti-Dumping Statute: "A hospital would violate the patient anti-dumping statute if it delayed a medical screening examination or necessary stabilizing treatment in order to prepare an ABN and obtain a beneficiary signature. The best practice would be for a hospital not to give financial responsibility forms or notices to an individual, or otherwise attempt to obtain the individual's agreement to pay for services before the individual is stabilized. This is because the circumstances surrounding the need for such services, and the individual's limited information about his or her medical condition, may not permit an individual to make a rational, informed consumer decision." This policy applies in any case in which EMTALA applies, not only to EMTALA cases seen in emergency rooms (ERs). Giving ABNs to beneficiaries under great duress is not permitted, regardless of the particular treatment setting or location. Even when a beneficiary does not appear to have a life threatening condition, rather, he or she is seeking primary care services at an ER, an ABN should not be given to the beneficiary in any case in which EMTALA applies until the hospital has met its obligations under EMTALA. An ABN that is otherwise appropriate may be given to a Medicare beneficiary who is seen in the ER after completion of an MSE, but an ABN should not be given unless there is a genuine reason to expect that Medicare will deny payment for the services because giving routine "blanket" ABNs to beneficiaries is not permitted (see §I.1.A.2.b). There always must be a reason for expecting that Medicare will deny payment for the services furnished to the individual beneficiary on a specific occasion, and that reason must appear on the ABN. EMTALA does not prohibit asking payment questions entirely, rather, only doing so before screening/stabilization. After screening/stabilization, EMTALA no longer applies and ABNs may be given, when otherwise appropriate, to beneficiaries who come to emergency care settings after they have received a medical screening examination and are stabilized.

2. Other Situations.--A physician or supplier may not shift liability to a beneficiary under great duress by giving an ABN to the beneficiary. ABNs given to any individual who is under great duress cannot be considered to be proper notice. It is inconsistent with the purpose of advance beneficiary notice, which is to facilitate an informed consumer decision by a beneficiary whether or not to receive an item or service and pay for it out-of-pocket, to attempt to obtain beneficiaries' signatures on ABNs during medical emergencies and other compelling, coercive circumstances where a rational, informed consumer decision cannot reasonably be made. For that reason, physicians and suppliers may not use ABNs to shift financial liability to beneficiaries in emergency care situations. Ambulance companies may not give ABN-Gs to beneficiaries or their authorized representatives in any emergency transport because such beneficiaries are under great duress. Skilled nursing facilities may not give ABN-Gs in the case of "middle-of-the-night" emergencies or in any other emergency circumstances, since the beneficiary clearly cannot make an informed consumer decision (see Section I.2.G). Consider any ABN-G or ABN-L given in any kind of coercive circumstances, including medical emergencies, to be defective. In all such coercive situations, find that the beneficiary did not know and could not reasonably have been expected to know that Medicare would not make payment. Determine the physician's or supplier's liability by

the appropriate knowledge standards which are used in cases where ABNs are not given and beneficiary agreements to pay are not obtained (see §§7300.5.B, 7330.D.1 of the MCM, and Section II.5). This policy regarding duress applies in any case in which a beneficiary is under great duress and cannot make an informed consumer decision. This is the basis for the “last moment delivery” policy that a beneficiary must be notified well enough in advance of receiving a medical service so that the beneficiary can make a rational, informed consumer decision. In any case of such “last moment delivery” of an ABN, the delivery may not be considered timely and the beneficiary may not be held liable (see Section I.1.C.5 regarding “last moment delivery” of the ABN).

C. ABNs for Claims Affected by the Physicians’ Services Refund Requirement.--Under §1842(1) of the Act, the prohibition against billing for unassigned physician services which are denied on the basis of §1862(a)(1) of the Act as not reasonable and necessary, the physicians’ services Refund Requirement provision, a refund is required under certain circumstances, unless a proper ABN-G was given the beneficiary and the beneficiary agreed to pay. (See §7330 of the MCM for instructions on determining situations where a refund under §1842(1) of the Act is required.)

D. ABNs for Claims Affected by the Medical Equipment and Supplies Refund Requirement.--Under §1834(a)(18)(A)(ii) of the Act, a refund is not required of the supplier if, before the medical equipment or supplies were furnished, the beneficiary was informed by the supplier that Medicare would not pay for the specific item or service and, after receiving such an advance beneficiary notice, the beneficiary agreed to pay for the item or service. The Refund Requirement provisions of §1834(a)(18) of the Act are incorporated by reference in §§1834(j)(4) and 1879(h) of the Act, which are also limits on beneficiaries’ liability for denied claims (unassigned and assigned, respectively) for medical equipment and supplies. (See Section II for the medical equipment and supplies Refund Requirement instructions.)

1. 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.--To qualify for waiver of the Refund Requirements 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. The supplier must obtain a signed ABN before furnishing the item to the beneficiary. Since it is the unsolicited telephone contact which is prohibited by law, giving advance beneficiary notice by telephone does not qualify as notice and is not permissible. The telephone notice process described in Section I.1.C.2 may not be used in this case. Do not accept any telephone ABN as effective notice to the beneficiary. Since giving or mailing a written 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 a written 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. (See §I.1.A.2.d.iv. for exception to prohibition on routine ABNs.)

2. ABNs for Medical Equipment and Supplies Claims Denied Under §1834(j)(1) of the Act (Because the Supplier Did Not Meet Supplier Number Requirements).--

a. To qualify for waiver of the Refund Requirements 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 ABN must convey to the beneficiary the certainty of denial, so that the beneficiary can make an informed consumer decision whether to

receive the medical equipment or supplies and pay for it out of pocket. The following is acceptable language for the ABN-G "Because:" box: "Medicare will pay for items furnished to you by a supplier of medical equipment and supplies only if the supplier has a Medicare supplier number. Payment for such items furnished to you by a supplier which does not have a supplier number is prohibited under the Medicare law. We do not have a Medicare supplier number, therefore, Medicare will not pay for any medical equipment and supplies which we furnish to you." It is particularly important that the beneficiary's signed agreement to pay should be dated by the beneficiary because, in this type of denial, any proper written advance notice with the beneficiary's signed agreement to pay shall be effective for any medical equipment or supplies purchased or rented from the same supplier within the one year following the date of the beneficiary's signed agreement to pay. This exception 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.

b. 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, §1879 of the Act, or, in the case of unassigned claims, under the applicable RR provision, §1834(j)(4) of the Act. 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 beneficiary disputes the supplier's allegation and conclusive proof of the allegation is not presented, the supplier's allegation may not be accepted. 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 under §1879 or §1834(j)(4) of the Act, 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. The following is acceptable language for the public notice: "Notice to Medicare Beneficiaries. Medicare will pay for medical equipment and supplies only if a supplier has a Medicare supplier number. We do not have a Medicare supplier number. Medicare will not pay for any medical equipment and supplies we sell or rent to you. You will be personally and fully responsible for payment." 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.

c. 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. (See Section I.1.A.2.d.iv for exception to prohibition on routine ABNs.) Given the potential for beneficiary disputes over suppliers' public notice efforts to result in supplier liability, all suppliers which do not have supplier numbers would be very well advised to provide the standard written ABN to all Medicare beneficiaries, obtaining their signed agreement. The use of written notices in conjunction with public notices will provide maximum protection to suppliers as well as more surely providing proper advance notice to beneficiaries so that they can make informed consumer decisions.

3. ABNs for Medical Equipment and Supplies Claims Denied in Advance Under §1834(a)(15) of the Act - Prior Authorization Procedures.-- To qualify for waiver of the Refund Requirements under §1834(j)(4)(B) and §1879(h)(2) of the Act (unassigned and assigned claims, respectively) for medical equipment and supplies for which payment is denied in advance under §1834(a)(15) of the Act, the ABN-G must clearly identify the particular item of medical equipment and supplies and must state in the "Because:" box either: "Medicare has denied payment in advance and we expect that Medicare will continue to deny payment." or "Medicare requires that we request an advance determination of coverage of this medical equipment and/or supplies. We have not requested an advance determination, so we expect that Medicare will deny payment.", as applicable. 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 you 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 (see Section II.5.B).

