Medicare Claims Processing Manual

Chapter 30 - Financial Liability Protections

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(Rev. 1587, 09-05-08)

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10 - Financial Liability Protections (FLP) Provisions of Title XVIII

(Rev. 1, 10-01-03)

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

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

The FLP provisions apply to individuals enrolled in the Medicare Fee-For-Service (FFS) program (Parts A and B), but are not applicable to Medicare M+C (Part C) enrollees nor to non-Medicare enrollees. The Advance Beneficiary Notices (ABNs) proper to the FLP provisions are to be used solely for individuals enrolled in the Medicare FFS program and are not to be used for Medicare M+C enrollees nor for non-Medicare enrollees.

The FLP provisions apply very specifically, on the basis of the statutory provision under which a particular denial occurs as well as other criteria described in this Chapter 30. The manner in which the FLP provisions apply varies by whether or not the claim is assigned or non-assigned, under Part A or Part B, and the statutory basis for denial of the claim. Following are frequently asked questions (FAQs) about differences between the Limitation On Liability and Refund Requirements provisions. More specific guidance follows later in this Chapter.

- **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)-(g) of 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**. Is there some difference in the significance of the beneficiary's signature on an Advance Beneficiary Notice (ABN) depending on whether LOL or RR applies?

- **A.2**. 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, these 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 provider, physician, practitioner, 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 an indication that an ABN was given.
- **Q.3**. The ABN forms indicate that, if Medicare denies payment, the beneficiary agrees to be personally and fully responsible for payment and to pay personally, either out of pocket or through any other insurance that the beneficiary has. Why is that, if LOL does not require the beneficiary to agree to make payment?
- **A.3**. 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.

20 - Limitation On Liability (LOL) Under §1879 Where Medicare Claims Are Disallowed

(Rev. 594, Issued: 06-24-05, Effective: 07-01-05, Implementation: 07-01-05)

Section 1879(a)-(g) of the Act provides financial relief to beneficiaries, providers, practitioners, physicians, and other suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain services and items for which Medicare payment would otherwise be denied. This section of the Act is referred to as "the limitation on liability provision."

The basic purpose of this provision is to protect beneficiaries and other claimants from liability in denial cases under certain conditions when services they received are found to be excluded from coverage for one of the reasons specified in §20.1.

Medicare payment under the limitation on liability provision is dependent upon two primary factors. First, the claims for the services or items furnished must have been denied for one of the reasons specified in §20.1. The second factor in determining if Medicare payment is made under the limitation on liability provision is whether the beneficiary and/or the provider, practitioner, physician, or other supplier knew or could reasonably have been expected to know that the items or services (for which Medicare payment was denied on one of the bases specified in §20.1) were not covered. A determination of whether the protection under the limitation on liability provision can be afforded for a denied claim is made as a result of a prepayment medical review or a post-payment audit review. Unfavorable determinations may be appealed.

Where items or services are denied for one of the reasons specified in §20.1, and the other conditions described above are met, the Medicare program makes payment when neither the beneficiary nor the provider, practitioner, or supplier knew, and could not reasonably be expected to have known, that the items or services were not covered. When the beneficiary did not have such knowledge, but the provider, practitioner, or supplier knew, or could have been expected to know, of the exclusion of the items or services, the liability for the charges for the denied items or services rests with the provider, practitioner or supplier. When the beneficiary knew or could have been reasonably expected to know that the items or services were not covered, the liability for the charges rests with the beneficiary, i.e., the beneficiary is responsible for making payment to the provider, practitioner or supplier.

The limitation on liability provision requires the contractor to identify each claim for items or services denied for one of the reasons specified in §20.1. Such denials are processed in the normal manner except that a special message is entered on the notice to the beneficiary and/or provider, practitioner or supplier. Remittance Advices (RA) to providers, practitioners, or suppliers indicate which items or services were denied for one of the reasons specified in §20.1 in a message included in the RA.

In some cases, the provider, practitioner, or supplier may submit a copy of an advance beneficiary notice (ABN) that satisfies the applicable requirements in §50 - §80. However, if the reason liability is at issue coincides with the end of coverage for a period of care in specific settings-- inpatient hospital, skilled nursing, home health, hospice or comprehensive outpatient rehabilitation facilities-- notification under the expedited determination process will be required as of July 1, 2005. See CR 3903 for preliminary information on the expedited process, including its interaction with liability notice policy.

NOTE: This chapter often uses the term "ABN" to signify all limitation of liability notices, not just a specific ABN form such as the CMS-R-131.

Providers annotate claims to indicate an ABN was given. In these cases, the contractor should not make an automatic finding that the service is denied for one of the reasons specified in §20.1 merely because an acceptable ABN has been submitted. The fact that there is an acceptable ABN must in no way prejudice the contractor determination as to whether there is or is not sufficient evidence to justify a denial for one of the reasons specified in §20.1.

20.1 - Coverage Denials to Which the Limitation on Liability Applies

(Rev. 1, 10-01-03)

B3-7300.2, B3-7300.3, CMS Rulings (No. 95-1, 96-2, 96-3, 97-1)

20.1.1 - Statutory Basis

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

A coverage determination for an item or service must be made before there can be a decision with respect to whether Medicare payment may be made under the limitation on liability provision. Medical review entities, acting for the Secretary, are authorized to make the coverage determinations. These entities include Fiscal Intermediaries (FIs), Carriers, Qualified Independent Contractors (QICs) and Quality Improvement Organizations (QIOs). In CMS Ruling 95-1 and hereafter in these instructions, these entities are referred to collectively as Medicare contractors. These entities must act in accordance with the Medicare statutes, regulations, national coverage instructions, accepted standards of medical practice, and CMS Rulings when making coverage determinations.

The claims payment and beneficiary indemnification provisions (§§1879(a) and (b)) of the limitation on liability provision are applicable only to claims for beneficiary items or services submitted by providers, or by suppliers (which includes physicians or other practitioners, or an entity other than a provider that furnishes health care services under Medicare) that have taken assignment, and only to claims for services, not otherwise statutorily excluded, that are denied on the basis of §§1862(a)(1), 1862(a)(9), 1879(e), or 1879(g) of the Act, which, under current law, include the following:

- Services and items found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A) of the Act);
- Pneumococcal vaccine and its administration, influenza vaccine and its administration, and hepatitis B vaccine and its administration, furnished to an individual at high or intermediate risk of contracting hepatitis B, that are not reasonable and necessary for the prevention of illness (§1862(a)(1)(B) of the Act);
- Services and items that, in the case of hospice care, are not reasonable and necessary for the palliation or management of terminal illness (§1862(a)(1)(C) of the Act);
- Clinical care services and items furnished with the concurrence of the Secretary and, with respect to research and experimentation conducted by, or under contract with, the Prospective Payment Assessment Commission or the Secretary, that are not reasonable and necessary to carry out the purposes of §1886(e)(6) of the Act (which concerns identification of medically appropriate patterns of health resources use) (§1862(a)(1)(D) of the Act);

- Services and items that, in the case of research conducted pursuant to <u>§1142</u> of the Act, are not reasonable and necessary to carry out the purposes of that section (which concerns research on outcomes of health care services and procedures) (§1862(a)(1)(E) of the Act);
- Screening mammography that is performed more frequently than is covered under §1834(c)(2) of the Act or that is not conducted by a facility described in §1834(c)(1)(B) of the Act and screening pap smears and screening pelvic exams performed more frequently than is provided for under §1861(nn) of the Act (§1862(a)(1)(F) of the Act);
- Screening for glaucoma, which is performed more frequently than is provided under §1861(uu);
- Prostate cancer screening tests (as defined in §1861(00)), which are performed more frequently than is covered under such section;
- Colorectal cancer screening tests, which are performed more frequently than is covered under §1834(d);
- The frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation;
- Custodial care (§1862(a)(9) of the Act);
- Inpatient hospital services or extended care services if payment is denied solely because of an unintentional, inadvertent, or erroneous action that resulted in the beneficiary's transfer from a certified bed (one that does not meet the requirements of §1861(e) or (j) of the Act) in a skilled nursing facility (SNF) or hospital (§1879(e) of the Act);
- Home health services determined to be noncovered because the beneficiary was not "homebound" or did not require "intermittent" skilled nursing care (as required by §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act) on or after July 1, 1987, and before December 31, 1995 (§1879(g)(1) of the Act); and.
- Hospice care determined to be noncovered because the beneficiary was not "terminally ill" (as required by §1861(dd)(3)(A) of the Act), as referenced by §1879(g)(2) of the Act since BBA 1997

20.1.2 - Dependent Services

(Rev. 1, 10-01-03)

When it is determined that Medicare payment will be made under the limitation on liability provision for claims for items or services that were denied for one of the reasons specified in §20.1.1, the payment determination includes claims for any dependent services that are denied as an indirect result of these denials. This longstanding CMS

policy is based on the fact that the cause for denial of payment for the qualifying service is the primary cause for denial of the dependent services. For example, where a particular qualifying service is denied as not reasonable and necessary under §1862(a)(1) of the Act, lack of medical necessity is the underlying reason for the denial of the dependent services. Therefore, if the limitation on liability protection applies to the denial of the qualifying service, it will also apply to the dependent service.

For example, under §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act, home health aide services can be covered only if a beneficiary needs intermittent skilled nursing care. When coverage is denied for intermittent skilled nursing services (the qualifying primary services) under §1862(a)(1) or (9) of the Act, home health aide services (the dependent services) likewise are not covered. In such cases, if Medicare payment is made under the limitation on liability provision for the primary services, it would be made for the dependent services as well, provided the services are otherwise covered (that is, all other conditions for payment of the dependent services are met including a physician's certification of the need for the dependent services and proof that the services are reasonable and necessary).

20.1.3 - Partial Denials Based on Reasonable and Necessary Levels of Care

(Rev. 1, 10-01-03)

The limitation on liability protection may also be applicable if a reduction in the level of payment occurs because the furnished services or items are at a level higher than was reasonable and necessary to meet the needs of the patient. This is because Medicare payment for the difference between reasonable and necessary services and items and those actually furnished is denied on the basis of §1862(a)(1)(A) of the Act as not reasonable and necessary. For example, if it is determined that the level of care furnished by a hospice (such as continuous home care) was not reasonable and necessary under §1862(a)(1)(A) because the care could have been given at a lower level (such as routine home care), Medicare payment under the limitation on liability provision may be made for the difference in reimbursement between the denied continuous home care and the approved routine home care if both the beneficiary and provider did not know, or could not reasonably have been expected to know, that payment would not be made for the higher level of care.

The limitation on liability protection may also be applicable if the contractor reduces the level of payment on the basis of §1862(a)(1) of the Act, that is, when partially denying a more extensive service or item on the basis that it is not reasonable and necessary, even though Medicare pays for a less extensive service or item. A case in which the level of payment is reduced 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.

For example, a deluxe or aesthetic feature of an upgraded item of medical equipment is an "excess component." Charge increases on the basis of purported premium quality services are not considered to be "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). 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."

20.2 - Denials for Which the Limitation On Liability Provision Does Not Apply

(Rev. 1, 10-01-03)

CMS Ruling 95-1, PM AB-02-168 Part I

Medicare payment under the limitation on liability provision cannot be made when Medicare coverage is denied on any basis other than one of the provisions of the law specified in §20.1.1. (See the Medicare Financial Management Manual, Chapter 3, concerning liability for overpayments arising from other causes.) There are certain claims, however, that may appear to involve a question of medical necessity, as described in §1862(a)(1) of the Act, but the actual Medicare payment denial is based on a statutory provision other than §1862(a)(1). Under these circumstances, Medicare payment under the limitation on liability provision cannot be made because the denial is not based on one of the statutory provisions specified in §20.1.1.

Section 1879(a) of the Act provides that Medicare payment will be made under the limitation on liability provision "when a determination is made that, by reason of §1862(a)(1) or (9) or by reason of a coverage denial described in subsection (g) of the Act, payment may not be made under Part A or Part B" and the conditions described in §1879(a)(2) are met. The statute thus explicitly restricts the application of the limitation on liability provision to cases that are decided on one of the statutory grounds we have specified in §20.1.1. In so providing, the Congress recognized that the issue of medical necessity of a service or item need never be reached if it were determined that the service or item would not otherwise be covered under the statute.

For example, when a Part B claim is submitted for ambulance services, the first step in processing the claim is to determine whether the services meet the requirements of §1861(s)(7) of the Act (that is, to ascertain that other methods of transportation are contraindicated) and, therefore, may be covered services under the Medicare statute. If other methods of transportation are contraindicated (and all other regulatory criteria met), only then must the Medicare contractor determine if the ambulance services are "reasonable and necessary" under §1862(a)(1). If other methods of transportation are not contraindicated, there is no reason for the Medicare contractor to make a medical necessity determination under §1862(a)(1) because the services have already been determined to be not otherwise covered under the Medicare statute.

Therefore, when items or services are denied for any reason other than one of the specific statutory bases for denial specified in §20.1.1, limitation on liability cannot be applied.

20.2.1 - Categorical Denials

(Rev. 1, 10-01-03)

Examples of circumstances in which Medicare payment under the limitation on liability provision cannot be made because the actual Medicare payment denial is based on a statutory provision other than §1862(a)(1) include, but are not limited to, the following categorical exclusions under §1862(a)(2)-(8) and (10)-(21) of the Act:

Personal comfort items (§1862(a)(6)).

- Routine physicals and most tests for screening (§1862(a)(7)).
- Most shots (vaccinations) (§1862(a)(7)).
- Routine eye care, most eyeglasses and examinations (§1862(a)(7)).
- Hearing aids and hearing examinations (§1862(a)(7)).
- Cosmetic surgery (§1862(a)(10)).
- Orthopedic shoes and foot supports (orthotics) (§1862(a)(8)).
- Dental care and dentures (in most cases) (§1862(a)(12)).
- Routine foot care and flat foot care (§1862(a)(13)).
- Services under a physician's private contract (§1862(a)(19)).
- Services paid for by a governmental entity that is not Medicare (§1862(a)(3)).
- Health care received outside of the U. S. not covered by Medicare (§1862(a)(4)).
- Services by immediate relatives (§1862(a)(11)).
- Services required as a result of war (§1862(a)(5)).
- Services for which there is no legal obligation to pay (§1862(a)(2)).
- Home health services furnished under a plan of care, if the agency does not submit the claim (§1862(a)(21)).
- Items and services excluded under the Assisted Suicide Funding Restriction Act of 1997 (§1862(a)(16)).

- 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) (§1862(a)(17)).
- Physicians' services performed by a physician assistant, midwife, psychologist, or nurse anesthetist, when furnished to an inpatient, unless they are furnished under arrangement with the hospital (§1862(a)(14)).
- 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 (§1862(a)(18)).
- Services of an assistant at surgery without prior approval from the peer review organization (§1862(a)(15)).
- Outpatient occupational and physical therapy services furnished incident to a physician's services (§1862(a)(20)).

NOTE: Refer to §1862(a) of the Act for a more complete listing than above.