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.--

a. To qualify for waiver of the Refund Requirements under §1834(j)(4)(C) of the Act, the ABN-G must clearly identify the particular item of medical equipment and supplies for which the supplier believes that Medicare will deny payment and must annotate in the "Because:" box the supplier's reason(s) it believes Medicare will deny payment.

b. The lack of a Certificate of Medical Necessity (CMN) for a particular Durable Medical Equipment (DME) item is an acceptable reason for expecting denial of a claim and would satisfy the requirements of what would constitute an acceptable notice; e.g., "Medicare cannot pay for this item because the doctor did not complete the certificate of medical need." Where a physician has been asked to render a CMN and refuses to do so, then the failure of a supplier to obtain a CMN would result in the claim being denied for medical necessity purposes. Giving an ABN is neither the first nor the only supplier action called for in this situation. While a supplier may ultimately give an ABN to a beneficiary, that is by no means the only responsibility of the supplier in this situation. The supplier first must make a good faith effort to obtain a CMN from the physician on a timely basis; this responsibility must not be simply shifted to beneficiaries through routinely giving ABNs. If the supplier's genuine efforts to obtain a CMN fail, then the supplier advising the beneficiary, in conjunction with giving an ABN, to request his or her physician to provide a CMN, would be a prudent practice.

E. ABN Standards for Partial Denials on the Basis of Medical Necessity.--Physicians and suppliers may give an ABN when they expect you to reduce the level of payment on the basis of §1862(a)(1) of the Act, that is, when they expect a partial denial of a more extensive service or item on the basis that it is not reasonable and necessary under §1862(a)(1) of the Act, even though you pay for a less extensive service or item. A case in which you reduce the level of payment because a component of the service or item is in excess of the beneficiary's medical needs is a medical necessity partial denial of that unnecessary component of the covered item or service. "Excess component" means an item, feature, or service, and/or the extent of, number of, duration of, or expense for an item, feature, or service, which is in addition to, or is more extensive and/or more expensive than, the item or service which is reasonable and necessary under Medicare's coverage requirements. The ABN given in the case of an expected partial denial must clearly identify, in the "Items or Services:" box, the excess component(s) of the item or service for which denial is expected (it is the part of the item or service that is expected to be denied that is the subject of the ABN, not the part that is expected to be paid) and must state in the "Because:" box the reason that Medicare is expected to deny payment for the specified excess component(s). Do not accept charge increases on the basis of purported premium quality services as "excess components" since that would constitute circumvention of payment limits and applicable charging limits (e.g., limiting charges in the case of unassigned claims for physicians' services and fee schedule amounts in the case of assigned claims). For example, a physician cannot charge extra amounts over Medicare payment limits for a service on the basis that his or her service is a "higher quality" than the same service furnished by other physicians and shift liability for that extra amount to a beneficiary who receives that service by obtaining the beneficiary's agreement to pay on an ABN. The "excess component" definition for partial denials, with respect to an item, feature, or service that is "more expensive" refers to increased charges attributable to furnishing something that is clearly more extensive, that is, more in number, more frequent, for a longer period of time, or with added features. It does not suffice to claim that an item or service is "better" or "higher quality."

F. ABN Standards for Upgraded Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).--When upgraded DMEPOS is to be furnished and the physician or supplier expects you to reduce the level of payment based on a medical necessity partial denial of coverage for additional expenses attributable to the upgrade, an ABN-G should first be delivered to the beneficiary and the signature of the beneficiary, agreeing to be personally and fully responsible for payment, should be obtained. The ABN should specify, in the "Items or Services:" box, the excess component(s) for which denial is expected (it is the upgrade features that are expected to be denied that are the subject of the ABN, not the standard items/services for which payment is expected) and must state in the "Because:" box the reason that Medicare is expected to deny payment for the specified excess component(s) related to the upgrade. Statements of reasons for predicting Medicare denial of payment at a level of detail similar to those in the Medicare Carriers Manual (MCM), Part 3 §7012, Item 15.0.ff., "Medical Necessity" are acceptable for ABN purposes, for example, "Your condition does not support the need for the special features of this equipment." An "upgrade," for purposes of these instructions, is synonymous with an "excess component," as defined in Section I.2.E. For example, a deluxe or aesthetic feature of an upgraded item of medical equipment is an "excess component." ABNs may not be used for substitution of a dissimilar item or service that is not both medically appropriate for the beneficiary's medical condition and consistent with the attending physician's original order for the item or service, e.g., ABNs may not be used for substitution of a wheelchair when a cane was prescribed, nor for a hospital bed when a wheelchair was prescribed. Any cost estimate provided on the ABN-G must relate to the extra expense for the upgrade features, over and above the Medicare allowable amount for the standard item or service, not to the total cost of the item or service.

G. ABN Standards for Services in Skilled Nursing Facilities (SNF).--Skilled nursing facilities may not give ABNs to beneficiaries in the case of "middle-of-the-night" emergencies, since the beneficiary is under duress and clearly cannot make an informed consumer decision. Authorized representatives for beneficiaries who are residents in SNFs are unlikely to be readily available for such emergencies and, depending upon the closeness of their personal relationship with the beneficiaries, may also be under duress in a medical emergency. SNF staff may not sign ABNs for beneficiaries as their authorized representatives. If there is an item or service which may predictably be

needed in such emergency situations, the SNF, or the physician or supplier that will furnish such an item or service to a beneficiary in the SNF, can give an ABN for a standing order for that item or service to the beneficiary, or to the authorized representative as appropriate, well in advance, when she or he is not in an emergency situation, in order to authorize furnishing the item or service when the need does arise (see Section I.2.A regarding standing orders). The effectiveness of such an ABN cannot extend beyond one year; at the end of a year, another ABN would need to be given. This procedure may be used for other, non-emergency items and services which are foreseeable, e.g., an ABN for a standing order for laboratory tests when the collection of samples may be at a time when the authorized representative is unlikely to be available, or the beneficiary may be at reduced capacity (e.g., the beneficiary will be awakened during the night). SNFs need to plan for the provision of ABNs given the particular needs of their resident population. A SNF which does not plan ahead may find itself in a situation where delivery of an ABN is not possible, in which case liability cannot be shifted to the beneficiary.

H. ABN Standards for Items and Services for Which ABNs Are Not Required.--Physicians and suppliers need use ABNs only when Medicare is expected (or certain) to deny payment on the basis of one of the following statutory exclusions: §1862(a)(1) & (9); §1834(a)(17)(B); §1834(j)(1); and §1834(a)(15) of the Act. ABNs are not required in the case of statutorily excluded items and services not listed above. Examples of exclusions for which ABNs are not required include, but are not limited to:

- Personal comfort items;
- Routine physicals and most tests for screening;
- Most shots (vaccinations);
- Routine eye care, eyeglasses and examinations;
- Hearing aids and hearing examinations;
- Cosmetic surgery;
- Most outpatient prescription drugs;
- Orthopedic shoes and foot supports (orthotics);
- Dental care and dentures (in most cases);
- Routine foot care and flat foot care;
- Services under a physician's private contract;
- Services paid for by a governmental entity that is not Medicare;
- Health care received outside of the USA;
- Services by immediate relatives;
- Services required as a result of war;
- Services for which the patient has no legal obligation to pay;
- Home health services furnished under a plan of care, if the agency does not submit the claim;
- Items and services excluded under the Assisted Suicide Funding Restriction Act of 1997;
- Items or services furnished in a competitive acquisition area by any entity that does not have a contract with the Department of Health and Human Services (except in a case of urgent need);
- Physicians' services performed by a physician assistant, midwife, psychologist, or nurse anesthetist, when furnished to an inpatient, unless they are furnished under arrangements by the hospital;
- Items and services furnished to an individual who is a resident of a skilled nursing facility or of a part of a facility that includes a skilled nursing facility, unless they are furnished under arrangements by the skilled nursing facility;
- Services of an assistant at surgery without prior approval from the peer review organization; and
- Outpatient occupational and physical therapy services furnished incident to a physician's services. (See §1862(a) of the Act for a more complete listing.)

ABNs also are not required when Medicare is expected to deny payment for an item or service which may be a Medicare benefit but for which the coverage requirements (not listed above) are not met, e.g., when a service is covered only in a qualifying setting and the service in question was not provided in such a qualifying setting. In situations in which ABNs are not required, the lack of an ABN, by itself, will not prevent a physician or supplier from collecting from a beneficiary. In situations in which ABNs are not required, physicians and suppliers are neither required to nor prohibited from voluntarily

giving some sort of notice to beneficiaries anyway, as a prudent customer service, however, since standard ABN forms include language asking for a claim to be submitted to Medicare, physicians and suppliers who wish to give notice in these situations should not use the CMS-R-131 ABN forms.

Section I.3 The Proper Use of the ABN (CMS-R-131).--

A. When An ABN Should Be Given.--

1. Whether an ABN should be given in a particular instance depends on the physician's or supplier's expectation of Medicare payment or denial.

a. If the physician or supplier expects Medicare to pay, an ABN should not be given.

b. If the physician or supplier "never knows whether or not Medicare will pay," an ABN should not be given.

c. If the physician or supplier expects Medicare to deny payment, the next question is: "On what basis is denial expected?"

i. If the item or service is not a Medicare benefit (e.g., routine physical and tests in the absence of signs and symptoms, routine foot care, dental care), neither the ABN-G nor the ABN-L should be given.

ii. If Medicare is expected to deny payment for an item or service which is a Medicare benefit because it does not meet a technical benefit requirement (e.g., an ambulance service denied due to an unapproved destination, diabetic care shoes not prescribed by a podiatrist or other qualified physician), neither the ABN-G nor the ABN-L should be given.

iii. If Medicare is expected to deny payment (entirely or in part) for the item or service because it is not reasonable and necessary under Medicare program standards (viz., "medical necessity denials" under §1862(a)(1) of the Act), the ABN-G or the ABN-L, as appropriate, should be given (this is applicable to all assigned Part B items and services, and to unassigned physicians' services and medical equipment and supplies). Certain screening tests (mammography, pap smear, pelvic exam, glaucoma, prostate cancer, colorectal cancer) have frequency limits under §1862(a)(1) of the Act, therefore, LOL applies and ABNs should be given when Medicare denial of payment for frequency is expected for any of these tests.

iv. If Medicare is expected to deny payment for medical equipment and supplies because it is not covered: (i) under §1834(a)(17)(B) of the Act, violation of the prohibition on unsolicited telephone contacts; (ii) under §1834(j)(1) of the Act, supplier number requirements not met; or (iii) under §1834(a)(15) of the Act, failure to obtain advance determination of coverage, the ABN-G should be given (this is applicable to both assigned and unassigned medical equipment and supplies).

2. Do not find a physician or supplier to have violated the prohibition on routine ABNs solely on the basis of the number of ABNs which the physician or supplier gives to beneficiaries, when those ABNs are justified by the physician or supplier having a genuine reason to give an ABN. Some physicians or suppliers (e.g., a physician furnishing acupuncture services) may give ABNs to most or all of their Medicare patients without violating the routine ABNs prohibition.

B. To Whom An ABN May Be Given.--An ABN may be given to a Medicare beneficiary or to the beneficiary's authorized representative, that is, to a person who is acting on the beneficiary's behalf when the beneficiary is temporarily or permanently unable to act for himself or herself. (See the definition of an authorized representative for ABN purposes in Section I.1.F.)

C. How An ABN May Be Given.--Delivery of an ABN occurs when the beneficiary or authorized representative (i.e., the person acting on the beneficiary's

behalf) both has received the notice and can comprehend its contents. An incomprehensible notice, or a notice which the individual beneficiary or his/her authorized representative is incapable of understanding due to the particular circumstances (even if others may understand), cannot be used to fulfill notice requirements. (See the applicable standards for delivery of an ABN in Section I.I.C.)

D. Choosing The Form To Use--Physicians and suppliers must use the OMB-approved ABNs (ABN-G and ABN-L) for use with Part B items and services. The ABN-G may be used for all situations, including laboratory tests, by all physicians and suppliers. The ABN-L may be used for laboratory tests, by any person or entity furnishing laboratory tests.

E. Filling Out The Forms--

1. Form Instructions for ABN-G and ABN-L --

a. Format of Insertions on ABN--The physician or supplier must ensure that the readability of the ABN facilitates beneficiary understanding. No insertion into the blanks and boxes of the ABN, if typed or printed, should use italics nor any font that is difficult to read. An Arial or Arial Narrow font, or a similarly readable font, in the font size range of 10 point to 12 point, is recommended. Black or dark blue ink on a white background is strongly recommended. A visually high-contrast combination of dark ink on a pale background is required. Low-contrast combinations and block shading are prohibited. If insertions are handwritten, they must be legible. In all cases, both the originals and copies of ABNs must be legible and high-contrast. When Spanish language ABNs are used, the physician or supplier should make insertions on the form in Spanish to the best of their ability. If this is impossible, the physician or supplier needs to take other steps as necessary to ensure that the beneficiary understands the notice.

b. Filling in the Form--

i. The ABN's header should have the identifying information of the billing entity. If the billing entity is a group practice, then the group practice may have its identifying information in the header. It may be prudent for each member of a group practice to also include their name in the header, but it is not required. A laboratory should put its own identifying information in the header where a client physician is delivering the ABN form to a beneficiary on behalf of the laboratory. ABNs included on laboratory requisition forms should have the identifying information of the laboratory in the header, not the client physician's information, even when stocks of the ABNs are provided to client physicians for their use in ordering tests. The physician or supplier puts his/her/its name, address, and telephone number at the top of the notice header; and may elect to include his/her/its logo (if any). Within these general rules, a notice header may be customized by the physician or supplier.

ii. "Patient name" Line--The physician or supplier enters the name of the patient, not substituting the name of an authorized representative.

iii. "Medicare Health Insurance Claim Number (HICN) Line"--The physician or supplier enters the patient's Medicare HICN. Do not invalidate an ABN solely for the lack of a Medicare HICN unless the beneficiary recipient of an ABN alleges that the ABN was signed by someone else of the same name and you cannot resolve the matter with certainty.

iv. ABN-G Customizable Boxes--In the section of the ABN-G beginning "We expect that Medicare will not pay for the item(s) or service(s) ...", in the first box "Items or Services:", the physician or supplier specifies the health care items or services for which he/she/it expects Medicare will not pay. The items or services at issue must be described in sufficient detail so that the patient can understand what items or services may not be furnished. HCPCS codes by themselves are not acceptable as descriptions. The use on the ABN of a list of the items and/or services which the particular physician or supplier frequently furnishes, with check-off boxes or some similar method of identifying the particular items or services for which denial is predicted, is an acceptable practice. Listing several items and/or services without

indicating which is/are applicable in the beneficiary's particular situation is not an acceptable practice and such an ABN is defective and will not protect the physician or supplier from liability. In the second box "Because:", the physician or supplier gives the reason why they expect Medicare to deny payment. The reason(s) must be sufficiently specific to allow the patient to understand the basis for the expectation that Medicare will deny payment. The physician or supplier may customize these two boxes for their own use.

v. ABN-L Customizable Boxes--In the section of the ABN-L beginning "Medicare probably will not pay...", the physician or supplier specifies the laboratory tests for which he/she/it expects Medicare will not pay in the customizable boxes. The laboratory tests at issue must be described in sufficient detail so that the patient can understand what laboratory tests may not be furnished. The use of standard laboratory test descriptions is permitted. HCPCS codes by themselves are not acceptable as descriptions. ABN-L has been designed with three columns with the specific reasons for expected denial captioning these columns. The physician or supplier enters or preprints laboratory tests in these three columns; the use of check off boxes is permitted. This format allows the physician or supplier to customize the ABN-L with a preprinted list of tests linked to the captioned reasons for denial. The boxes containing three columns for laboratory tests and reasons for expecting denial on the ABN-L may be customized by the physician or supplier, except that the captions (reasons) for the left and center columns may not be revised while the right column (experimental and research use exclusion) may be revised or deleted at the discretion of the user. Use of the right column to specify the frequency and/or duration of a standing order is permissible (see §I.2.A). Use of a fourth category, "Other:" is permissible.

vi. "Estimated Cost" Line--The physician or supplier may provide the patient with an estimated cost of the items and/or services. The patient may ask about the cost and jot down an amount in this space. The physician or supplier should respond to such inquiries to the best of their ability. The lack of an amount on this line, or an amount which is different from the final actual cost, does not invalidate the ABN; an ABN should not be considered to be defective on that basis. In the case of an ABN which includes multiple items and/or services, it is permissible for the physician or supplier to give estimated amounts for the individual items and/or services rather than an aggregate estimate of costs. Amounts may be provided either with the description of items and services or on the "Estimated Cost" line.

vii. Options 1 & 2 Boxes--The patient must personally select an option. Do not accept as evidence of beneficiary notice any ABN on which the physician or supplier has pre-selected an option; pre-selecting options is prohibited.

viii. In the "Date" blank, the patient, or his or her authorized representative, should enter the date on which he or she signed the ABN. If the date is filled in by the physician or supplier and the beneficiary or his or her authorized representative does not dispute the date, you should accept that date. Do not reject ABNs simply because the date is typed or printed. In the "Signature of patient ..." blank, the patient, or person acting on his or her behalf, must sign his or her name.