20.2.2 - Technical Denials

(Rev. 1, 10-01-03)

Examples of circumstances in which Medicare is expected to deny payment for an item or service which may be a Medicare benefit but for which the coverage requirements are not met, include, but are not limited to, the following technical denials:

- Payment for the additional cost of a private room in a hospital or SNF is denied when the privacy accommodations are not required for medical reasons. Medicare payment for the additional cost is denied on the basis of §1861(v)(2) of the Act.
- Payment for a dressing is denied because it does not meet the definition for "surgical dressings" in §1861(s)(5) of the Act. Accordingly, Medicare payment is denied on the basis of §1861(s)(5) of the Act.
 - Payment for SNF stays not preceded by the required 3-day hospital stay.
- Payment for SNF stay because the beneficiary did not meet the requirement for transfer to a SNF and for receiving covered services within 30 days after discharge from the hospital and because the special requirements for extension of the 30 days were not met.
- Payment for home health services because they were not ordered on a plan of treatment or subsequent amendment.
- Payment for any form of parenteral and enteral nutrition therapy because the beneficiary did not qualify for the prosthetic device benefit under §1861(s)(8) of the Act.

- Payment for items that do not meet the definition of durable medical equipment (§1861(n)). Such items can never be covered even though in an individual case they may seem medically necessary because of the patient's condition.
- Payment for a medically unreasonable or unnecessary item or service that is also barred because of failure to meet a condition of payment required by regulations, as in the following examples:
- a. Drugs and biologicals which are usually self-administered by the patient $(\S1861(s)(2)(A)\&(B))$;
- b. Ambulance services denied because transportation by other means is not contraindicated or because regulatory criteria specified in 42 CFR 410.40, such as those relating to destination or nearest appropriate facility, are not met. In such circumstances, Medicare payment is denied on the basis of §1861(s)(7) of the Act. (See the Medicare Benefit Policy Manual, Chapter 10).

NOTE: The limitation on liability provision could apply, however, where payment for ambulance services was fully or partially denied as unreasonable, as in the following examples. A transport by air ambulance when the transporting entity has a reasonable basis to believe that the transport can be done safely and effectively by ground ambulance transportation. A level of care downgrade, e.g., from Advance Life Support (ALS)-2 to ALS-1, or from ALS to Basic Life Support, when the transport at the lower level of care is a covered transport. A transport from a residence to a hospital for a service that can be performed more economically in the beneficiary's home. A transport of a skilled nursing facility patient to a hospital or to another SNF for a service that can be performed more economically in the first SNF.)

c. Other items or services that must be denied under 42 CFR 410.12 through 410.105 of the Medicare regulations.

A reduction in allowed charges results from the contractor's determination that the claim does not meet the reasonable charge criteria, since the authority for reasonable charge reductions is found in §1842. However, when the contractor determines that a claim is to be allowed as a lesser service, the partial denial is based on a decision that the greater service is not reasonable and necessary per §1862(a)(1) and therefore, limitation on liability can apply.

30 - Determining Liability for Disallowed Claims Under §1879 (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

See §20 for the criteria that must be met before the contractor considers limitation on liability as discussed in the following subsections.

Ordinarily a finding is made that the beneficiary did not know nor could reasonably have been expected to know that the items or services were not covered by Medicare, unless there is evidence as discussed in §40.2. The procedures for determining whether the

provider knew or could reasonably have been expected to know of the noncoverage of services are discussed in §40.1.

30.1 - Determining Beneficiary's Liability

(Rev. 1, 10-01-03)

A3-3432.1, CMS Ruling 95-1, PM AB-02-168

The contractor presumes that the beneficiary did not know that services are not covered **unless** the evidence indicates that written notice was given to the beneficiary. In some cases, the beneficiary may have been given notice in a recent previous claim that a type of care is not covered. More commonly, as indicated above, the provider, practitioner, or supplier gives an ABN to the beneficiary that a particular stay or course of treatment is not covered or that coverage ended at a particular time. (See §40.2 regarding when a beneficiary is on notice of noncoverage.) On any claim to which limitation on liability applies, the beneficiary liability determination is to be made first by the contractor, followed (as may be necessary) by the provider, practitioner, or supplier liability determination.

30.1.1 - Beneficiary Determined to Be Liable - Right to Appeal

(Rev. 1, 10-01-03)

Under §1879(c) of the Act and 42 CFR 411.404, the beneficiary is held to be liable when it is determined that he or she had prior knowledge that Medicare payment for the service or item would be denied or could reasonably have been expected to have had such knowledge. 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 provider, practitioner, or supplier notified the beneficiary by properly delivering the approved Advance Beneficiary Notice (ABN), of the certainty or likelihood that Medicare would not pay for the specific service. In these instances, the contractor determines that the beneficiary is liable and the beneficiary is held responsible for expenses incurred for services or items for which Medicare payment is denied, regardless of whether the provider, practitioner, or other supplier had knowledge. The Medicare program makes no payment to the beneficiary, provider, practitioner, or other supplier. However, the beneficiary can appeal both the coverage issue, and the contractor's determination of beneficiary liability for the cost of the noncovered care. (See Chapter 29, "Appeals of Claim Decisions.") 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 belied by the favorable payment decision.

30.1.2 - Beneficiary Determined to Be Without Liability

(Rev. 1, 10-01-03)

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. Unless evidence indicates that the beneficiary knew or had reason to know that the items or services received were noncovered, the contractor presumes that the beneficiary did not know that the services are not covered. Under §1879(a)(2) of the Act and the accompanying regulations at 42 CFR 411.400(a)(2), the Medicare program must make payment when the provider, practitioner, or other supplier did not know and could not reasonably have been expected to know that the services or items would be denied. In these instances, the usual deductible and coinsurance amounts apply. The number of days or visits paid for under the limitation on liability provision is charged to the beneficiary's utilization record. Medicare payment may also be made under §1154(a)(2)(B) of the Act and 42 CFR 411.400(b)(2) for a 1-day "grace period" after the date of notice to the provider or to the beneficiary, whichever is earlier, if additional time is needed to arrange for post-discharge care. If it is determined thereafter by a QIO or the Medicare contractor that even more time is required in order to arrange post-discharge care, 1 additional "grace period" day is paid. Initial approval of 2 or more "grace period" days is not permitted. The "grace period" is applicable only if circumstances would have permitted Medicare program payment under §1879(a)(1) and (2) of the Act and 42 CFR 411.400(b)(2), that is, protection under the limitation on liability provision was afforded both to the beneficiary and the provider;

Unless the provider is found to be liable for the items for which the beneficiary was not held liable:

- All days or HHA visits for which the beneficiary received the benefit of limitation on liability (regardless of whether Medicare payment is made) are charged to the beneficiary's utilization record of hospice and SNF days and HHA visits, as though covered under Medicare; and
- Such days and visits are shown as having been used on CMS' notice to the beneficiary.

Under §1879(b) of the Act and 42 CFR 411.402, Medicare does not make payment when it is determined that the provider, practitioner, or other supplier had prior knowledge that Medicare would deny payment for services or items or could reasonably have been expected to have had this knowledge. In these instances, the beneficiary is not responsible for paying the deductible and coinsurance charges related to the denied claim and the beneficiary's Medicare utilization record is not charged for the services and items furnished, effective for all services or items furnished on or after January 1, 1988.

30.2 - Determining Provider, Practitioner, or Supplier Liability

(Rev. 1, 10-01-03)

A3-3432.2, CMS Ruling 95-1

30.2.1 - General

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

The contractor holds the provider, practitioner, or supplier liable for noncovered services if it is determined that the provider:

- Had actual knowledge of the noncoverage of services in a particular case, or
- Could reasonably have been expected to have such knowledge.

However, it does not hold a provider, practitioner, or supplier liable under §1879 where the provider, practitioner, or supplier indicates on the claim (via Occurrence Code 32 or the HCPCS code modifier "GA" on contractor claims) that they have given the beneficiary, before furnishing the items or services, an ABN. In such a case, the contractor holds the beneficiary, not the provider, practitioner, or supplier, liable for the denied charges.

30.2.2 - Provider/Practitioner/Supplier is Determined to Be Liable - Right to Appeal

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

A provider, practitioner, or supplier that is determined liable for all or a portion of the charges for noncovered items and services furnished a beneficiary may appeal such a decision by the contractor. (See Chapter 29, "Appeals of Claims Decisions.")

NOTE: Under §1879(b) of the Act and 42 CFR 411.402 et seq., if the provider, practitioner, or other supplier is considered to be liable and requests and receives payment from the beneficiary or any person(s) who assumed financial responsibility for payment of the beneficiary's expenses, the Medicare program indemnifies the beneficiary or other person(s) for any amounts paid by the beneficiary. This includes any deductible or coinsurance charges paid by or on behalf of the beneficiary. Further, these indemnification payments are considered an overpayment to the provider, practitioner, or other supplier. The limitation on liability provision applies to third party payers, including liability insurers. Therefore, a provider, practitioner, or supplier that the contractor determines liable may not seek payment from a third party payer without being subject to recovery action that could occur if it sought payment from the beneficiary.

30.2.3 - Provider/Practitioner/Supplier Determined to Be Without Liability

(Rev. 1, 10-01-03)

If the contractor determines that neither the provider, practitioner, or supplier nor the beneficiary knew or had reason to know that the services provided the beneficiary were not covered, the Medicare program will accept liability and make payment. (See §110.1.)

40 - Determining Knowledge for FLP Purposes

(Rev. 1, 10-01-03)

CMS Ruling 95-1

The proper application of all the financial liability protections (FLP) provisions requires determinations about beneficiaries' knowledge (or lack of knowledge), before items and/or services were furnished, that Medicare was certain or likely to deny payment for the items or services. For the protection under the Limitation On Liability (LOL) provision or any Refund Requirements (RR) provision to be afforded, lack of prior knowledge that Medicare payment for the item or service would be denied must first be established. Two determinations must be made to establish knowledge: first, whether and when the beneficiary knew or should have known that Medicare payment for the item or service would be denied (see §40.2), and, second, whether and when the provider, practitioner, or other supplier knew or should have known that Medicare payment for the item or service would likely be denied (see §40.1). The principles for determining knowledge described in §\$40.1 and 40.2 apply, unless otherwise explicitly specified, to determinations of knowledge with respect to denials under these FLP provisions:

- Limitation On Liability (LOL) under §1879(a)-(g);
- Refund Requirements (RR) for Non-assigned Claims for Physicians Services under §1842(1); and
- Refund Requirements (RR) for Assigned and Non-assigned Claims for Medical Equipment and Supplies under §§1834(a)(18), 1834(j)(4), and 1879(h).

40.1 - Determining Whether Provider, Practitioner, or Supplier Had Knowledge of Noncoverage of Services

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

The Medicare contractors determine, based on the information they maintain and/or disseminate to a particular provider, practitioner or other supplier, whether the provider, practitioner or other supplier actually had prior knowledge that services or items would likely be denied or whether knowledge reasonably could have been expected. The determination of actual or expected knowledge is based on all the relevant facts pertaining to each particular denial. In accordance with regulations at <u>42 CFR 411.406</u>, evidence that the provider, practitioner, or other supplier did, in fact, know or should have known that Medicare would not pay for a service or item includes:

- A Medicare contractor's prior written notice to the provider, practitioner, or other supplier of Medicare denial of payment for similar or reasonably comparable services or items;
- Medicare's general notices to the medical community of Medicare payment denial
 of services and items under all or certain circumstances (such notices include, but
 are not limited to, manual instructions, bulletins, contractors' written guides, and
 directives); and

.

• Provision of the services and items was inconsistent with acceptable standards of practice in the local medical community (refer to §40.1.3 and §40.1.4).

If any of the circumstances described above exists, a provider, practitioner or other supplier is held to have knowledge.

40.1.1 - Criteria for Determining Practitioner and Other Supplier Knowledge

(Rev. 1, 10-01-03)

The practitioner or other supplier, at the initial determination, is presumed to have had the requisite knowledge of likely Medicare denial of payment for denied services or items and, thereby, to be liable, with one exception. If a practitioner or other supplier gives the beneficiary proper written advance beneficiary notice that Medicare will likely deny payment for the service or item to be furnished, and so documents the claim, the beneficiary is held liable for the denied services or items at the initial determination. Such a notice constitutes proof that both the beneficiary and the practitioner or other supplier had prior knowledge that Medicare payment would be denied for the service or item in question. When both the beneficiary and the practitioner or other supplier are found to have had the requisite knowledge of likely Medicare denial, the beneficiary is held liable. The issue of whether the practitioner or other supplier is liable arises only when the beneficiary has already been found not liable.

If the practitioner or other supplier cannot show that the beneficiary received proper written advance beneficiary notice, the practitioner or other supplier will be presumed to have knowledge (and, thereby, liability) unless he/she/it can prove that he/she/it did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service or item. If the practitioner or other supplier can make such a convincing showing, the contractor will find that the practitioner or other supplier did not have the requisite knowledge.

40.1.2 - Criteria for Determining Provider Knowledge

(Rev. 1, 10-01-03)

A provider is always considered to have prior knowledge, and no Medicare payment will be made to any provider for any claim, if previous notification was given or if for any other reason the provider clearly should have known that the claim would be denied. Criteria for determining whether a provider had knowledge or should have had knowledge that services or items would be denied are in regulations at 42 CFR 411.406, which cites various forms and methods of notification that provide sufficient evidence that the provider knew or should have known that the services or items would be denied. Such notices are sufficient notice for all subsequent claims involving that same service or item under similar or reasonably comparable conditions. In general, notification often is provided by one of the following sources:

- The provider's utilization review committee informed the provider in writing that the services were not covered;
- The provider previously submitted a no-payment claim (i.e., a pro forma filing in which no payment is sought, rather, only a formal payment denial determination is requested), or submitted a claim for Medicare payment only at the request of the beneficiary;
- The provider issued a written advance beneficiary notice of the likelihood of Medicare payment denial for a service or item to the beneficiary;
- Medicare has issued manuals, bulletins, memoranda, etc., advising providers of
 the noncoverage of a particular service or category of services. All participating
 providers are issued instructions that discuss and define coverage and
 noncoverage of specified services under Medicare. For example, instructions in
 the Medicare Benefit Policy Manual define covered care and provide examples of
 unskilled services that Medicare does not cover;
- A Medicare contractor previously issued a written notice to the provider that
 Medicare payment for a particular service or item is denied. This also includes
 notification of Quality Improvement Organization (QIO) screening criteria
 specific to the condition of the beneficiary for whom the furnished services are at
 issue and of medical procedures subject to preadmission review by the QIO.
 Instructions for application of limitation on liability to QIO determinations are in
 the QIO Manual;
- The provider was previously notified by telephone and/or in writing that care is not covered or that covered care has ended; or
- A general bulletin or newsletter was issued to providers advising that a specific service or item is not considered reasonable and necessary.

The provider is accountable for information contained in the patient's medical records, such as the patient's medical chart, attending physicians' notes, or similar records, since these are provider records. Where it is clear and obvious from review of a particular medical record that the patient received only noncovered services described in the Medicare Benefit Policy Manual, the provider is held to have knowledge of noncoverage. Clear-cut decisions as to noncovered care may not be possible in some cases since patients may, for example, require a combination of skilled and unskilled services during a SNF stay or when receiving services at home. Evidence based upon medical records, such as that described in the following list, clearly indicates knowledge that Medicare payment for services or items would be denied and the date of such knowledge:

- A physician clearly indicated in the patient's medical record that the patient no longer needed the services or the level of care provided;
- The physician indicated the patient could be discharged;

- The attending physician refused to certify or recertify the patient's need for a particular level of care covered by Medicare because he/she determined that the patient does not require a covered level of care; or
- The contractor requested additional medical evidence after a certain number of days to determine whether continued coverage is warranted. However, the provider did not submit the evidence within the stipulated time.

EXAMPLE: Based on an admission notice and medical information, it was conditionally projected that SNF coverage was likely to extend for 12 days. The SNF must submit additional evidence of coverage within the 12 days. If the SNF failed to do so, its liability can be waived only through the 12th day of the stay, if the contractor later determined the services were not covered under §1862(a)(l) or (9). The contractor follows the established procedure for requesting additional evidence needed in a particular case to permit a decision on coverage. Where the beneficiary is still an inpatient at the SNF, the contractor advises the SNF that the additional information must be submitted (i.e., postmarked), within five workdays of a telephone request, or if a telephone request is not feasible, postmarked within seven workdays of the date of a written request. If this requirement is met, the SNF is protected from liability under the limitation on liability provision through the date the contractor made the coverage determination based on the requested additional evidence and notified the SNF. If the evidence is not submitted within the required five to seven days, the SNF is protected from liability only through the date the additional evidence was requested.

40.1.3 - Acceptable Standards of Practice

(Rev. 1, 10-01-03)

In situations in which services or items furnished do not meet locally acceptable standards of practice, the provider, practitioner, or other supplier is considered to have known that Medicare payment for the services or items would be denied. Providers, practitioners, and other suppliers are always responsible for knowing locally acceptable standards of practice; their local licensure is premised on the assumption that they have such knowledge. Medicare payment to providers, practitioners, or other suppliers is premised on the presumption that they have such knowledge, as evidenced by their licensure. No other evidence of knowledge of local medical standards of practice is necessary. Medicare contractors, in determining what "acceptable standards of practice" exist within the local medical community, rely on published medical literature, a consensus of expert medical opinion, and consultations with their medical staff, medical associations, including local medical societies, and other health experts. "Published medical literature" refers generally to scientific data or research studies that have been published in peer-reviewed medical journals or other specialty journals that are well recognized by the medical profession, such as the "New England Journal of Medicine" and the "Journal of the American Medical Association." By way of example, consensus of expert medical opinion might include recommendations that are derived from technology assessment processes conducted by organizations such as the Blue Cross and Blue Shield Association or the American College of Physicians, or findings published by the Institute of Medicine.

40.1.4 - Fraud, Abuse, Patently Unnecessary Items and Services

(Rev. 1, 10-01-03)

Generally, the protection under the financial liability protections provisions (LOL and RR) cannot be afforded to providers, practitioners, or other suppliers if a formal finding of fraud or abuse has been made with regard to a provider's, practitioner's, or other supplier's billing practices. In cases in which a formal finding of fraud or abuse is made, an immediate finding of liability for the provider, practitioner, or other supplier results. The contractor makes an immediate finding of liability, not only in fraud and abuse, but also in other situations where a provider, practitioner, or other supplier furnishes and claims payment for services that are so patently unnecessary that all providers, practitioners, and other suppliers could reasonably be expected to know that they are not covered. Generally, this would be the case where abuse has been identified in a particular claim. Abuse exists when a provider, practitioner, or other supplier furnishes services that are inconsistent with accepted sound medical practices, are clearly not within the concept of reasonable and necessary as defined by law or regulations, and, if paid for, would result in an unnecessary financial loss to the program.

40.2 - Determining Whether Beneficiary Had Knowledge of Noncoverage of Services

(Rev. 1, 10-01-03)

CMS Ruling 95-1, A3-3439.1, B3-7300.5

40.2.1 - Beneficiary Knowledge Standards

(Rev. 1, 10-01-03)

Beneficiary knowledge standards vary between the §1879 LOL provision and the two Refund Requirements, for physician services and for medical equipment and supplies.

Limitation On Liability - §1879(a)(2) of the Act requires that the beneficiary "did not know, and could not reasonably have been expected to know, that payment would not be made* * *," for items or services that are excluded from coverage for one of the reasons specified in §20.1, in order for the LOL protection to be afforded. This includes knowledge based on written notice having been provided to the beneficiary, as well as any other means from which it is determined that the beneficiary knew, or should have known, that payment would not be made.

Physician Refund Requirement - §1842(l)(1)(C)(ii) requires that "before the service was provided, the individual was informed that payment under this part may not be made for the specific service and the individual has agreed to pay for that service," that is, for physician services that are denied because they were not reasonable and necessary under §1862(a)(1) of the Act, in order for the refund requirement protection to be afforded.

Medical Equipment and Supplies Refund Requirement - §1834(a)(18)(A)(ii) [which is incorporated by reference into §1834(j)(4) and §1879(h)] requires that "before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient has agreed to pay for that item," that is, for medical equipment and supplies denied on the basis of §1834(a)(17)(B), §1834(j)(1), §1834(a)(15), or §1862(a)(1) of the Act, in order for the refund requirement protection to be afforded.

In both Refund Requirement cases, the beneficiary's knowledge must be evidenced by a signed advance beneficiary notice and agreement to pay personally in case of a denial.

40.2.2 - Written Notice as Evidence of Knowledge

(Rev. 1, 10-01-03)

The CMS regulations at 42 CFR 411.404 provide one basis for determining beneficiary knowledge that payment would not be made for items or services that are excluded from coverage. These regulations provide that a beneficiary will be considered to know, **based on written notice**, that services or items were excluded from coverage. Under these regulations, there is a presumption that he or she knew, or could reasonably have been expected to know, that Medicare payment for a service or item would be denied if advance written notice has been given either to the beneficiary or to someone acting on his or her behalf that the items or services were not covered.

In accordance with 42 CFR 411.404, a written notice of Medicare denial of payment must contain sufficient information to enable the beneficiary to understand the basis for the denial. Such notice constitutes sufficient documentation to show that the beneficiary had prior knowledge of the likelihood of denial of that claim, and of future claims filed by, or on behalf of, the beneficiary that involve that same or a similar item or service. In addition, a written notice of Medicare denial of payment from a Medicare contractor for a recent previous claim for a particular service or item received by the beneficiary serves as prior written notice for future claims filed by or on behalf of the beneficiary that involve that same or a similar service or item. A notice that a beneficiary received within the twelve months before the claims denial at issue may be considered as evidence of prior knowledge with respect to such same or similar service or item that is denied payment by Medicare for the same reason in both the earlier and the later cases.

40.2.3 - Sources of Written Notice

(Rev. 1, 10-01-03)

Generally, the required written notice of the certainty or likelihood of Medicare payment denial must be furnished to the beneficiary (or to the beneficiary's authorized representative) by:

• A provider, practitioner, or other supplier before the service or item was furnished;

- The provider, after the Medicare contractor, during the course of the patient's stay, advised the provider that covered care had ceased;
- A provider utilization review committee that, on admission or during the patient's stay, advised that the patient no longer required covered care; or
- The Medicare contractor.

40.2.4 - Other Evidence of Knowledge

(Rev. 1, 10-01-03)

While 42 CFR 411.404 provides criteria for beneficiary knowledge **based on written notice,** §1879(a)(2) of the Act specifies only that **knowledge** must not exist in order to apply the limitation on liability 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 referred to in 42 CFR 411.404, is rebutted. For example, if the beneficiary admits that he or she had prior knowledge that payment for a service or item would be denied, no further evidence is required; the absence of a written notice is moot.

The failure of any provider, practitioner, or other supplier to furnish to a beneficiary proper advance notice of the likelihood of denial is not sufficient to afford the beneficiary the protection of the limitation on liability provision if the contractor has proof that the beneficiary, nonetheless, had the requisite knowledge that the service would be denied. In any case in which the contractor has such evidence of prior knowledge on the beneficiary's part, the beneficiary must be held liable under the limitation on liability provision.

40.3 - Advance Beneficiary Notice Standards

(Rev. 1, 10-01-03)

PM AB-02-168

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 certainly or 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 provider, practitioner, or supplier expects payment for the items or services to be denied by Medicare, the provider, practitioner, or supplier must advise the beneficiary before items or services are furnished that, in its 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 provider, practitioner, or supplier must issue an ABN each time, and as soon as, it makes the assessment that Medicare payment certainly or probably will not be made. A provider, practitioner, or supplier (that is, a qualified notifier as defined in §40.3.2), shall notify a beneficiary by means of timely (as defined in §40.3.3) and effective (as defined in §40.3.4) delivery of a proper notice document (as defined in §40.3.1) to a qualified recipient, viz., to the individual beneficiary or to the beneficiary's authorized representative (as defined in §40.3.5). Any Advance Beneficiary Notice (ABN) must meet the following notice standards in order to be acceptable as evidence of the beneficiary's knowledge for the purposes of the FLP provisions, LOL and RR, except as otherwise explicitly specified. A notification which does not meet the following ABN standards may be ruled defective and may not serve to protect the interests of the notifier (provider, practitioner, or supplier). Any requirement to furnish a notice to a beneficiary is not met by delivery of a defective notice.

40.3.1 - Proper Notice Documents

(Rev. 1, 10-01-03)

When, for a particular purpose, an approved standard form (e.g., Form CMS-R-131, Form CMS-R-296) exists, it constitutes the proper notice document. Notices not using a mandatory standard notice form may be ruled defective. In the absence of such a standard form, approved model notice language constitutes the proper notice document. A notifier's unapproved modification of either a standard form or model notice language may render that notice defective.

40.3.1.1 - Readability Requirements

(Rev. 1, 10-01-03)

Both the originals and copies of ABNs must meet the following conditions to facilitate beneficiary understanding:

- Do not use italics, nor any font that is difficult to read, nor reversed print (e.g., white on black). Examples of easily readable fonts include, but are not limited to, Arial, Arial Narrow, Times Roman, Courier. On standard forms, the published fonts may not be changed to any other font;
- Use at least a 12 point font size;
- Use a visually high-contrast combination of dark ink on a pale background.
- Do not block-shade ("highlight") notice text; and
- Insertions in forms' blanks, if any, must be typed, printed, or legibly handwritten.

40.3.1.2 - Specificity, Delivery, and Receipt

(Rev. 1, 10-01-03)

An ABN must:

Be written in lay language;

Cite the particular items or services for which payment will be or is likely to be denied;

Cite the notifier's reasons for believing Medicare payment will be or is likely to be denied. (See §40.3.8);

Be delivered by a qualified notifier to the beneficiary (or to the beneficiary's authorized representative), before those items or services were furnished; and

Be received by, and its contents must be comprehended by, the beneficiary (or authorized representative).

40.3.1.3 - Defective Notice

(Rev. 1, 10-01-03)

An ABN is not acceptable evidence if:

The notice is unreadable, illegible, or otherwise incomprehensible, or the individual beneficiary (or authorized representative) is incapable of understanding the notice due to the particular circumstances (even if others may understand);

The notice is given during any emergency, or the beneficiary is under great duress, or the beneficiary (or authorized representative) is, in any way, coerced or misled by the notifier, by the contents of the notice, and/or by the manner of delivery of the notice. (See §40.3.7);

The notifier routinely gives this notice to all beneficiaries for whom the notifier furnishes items or services. (See §40.3.6);

The notice is no more than a statement to the effect that there is a possibility that Medicare may not pay for the items or services. (See §40.3.6); or

The notice was delivered to the beneficiary (or authorized representative) more than one year before the items or services are furnished.

NOTE: A previously furnished ABN is acceptable evidence of notice for current items or services if the previous ABN cites similar or reasonably comparable items or services for which denial is expected on the same basis in both the earlier and the later cases. A written denial (on the same basis in both the earlier and the later cases) of payment from a Medicare contractor for a claim for the same or similar items or services received by the beneficiary not more than one year previously is acceptable evidence of notice for current items or services.

40.3.2 – Qualified Notifiers

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

An ABN must be delivered to the beneficiary (or authorized representative) by a qualified notifier such that the beneficiary (or authorized representative) may have confidence in and rely upon the accuracy and credibility of the notice. A QIO, contractor, group or committee responsible for utilization review for the provider that furnished the services, or provider, practitioner, or supplier that furnished or ordered the items and/or services (including their staff and employees) is a qualified notifier for delivery of ABNs for the purposes of the limitation on liability provision and the refund requirements provisions. In this section, when explaining the "notifier's" liability risks, etc., it is generally the provider, practitioner, or supplier that furnished or ordered the items and/or services to which reference is made.

40.3.3 - Timeliness

(Rev. 1, 10-01-03)

A beneficiary must be notified far enough in advance of an event about which a decision must be made by the beneficiary (e.g., receiving a medical service) so that the beneficiary can make a rational, informed consumer decision without undue pressure. Last minute notification can be coercive, and a coercive notice is a defective notice. 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 standard does not constitute a blanket prohibition on delivery of notice after a beneficiary has entered an examination room, a draw station, a sales room, and is ready to receive services or items. If a situation arises during an encounter when a notifier sees a need for a previously unforeseen service and expects that Medicare will not pay for it, delivery of a notice is permissible, provided that the beneficiary is capable of receiving notice 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 notice before any service is initiated.

40.3.4 - Effective Delivery

(Rev. 1, 10-01-03)

Delivery of a notice occurs when the beneficiary (or authorized representative) both has received the notice and can comprehend its contents.

40.3.4.1 - Basic Delivery Requirements

(Rev. 1, 10-01-03)

The notifier should hand-deliver the ABN to the beneficiary or authorized representative. (Where hand-delivery is impossible, e.g., in furnishing items and services by telephone order, mail order, over the internet, etc., ABNs still need to be executed in advance of furnishing the item or service, e.g., by mail, fax, using an online form) Delivery is the notifier's responsibility. The contractor will consider delivery of an ABN by a notifier's staff or employees to be delivery by the notifier. If the beneficiary alleges non-receipt of notice and the notifier cannot show that notice was received by the beneficiary, the contractor will not find that the beneficiary knew or could reasonably have been expected to know that Medicare would not pay; i.e., it will hold the notifier liable and the beneficiary not liable. The ABN must be prepared with an original and at least one copy. The notifier must retain the original and give the copy to the beneficiary or authorized representative. (In a case where the notifier 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 notifier 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 contractor by the notifier is different in any material respect from the ABN he/she signed, the contractor will give credence to the beneficiary's allegations.

40.3.4.2 - Telephone Notice

(Rev. 1, 10-01-03)

The contractor will 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, the contractor will accept the time of the telephone notice as the time of ABN delivery.

40.3.4.3 - Capable Recipient

(Rev. 1, 10-01-03)

The contractor will 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 notifier 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, the contractor will hold that the beneficiary did not receive proper notice, hold that the beneficiary is not liable, and will hold the notifier liable.

40.3.4.4 - Responsiveness to Inquiries

(Rev. 1, 10-01-03)

The contractor will hold that a beneficiary did not receive proper notice in any case where it finds that the notifier 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 its assessment that items or services may not be covered.

40.3.4.5 - Identification of Notifier

(Rev. 1, 10-01-03)

In the case of an ABN on which the notifier's identifying information in the header of the ABN form identifies the entity or person that obtained the ABN, rather than the entity or person 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), the contractor will consider the ABN form to be valid so long as it was otherwise properly executed.

40.3.4.6 - Dealing With Beneficiary Refusals

(Rev. 1, 10-01-03)

A beneficiary (or authorized representative) who has been given an ABN may decide to receive the item or service. In this case, the beneficiary should 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 so indicate. 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 notifier 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. Additionally, the notifier may annotate the

ABN, and have the annotation witnessed, indicating the circumstances and persons involved.