2. Signature Requirements for ABN-G and ABN-L.--

a. The beneficiary himself or herself may sign an ABN. In the case of a beneficiary who is incapable or incompetent, his or her "authorized representative," as defined for ABN purposes in Section I.1.F may sign an ABN. The policy enunciation in Section I.1.F of who may be an "authorized representative" supersedes the previous policy that "generally applicable rules of the Medicare program with respect to who may sign for a beneficiary apply to signing notices, including ABNs." The regulations on signature requirements for claims purposes at 42 CFR 424.36(b) do not apply to ABNs except that, with respect solely to ABNs for unassigned claims for physicians' services, someone eligible to sign for the beneficiary under 42 CFR §424.36(b), who is an "authorized representative" as defined for ABN purposes in Sections I.1.F and I.1.F.3 notwithstanding, may sign an ABN.

b. If the beneficiary's (or authorized representative's) signature is absent from an ABN, in case of a dispute as to the beneficiary's (or

authorized representative's) receipt of the ABN, give credence to the beneficiary's (or authorized representative's) allegations regarding the ABN, except as specified in Section I.3.F.2.

c. The physician or supplier must obtain the signed and dated ABN from the beneficiary, either in person or, where this is not possible, via return mail from the beneficiary or authorized representative acting on the beneficiary's behalf as soon as possible after the ABN has been signed and dated. The beneficiary retains the patient's copy of the signed and dated ABN and returns the original. The physician or supplier retains the original ABN. These copies will be relevant in case of any future appeal. Do not require physicians and suppliers to routinely submit copies of all ABNs to you.

F. Resolving Beneficiary Problems.--

1. A beneficiary who has been given either ABN-G or ABN-L (or the person acting on the beneficiary's behalf) may decide to receive the item or service. In this case, the beneficiary should select option 1 to indicate that he/she is willing to be personally and fully responsible for payment. When a beneficiary decides to decline an item or service, he/she should select Option 2. There is no third option. The beneficiary cannot properly refuse to sign the ABN at all and still demand the item or service. If a beneficiary refuses to sign a properly executed ABN, the physician or supplier should consider not furnishing the item or 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. If the beneficiary refuses to sign the ABN, the physician or supplier should annotate the ABN, and have the annotation witnessed, indicating the circumstances and persons involved.

2. In the case of claims to which Limitation on Liability protections under §1879(a), (b), and (c) of the Act apply, if the physician or supplier does furnish the item or service, the beneficiary's signature is meant to attest to receipt of the ABN; it has "agreement to pay" language so that it is absolutely clear to the beneficiary what the implications for him or her are. Once the beneficiary has read a properly executed ABN, he or she is "on notice;" that is, the beneficiary "knew, or could reasonably have been expected to know, that payment could not be made." The beneficiary has two legitimate choices: a) To obtain the service and be prepared to pay out of pocket, that is, personally or by any other insurance coverage, or b) Not to obtain the service. If the beneficiary demands the service and refuses to pay, the physician or supplier should have a second person witness the provision of the ABN and the beneficiary's refusal to sign. They should both sign an annotation on the ABN attesting to having witnessed said provision and refusal. Where there is only one person on site (e.g., in a "draw station"), the second witness may be contacted by telephone to witness the beneficiary's refusal to sign the ABN by telephone and may sign the ABN annotation at a later time. The unused patient signature line on the ABN form may be used for such an annotation; writing in the margins of the form is also permissible. The physician or supplier should file as having given the ABN, with a GA modifier. The beneficiary will be held liable per §1879(c) of the Act in case of a denial.

3. In the case of claims to which Refund Requirement protections under §§1834(a)(18), 1834(j)(4), 1842(l), or §1879(h) of the Act apply, if the physician or supplier does furnish the item or service, the beneficiary's signature is meant to attest both to receipt of the ABN and to the beneficiary's agreement to pay. The beneficiary both must receive a properly executed ABN so that he or she is "on notice" (that is, the beneficiary "knew, or could reasonably have been expected to know, that payment could not be made") and must agree to pay. The beneficiary has the same two legitimate choices: a) To obtain the service and be prepared to pay out of pocket, that is, personally or by any other insurance coverage, or b) Not to obtain the service. If the beneficiary demands the service and refuses to pay (in other words, selects Option 1 but will not sign or else marks out the agreement to pay language), the physician or supplier must take into account the fact that it will not be able to collect from the beneficiary in deciding whether or not to furnish the items or services. Although there would be little point in having a second person witness the provision of the ABN and the beneficiary's refusal to agree to pay (because the requirement that the beneficiary agree to pay still would not be fulfilled), the physician or supplier may annotate the ABN, as described in paragraph 2, above. The physician or supplier, if the items or services are furnished despite the

beneficiary's refusal to pay, should file the claim using the GZ modifier, that is, as not having obtained a signed ABN, since it was not completed properly by the beneficiary. Do not hold the beneficiary liable per §§1834(a)(18), 1834(j)(4), 1842(l), or §1879(h) of the Act in case of a denial. Do not hold the physician or supplier liable.

4. In either case (F.2 and F.3, above), the beneficiary who does receive an item or service, of course, always has the right to a Medicare determination and the claim must be filed with Medicare in accordance with §1848(g)(4) of the Act.

G. Demand Bills--A demand bill is a complete, processable claim which must be submitted promptly to Medicare by the physician or supplier at the timely request of the beneficiary, the beneficiary's representative, or, in the case of a beneficiary dually entitled to Medicare and Medicaid, a state as the beneficiary's subrogee. A demand bill is requested usually, but not necessarily, pursuant to notification of the beneficiary (or representative or subrogee) of the fact that the physician or supplier expects Medicare to deny payment of the claim. When the beneficiary (or representative or subrogee) selects an option on an ABN that includes a request that a claim be submitted to Medicare, no further demand is necessary; a demand bill must be submitted. When a beneficiary chooses Option 1 on an ABN-G or an ABN-L and receives the item or service, claims submission is mandatory. The physician or supplier must submit a claim to you, billing as covered, for an initial determination. On such a claim, a GA modifier must appear on the CMS-1500 in item 24D. The GA modifier indicates that an ABN was furnished by the physician or supplier and is on file in their office and it also documents the physician's or supplier's expectation that Medicare will not pay the claim. (The GA modifier is mandatory; it must be used anytime an ABN was obtained. The use of the GZ modifier is optional. A GZ modifier may be included on the CMS-1500 in item 24D if the physician or supplier wishes to indicate that denial for medical necessity is expected but an ABN was not obtained. Reject as unprocessable any claim line item including both the GA and GZ modifiers, as they are mutually exclusive.) Do not change your process for making an initial determination on the basis that a claim was submitted with a GA or GZ modifier. The provision of an ABN and/or the inclusion of a GA or GZ modifier by the physician or supplier only represent the physician's or supplier's assessment that Medicare will deny payment. You must make your initial determination on the usual bases. You may not auto-deny any claim solely on the basis of a GA or GZ modifier. After you have denied payment on a claim, take into account the presence of the GA or GZ modifier in determining the liability of the beneficiary and the physician or supplier. If you receive a claim that does not include a GA modifier, but a properly executed ABN is submitted with the claim, you should add the GA modifier to the claim yourself.

Part I - EXHIBITS:

- Exhibit 1.-- Advance Beneficiary Notice (CMS-R-131-G) for general use.
- Exhibit 1S.-- Spanish Advance Beneficiary Notice (CMS-R-131-G) for general use.
- Exhibit 2.-- Advance Beneficiary Notice (CMS-R-131-L) for laboratory tests.
- Exhibit 2S.-- Spanish Advance Beneficiary Notice (CMS-R-131-L) for laboratory tests.

For the online replicable copies of CMS-R-131 forms (G & L) in PDF format, go to the CMS Beneficiary Notices Initiative (BNI) webpage at <http://cms.hhs.gov/medicare/bni/>. Additional information may be found at Medlearn <http://cms.hhs.gov/medlearn/refabn.asp> – Advance Beneficiary Notice Quick Reference Guide. Do not replicate the forms in the following exhibits for actual use.