- A. In the case of claims to which Limitation on Liability protections under §1879 of the Act apply, if the notifier 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 notifier 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. An 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 notifier should file its claim as having given the ABN. The beneficiary will be held liable per \$1879(c) of the Act in case of a denial.
- B. 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 (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 above. The physician or supplier, if the items or services are furnished despite the beneficiary's refusal to pay, should file the claim as not having obtained a signed ABN, since it was not completed properly by the beneficiary. The contractor will 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 and will hold the physician or supplier liable.
- C. In either case, 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.

40.3.5 - Authorized Representatives

(Rev. 1, 10-01-03)

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. A notifier's inability to give notice to a beneficiary directly or through an authorized representative does not allow the notifier to shift liability to the beneficiary.

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 notice.

An authorized representative should have the beneficiary's best interests at heart and should be reasonably expected to act in a manner which is protective of the person and the rights of the beneficiary. In the absence of some more compelling consideration, the order of priority of authorized representatives is:

- A. The spouse, unless legally separated.
- B. An adult child.
- C. A parent.
- D. An adult sibling.
- E. A close friend (defined as "an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, and who is reasonably available").

An authorized representative should have no relevant conflict of interests with the beneficiary. A notifier (including the notifier's employees) that has a conflicting interest (such as shifting financial liability to the beneficiary) is not qualified to be an authorized representative.

A person (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 may be an authorized representative. In states which have health care consent statutes providing for health care decision-making by surrogates on behalf of patients who lack advance directives and guardians, reliance upon individuals appointed or designated under such statutes to act as authorized representatives is permissible, as may be necessary.

In case of necessity, a disinterested third party, such as a public guardianship agency, may be an authorized representative, e.g., 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.), and there is no one who can be genuinely considered to be the beneficiary's choice as his or her authorized representative.

40.3.6 - Routine Notice Prohibition

(Rev. 1, 10-01-03)

In general, the "routine" use of ABNs is not effective. By "routine" use, CMS means giving ABNs to beneficiaries where there is no specific, identifiable reason to believe Medicare will not pay. Notifiers should not give ABNs to beneficiaries unless the notifier 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 the contractor identifies a pattern of routine notices in situations where such notices clearly are not effective, it will write to the notifier and remind it of these standards. In general, routinely given ABNs are defective notices and will not protect the notifier from liability. However, ABNs may be routinely given to beneficiaries when all or virtually all beneficiaries may be at risk of having their claims denied. §40.3.6.4 specifies circumstances in which ABNs may be routinely given.

40.3.6.1 - Generic ABNs

(Rev. 1, 10-01-03)

"Generic ABNs" are routine ABNs to beneficiaries which do no more than state that Medicare denial of payment **is possible**, or that the notifier 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 notifier from liability.

40.3.6.2 - Blanket ABNs

(Rev. 1, 10-01-03)

A notifier should not give an ABN to a beneficiary unless the notifier 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.

40.3.6.3 - Signed Blank ABNs

(Rev. 1, 10-01-03)

A notifier 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. The contractor will hold any ABN that was blank when it was signed to be defective notice that will not protect the notifier from liability.

40.3.6.4 - Routine ABN Prohibition Exceptions

(Rev. 1, 10-01-03)

ABNs may be routinely given to beneficiaries and considered to be effective notices which will protect notifiers in the following exceptional circumstances:

- A. 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 by physicians are denied as not reasonable and necessary), an ABN that gives as the reason for expecting denial 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, the notifier should submit the claim as a demand bill.
- **B.** 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 that gives as the reason for expecting denial that: "Medicare does not pay for services which it considers to be experimental or for research use." Alternative, more specific, language with respect to Medicare coverage for clinical trials may be substituted as necessary as the ABN's reason for expecting denial.
- C. 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 the contractor's local medical review policy (LMRP), because all or virtually all beneficiaries may be at risk of having their claims denied in those circumstances, the notifier may routinely give ABNs to beneficiaries. In any such routine ABN, the notifier must state the frequency limitation as the ABN's reason for expecting denial (e.g., "Medicare does not pay for this item or service more often than **frequency limit**").
- **D.** 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.

NOTE: A routine ABN, like any other ABN, is effective only for the reason for expecting denial that is specified on the ABN. Such a routine ABN will not be effective notice, that is, will not shift liability to the beneficiary, in the case of any Medicare denial of the claim for any reason other than that specified on the ABN.

40.3.7 - Standards for Situations Where the Beneficiary is in a Medical Emergency or Is Otherwise Under Great Duress

(Rev. 1, 10-01-03)

An ABN 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 §40.3.4.3). 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 notifier may be held liable.

40.3.7.1 - Emergency Medical Treatment and Active Labor Act (EMTALA) Situations

(Rev. 1, 10-01-03)

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. The CMS published this policy in the November 10, 1999 OIG/HCFA 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 §40.3.6.2). 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.

40.3.7.2 - Other Situations

(Rev. 1, 10-01-03)

A provider, practitioner, 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, providers, practitioners, and suppliers may not use ABNs to shift financial liability to beneficiaries in emergency care situations. Ambulance companies may not give ABNs to beneficiaries or their authorized representatives in any emergency transport because such beneficiaries are under great duress. Skilled nursing facilities may not give ABNs 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. The contractor will consider any ABN given in any kind of coercive circumstances, including medical emergencies, to be defective. In all such coercive situations, the contractor will find that the beneficiary did not know and could not reasonably have been expected to know that Medicare would not make payment. The contractor will determine the provider's, practitioner'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. 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.

40.3.8 - Reason for Predicting Denial

(Rev. 1, 10-01-03)

Statements of reasons for predicting Medicare denial of payment at a level of detail similar to the approved "Medical Necessity" messages for MSNs 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 notifier 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. 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 notifier 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.), the contractor will not invalidate an ABN on the basis of citing more than one reason for denial.

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

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

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

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

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

- *Limitation On Liability (LOL) under §1879(a)-(g) of the Act;*
- Refund Requirements (RR) for Non-assigned Claims for Physicians Services under §1842(1) of the Act; and

Refund Requirements (RR) for Assigned and Non-assigned Claims for Medical Equipment and Supplies under §§1834(a)(18), 1834(j)(4), and 1879(h) of the Act.

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

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

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

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

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

50.3 - *ABN Scope*

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

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

The revised ABN replaces the following notices:

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

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

50.3.1 - Mandatory ABN Uses

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

The following are statutory provisions requiring delivery of the ABN:

- *§1862(a)(1) of the Act (not reasonable and necessary);*
- §1834(a)(17)(B) of the Act (violation of the prohibition on unsolicited telephone contacts);
- §1834(j)(1) of the Act (medical equipment and supplies supplier number requirements not met);
- §1834(a)(15) of the Act (medical equipment and/or supplies denied in advance).
- *§1862(a)(9) of the Act (custodial care);*
- $\S1879(g)(2)$ of the Act (hospice patient who is not terminally ill).

50.3.2 - Voluntary ABN Uses

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

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

the Notice of Exclusion from Medicare Benefits (NEMB) for care that is never covered such as:

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

50.4 - Issuance of the ABN

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

50.4.1 - Issuers of ABNs (Notifiers)

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

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

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

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

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

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

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

50.4.2.-Recipients of the ABN

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

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

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

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

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

50.5 - ABN Triggering Events

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

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

A. Initiations

An initiation is the beginning of a new patient encounter, start of a plan of care, or beginning of treatment. If a notifier believes that certain otherwise covered items or

services will be noncovered (e.g. not reasonable and necessary) at initiation, an ABN must be issued prior to the beneficiary receiving the non-covered care.

B. Reductions

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

C. Terminations

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

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

50.6 - ABN Standards

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

50.6.1 - Proper Notice Documents

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

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

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

A. Language Choice

The ABN is available in English and Spanish under a dedicated link on the top left-hand margin of the web page given above: "FFS ABN". Notifiers should choose the appropriate version of the ABN based on the language the beneficiary best understands. Insertions must be in English when the English-language ABN is used. Similarly, when a Spanish-language ABN is used, the notifier should make insertions on the notice in Spanish if applicable. In addition, verbal assistance in other languages may be provided

to assist beneficiaries in understanding the document. However, the printed document is limited to the OMB-approved English and Spanish versions. Notifiers should document any types of translation assistance that are used in the "Additional Information" section of the notice. The notifier must retain either the English or Spanish ABN as signed by the beneficiary.

B. Effective Versions

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

50.6.2 - General Notice Preparation Requirements (Rev. 1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

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

- A. Number of Copies: A minimum of two copies, including the original, must be made so the beneficiary and notifier each have one. The notifier should retain the original whenever possible.
- **B. Reproduction**: Notifiers may reproduce the ABN by using self-carbonizing paper, photocopying, digitized technology, or another appropriate method. All reproductions must conform to applicable form and manual instructions.
- C. Length and Size of Page: The ABN form must not exceed one page in length; however, attachments are permitted for listing additional items and services. If an attachment sheet is used, a notation such as "See Attached Page" must be inserted in the items/services (D) area of the ABN notice. Attachment pages must include the following:
 - Beneficiary's name;
 - *Identification number (optional);*
 - *Date of issuance;*
 - Table listing the additional items and/or services (D), the reasons Medicare may not pay (E), and the estimated costs (F); and
 - A space underneath the table designated for Blanks (D)-(F), in which the beneficiary inserts his or her initials to acknowledge receipt of the attachment page.

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

- **D.** Contrast of Paper and Print: A visually high-contrast combination of dark ink on a pale background must be used. Do not use reversed print (i.e. white print on black paper), or block-shaded (highlighted) text.
- **E. Font:** To the extent practicable, the fonts as they appear in the ABN downloaded from the CMS web site should be used. Any changes in the font type must be based solely on limitations of the notifier's software and/or hardware. In such cases, notifiers should use alternative fonts that are easily readable, such as Arial, Arial Narrow, Times New Roman, and Courier. Font style and formatting must be maintained regardless of font type used.

Any other changes to the font, such as italics, embossing, bold, etc., should not be used since they can make the ABN more difficult to read. The font size generally should be 12-point. Titles should be 14 to 16-point, but insertions in blanks of the ABN can be as small as 10-point if needed.

Information inserted by notifiers in the blank spaces on the ABN may be typed or legibly hand-written.

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

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

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

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

Notifiers must exercise caution before adding any customizations beyond these

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

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

50.6.3 - Completing the ABN

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

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

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

A. Header

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

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

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

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

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

B. Body

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

- Item
- Service
- Laboratory test
- Test
- Procedure
- Care
- Equipment
- The notifier must list the specific items or services believed to be noncovered under the header of Blank (D).
- In the case of partial denials, notifiers must list in Blank (D) the excess component(s) of the item or service for which denial is expected.
- For repetitive or continuous noncovered care, notifiers must specify the frequency and/or duration of the item or service. See § 50.14.3 for additional information.
- General descriptions of specifically grouped supplies are permitted. For example, "wound care supplies" would be a sufficient description of a group of items used to provide this care. An itemized list of each supply is generally not required.
- When a reduction in service occurs, notifiers must provide enough additional information so that the beneficiary understands the nature of the reduction. For example, entering "wound care supplies decreased from weekly to monthly" would be appropriate to describe a decrease in frequency for this category of supplies; just writing "wound care supplies decreased" is insufficient.

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

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

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

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

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

For a service that costs \$250:

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

For a service that costs \$500:

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

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

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

C. Options

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

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

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

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

□ OPTION 2. I want the (D)_____ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.

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

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

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

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

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

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

D. Additional Information

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

- A statement advising the beneficiary to notify his or her provider about certain tests that were ordered, but not received;
- Information on other insu
- An additional dated witness signature; or
- Other necessary annotations.

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

E. Signature Box

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

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

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

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

50.6.4 - Retention

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

Retention Requirements

The ABN must be prepared with an original and at least one copy. The beneficiary is given his or her copy of the signed and dated ABN immediately, and the notifier should retain the original ABN in the beneficiary's record. In certain situations, such as delivery

by fax, the notifier may not have access to the original document upon signing. Retention of a copy of the signed document would be acceptable in specific cases such as this.

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

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

50.6.5 - Other Considerations During ABN Completion (Rev. 1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A. Beneficiary Changes His or her Mind

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

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

B. Beneficiary Refuses to Complete or Sign the Notice

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

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

C. Routine Notice Prohibition

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

(See §40.3.6.4, "Routine ABN Prohibition Exceptions")

50.7 - ABN Delivery Requirements

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

50.7.1 - Effective Delivery

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

A. Delivery Requirements

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

- 1. Delivered by a suitable notifier to a capable recipient and comprehended by that recipient.
- 2. Provided using the correct OMB approved notice with all required blanks completed.
 - Failure to use the correct notice may lead to notifiers being found liable since the burden of proof is on the notifier to show knowledge was conveyed to the beneficiary according to CMS instructions.
- 3. Delivered to the beneficiary in person if possible.
- 4. Provided far enough in advance of delivering potentially noncovered items or services to allow sufficient time for the beneficiary to consider all available options.
- 5. Explained in its entirety, and all of the beneficiary's related questions are answered timely, accurately, and completely to the best of the notifier's ability.
 - The notifier should direct the beneficiary to call 1-800-MEDICARE if the beneficiary has questions he or she cannot answer. If a Medicare contractor finds that the notifier refused to answer a beneficiary's inquiries or direct them to 1-800-MEDICARE, the notice delivery will be considered defective, and the notifier will be held financially liable for noncovered care.
- 6. Signed by the beneficiary or his or her representative.

B. Period of Effectiveness

An ABN can remain effective for up to one year. ABNs may describe treatment of up to a year's duration, as long as no other triggering event occurs. If a new triggering event

occurs within the 1-year period, a new ABN must be given. See § 50.5 – Triggering Events.

C. Incomplete ABNs

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

50.7.2 - Options for Delivery Other than In-Person (Rev. 1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

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

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

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

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

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

50.7.3 - Effects of Lack of Notification, Medicare Review and Claim Adjudication

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

A. Beneficiary Liability

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

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

B. Provider Liability

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

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

50.7.3.1 - 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 (Rev. 1, 10-01-03)

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. Telephone notice may not be used in this case. The contractor will 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 §40.3.6.4.D, "Routine ABN Prohibition Exceptions.")

50.7.3.2 - ABNs for Medical Equipment and Supplies Claims Denied Under §1834(j)(1) of the Act (Because the Supplier Did Not Meet Supplier Number Requirements) (Rev. 1, 10-01-03)

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.

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.

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 §40.3.6.4.D, "Routine ABN Prohibition Exceptions.") 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.

50.7.3.3 - ABNs for Medical Equipment and Supplies Claims Denied in Advance Under §1834(a)(15) of the Act - Prior Authorization Procedures (Rev. 1, 10-01-03)

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 §150.5.2, "Knowledge Standards for §1834(a)(15) Denials.")

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

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

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

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

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

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

A refund is required under $\S1834(a)(18)$ or $\S1879(h)(3)$ of the Act for both assigned and unassigned claims unless prior to furnishing the item, a valid ABN was issued notifying the beneficiary of potential nonpayment because the supplier violated the prohibition against unsolicited telephone contacts. The supplier must obtain a signed ABN before furnishing the item to the beneficiary.

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

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

50.10 - ABNs for Claims Denied Under §1834(j)(1) of the Act (Supplier Did Not Meet Supplier Number Requirements) (Rev. 1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

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

A supplier can qualify for a waiver of the refund requirements if adequate public notice is given to beneficiaries informing them of the supplier's failure to meet Medicare's supplier number requirements. An example of adequate public notice would include clearly visible signs posted at the suppliers place of business. If a supplier only conducts business via the internet, a clearly visible notice on the supplier's internet business site is acceptable as long as such notice is also available in printed materials, such as a supplier's catalog. These public notices must be readily visible, in easily readable plain language, in large print, and must be provided in the language(s) commonly used in the

locality. The supplier will qualify for a waiver of the Refund Requirements as long as the adequacy of such public notice is not disputed by the beneficiary.,

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

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

Medicare contractors presume that suppliers know that a supplier number is required in order for Medicare to make payment. Thus, a supplier would have to submit evidence to the contrary to rebut this presumption. However, this presumption is not rebuttable if a supplier has previously received a claim denial $\S1834(j)(1)$.

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

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

50.11.1 - Situations In Which Advance Coverage Determinations Are Mandatory

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

A request for an advance determination of coverage of medical equipment and supplies is mandatory under $\S1834(a)(15)(C)(i)$ & (ii) of the Act when:

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

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

50.11.2 - Situations In Which Advance Coverage Determinations Are Optional

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

A request for an advance determination of coverage of medical equipment and supplies is optional under $\S1834(a)(15)(C)(iii)$ of the Act when the item is customized and either the patient or the supplier requests an advance determination. In cases where an advance coverage determination is optional and the beneficiary requests such a determination, an ABN must be furnished prior to furnishing the requested item.

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

50.12 - Collection of Funds and Refunds (Rev. 1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

A. Collection of Funds

A beneficiary's agreement to be responsible for payment on an ABN means that the beneficiary agrees to pay for expenses out-of-pocket or through any insurance other than Medicare that the beneficiary may have. The notifier may bill and collect funds from the beneficiary for noncovered items or services immediately after an ABN is signed, unless prohibited from collecting in advance of the Medicare payment determination by other applicable Medicare policy, State or local law.

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

B. Refund Requirements Requiring Liability Notice

Under the Refund Requirements in §§1842(1) and 1879(h) of the Act, a beneficiary must receive a properly executed ABN so that is "on notice" of liability. By signing the ABN, the beneficiary acknowledges that he or she understands the potential for liability and agrees to pay for the item or service described. The refund requirements requiring ABNs are:

- 1. Supplier claims under §1879(h) of the Act, citing three specific requirements when assignment is accepted:
 - a. $\S1834(j)(1)$, when supplier number requirements for medical equipment and supplies are not met;
 - b. §1834(a)(15), when medical equipment and/or supplies are denied in advance; or

- c. §1834(a)(17)(B), when there is a violation of the prohibition on unsolicited telephone contacts for medical equipment and supplies.
- 2. Physician claims under §1842(1) from non-participating physicians when assignment is not accepted for individual items and services that are denied on the basis of §1862(a)(1).

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

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

The physicians' services refund requirement provision, found in §1842(1) of the Act as amended by the Omnibus Budget Reconciliation Act (OBRA) of 1986, requires timely refunds for certain services. When a reduction in payment, not a full denial, occurs, the physician must refund to the beneficiary any amounts collected which exceed the Medicare payment for the less extensive item or service. These refund requirements apply to both participating and non-participating physicians.

When the beneficiary signs an ABN agreeing to accept responsibility for payment before services are delivered, the collected funds can be retained. A refund is not required if the physician did not know and could not reasonably have been expected to know that Medicare would not pay for the services because they were not reasonable and necessary.

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

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

50.12.2 - DMEPOS Refund Requirements (RR) Provision for Claims for Medical Equipment and Supplies (Rev. 1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

All suppliers who sell or rent medical equipment and supplies to Medicare beneficiaries are subject to the refund provisions of $\S\S1834(a)(18)$, 1834(j)(4) and 1879(h) of the Act, whether accepting assignment or not. Medical equipment and supplies are defined in the following statutes applicable to this section:

• *Durable medical equipment, as defined in §1861(n) of the Act;*

- Prosthetic devices, as described in §1861(s)(8) of the Act;
- Orthotics and prosthetics, as described in §1861(s)(9) of the Act;
- Surgical dressings, as described in §1861(s)(5) of the Act;
- Home dialysis supplies and equipment, as described in $\S1861(s)(2)(F)$ of the Act;
- *Immunosuppressive drugs, as described in §1861(s)(2)(J) of the Act;*
- Therapeutic shoes for diabetics, as described in §1861(s)(12) of the Act;
- Oral drugs prescribed for use as an anticancer therapeutic agent, as described in §1861(s)(2)(Q) of the Act;
- Self-administered erythropoietin, as described in §1861(s)(2)(P) of the Act; and
- *Other items as determined by the Secretary.*

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

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

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

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

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

A required refund must be made within specified time limits:

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

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

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

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

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

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

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

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

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

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

A. Background of the Subject

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

B. Origin of the Case

A brief description of how the violations were discovered.

C. Statement of Facts

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

D. Documentation

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

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

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

50.14 - Special Considerations

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

50.14.1 - Obligation to Bill Medicare

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

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

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

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

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

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

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

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

50.14.4 - Hospice and CORF

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

50.14.4.1 - Special Issues Associated with the Advance Beneficiary Notice (ABN) Issued to Hospice Patients

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

A. General Use

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

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

- Ineligibility because the beneficiary is not "terminally ill" as defined in §1879(g)(2) of the Act;
- Specific items or services that are billed separately from the hospice payment, such as physician services, are not reasonable and necessary as defined in either §1862(a)(1)(A) or §1862(a)(1)(C); or

• The level of hospice care is determined to be not reasonable or medically necessary as defined in §1862(a)(1)(A) or §1862(a)(1)(C), specifically for the management of the terminal illness and/or related conditions.

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

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

B. Hospice Care Delivered by Non-Hospice Providers

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

C. When ABNs Are Not Required for Hospice Services

1. Revocations

Hospice beneficiaries or their representatives can revoke the hospice benefit. Revocations are not considered terminations under liability notice policy since the beneficiary is exercising his or her own freedom of choice. Therefore no ABN is required.

2. Respite Care Beyond Five Consecutive Days

Mandatory notification is not required when respite care exceeds five consecutive days, because payment for respite care is limited to this time period under the Act. Respite care on the sixth consecutive day is therefore considered outside the definition of the hospice benefit, and the hospice provider is not required to issue an ABN. However, CMS encourages hospice providers to give the ABN as a voluntary notice to inform patients of possible financial liability in such cases.

3. Transfers

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

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

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

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

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

(B) Patient Name:	(C) Identification Number:	
Ivance $oldsymbol{B}$ eneficiary N otice of N oncoveraș	$_{ m Re}\left(ABN ight)$	
OTE: If Medicare doesn't pay for (D)		
(D)	(E) Reason Medicare May Not Pay:	(F) Estimated Cost:

WHAT YOU NEED TO DO NOW:

• Read this notice, so you can make an informed decision about your care.

also want Med Summary Notice payment, but I does pay, you ask to be paid ask to be paid choice I am I pay. This notice gives our of the Summary Notice Summary Notice I am I pay.	care billed for an official of e (MSN). I understand to can appeal to Medicare will refund any payments. 12. I want the (D) now as I am responsible. 3. I don't want the (D)	decision on paymethat if Medicare does by following the case I made to you, le	eve. You may ask to be paid now ent, which is sent to me on a Me besn't pay, I am responsible for directions on the MSN. If Medica ss co-pays or deductibles. eve, but do not bill Medicare. You	edicare are ou may
I) Additional Information: This notice gives our c			d above. I understand with thi ot appeal to see if Medicare wo	
This notice gives our o				
	e billing, call 1-800-MEDI	ICARE (1-800-63	a. If you have other questions 3-4227/ TTY : 1-877-486-2048).	
(I) Signature:	. , ,		(J) Date:	

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

Form CMS-R-131 (03/08)

Form Approved OMB No. 0938-0566

(A) Notifier(s):	Approved Customize	d ABN (CMS-R-131) for Providers of Laboratory Services
(B) Pa	atient Name:	(C) Identification Number:
	ADVANCE BE	ENEFICIARY NOTICE OF NONCOVERAGE (ABN)
	doesn't pay for items checke	d or listed in box (D) below, you may have to pay. Medicare
		th care provider have good reason to think you need. sted or checked in box (D) below.

(E) Reason

Medicare

May Not Pay:

(F)		
Estimated		
Cost:		

WHAT YOU NEED TO DO NOW:

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

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

(G) Options:	Check only one box. We cannot choose a box for you.
billed for an officia understand that if I	want the (D)listed above. You may ask to be paid now, but I also want Medicare all decision on payment, which is sent to me on a Medicare Summary Notice (MSN). It Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by tions on the MSN. If Medicare does pay, you will refund any payments I made to you, less bles.
	want the (D)listed above, but do not bill Medicare. You may ask to be paid now as r payment. I cannot appeal if Medicare is not billed .
	on't want the (D) listed above. I understand with this choice I am not responsible cannot appeal to see if Medicare would pay.

Additional Information:

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

Sig	ning	below	means	that	vou i	have	received	and	und	erstand	this	notice.	You a	lso	receive	a co	ρv	
\sim \sim		0000			,								- 0				PJ	•

(I) Signature:	(J) Date :

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

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

60 - Form CMS-R-296 Home Health Advance Beneficiary Notice (HHABN)

(Rev. 1, 10-01-03)

PM A-03-024, PM A-03-025

Following are the standards for use by Home Health Agencies (HHAs) in implementing the Home Health Advance Beneficiary Notice (HHABN) requirements. This section provides instructions, consistent with the home health prospective payment process, regarding the notices that HHAs must provide to home health beneficiaries in advance of furnishing what HHAs believe to be noncovered care or of reducing or terminating ongoing care. HHAs must also meet the ABN Standards in §40.3 in completing and delivering HHABNs.

60.1 - Background on the HHABN

(Rev. 1025, Issued: 08-11-06; Effective/Implementation Dates: 09-01-06)

Since 2002, home health agencies (HHAs) have issued one-page HHABNs related to the absence or cessation of Medicare coverage when a beneficiary had liability protection under §1879 of the Social Security Act (the Act; see 60.2 H. below). This section also takes into account not only notification responsibilities under §1879, but also those under §1891 of the Act, the Conditions of Participation (COPs) for HHAs, in accordance with the 2nd Circuit's decision in LUTWIN V. THOMPSON. In particular, HHABNs are required more frequently for reductions and terminations. For example:

- HHABNs are required more frequently for changes in noncovered home care;
- HHABNs are now required in some situations where qualifying requirements for Medicare benefits are not being met, such as when there is a lack of physician orders for further home care; and
- HHABNs are required in a larger number of circumstances where covered care is reduced or terminated.

These HHABN instructions also take into account expedited determination notice requirements, which were implemented in 2005. As detailed below (see 60.2 B), the HHABN and expedited determination notices are now the only two types of notices an HHA will need to use to convey liability to beneficiaries.

60.2 - Scope of the HHABN

(Rev. 1025, Issued: 08-11-06; Effective/Implementation Dates: 09-01-06)

A. Statutory Authorization for HHABN

The requirement to give an HHABN is based on §1879 of the Act with its financial liability protections, and §1891, the COPs for HHAs (the COPs are further implemented

through Title 42 of the Code of Federal Regulations (CFR), Part 484.) In particular, relative to written notification, §1891(a)(1)(E) stipulates that beneficiaries have:

'The right to be fully informed orally and in writing (in advance of coming under the care of the [home health] agency) of --

- (i) all items and services furnished by (or under arrangement with) the agency for which payment may be made under this title,
- (ii) the coverage available for such items and services under this title, title XIX or any other Federal program of which the agency is reasonably aware,
- (iii) any charges for items and services not covered under this title and any charges the individual may have to pay with respect to items and services furnished by (or under arrangement with) the agency, and
- (iv) any changes in the charges or items and services described in clause (i), (ii) or (iii)."

The following chart summarizes the notice requirements under §1879 and §1891, which can also vary based on whether the home health benefit is at issue or if other care delivered by HHAs is involved (see 60.2 E below). Note CMS has designated the HHABN as the standard notification vehicle in all these cases:

Overview of HHABN Statutory Authorization

HHABN Requirement	HH Benefit	HHA Services "Outside the HH Benefit*"
§1891 Notification of Plan of Care (POC) Reductions and Terminations	Required	Not Required
§1879 Liability Notification for a Defined Medicare Benefit	Required	Required
Liability Notification for Care that is Not a Defined Medicare Benefit	Not Applicable	Voluntary

^{*} For definition, see 60.2 E below

B. HHABNs and Other Liability Notices

Since 2006, the HHABN has a broader scope that makes some other liability-related notices formerly used by HHAs unnecessary. Subsequently, HHAs no longer use:

- The general ABN (CMS-R-131) for Part B non-covered items/services outside the home health benefit-- HHAs use the HHABN for all benefits.
- The voluntary notices, Notice of Exclusion from Medicare Benefits (NEMB) or the NEMB-Home Health Agency (NEMB-HHA), for noncovered care outside the definition of a Medicare benefit -- HHAs use the HHABN for voluntary as well as mandatory liability notification.

Along with the HHABN, HHAs must use expedited determinations notices when required. [In short, expedited determination notices are given to beneficiaries before the termination of all Medicare covered services, so they are alerted to their right to obtain an independent, immediate review by a Quality Improvement Organization (QIO) of the decision to end coverage. For Original (Fee-For-Service, "FFS") Medicare, the first or Generic Expedited Determination Notice is entitled, "Notice of Medicare Provider Non-Coverage," Form Number CMS-10123, and the second or detailed notice is called the "Detailed Explanation of Non-Coverage," Form Number CMS-1024.] Links for "FFS HHABN" and "FFS ED Notices" are links found on CMS Web site at:

http://www.cms.hhs.gov/BNI/

Instructions for the expedited notices, like the HHABN, will ultimately be placed in this chapter (a new and independent section), since this chapter is the primary source of guidance on all such notices used in Original Medicare.

C. HHABN Issuers and Recipients

Only HHAs, no other types of Medicare providers, issue the HHABN. HHAs issue HHABNs only for services that they bill or furnish, not for items or services that beneficiaries under their care may permissibly obtain from other sources (note this policy generally applies to all financial liability protection notices that are used to meet the requirements of §1879 of the Act).

An example is when durable medical equipment (DME) suppliers, and not HHAs, are providing equipment to beneficiaries receiving home care. In such cases, it is the supplier's responsibility, as the entity billing the equipment, not the HHA's, to notify the beneficiary of potentially noncovered items they may deliver. Suppliers use the general ABN and follow the instructions for this notice found elsewhere in this chapter. Another example is when an HHA has an intravenous infusion division, but a pharmacy provides medications to be infused and bills the patient's drug benefit directly. Here the pharmacy does the billing, and therefore would have any applicable notification responsibility. (Note there is no ABN-type notification requirement for Medicare Part D, only potentially for drugs provided under Part B (of Original Medicare)).

Regarding beneficiaries receiving the HHABN, §1879 financial liability protection notices like the HHABN continue to be used solely for beneficiaries enrolled in Original Medicare, as §1879 of the Act applies only to Parts A and/or B of the Program. **HHABNs are not used in Medicare managed care.** When a beneficiary transitions to Medicare managed care from Original Medicare during a home health episode, no HHABN is required assuming there is no potential liability for payment or need to provide notification of changes in care. In this case, the beneficiary is still

receiving the same basic Medicare covered care, just the type of Medicare "plan" is changing from Original Medicare to managed care (i.e., Medicare Advantage).