Exhibit 1
Advance Beneficiary Notice (CMS-R-131-G) For General Use

Patient's Name:

Medicare # (HICN):

ADVANCE BENEFICIARY NOTICE (ABN)

NOTE: You need to make a choice about receiving these health care items or services.

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

Items or Services:

Because:

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

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

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

Option 1. YES. I want to receive these items or services.

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

Option 2. NO. I have decided not to receive these items or services.

I will not receive these items or services. I understand that you will not be able to submit a claim to Medicare and that I will not be able to appeal your opinion that Medicare won't pay.

Date

Signature of patient or person acting on patient's behalf

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

Exhibit 1S
Spanish Advance Beneficiary Notice (CMS-R-131-G) For General Use.

Nombre del paciente:

No. de Medicare (HICN):

NOTIFICACIÓN PREVIA AL BENEFICIARIO DE MEDICARE (ABN)

NOTA: Usted debe tomar una decisión sobre su deseo de recibir estos servicios o productos de atención de salud.

Nosotros anticipamos que Medicare no va a pagar el (los) servicio (s) o producto (s) descrito(s) a continuación. Medicare no cubre todos los costos de atención de salud. Medicare paga sólo por los servicios y productos cubiertos cuando las reglas de Medicare son cumplidas. El hecho de que Medicare no pague por un servicio o producto determinado no significa que usted no deba recibirlo. Puede que exista una buena razón por la cual su médico se lo ha recomendado. En este momento, y en su caso particular, **es probable que Medicare no pague los siguientes exámenes:**

Servicios o Productos:

Porque:

El propósito de este formulario es ayudarle a tomar una decisión basada en su deseo de recibir estos servicios o productos, entendiendo que posiblemente tendrá que pagarlos por su propia cuenta.

Antes de tomar una decisión respecto a sus opciones, debería:

- Leer cuidadosamente este aviso en su totalidad.
- Pedirnos una explicación si no entiende por qué Medicare probablemente no pague.
- Preguntarnos cuánto le costarán a usted estos productos o servicios **Costo estimado:** \$ _____, en caso de que tenga que pagarlos por su propia cuenta o por medio de otro plan de seguro.

FAVOR ELEGIR UNA OPCIÓN. MARQUE UNA CASILLA. FIRME Y FECHE LA OPCIÓN SELECCIONADA.

Opción 1. Sí. Quiero recibir estos servicios o productos.

Comprendo que Medicare no tomará una decisión respecto a si pagará o no a menos que yo reciba estos servicios o productos. Favor presentar mi reclamación a Medicare. Comprendo que esta oficina podrá enviarme una factura por estos servicios o productos y que quizás yo tenga que pagar la factura antes de que Medicare haya tomado su decisión. Si Medicare aprueba el pago, esta oficina me reembolsará cualquier pago que les haya hecho y que se me deba devolver. Si Medicare no aprueba el pago, acepto asumir personalmente la responsabilidad total por el pago correspondiente. Es decir, pagaré personalmente, ya sea con fondos propios o a través de otro plan de seguro que yo tenga. Comprendo que puedo apelar la decisión de Medicare.

Opción 2. NO. He decidido no recibir estos servicios o productos.

No recibiré estos productos o servicios. Comprendo que esta oficina no podrá presentar a Medicare una reclamación para su consideración y que yo no podré apelar a la opinión de ustedes de que Medicare probablemente no pague.

Firma del paciente o de la persona que actúe en su nombre

Fecha

NOTA: La información sobre su salud se mantendrá confidencial. Toda información que recolectemos sobre su persona permanecerá en nuestros archivos y se mantendrá estrictamente confidencial. Si se presenta una reclamación a Medicare, la información relacionada con su salud que aparece en este formulario puede hacerse disponible a Medicare. Por su parte, Medicare mantendrá confidencial toda información sobre su salud que se haga disponible a dicha organización.

Exhibit 2

Advance Beneficiary Notice (CMS-R-131-L) For Laboratory Tests.

Patient's Name:

Medicare # (HICN):

ADVANCE BENEFICIARY NOTICE (ABN)

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

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

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

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

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

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

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

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

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

Exhibit 2S
Spanish Advance Beneficiary Notice (CMS-R-131-L) For Laboratory Tests.

Nombre del paciente:

No. de Medicare (HICN):

NOTIFICACIÓN PREVIA AL BENEFICIARIO DE MEDICARE (ABN)

NOTA: Usted debe tomar una decisión sobre su deseo de recibir estos exámenes de laboratorio.

Nosotros anticipamos que Medicare no va a pagar el (los) exámene(s) de laboratorio descrito(s) a continuación. Medicare no cubre todos los costos de atención de salud. Medicare paga sólo por los servicios y productos cubiertos cuando las reglas de Medicare son cumplidas. El hecho de que Medicare no pague por un servicio o producto determinado no significa que usted no deba recibirlo. Puede que exista una buena razón por la cual su médico se lo ha recomendado. En este momento, y en su caso particular, **Medicare probablemente no va a pagar por los exámenes de laboratorio indicados a continuación por las siguientes razones:**

Porque no se realizan normalmente dada la condición médica que usted tiene.	Porque se ha realizado con más frecuencia de lo aceptado por Medicare	Porque son exámenes experimentales o realizados con fines investigativos.

El propósito de este formulario es ayudarle a tomar una decisión basada en su deseo de recibir estos exámenes de laboratorio, entendiendo que posiblemente tendrá que pagarlos por su propia cuenta.

Antes de tomar una decisión respecto a sus opciones, debería:

- Leer cuidadosamente este aviso en su totalidad.
- Pedirnos una explicación si no entiende por qué Medicare probablemente no pague.
- Preguntarnos cuánto le costarán a usted estos exámenes de laboratorio **Costo estimado: \$ _____**, en caso de que tenga que pagarlos por su propia cuenta o por medio de otro plan de seguro.

FAVOR ELEGIR UNA OPCIÓN. MARQUE UNA CASILLA. FIRME Y FECHE LA OPCIÓN SELECCIONADA.

Opción 1. SÍ. Quiero recibir estos exámenes de laboratorio.
 Comprendo que Medicare no tomará una decisión respecto a si pagará o no a menos que yo reciba estos exámenes de laboratorio. Favor presentar mi reclamación a Medicare. Comprendo que el laboratorio podrá enviarme una factura por estos productos o servicios y que quizás yo tenga que pagar la factura antes de que Medicare haya tomado su decisión. Si Medicare aprueba el pago, el laboratorio me reembolsará cualquier pago que les haya hecho y que se me deba devolver. Si Medicare no aprueba el pago, acepto asumir personalmente la responsabilidad total por el pago correspondiente. Es decir, pagaré personalmente, ya sea con fondos propios o a través de otro plan de seguro que tenga. Comprendo que puedo apelar la decisión de Medicare.

Opción 2. NO. He decidido no recibir estos exámenes de laboratorio.
 No recibiré estos productos o servicios. Comprendo que el laboratorio no podrá presentar a Medicare una reclamación para su consideración y que yo no podré apelar a la opinión de ustedes de que Medicare probablemente no pague. Avisaré a mi médico que ordenó estos exámenes de laboratorio que no los recibí.

Firma del paciente o de la persona que actúe en su nombre

Fecha

NOTA: La información sobre su salud se mantendrá confidencial. Toda información que recolectemos sobre su persona permanecerá en nuestros archivos y se mantendrá estrictamente confidencial. Si se presenta una reclamación a Medicare, la información relacionada con su salud que aparece en este formulario puede hacerse disponible a Medicare. Por su parte, Medicare mantendrá confidencial toda información sobre su salud que se haga disponible a dicha organización.

Part II - Instructions for Carriers and Suppliers on Limits on Beneficiary Liability for Medical Equipment and Supplies

Following are the procedures for use by carriers and suppliers in implementing §§1834(a)(18), 1834(j)(4) and 1879(h) of title XVIII of the Social Security Act (the Act). References herein to manual sections are references to the Medicare Carriers Manual, (MCM) Part 3. References herein to “you” and “your” refer to the Medicare carrier; these instructions will be manualized as a new section 7340 in the MCM.

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 subsection II.1, which are furnished on or after January 1, 1995, and for which Medicare payment is denied for one of several reasons specified in subsections II.2 and II.3 below, may be limited as follows. For both assigned and unassigned claims, for which it is held that 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 it is held that 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 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 (see MCM §7300.ff and §7320.ff); 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 (see Section I.2.E & F of this PM). A partial denial may be used to base payment on the least costly, medically appropriate, alternative (see MCM §§2100.2 and 7501.1C). 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 MCM §7330.B 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.