NOTE: In the instructions in this section, the term "beneficiary" is used either to mean the beneficiary or the beneficiary's authorized representative, as applicable. Therefore, these instructions apply whether the HHA gives the HHABN to a beneficiary or an authorized representative. For more information on authorized representatives, see this chapter, §40.3.5 and §40.3.4.3. Note an authorized representative can sign and date an HHABN without further annotation when properly designated.

HHAs should contact their Regional Home Intermediary (RHHI) if they have questions on the HHABN or related instructions, since RHHIs administer home health benefits for Original Medicare. Beneficiaries may be directed to call 1-800-MEDICARE.

D. Effect of Other Insurers/Payers

If a beneficiary is eligible for both Original Medicare and Medicaid (a "dual eligible"), or if Original Medicare and another insurance program or payer, HHABN requirements are modified when a triggering event occurs (see 60.3 below for discussion of triggering events). For example, when a beneficiary is a dual eligible, and is receiving services that are covered only under Medicaid-- so that from Medicare's perspective, all care is noncovered-- an HHABN has to be issued only at the initiation of this noncovered care. Therefore, there would be no need for delivery of other HHABNs at subsequent triggering events, such as reductions in care, as long as coverage remained the same and the HHABN given at initiation was still effective. No additional HHABN would need to be given, unless: (1) the beneficiary again became eligible for Medicare coverage and a triggering event occurred, or (2) continuous treatment lasted for more than a year.

The same principle applies for beneficiaries who have Medicare and additional health insurance or payers other than Medicaid, when the other insurance or payer provides coverage and Medicare does not. Other payers can include: waiver programs, Office on Aging funds, community agencies (e.g., Easter Seals) and grants. However, if there is secondary or any subsequent Medicare coverage, HHABNs must again be issued at all triggering events.

NOTE: When Medicare beneficiaries have no coverage in addition to Medicare, HHAs must provide HHABNs at all triggering events, whether care is covered or noncovered.

Regarding timing of notification in cases when periods of Medicare covered and other payer/insurer covered care overlap, there is some flexibility. A common example is "split billing" nursing hours paid by Medicaid above those allowed by Medicare in keeping with its coverage policy on intermittent need. If an HHABN was given prior to/at the beginning of the period, such as a recertification period, where split billing was to be done, and explicitly described the care only Medicaid covers, another HHABN would not have to be given just because Medicare coverage ended after that point, assuming the previously given HHABN was still effective (see 60.6). However, the

HHA could instead choose to wait to issue the HHABN for the ongoing noncovered care until Medicare coverage was ending-- HHAs can determine which approach will lead to the most effective communication with each individual beneficiary they serve. Note, however, expedited determination notices must be issued when termination of Medicare coverage occurs, in accordance with requirements for this distinct appeal right.

E. Use of HHABNs for All Home Health Services

Since 2006, HHABNs are used both within and outside of the Medicare home health benefit. If HHAs are administering home health plans of care, related items and services are considered delivered under the home health benefit. Examples of services outside the home health benefit include equipment delivered when HHAs are acting as durable medical equipment suppliers, or possibly when administering therapy to non-homebound beneficiaries under a therapy, not home health, plan of care.

In terms of billing, this distinction is drawn by the type of bill: care that is part of the home health benefit is billed with either a 32X or 33X, care outside the home health benefit is billed with 34X. For the HHABN, items or services within and outside of the home health benefit are defined in the same way as they are in billing. Note that:

- Any Medicare benefit can be either covered or noncovered, depending on individual circumstances involved; and
- Generally the term "care outside the benefit" includes: (1) benefits other than the one under consideration (in this section, home health), and (2) items or services that are never-covered as Medicare benefits (see F. immediately below for more on noncovered care).

NOTE: There are differences in when the HHABN has to be issued based on whether care is, or is not, provided under the home health benefit (see 60.3 below).

F. Noncovered Services

Generally, coverage equates with payment. Covered services are those which Medicare pays in accordance with its established policies, and in Medicare manuals the term "covered" most often means usually or potentially covered under Medicare policy.

Conversely, if a service is "noncovered" in Medicare, this usually means Medicare normally is not expected to or will not pay. Lack of eligibility for a benefit, such as failure to meet the homebound criterion for Medicare to cover home care, is an example of noncoverage due to coverage/payment policy. (Note that while such policy is often the reason payment is not expected, there are other reasons, such as a beneficiary's lack of eligibility for a Part of Medicare, that are different from lack of eligibility for a specific benefit like home health).

There are two basic types of noncovered services under policy as described above:

- Never-Covered Care. Items or services that Medicare never covers, such as: (1) defined exclusions like routine foot care cited under §1862(a)(13)(C) of the Act, or (2) care that is not described as covered either in broad categories under Title 18 of the Act (the authorizing statute for Medicare), or in more specific national or local Medicare coverage decisions. Examples of such services which HHAs deliver include: telemonitoring of health status, geriatric alcohol prevention programs.
- Usually Covered Care. Items or services that Medicare usually covers, but are
 denied in individual cases for specific reasons, such as when the service in
 question is considered not reasonable and necessary in a particular case.

Never-Covered Care -- Home Health Benefit. Preliminary guidance on the HHABN in 2006 stated that "never-covered" services, when included on the home health plan of care, must be treated like other on the plan in terms of HHABN notification. However, this instruction clarifies that the COPs for HHAs do not require notification for such never-covered care, even when described on home health care plans, as long as there are no charges to the beneficiary. That is, consistent with §1891(a)(1)(E)(iii)-(iv), which focus on charges: notice only has to be given when items and services never-covered under this title are provided to beneficiaries AND the beneficiary is charged for that care. **If there are no charges, there is no notification requirement.**

Never-Covered Care -- Outside the Home Health Benefit. Never-covered services that are either benefits other than home health or cannot be categorized as a Medicare benefit at all are not subject to HHABN notification requirements as discussed above relative to the home health benefit. Such care is not required to be administered under home health plans of care, and is not necessarily concurrent with Medicare covered home care. The HHABN may not be required even if HHAs charge for this care, as long as there is no beneficiary liability as recognized under §1879 of the Act (see H. immediately below). If §1879 does not apply to care outside the benefit, use of the HHABN is voluntary.

Usually Covered Care (Noncovered in an Individual Case). In contrast to never-covered services, note that §1891(a)(1)(E)(i)-(ii) require notification for "all items and services furnished... for which payment may be made under this title." These sections do not reference charges, and set a higher notification standard when care "may" be covered (paid) by Medicare (i.e., this care is not "never-covered" because it can be covered in certain cases). HHABN notification is required when such noncovered items or services are on home health plans of care and reduced or terminated, whether or not there are charges. Again, there is no parallel notification requirement for care outside the home health benefit not administered under home health care plans.

G. Bundled Payment

For home health, the primary example of bundled payment is the 60-day episode under the home health prospective payment system. This is a global payment for all Medicare covered home care needed in the 60 day episode; it is not based on individual items and services. (Note there are a few exceptions, since separate payment is made for DME osteoporosis drugs provided under the benefit during the episode.)

NOTE: Items and services that Medicare never covers, as opposed to service Medicare usually covers but may not in an individual case (for reasons such as a lack of medical necessity, see F. immediately above), are not considered part of the bundled home health prospective payment. Never-covered care is not within the definition of any Medicare benefit. Examples of never-covered care specific to the home health benefit include: care provided to beneficiaries who are not homebound, telemonitoring, and full-time skilled nursing care.

Initiation. HHABNs are not required at initiation of bundled care since the related payment is for any related services that are potentially covered as part of the home health benefit. This is consistent with ongoing financial liability protection policy, which states such notices cannot be used, in effect, to double charge by collecting funds from a beneficiary for care Medicare has already covered in a bundle (see 50.7.7.6 in this chapter on bundled payment; and note Chapter 7 in Pub.100-02, the Medicare Benefit Policy Manual, describes the home health benefit in detail--this manual is 100-04 in the same series).

NOTE: If an HHABN was not given at admission/start of care because an HHA was delivering covered and noncovered care in the same bundled payment, and subsequently care continued and became completely noncovered, then an HHABN would have to be issued (see F. above, and 60.3 C. below).

Reductions. After initiation, for care considered within a bundle, HHAs must issue HHABNs if during the 60-day episode reductions occur in care that Medicare usually covers. This assures that the beneficiary is aware of these changes as required under the COPs. Such notification is required even if there is no additional liability for the beneficiary (i.e., because the 60-day payment remains the same despite the change, or the payment group changes but the beneficiary still has no liability).

Terminations. For terminations of bundled care under the home health benefit, HHABNs are not required, since expedited determination notices fulfill notification requirements. An HHABN is only required if: (1) expedited determination notification requirements do not apply; and/or (2) completely noncovered care continues after coverage ends (see 60.3 below).

H. Limitation of Liability

Home Health Benefit. Historically, CMS has required HHABNs only in those specific situations where "limitation on liability" (LOL) protection was afforded under §1879 of the Act for items(s) and/or service(s) ordered by physicians that HHAs believed Medicare would not cover. Prior to 2006, CMS also only required that HHABNs be issued for care that was part of the home health benefit.

Under these instructions, HHAs continue to use the HHABN in these circumstances, that is, in order to charge beneficiaries for home care presumed to be noncovered, assuming beneficiaries make choices to receive such care and accept liability. The chart below lists anticipated denial reasons where §1879 protections apply.

Application of LOL for the HH Benefit

Citation from the Act	Brief Description of Situation	Explanation
§1862(a)(1)(A)	Care is not reasonable and necessary	Medicare does not pay for such care
§1862(a)(9)	Custodial care is the only care delivered	Medicare does not usually pay for such care, except for some hospice services
§1879(g)(1)(A)	Beneficiary is not homebound	Medicare requires that a beneficiary cannot leave home (with certain exceptions) in order to cover services under the home health benefit
§1879(g)(1)(B)	Beneficiary does not need full time skilled nursing care	Medicare requires an intermittent need in order to cover such services under the home health benefit

Another change in HHABN policy is that HHABNs are not only required in situations where LOL protection is available regardless of financial liability. This is necessary to meet HHA notification requirements under §1891 of the Act (see A. immediately above).

Outside the Home Health Benefit. With HHABNs given for care outside the home health benefit, the usual reason for presumed noncoverage will be under §1862(a)(1)(A) of the Act, namely that care is not reasonable and necessary. Note that the required frequency of notification for such care has not changed, only the particular notice employed (see 60.2 above, particularly B. and E.).

60.3 - HHABN Triggering Events

(Rev. 1025, Issued: 08-11-06; Effective/Implementation Dates: 09-01-06)

Generally, HHAs are required to issue HHABNs whenever they believe they are about to deliver noncovered item(s) and/or service(s) at three points in time, called "triggering events":

Definition of Triggering Events

EVENT	DESCRIPTION	
A. Initiation	When an HHA expects that Medicare will not cover any item(s) and/or service(s) delivered under a planned course of treatment from the start of a spell of illness, OR before the delivery of one-time item(s) and/or service(s) that Medicare is not expected to cover.	
B. Reduction	When an HHA reduces or stops some item(s) and/or service(s) during a spell of illness, while continuing others, including when one home health discipline ends but others continue, independent of Medicare coverage.	
C. Termination	When an HHA ends delivery of either all Medicare-covered care, or all care in total.	

NOTE:

- See A., B. and C. immediately below for more information on each triggering event.
- See D. below for certain limited exceptions for the home health benefit when an HHABN is not required even though a triggering event may have occurred.

Home Health Benefit. HHAs must issue HHABNs at triggering events when either §1879 or §1891 of the Act apply (see 60.2 A. and H. above), as summarized in the following charts:

TABLE A - Triggering Events For the HH Benefit: §1879 or §1891 Applies

Application:	Medicare COVERED CARE
Population:	All Beneficiaries
Initiations	Not Required
Reductions	HHABN
Terminations for Coverage Reasons*	Generic Expedited Determination Notice**
Terminations not based on Coverage*	HHABN

^{*} For definition, see C. below.

^{**}HHABNs are also given ONLY if noncovered care continues after coverage ends. See C. below on terminations.

TABLE B - Triggering Events For the HH Benefit: §1879 or §1891 Applies

Application:	Medicare NONCOVERED CARE				
	Beneficiaries with other	Beneficiaries with no			
Population:	coverage (i.e., Medicaid)	other coverage			
Initiations*	HHABN	HHABN			
Reductions	Not Required	HHABN			
Terminations**	Not Required	HHABN			

^{*} Of completely noncovered care, see C. below.

Outside the Home Health Benefit. HHAs must issue HHABNs for triggering events only when required under §1879 (see 60.2 H. above), summarized as follows:

TABLE A - Triggering Events Outside the HH Benefit - §1879 Applies

Application:	Medicare COVERED CARE		
Population:	All Beneficiaries		
T opulation:	The Deficient 103		
Initiations	Not Required		
Reductions	HHABN		
Terminations for Coverage Reasons*	Generic Expedited Determination Notice** and/or HHABN		
Terminations not based on Coverage*	Not Required		

^{*} For definition see discussion in C. below on terminations.

^{**} In contrast to Table A above, there are no expedited determination requirements when care is noncovered.

^{**} Expedited determinations are only required at the end of a planned course of covered treatment usually delivered over the course of time, such as when administering a therapy plan of care, and are not used for one-time or sporadic item(s) or service(s). (Note one-time items or services are classified as initiations, not terminations (see A. below).) HHABNs are also given ONLY if noncovered care continues after coverage ends. When expedited determination notices are not required, the HHABN is required only if LOL applies (see 60.2 H).

TABLE B - Triggering Events Outside the HH Benefit - §1879 Applies

Application:	Medicare NONCOVERED CARE					
Population:	Beneficiaries with other coverage (i.e., Medicaid)	Beneficiaries with no other coverage				
Initiations*	HHABN	HHABN				
Reductions	Not Required	Not Required				
Terminations **	Not Required	Not Required				

^{*} Of completely noncovered care, see C. below.

NOTE:

- When §1879 does not apply and care is outside the home health benefit, such as care that is part of another Medicare benefit, notification of liability with the HHABN is voluntary, not required.
- These notice delivery rules are unique for HHAs. HHAs that also operate as hospices or other types of Medicare providers or suppliers (under separate provider or supplier identification numbers), should NOT assume these requirements are applicable to other types of providers.
- For ongoing continuous (long-term) noncovered care exceeding a year in duration, another HHABN must be given as each new year begins, assuming coverage remains the same and therefore HHABN requirements still apply. This is in keeping with standing Medicare liability notice practices that serve to confirm both beneficiary retention of coverage information and that coverage status is in fact unchanged (see 50.7.1 in this chapter).
- See 60.4 G.2.b below for a summary of triggering events further broken down by which option box language is used on the HHABN.

A. Initiations

With respect to the initial assessment of a beneficiary, prior to admission (i.e., start of care), no notification is required if the HHA only assessed the beneficiary, did not admit him/her, and did not charge for the assessment. However, if an HHA charges for an assessment, the HHA must provide notice to the beneficiary before charging for the service as cited in Chapter 10 of this manual (50 F).