Section II.1 Definition of Medical Equipment and Supplies.--The following definitions of medical equipment and supplies control the application of the provisions of this section.

A. For unassigned claims denied on the basis of the prohibition on unsolicited telephone contacts under §1834(a)(17)(B) of the Act, the term “medical equipment and supplies” means:

- Durable medical equipment, as defined in §1861(n) of the Act; and
- Medical supplies, as described in §1861(m)(5) of the Act, including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care.

B. For unassigned claims denied on the basis of not being reasonable and necessary under §1862(a)(1) of the Act; or Medicare payment being denied in advance under §1834(a)(15) of the Act; the term “medical equipment and supplies” means:

- 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; and
- Such other items as the Secretary may determine.

C. For unassigned claims denied on the basis of failure of the supplier to meet supplier number requirements under §1834(j)(1) of the Act, the term “medical equipment and supplies” means:

- 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
- Such other items as the Secretary may determine.

D. For assigned claims denied on the basis of the prohibition on unsolicited telephone contacts under §1834(a)(17)(B) of the Act; or Medicare payment being denied in advance under §1834(a)(15) of the Act; the term “medical equipment and supplies” means:

- 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; and
- Such other items as the Secretary may determine.

E. For assigned claims denied on the basis of failure of the supplier to meet supplier number requirements under §1834(j)(1) of the Act, the term “medical equipment and supplies” means:

- 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
- Such other items as the Secretary may determine.

F. For assigned claims denied on the basis of not being reasonable and necessary under §1862(a)(1) of the Act, the term “medical equipment and supplies” means:

- Durable medical equipment, as defined in §1861(n) of the Act;
- Medical supplies, as described in §1861(m)(5) 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; and
- Such other items as the Secretary may determine.

Section II.2. Items and Services Furnished On an Unassigned Basis On or After January 1, 1995.--Nonparticipating suppliers which (1) Do not accept assignment, (2) Do not claim payment after the death of the beneficiary, and (3) Do not bill under the indirect payment procedure in §7065 of the MCM, if held to be liable, must refund to beneficiaries any amounts collected for medical equipment and supplies for which Medicare payment is denied for one of the following reasons:

- Under §1834(a)(18)(A) of the Act, the supplier violated the prohibition on unsolicited telephone contacts under §1834(a)(17)(B) of the Act; and
- Under §1834(j)(4) of the Act, the supplier did not meet supplier number requirements under §1834(j)(1); or the item is denied in advance under §1834(a)(15) of the Act; or payment is denied as not reasonable and necessary under §1862(a)(1) of the Act.

In any such payment denial under §1834(a)(17)(B), §1834(j)(1), §1834(a)(15), or §1862(a)(1) of the Act, the beneficiary has no financial responsibility and the refund provisions of §§1834(a)(18), 1834(j)(4) or 1879(h) of the Act, as appropriate, apply, if it is held that the supplier knew or should have known of the likelihood that payment would be denied and that the beneficiary did not know.

For medical equipment and supplies furnished prior to January 1, 1995, Federal law does not limit beneficiaries' liability with respect to unassigned claims for which payment was denied.

Section II.3 Items and Services Furnished On an Assigned Basis On or After January 1, 1995.--Under §1879(h) of the Act, suppliers, whether nonparticipating or participating, which accept assignment, if held to be liable, must refund to beneficiaries any amounts collected for medical equipment and supplies for which Medicare payment is denied for one of the following reasons:

- Under §1879(h)(1) of the Act, payment is denied because the supplier did not meet the supplier number requirements under §1834(j)(1) of the Act;
- Under §1879(h)(2) of the Act, payment is denied in advance under §1834(a)(15) of the Act; and
- Under §1879(h)(3) of the Act, payment is denied based on §1834(a)(17)(B) of the Act, the prohibition on unsolicited telephone contacts.

In any such payment denial under §1834(j)(1), §1834(a)(15), or §1834(a)(17)(B) of the Act, the beneficiary has no financial responsibility and the refund provisions apply, if it is held that the supplier knew or should have known of the likelihood that payment would be denied and that the beneficiary did not know. However, in a denial of an assigned claim under §1862(a)(1) of the Act (i.e., payment is denied because the item or service is not reasonable and necessary), the §1879 Limitation on Liability provisions which applied to such denials prior to January 1, 1995, still apply (see MCM §7300.ff and §7320.ff).

Section II.4 Time Limits for Making Refunds.--A refund of any amounts collected must be made to the beneficiary on a timely basis. Refund is considered to be on a timely basis only if made within the following time limits:

- If the supplier does not request review of the initial denial or reduction in payment within that time, the refund must be made to the beneficiary within 30 days after the date the supplier receives the remittance advice (RA). (See subsection II.8 for notice requirements.)
- If the supplier requests review within 30 days of receipt of the notice of the initial determination, the refund must be made to the beneficiary within 15 days after the date the supplier receives the notice of the contractor's determination of the supplier's appeal.

Section II.5 Supplier Knowledge Standards for Waiver of Refund Requirement.--A refund is not required of the supplier if the supplier did not know and could not reasonably have been expected to know that Medicare would not pay for the medical equipment or supplies. Following are the knowledge standards applicable to the different types of denials.

A. Knowledge Standards for §1862(a)(1) Denials.--In determining whether the supplier knew, or could reasonably have been expected to know, that Medicare would not pay on the basis of medical necessity, apply the same rules that are applicable in determining supplier liability under §1879 of the Act. (See §7300.5 B of the MCM.)

B. Knowledge Standards for §1834(a)(15) Denials.--

i. 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 you 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.

ii. 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, respectively, when:

- The item is on the list developed by the Secretary under §1834(a)(15)(A) of items which are frequently subject to unnecessary utilization in your carrier service area; or

- The supplier is on the list developed by the Secretary under §1834(a)(15)(B) of the Act of suppliers for which a substantial number of claims have been denied as not reasonable and necessary under §1862(a)(1) of the Act or the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier.

iii. 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 a customized item (other than inexpensive items specified by the Secretary) and the patient to whom the item is to be furnished or the supplier requests an advance determination.

iv. 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 your regular newsletter/bulletin publication. The supplier would have to submit convincing evidence to the contrary to rebut this presumption.

v. 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 you 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 non-rebuttable presumption.

vi. Any denial of a claim for a particular item furnished by a particular supplier because the item is on the §1834(a)(15)(A) list of potentially overutilized items is actual notice to that supplier that an advance determination must be requested for all future claims for that item, and for any other items which are identified in the same notification of denial as being on the list of potentially overutilized items. Presume, on that basis, that that supplier has knowledge that an advance determination must be requested for all future claims for any and all items which are identified in the notification of denial as being on the list of potentially overutilized items. This is a non-rebuttable presumption.

vii. Any denial of a claim for an item furnished by a particular supplier because the supplier is on the §1834(a)(15)(B) list of suppliers, is actual notice to that supplier that an advance determination must be requested for all future claims for any item of medical equipment and supplies which that supplier furnishes. Presume, on that basis, that that supplier has knowledge that an advance determination must be requested for all future claims for any and all items of medical equipment and supplies which it furnishes. This is a non-rebuttable presumption.

viii. In the case of an optional request for an advance determination of coverage of a customized item of medical equipment and supplies under §1834(a)(15)(C)(iii) of the Act by the patient to whom the item is to be furnished or the supplier, 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 you 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 non-rebuttable presumption.

ix. 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 he or she receives a proper advance beneficiary notice (ABN) to that effect from the supplier before the item is furnished to him or her. (See Section I.2.D.3 regarding ABNs for such cases.)

C. Knowledge Standards for §1834(a)(17)(B) Denials.--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 your 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 non-rebuttable.

D. Knowledge Standards for §1834(j)(1) Denials.--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 your 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 you find 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 non-rebuttable.

E. Additional Knowledge Standards for All Medical Equipment and Supplies Denials.--You 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.

Section II.6 Advance Beneficiary Notice Standards for Waiver of Refund Requirement.--A refund is not required of the supplier if, before the medical equipment or supplies were furnished, the beneficiary was informed by the supplier that Medicare would not pay for the specific item or service and, after receiving such an advance beneficiary notice, the beneficiary agreed to pay for the item or service. This requirement for advance notice may be satisfied by a properly executed Advance Beneficiary Notice (ABN) form CMS- R-131-G used in accordance with the instructions at Section I.6.

Section II.7 Appeal Rights.--

A. Supplier Rights to Appeal Carrier Determinations.--Nonparticipating suppliers have the same rights to appeal your determination in an unassigned claim for medical equipment and supplies if you deny 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. While the time limits in §12005 and §12007 of the MCM apply for filing requests for review and hearing, refunds must be made within the time limits specified in subsection II.4. An adverse advance determination of coverage under §1834(a)(15) of the Act is not an initial determination on a claim for payment for items furnished and, therefore, is not appealable.

B. Beneficiary Appeal Rights.--In addition to his/her right to appeal your 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 request for review 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 review of the denial or asserts that a refund is not required because one of the conditions in subsection II.5 is met. These procedures apply to the hearing process as well.

Section II.8 Processing Initial Denials.--In any unassigned claim for medical equipment and supplies furnished on or after January 1, 1995, in which you deny 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 (an explanation of Medicare benefits (EOMB) or 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 should be implemented within your current operating budget. It 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 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 must in no way prejudice your 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 EOMB or

MSN notice to the beneficiary. If the beneficiary did not sign an ABN and the supplier included a GZ modifier on the CMS-1500 to that effect, include, in addition to one of the denial notices in §7012.15.0.ff., the following initial beneficiary notice in the EOMB or MSN sent to the beneficiary.

A. Initial Beneficiary Notice.--"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 the items or services, that Medicare probably would deny payment, you may be entitled to a refund of any amounts you paid. However, if the supplier requests a review of this claim within 30 days, a refund is not required until we complete our review. If you paid for this service and do not hear anything about a refund within the next 30 days, contact your supplier."

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 EOMB, (see §7012.15.0.ff. of the MCM); 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 (signed ABN not obtained), include in the notice to the supplier the following Notice 2.

Notice 1. – Signed Advance Beneficiary Notice Obtained

"(The item or service identified above has been denied because/Although payment has been made to the patient,) the information furnished did not substantiate the need for the item or service. Since you informed the beneficiary in writing prior to furnishing the item or service that Medicare was likely to deny payment for the item or service and the beneficiary signed a statement agreeing to pay, the beneficiary is liable for this item or service."

or,

Notice 2. – Signed Advance Beneficiary Notice Not Obtained

"(The item or service identified above has been denied because/ Although payment has been made to the patient,) the information furnished did not substantiate the need for the item or service.

If you have collected any amount from the patient, the law requires you to 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 item or service; or
- If you notified the beneficiary in writing before providing the item or service that Medicare likely would deny the item or service, and the beneficiary signed a statement agreeing to pay for the item or service.

If either exception applies to you, or if you believe the carrier was wrong in its determination that Medicare does not pay for this item or service, you should request review of this determination by the carrier within 30 days of receiving this notice. Your request for review should include any additional information necessary to support your position.

If you request review within this 30-day period, you may delay refunding the amount to the beneficiary until you receive the results of the review. If the review determination is

favorable to you, you do not have to make any refund. If, however, the review is unfavorable, the law specifies that you must make the refund within 15 days of receiving the unfavorable review decision.

The law also permits you to request review of the determination at any time within 6 months of receiving this notice. A review requested after the 30-day period does not permit you to delay making the refund. Regardless of when a review 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 (carrier 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 to claims you automatically deny under the A/B link procedures in §4169 of the MCM. In those cases, the Quality Improvement Organization (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.

Section II.9 Processing Beneficiary Requests for Review.--Where a beneficiary requests a review of the initial denial, process the review in the normal fashion except that, where the review results in a reversal, include the following special paragraph in the review notice sent to the beneficiary:

"The supplier which furnished this item or service has been informed of this decision and advised that it may collect its full charge for the item or service."

Add paragraph U7 (see §7014.2 of the MCM) to the header.

In addition, if the reversal is for full payment except for a reasonable charge reduction, incorporate paragraph U10 (see §7014.2 of the MCM) in the notice.

Send the supplier which furnished the item or service a separate notice which clearly identifies the item or service for which payment is being made (i.e., include the patient's name, health insurance claim number, a description of the item or service billed by procedure code, date and place of service, and amount of the charge. Include the following language:

"You were previously advised that Medicare payment could not be made for this item or service. However, after reviewing this claim, we have determined that payment may be made. Therefore, if you have already refunded the amounts you collected from the beneficiary for this item or service, you may recollect these amounts."

Section II.10 Processing Supplier Requests for Review.--Where a supplier requests a review, notify the beneficiary as discussed in subsection II.7 B. The review process consists of three stages, even though the supplier may be contesting only one issue (e.g., the supplier may assert that it did not know, and could not have reasonably have been expected to know, that Medicare would not pay for the items or services).

A. Review of the Denial of Payment--The first stage of the review is a new, independent, and critical reexamination of the facts regarding the denial of payment. If you find that the initial denial of payment was appropriate, go on to stage B.

B. Beneficiary Given Advance Beneficiary Notice and Agreed to Pay--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, ask the supplier to furnish a copy of the ABN. Examine the ABN to determine whether it meets the standards in subsection II.6. In the absence of acceptable evidence of advance beneficiary notice, go on to stage C.

C. Supplier Knowledge--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, 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 subsection II.5.

Section II.11 Guide Paragraphs for Inclusion in Review Determination-- Upon completion of your review, send the supplier a review notice. Send a copy to the beneficiary. If the initial payment determination is reversed to payment, include in the review notice the supplier notice language required in subsection II.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. Although you have 6 months from the date of this notice in which to request a hearing on this decision if the amount in controversy is \$100 or more, 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 carrier 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.

Section II.12 Supplier Fails to Make Refund.--Under §1834(a)(18)(B) of the Act, a supplier which knowingly and willfully fails to make refund within the time limits in subsection II.4 may be subject to sanctions under §1128A of Title XI of the Social Security 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 carrier 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 your attention as a result of a beneficiary complaint or a referral from the Social Security Administration (SSA) or the Centers for Medicare & Medicaid Services (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 you determine that a supplier failed to make a refund, 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. 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. Recontact 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.

Section II.13 CMS Regional Office (RO) Referral Procedures.--Prior to submitting any materials to the RO, 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.

Section II.14 Imposition of Sanctions.--Section 1834(a)(18)(B) of the Act provides that if a supplier knowingly and willfully fails to make required refunds, the Secretary may impose the sanctions provided in §1842(j)(2) of the Act in the same manner as such sanctions are authorized under §1128A of the Act. These include civil money penalties, assessments, and exclusion from the Medicare program for a period of up to 5 years. The CMS RO will make the determination on whether to proceed in developing a monetary penalty or program exclusion case based upon a failure to make refunds.

Section II.15 Supplier's Right to Recover Resaleable Items for Which Refund Has Been Made.--If you deny 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 rerentable, permits the supplier to repossess that item for resale or rerental. In the case of consumable items or any other items which are not fit for resale or rerental and which cannot be made fit for resale or rerental, 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 resaleable or rerentable.

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 rerentable 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 his/her 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 you a new Part B claim based on the resale or rerental 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 rerented 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 rerental 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 it is determined that the supplier is obligated to make a refund, it must repay Medicare those rental payments that it received for the item. However, the Medicare beneficiary must return the item to the supplier.

Part III - Instructions for Fiscal Intermediaries and Providers on Advance Beneficiary Notice (ABN) Standards for Items and Services for Which Institutional Part B Claims Will Be Processed by Fiscal Intermediaries and on Limits on Beneficiary Liability for Medical Equipment and Supplies

Section III.1. Incorporation by Reference of Part I & Part II of this PM.--

A. Physicians, suppliers, and providers, and the fiscal intermediaries processing their claims, must follow the general requirements for ABNs as they are enunciated in Part I of this PM and, as applicable, the general requirements for implementing limits on beneficiary liability for medical equipment and supplies (the DMEPOS Refund Requirements) as they are enunciated in Part II of this PM. With respect to demand bills, they must follow the instructions in Part III of this PM.