In their admission processes for home care, HHAs provide information on covered and noncovered charges as required under the COPs for HHAs. CMS does not mandate that a standardized notice format, like the HHABN, be used in the admission process when covered care is to be delivered. The HHABN is only issued to a beneficiary at initiation

^{**} In contrast to Table A above, there are no expedited determination requirements when care is noncovered.

when care is completely noncovered by Medicare. If there is delivery of some noncovered care from initiation, such as when there is a noncovered part of bundled care that is covered as a whole (see 60.2 G. above), an HHABN is not required. Another example of HHABNs not being required at initiation is when Medicare covered nursing hours will be provided up to the Medicare limit, and hours beyond that limit will also be provided and paid by Medicaid for a dually eligible beneficiary.

Initiation of completely noncovered care is usually a triggering event for all beneficiaries for all benefits (the exception is care outside the home health benefit when LOL does not apply, see 60.2 H above). Relative to the home health benefit, if another payer or insurer provides coverage after that point while that beneficiary remains ineligible for coverage under Medicare, HHAs do not need to issue HHABNs for subsequent triggering events for up to a year (see 60.2 D. above). For other benefits, HHAs are not required to issue HHABNs for other triggering events after initiation when care remains completely noncovered.

One-Time Items/Services. Neither HHABNs nor expedited determination notices are necessary for one-time treatments not covered by Medicare where there is no beneficiary liability. If, however, the beneficiary is charged, the HHABN may be required. Any one-time care (that which is provided and completed in a single encounter) is considered an initiation in terms of triggering events, since such care cannot be reduced or terminated over time.

Under the home health benefit, one-time services are uncommon, such as episodes that are truncated to one visit because of a beneficiary's death. In such cases, HHABNs would not have been required since services at delivery would have been presumed to be covered. If an HHA knowingly plans to provide a potentially noncovered one-time service or item, under the home health benefit (including related assessments), an HHABN must be issued unless: (1) there are no charges to the beneficiary, or (2) a recognized exception applies (see D below). If a one-time service is provided under another Medicare benefit, such as when HHAs provide DME as suppliers under Part B, HHABNs are only required when the item supplied is not believed to be reasonable or necessary for treatment (LOL applies, see 60.2 H. above).

B. Reductions

Reductions and terminations are sometimes confused, but in the case of reductions, HHAs must be discontinuing some, but not all, care. For example, reductions may include cases where one type of care ends but other type(s) continue, such as the end of one discipline under the home health benefit (skilled nursing) while another (physical therapy) continues.

For most beneficiaries receiving the home health benefit, HHABNs are required for reductions whether or not the care that is ending (the reduction) or the care that continues afterward is covered by Medicare, unless an explicit exception applies (see D. below). Only beneficiaries that are receiving completely noncovered care under Medicare that is covered through another payer or insurer are excepted (see 60.2 D above and the 2 Table Bs at the beginning of this section, as well as D. below). Outside the home health benefit,

HHAs are only required to issue HHABNs when Medicare covered care is being reduced and LOL applies (see 60.2 H. above).

C. Terminations

Termination is the complete cessation of all item(s) and/or service(s) at the end of a course of treatment, as opposed to reductions, where only some care ends. Particularly because of expedited determination notice requirements effective July 2005, HHABNs are not always required at termination of home care.

The HHABN and generic expedited notices address different things: the generic notice gives information on the right to a quick decision from a QIO affirming or disputing the end of all covered care. The right to an expedited determination only applies when coverage for a course of treatment under certain Medicare benefits is terminated for Medicare coverage reasons (see "Reasons for Termination" below). Instructions for expedited determinations are in Transmittal 594, CR 3903 dated June 24, 2005 (which will be added to this chapter in the future). Home health and therapy (i.e., administered under a therapy, not home health, plan of care) would likely be the only benefits HHAs provide to which the expedited right applies. In contrast to expedited determination notices, the HHABN provides information on potential liability for care that would be delivered after coverage ends, and on claim-related appeal rights.

Beneficiaries must receive notice for ANY terminations of home care. For the purposes of the COPs for HHAs, either an expedited determination notice or an HHABN can fulfill this requirement. If §1879 requirements also apply (i.e., noncovered care for which the beneficiary may be liable will continue after termination of coverage), the HHABN must also be provided. A generic expedited determination notice must be issued at termination if: (1) the reason care is ending is related to Medicare coverage policy, and (2) noncovered care will not continue after coverage ends.

Reasons for Termination. Regarding (1) in the paragraph above, common examples of care ending for Medicare coverage reasons for the home health benefit are lack of a physician order or a beneficiary no longer being homebound. Outside the home health benefit, lack of orders is also a common reason for noncoverage of other benefits.

Expedited determination notices are required in these situations. Terminations not related to coverage policy are likely when HHAs decide to stop providing some or all care for their own financial and/or other reasons, regardless of Medicare policy or coverage. For example, this could occur due to the availability of staffing, closure of the HHA or concerns for staff safety in a beneficiary home. It could also be a situation such as a termination of an HHA's provider agreement with Medicare, which though not necessarily the HHA's choice, still does not affect a given beneficiary's eligibility for Medicare covered home care, nor is such a termination based on Medicare coverage policy.

NOTE: As with other triggering events, exceptions to HHABN notification requirements may apply (see D. immediately below).

Dual Eligible Example. If a dually eligible beneficiary who has been receiving home care services under Medicare ceases to be homebound, the payer/insurer becomes Medicaid. Since triggering event definitions are written in the context of Medicare coverage, an expedited determination notice is given because Medicare coverage is terminating, but since Medicare noncovered (Medicaid covered) care will be continuing from that point forward, an HHABN is issued too because of the initiation of noncovered care from Medicare's perspective. Medicare requires that its beneficiaries be informed of potential liability in advance of actually incurring that liability (i.e., receiving the noncovered care), when LOL applies (see 60.2 H. above), even if another payer/insurer exists and is likely to provide coverage (see 60.2 D above and D. below).

D. Exceptions to HHABN Notification Requirements

HHABN notification requirements for care outside the home health benefit are much smaller in scope than requirements than when the home health benefit is being delivered (see the tables at the beginning of this section for illustration of this point). **Therefore, the following exceptions in the table below were developed to apply only to the home health benefit.** (Note that for services "outside the home health benefit" (see 60.2 E. for definition), HHABNs would not be required in any of the cases listed below, with the possible exception of meeting patient goals if noncovered care continued thereafter and LOL applied (see 60.2 H above and 14. in the table below)).

Table of Exceptions to HHABN Notification Requirements - HH Benefit

#	EXCEPTION	APPLICATION	DESCRIPTION
1	Increases in Care	General	Any increases whether under the original plan of care (POC) or subsequent orders (includes noncovered care simultaneous to but exceeding Medicare coverage, i.e., private duty nurses, other payer/insurer coverage).
2	Transfers	General	Transfers to other covered care, i.e., another home health agency or another type of Medicare provider (includes worsening patients needing hospitalization, until such time as the patient returns to the HHA's care).
3	Emergency or Unplanned Situations	General	Emergencies or unplanned situations beyond the HHA's control (i.e., natural disasters, staff member illnesses or transportation failures).
4	Changes in Caregiver or Personnel	General	Any changes in HHA caregivers or personnel as decided by the HHA.

#	EXCEPTION	APPLICATION	DESCRIPTION	
5	Changes in Arrival or Departure Time	General	Any changes in expected arrival or departure time for HHA staff as determined by the HHA.	
6	Changes in Brand	General	Any changes in brand of product, i.e., the same item produced by a different manufacturer as determined by the HHA.	
7	Free Care Never- covered by Medicare*	General	Care that is never-covered by Medicare under any circumstances and for which the HHA will not charge the beneficiary.	
8	Free Initial Assessment (never- covered by Medicare)**	Initiation	Initial assessments (in cases where beneficiaries are not admitted) for which HHAs do not charge.	
9	Noncovered Parts of a Covered Bundled Payment***	Initiation	Noncovered item(s)/service(s) that are part of care covered in total under a Medicare bundled payment (i.e., HH PPS episode payment).	
10	Length of Visit/Care	Reductions	Any change in the duration of services included in the POC and communicated to the beneficiary by the HHA, i.e., shorter therapy sessions as health status improves, perhaps going from an hour to 45 minutes.	
11	Lessening the Number of Items or Services	Reductions	Only applicable to reductions anticipated in the POC and communicated by the HHA to the beneficiary (see 1. and 2. below table for further discussion).	
12	Changes in Services within a Discipline	Reduction	Changes in the mix of services delivered in a specific discipline (i.e., skilled nursing) with no decrease in frequency with which that discipline is delivered (see 3. below table for examples).	
13	Changes in Modality of Care Resulting in Use of Different Supplies	Reduction	Changes in the modality affecting supplies employed as part of specific treatment (i.e., wound care) with no decrease in the frequency with which those supplies are provided (see 4. below table for examples).	

#	EXCEPTION	APPLICATION	DESCRIPTION
14	Patient Goals Met	Terminations All care (every discipline) ending patient goals met and/or physician completed (note an expedited determination notice must still in this case).	
15	Beneficiary Choice	Reduction or Termination	Changes in care that are the beneficiary's decision and are documented in the medical record.
16	Exclusive Coverage under Other Payer/Insurer****	Reduction or Termination	When there is no applicable Medicare coverage but another payer/insurer will cover the beneficiary's care.

^{*} See 60.2 F (above).

1. Ranges in Orders ("11" in chart above)

Section 30.2.2 of Chapter 7 of Pub. 100-02, Medicare Benefit Policy Manual, allows the use of ranges when physicians write home health care orders. An example of orders given in ranges is: "therapy 2–3 times per week for 3 weeks", as opposed to more prescriptive orders allowing HHAs less flexibility in judging patient progress (as well as making revisions in orders more likely): "3 visits a week for 2 weeks, 2 visits the final week". Since the purpose of the HHABN is to keep the beneficiary informed of specific changes in the POC, the use of ranges on HHABNs is not permitted. That is, language on the HHABN cannot be open-ended as to when a specific change described would occur, particularly if listing a number of potential future changes in a range that is not projected to occur at specific points in time or with the achievement of specific goals (see 2. immediately below).

2. Advance Notification ("11" in chart above)

Some HHAs do not believe they can accurately inform beneficiaries of specific timeframes based on the POC developed from physician orders, because they cannot guarantee that patient's progress will conform to such plans. Other HHAs do feel comfortable advising their beneficiaries in advance, perhaps as part of reviewing the plan of care for the upcoming 60-day episode. If an HHA is comfortable giving advance notice of all triggering events anticipated in the POC, such notice can be given before the period begins or prior to the first triggering event. Another HHABN would then not have to be given in that period as long as treatment did in fact conform to expectations. However, if patient progress was not what was anticipated, or if a change in orders occurred, or for any other reason the previous HHABN no longer captured all reductions/terminations for the period, another HHABN would be required.

^{**} See A. immediately above.

^{***} See 60.2 G.

^{****} See 60.2 D.

Alternatively, an HHABN could be provided in advance of each triggering event. There is no mandate to take one approach over the other.

NOTE:

- When a certain type of service/home health discipline is close to ending, HHAs can use an endpoint describing when specific goals are met. This assumes the HHA either describes the actual goal on the HHABN ("you can transfer from bed to a chair independently") or fully explains verbally what the term "goals met" (if used on the HHABN) means to the affected beneficiary—the medical record would also make clear the goal at issue had been discussed with the beneficiary. However, if physician orders exist for specific frequencies of care, this approach cannot be used as an alternative to what is specified in the order.
- Sometimes the statement is made that any change in a physician order, and subsequently, the home health POC, requires an HHABN be provided. Given the nature of the home health benefit, services are usually decreasing as a patient improves; thus, subsequent orders would likely be for a reduced number of services. However, new orders can still have one of four possible results: stopping care altogether, reducing care (the most common by far), maintaining care at the same level, or increasing care. Of these possibilities, it is only when reductions or terminations occur that HHABNs may be required.

3. Use of the HHABN within Home Health Disciplines ("12" in chart above)

Regarding item(s) or service(s) provided within the scope of a single one of the six home health disciplines (see Chapter 7 of Pub. 100-02, Medicare Benefit Policy Manual for basic information on this benefit), an HHABN is only required when the frequency of that discipline is reduced, such as from 3 to 2 visits a week.

EXAMPLES:

- A beneficiary is receiving several skilled nursing services during visits that are scheduled 3 times a week. One service within that discipline, a Protime draw 1 time a week, is discontinued. Other skilled nursing services (wound care and education) continue, such that skilled nursing visits continue to occur 3 times per week. No HHABN is required when the Protime draws are discontinued, only when skilled nursing is reduced in frequency.
- A beneficiary is receiving physical therapy 3 times a week. The therapist changes the beneficiary from a walker to a cane while continuing to visit at the same frequency. No HHABN is required.

4. Use of the HHABN when Changes in Modality Affect Supplies ("13" in chart above)

When an HHA is providing multiple supplies for complex treatments such as wound care, HHABNs are not required if there is a change in the modality of this treatment, only when supplies are reduced.

EXAMPLES:

Specific wound care products like Mesalt and Alldress are stopped, and a Hydrogel pad is started. Since this represents a change in the modality (or intervention), not a reduction, no HHABN is necessary. However, if the frequency of the provision of wound care supplies was reduced, such as from 3 to 2 times a week, an HHABN would be required.

A beneficiary is receiving just skilled nursing care and supplies for wound care. Once the beneficiary learns to do his own wound care, the frequency of skilled nursing visits decreases, and an HHABN is required for this service reduction (although the provision of wound care supplies may stay the same for a time). As the wound continues to heal and the beneficiary is performing wound care less often, at the point fewer supplies are needed, an HHABN is required for that subsequent reduction in the frequency of supplies.

60.4 - Completing the HHABN

(Rev. 1025, Issued: 08-11-06; Effective/Implementation Dates: 09-01-06)

A. Notices

HHABNs are available at:

http://www.cms.hhs.gov/BNI/

The notice is available in English and Spanish, and in PDF and Word formats, under a dedicated link on the top left-hand margin: "FFS HHABN".

The HHABN is the Office of Management and Budget (OMB) approved standard notice for use by Medicare HHAs to: (1) advise Medicare beneficiaries of potential liability for noncovered item(s) and/or service(s) they deliver, allowing such HHAs to collect payment up-front from beneficiaries in such cases, and (2) inform beneficiaries of changes in the POC when required by the COPs for HHAs. HHAs are strongly advised to use the approved standard notice, as failure to use this notice could result in improper notification (see 60.6 below).

B. Choosing the Correct Language Version

HHAs should choose the appropriate version of the HHABN based on the language the beneficiary best understands. When Spanish-language HHABNs are used, the HHA should make insertions on the notice in Spanish. If this is impossible, additional steps need to be taken to ensure that the beneficiary comprehends the content of the notice.

C. Compliance with Paperwork Reduction Act of 1995

Consistent with the Paperwork Reduction Act of 1995, the valid OMB control number for this information collection appearing on the HHABN is 0938-0781. The estimated time required to complete this information collection ranges from 4 to 18 minutes for a single notice, depending on the option box language used (see F. 2 immediately below). This includes the time to prepare the notice, review it with the beneficiary and obtain beneficiary choices and signature.

Commenters may send comments concerning the accuracy of the time estimate(s) or suggestions for improving this notice to:

Centers for Medicare & Medicaid Services Attn: Reports Clearance Officer Room C4-26-05 7500 Security Boulevard Baltimore, Maryland 21244-1850

D. Effective Dates

HHABNs are effective as of the OMB approval date given at the bottom of each notice. The routine approval is for 3-year use. HHAs are expected to exclusively employ the effective version of the HHABN.