B. These instructions on the use of ABNs apply to all claims for Part B items and services furnished by institutional providers and/or processed by fiscal intermediaries (inclusive of, e.g., Part B claims submitted by a physician or other supplier for processing by a fiscal intermediary, Part B claims for medical and other health services furnished by an HHA, Part B claims for certain items and services when furnished by a participating SNF (either directly or under arrangements) to an inpatient of the SNF, if payment for these services cannot be made under Part A). Providers must utilize ABN procedures for these Part B items and services furnished to Medicare beneficiaries, including dually-eligible (viz., Medicare and Medicaid) beneficiaries. They must not give inpatient notices of noncoverage (e.g., Notices of Non-Coverage/Hospital Issued Notices of Noncoverage NONCs/HINNs) to beneficiaries for Part B items and services. They must not give Medicare ABNs to patients who are not Medicare beneficiaries.

Section III.2. ABNs for Medical and Other Health Services Furnished by an Home Health Agency (HHA) under Part B.-- Part B of Medicare is designed to supplement the basic Part A coverage. In addition to providing coverage for unlimited home health visits in a calendar year (see HHA Manual §215.2), Part B provides coverage for certain “medical and other health services.” Reimbursement may be made to an HHA that furnishes, either directly or under arrangements with others, certain medical and other health services (see HHA Manual §219). The instructions in Part I and Part II of this PM are applicable with respect to Part B claims for medical and other health services furnished by an HHA.

Section III.3. ABNs for Part B Services Furnished in a Skilled Nursing Facility (SNF).-- Insofar as (per SNF Manual §260.A) payment may be made under Part B for certain items and services when furnished by a participating SNF (either directly or under arrangements) to an inpatient of the SNF, if payment for these services cannot be made under Part A (e.g., the beneficiary has exhausted his/her allowed days of inpatient SNF coverage under Part A in his/her current spell of illness or was determined to be receiving a noncovered level of care, or the 3-day prior hospitalization or the transfer requirement is not met), the instructions in Part I and Part II of this PM are applicable with respect to such Part B claims. (See also SNF Manual §529 and §534.)

Section III.4. Demand Bills.--A demand bill is a complete, processable claim which must be submitted promptly to Medicare by the physician, supplier or provider at the timely request of the beneficiary, the beneficiary's representative, or, in the case of a beneficiary dually entitled to Medicare and Medicaid, a State as the beneficiary's subrogee. A demand bill is requested usually, but not necessarily, pursuant to notification of the beneficiary (or representative or subrogee) of the fact that the physician, supplier or provider expects Medicare to deny payment of the claim. When the beneficiary (or representative or subrogee) selects an option on an ABN that includes a request that a claim be submitted to Medicare, no further demand is necessary; a demand bill must be submitted.

A. The physician, supplier or provider always must submit a claim, billing as covered, for an initial determination when it gave an ABN on the basis of the likelihood of denial of payment. On such a claim, the physician, supplier or provider must enter occurrence code 32 on the UB-92 in one of the fields numbered 32 through 35. This code

indicates the date the physician, supplier or provider gave the ABN to the beneficiary. It is the occurrence code 32, and not any condition code that indicates to the fiscal intermediary that an ABN has been issued. Occurrence code 32 is mandatory; it must be used anytime a signed ABN was obtained.

B. A physician, supplier or provider that has obtained a signed ABN should not enter condition code 20 (the demand bill condition code) on the UB-92, except where otherwise required to use condition code 20 for claims (viz., home health or skilled nursing facility claims) that require 100 percent complex manual medical review. The fiscal intermediary should not process a claim with both occurrence code 32 and condition code 20 any differently than it would handle a claim with occurrence code 32 only, not including condition code 20, except as otherwise provided for claims that require 100 percent complex manual medical review. The fiscal intermediary must not routinely deny payment for services billed with occurrence code 32 or condition code 20. The provision of an ABN by the physician, supplier or provider only represents its assessment that Medicare will deny payment. The fiscal intermediary must make its initial determination on the usual bases, without being influenced by occurrence code 32 and/or condition code 20 being on the claim. After the fiscal intermediary has denied payment on a claim, it must take into account the presence of occurrence code 32 in determining the liability of the beneficiary and the physician, supplier or provider with respect to those item(s) and/or service(s) for which the ABN was given and signed.

C. The physician, supplier or provider may submit claims, for initial determination, for statutorily excluded services, if the beneficiary requests it. On claims for statutorily excluded services, the physician, supplier or provider should enter a condition code 21 on the UB-92 in one of the fields numbered 24 through 30 to indicate that it realizes that the furnished services are excluded, but that it is requesting a denial notice from Medicare in order to bill Medicaid or other insurers. This is also known as a "no-pay" claim. The fiscal intermediary must handle such a claim in the same manner as it handles all other claims with condition code 21 entered on them.

**Part IV - Instructions for Regional Home Health Intermediaries (RHHIs)
and Hospices on Advance Beneficiary Notice (ABN) Standards
for Certain Hospice Claims**

Section IV.1. Incorporation by Reference of Part I of this PM.--Hospices and Regional Home Health Intermediaries (RHHIs) processing hospice claims must follow the general requirements for ABNs as they are enunciated in Part I of this PM. Insofar as those requirements are specifically applicable to two types of potential hospice claims denials, hospices and RHHIs must follow the instructions in Part IV of this PM.

Section IV.2. Denial Situations that Call for ABNs.--There are two situations in which hospice services may be denied, for which an ABN is appropriate:

(A) Due to ineligibility (the beneficiary is not “terminally ill” within the statutory definition in §1861(dd)(3)(A) of the Act, per §1879(g)(2) of the Act); and

(B) Because a level of care is determined inappropriate for the hospice patient (under §1862(a)(1) of the Act).

Section IV.3. Acceptable ABN Language.--Hospices are required to give an ABN to Medicare beneficiaries when the hospice believes that Medicare will deny payment on one of the bases listed in §IV.2. When preparing such an ABN, the hospice must use the following approved language for filling in the “Items or Services” and “Because” boxes on the CMS-R-131-G form, as follows:

- (A) Ineligibility:
Box 1: Item or Services: “The Medicare hospice benefit.”
Box 2: Because: “We have determined that you are not eligible under Medicare rules for certification as having a terminal prognosis as defined in the law.”
- (B) Level of Care:
Box 1: Item or Services: “The hospice General Inpatient Care level of care.” OR “the hospice Continuous Home Care level of care.”
Box 2: Because: “We have determined that you do not require this level of service.”

Section IV.4. Demand Bills.--A demand bill is a complete, processable claim which must be submitted promptly to Medicare by the hospice at the timely request of the beneficiary, the beneficiary's representative, or in the case of a beneficiary dually entitled to Medicare and Medicaid, a state as the beneficiary's subrogee. A demand bill is requested usually, but not necessarily, pursuant to notification of the beneficiary (or representative or subrogee) of the fact that the hospice expects Medicare to deny payment of the claim. When the beneficiary (or representative or subrogee) selects an option on an advance beneficiary notice that includes a request that a claim be submitted to Medicare, no further demand is necessary; a demand bill must be submitted.

A. The hospice always must submit a claim, billing as covered, for an initial determination when it gave an ABN on the basis of the likelihood of denial of payment. On such a claim, the hospice must enter “occurrence” code 32 on the UB-92 in one of the fields numbered 32 through 35. This code indicates the date the hospice gave the ABN to the beneficiary. It is the occurrence code 32, and not any “condition” code, that indicates to the RHHI that an ABN has been issued. Occurrence code 32 is mandatory; it must be used anytime an ABN was obtained.

B. A hospice that has obtained a signed ABN should not enter “condition” code 20 (the demand bill condition code) on the UB-92. The RHHI should not process a claim with both occurrence code 32 and condition code 20 any differently than it would handle a claim with occurrence code 32 only, not including condition code 20. The RHHI must not routinely deny payment for hospice services billed with either occurrence code 32 or condition code 20, or both. The provision of an ABN by the hospice only represents the hospice's assessment that Medicare will deny payment. The RHHI must make its initial determination on the usual bases, without being influenced by occurrence code 32

and/or condition code 20 being on the claim. After the RHHI has denied payment on a claim, it must take into account the presence of occurrence code 32 in determining the liability of the beneficiary and the hospice with respect to those service(s) for which the ABN was given and signed.

C. The hospice may submit claims, for initial determination, for statutorily excluded services, if the beneficiary requests it. On claims for statutorily excluded services, the hospice should enter a condition code 21 on the UB-92 in one of the fields numbered 24 through 30 to indicate that it realizes that the furnished services are excluded, but that it is requesting a denial notice from Medicare in order to bill Medicaid or other insurers. This is also known as a “no-pay” claim. The RHHI must handle such a claim in the same manner as it handles all other claims with condition code 21 entered on them.