E. Ongoing Care Situations

Generally, the HHABN version that should be used is the one effective when the triggering event requiring notification occurs, such as a reduction or termination in care. For prior admissions, specifically noncovered admissions when HHABNs are required at initiation of care, there is no need to re-notify beneficiaries who have received prior HHABN versions just because a new version has become effective.

F. General Notice Requirements

The following are the general instructions HHAs must follow in preparing an HHABN:

- **1. Number of Copies:** A minimum of two copies, including the original, must be made so the beneficiary and HHA each have one.
- **2. Reproduction**: HHAs may reproduce the HHABN by using self-carbonizing paper, photocopying the HHABN, or using another appropriate method. All reproductions must conform to applicable instructions.
- **3. Length and Page Size:** The HHABN must NOT exceed one page in length. The HHABN is designed as a letter-sized form. If necessary, it may be expanded to a legal-sized page to accommodate information HHAs insert in the notice, such as the HHA's name, list of item(s) and/or service(s) that will no longer be provided, and cost information.

- **4.** Contrast of Paper and Print: A visually high-contrast combination of dark ink on a pale background must be used. Do not use reversed print (e.g., white on black), or blockshade (highlight) notice text.
- **5. Modification**: The HHABN may not be modified, except as specifically allowed by these instructions.
- **6. Font:** The HHABN must meet the following requirements in order to facilitate beneficiary understanding:
 - **a. Font Type:** To the greatest extent practicable, the fonts as they appear in the HHABN downloaded from either RHHI or CMS Web site should be used. Any changes in the font type should be based solely on software and/or hardware limitations of the HHA. Examples of easily readable alternative fonts include: Arial, Arial Narrow, Times New Roman, and Courier.
 - **b. Font Effect/Style:** Any changes to the font, such as italics, embossing, bold, etc., should not be used since they can make the HHABN more difficult to read.
 - **c. Font Size:** The font size generally should be 12 point. Titles should be 18 point, but insertions in blanks of the HHABN can be as small as 10 point if needed.
 - **d. Insertions in Blanks:** Information inserted by HHAs in the blank spaces on the HHABN may be typed or legibly hand-written.
- **7. Customization:** HHAs are permitted to do some customization of HHABNs, such as pre-printing agency-specific information to promote efficiency and to ensure clarity for beneficiaries. Guidelines for customization are:
 - **a.** HHAs may have multiple versions of the HHABN specialized to common treatment scenarios, using all the required language and formatting of the HHABN, but with pre-printed language in its blanks.
 - **b.** HHAs may print different versions of HHABNs on different color paper to easily differentiate the versions, but in all cases high-contrast combinations of light paper and dark font color should be used.
 - **c.** HHAs may also differentiate versions of their HHABNs by adding letters or numbers in the header area.
 - **d.** Maintaining underlining in the blank spaces is not required.
 - e. Information in blanks that is constant can be pre-printed, such as the HHA's name, or Medicare's telephone (1-800-MEDICARE or 1-800-633-4227) and/or TTY (1-877-486-2048) numbers. Note the TTY phone number only needs to be entered when appropriate and based on the needs of beneficiaries

- **f.** If pre-printed multiple options are used describing the items or services and reasons for noncoverage, the beneficiary should only see information applicable to his/her case clearly indicated in each blank or checked off in a checkbox.
- **g.** Checkboxes for disciplines, if used to describe item(s) and/or service(s), must still allow for explanation of what is changing; for example:
 - "Physical Therapy: Reduced to 2 times per week." Just checking off a discipline without an explanation could render the notice invalid.
- **h.** HHAs should have available HHABNs without pre-printed information on hand for staff to use in unusual cases that do not conform to pre-printed language for items or services or reasons for noncoverage.

NOTE:

- HHAs must exercise caution before adding any customizations beyond these guidelines, since changing HHABNs too much could result in invalid notice and provider liability for noncovered charges. Medicare's liability notice policy generally bases validity determination on two factors: effective delivery and beneficiary comprehension (see 60.6 below).
- Medicare does not validate adaptations of the HHABN made by individual HHAs. Validity judgments are generally made by RHHIs, usually when reviewing HHABN-related claims.

G. Completing Sections of the HHABN

The new HHABN continues to be a one-page notice, composed of four sections:

- Header Section
- Body Section
- Option Boxes
- Signature/Date Section

The HHABN file contains four pages. The first page is instructional and never distributed to beneficiaries—it is marked "SAMPLE" in the bottom right corner. It has instructions for filling in the blanks and boxes in the notice. To differentiate the instructions from the actual notice text, the instructions are printed in a different font in the appropriate blanks.

The next three pages are "ready to use" HHABNs. The second page is an HHABN with Option Box 1 text placed into the boxed area of the notice-- it is marked "OPTION BOX 1" in the bottom right corner. The third page is an HHABN with Option Box 2 text in the

boxed area-- it is marked "OPTION BOX 2" in the bottom right corner. The last page is also a blank HHABN, with Option Box 3 text in the boxed area -- it is marked "OPTION BOX 3" in the bottom right corner. See section 2.b below on which option box to use.

1. The Header Section

HHAs are permitted to customize the header section of the HHABN. The header section is above the title of the notice, "Home Health Advance Beneficiary Notice," which appears in larger point font size at the top of the page.

After downloading the notice from a RHHI/CMS Web site, HHAs may add identifying information, including the HHA's name, logo, and billing address. At a minimum, information allowing the beneficiary to contact the HHA must appear, including the provider's name and address (telephone number is given elsewhere on the notice).

2. The Body Section and Option Boxes

a. Instructions for the Body Section

The body section of the HHABN is below the header and above the option boxes. The HHA starts by inserting standard information into the following two blanks in this section:

Step 1: The HHA inserts its name in the blank space provided in the sentence beginning: "WE,, YOUR HOME HEALTH AGENCY,". Since the entry in the "Step 1" blank is the same no matter what option box is used, the name can be pre-printed in the notice.
Step 2: In the next blank beginning: "ARE LETTING YOU KNOW THAT WE", the HHA inserts the appropriate phrase, depending on which option box is used (see b. immediately below).
Step 3: The HHA must describe on the blank lines immediately after: "WITH THE FOLLOWING ITEMS AND/OR SERVICES:" the item(s) and/or service(s) anticipated to be noncovered that are the reason for issuing the HHABN.

Regarding Step 3:

- The HHA should describe either the items or services that: (1) Medicare will no longer cover but may still be provided by the HHA (this applies only when Option Box 1 is used, see b. immediately below), (2) the applicable reduction in items or services, or (3) the termination of all Medicare-covered care.
- General descriptions of multi-faceted services or supplies are permitted. For example, "wound care supplies" would be a sufficient description of a group of items used to provide this care. An itemized list of each supply is not required.
- The HHABN should be used to describe reductions in either supplies or services.

This is even true for care, like wound care, where delivery of supplies and services is highly integrated. Thus, notice would still be required if frequency of services was reduced although level of supplies remained constant. The converse would also be true, i.e., services remain constant and the level of supplies is decreased.

- When a reduction occurs, enough additional information must be included so that the beneficiary understands the nature of the reduction. For example, entering "wound care supplies weekly (now to be provided monthly)" would be appropriate to describe a decrease in frequency for this category of supplies, whereas just writing "wound care supplies" would not be sufficient in this particular case.
- Changes in the modality or interventions that are part of a service like wound care are not considered reductions. Again, if the frequency of the service is reduced, an HHABN would be required. (See 60.3, D.4 above.)
- AN HHA may add date information in the blank where items and/or services are described on the HHABN to help a beneficiary better understand when noncoverage begins. Note however that policy on timely HHABN delivery remains the same: the HHABN has to be issued before the care in question is provided, so that the beneficiary can make an informed choice on accepting responsibility for payment when payment is at issue. The time frame for how far before giving the notice is flexible, though notification must occur with enough advance that the beneficiary has time to make an informed choice.

Step 4: After the word: "BECAUSE:____..." the HHA must describe why the item(s) and/or service(s) listed are expected not to be covered by Medicare, or will no longer be provided by the HHA.

Regarding Step 4:

- The reasons provided must be in plain language that allows the beneficiary to understand why the notice is being given and enables the beneficiary to make an informed choice about accepting financial liability (when applicable). The information must convey more than simply that care is "not reasonable or necessary." A large amount of text is not required, nor is a citation to an actual policy document.
- The level of detail in the reason given should at a minimum be similar to that found in a Medicare Summary Notice (MSN) message. For example, a Step 4 entry could be: "you are no longer homebound" or, even more consistent with the related MSN message: "you can now leave your home unaided." Both phrases are simply worded examples of concise yet complete explanations of a common yet specific reason why, according to Medicare policy, the home health benefit may not be covered for an improving individual. If needed, supplemental explanations should be provided verbally when delivering the notice.
- If multiple item(s) and/or service(s) are listed by the HHA in Step 3, and different reasons exist for including each item or service on the HHABN, the HHA is

responsible for providing sufficient information in Step 4 to allow the beneficiary to understand each reason specifically associated with each item or service listed.

Step 5: In the paragraph beginning: "IF YOU HAVE QUESTIONS . . .", the HHA must enter its own telephone number, and/or provide a TTY number, or directions for using another telecommunication system for speech or hearing impaired beneficiaries when appropriate.

b. Use of the Option Boxes

There are three choices of option box language, and each can be linked to specific statutory authority:

Authority Supporting HHABN Option Boxes

Application	HH Benefit	Outside HH Benefit*
§1879 Liability Notice given prior to care to alert the beneficiary of potential liability for Medicare	HHABN –	HHABN –
benefit	Option Box 1	Option Box 1
§1891 COP-Required Notice alerting beneficiaries to changes in care, specifically occurring because	HHABN –	None Required
the HHA will no longer provide services for their own business or financial reasons	Option Box 2	
§1891 COP-Required Notice alerting beneficiaries of changes in the POC based on physician orders	HHABN –	None Required
of changes in the FOC based on physician orders	Option Box 3	
Voluntary Notice alerting beneficiaries of potential financial liability for care that is not part of a defined Medicare benefit** or when not	Not Applicable	Voluntary use of HHABN -
otherwise required by LOL policy (i.e., formerly NEMB or NEMB-HHA was used)		Option Box 1

^{*} See 60.2 E. above for definition.

The appropriate option box is placed in the middle of the HHABN between the Body and Signature and Date sections. An overview of option box use is provided in the following chart based on context of use (rather than supporting authority).

^{**} See 60.2 E. and F.

General Summary of Option Box Use

Option Box	Possible Beneficiary Liability	Assessments without Admission	Home Health Benefit Use	Other Medicare Benefit Use*	Care Not a Medicare Benefit*	Contains Billing Information
1	Must use	Use if charging beneficiary	Yes	Yes	Voluntary use	Yes
2	Can't use	Voluntary use if not charging	Yes	No	No	No
3	Can't use	Can't use	Yes	No	No	No

^{*} See 60.2 E. and F.

Note with regard to triggering events and the option boxes:

- Only Option Box 1 HHABNs are given with generic expedited determination notices when potential liability for noncovered care exists after coverage.
- Multiple instances of a single triggering event may be described on a single HHABN, assuming that HHABN is appropriate to each event.

EXAMPLES:

- Two reductions happening simultaneously both due to changes in the physician order can both be described on a single Option Box 3 HHABN (i.e., goals being met for one discipline -- physical therapy -- and a reduction in skilled nursing care).
- Less common cases where multiple different triggering events occur simultaneously may require separate HHABNs, such as with an initiation of completely new noncovered care (and for which the beneficiary may be liable), and a reduction in ongoing covered care due to physician orders (with no liability). Option Box 1 must be used any time there is liability, Option Box 3 could be used for the reduction related to orders. If such events were combined on a single Option Box 1 HHABN, the HHA would still have to assure the beneficiary understood which event entailed potential liability (and which did not).

The following chart summarizes the circumstances in which each option box should be used.

Triggering Event	Option Box 1	Option Box 2	Option Box 3
INITIATIONS			
Initiations of Entirely Noncovered Treatment, Any Medicare Benefit, when §1879 LOL* Applies	Yes	No	No
One-time Noncovered Items/Services, Beneficiary Liable, Any Medicare Benefit, §1879 LOL* Applies	Yes	No	No
One-time Noncovered Items/Services, §1879 LOL* Does Not Apply and/or Not a Medicare Benefit	Voluntary	No	No
REDUCTIONS			
Any Reduction for HHA Reasons (Unrelated to Coverage)**, No Beneficiary Liability, HH Benefit	No	Yes	No
Any Reduction by Physician Order, No Beneficiary Liability, HH Benefit	No	No	Yes
Any Other Reductions, HH Benefit	Yes	No	No
Other Covered Care Reductions, Other Medicare Benefits, §1879 LOL* Applies	Yes	No	No
Any Other Reductions (Outside HH Benefit)***	Voluntary	No	No
TERMINATIONS			
Any Termination for HHA Reasons (Unrelated to Coverage)**, No Beneficiary Liability, HH Benefit	No	Yes	No
Covered Care Termination for Coverage Reasons (Including Physician Orders), HH Benefit	Yes***	No	No
Covered Care Termination for Coverage Reasons (Including	Yes****	No	No

Physician Orders), Any Medicare Benefit Subject to Expedited Determinations (i.e., therapy delivered by HHAs under a therapy plan of care)			
Any Other Terminations (services not subject to Expedited Determinations or §1879 LOL)	Not Required	No	No

^{*} See 60.2 H for definition.

Instructions specific to each option box follow.

i. Instructions for Option Box 1

Option Box 1 is used in any of the following situations (see the charts earlier in this section for guidance on when to use this option box for different triggering events.):

- A beneficiary faces potential liability/will be receiving noncovered care/will be charged.
- A beneficiary wants a claim filed for potentially noncovered care the HHA provides.
- The care at issue is outside the Medicare home health benefit.
- A beneficiary will be charged for an assessment although not admitted to care.
- Any circumstance that may arise for which neither Option Box 2 nor 3 is appropriate.

If Option Box 1 is being used, HHAs should insert the most appropriate of the following phrases in the Step 2 blank in the body of the HHABN:

- "will not provide you (if choosing Box 1 below)"
- "will no longer provide you (if choosing Box 1 below)"
- "believe Medicare will not provide you"
- "believe Medicare will no longer provide you"

The text insertion for Option Box 1 is in quotation marks below:

^{**} See 60.3 C for definition.

^{***} See 60.2 E for definition.

^{****} Expedited Determination Notice MUST be given, and HHABN is also needed **only** when noncovered care continues after coverage ends.

Option Box 1 Text

"The estimat	ted cost of the items and/or services listed above is \$
	. If you have other insurance, please see #3 below.
	ree options available to you. You must choose only one of these hecking the box next to the option and then signing below:
□ 1.	I don't want the items and/or services listed above. I understand that I won't be billed and that I have no appeal rights since I will not receive those items and/or services.
□ 2.	I want the items and/or services listed above, and I agree to pay myself since I don't want a claim submitted to Medicare or any other insurance I have. I understand that I have no appeal rights since a claim won't be submitted to Medicare.
□ 3.	I want the items and/or services listed above, and I agree to pay for the items and/or services myself if Medicare or my other insurance doesn't pay. Send the claim to:
	(Please check one or both boxes):
	□ Medicare
	□ My other insurance
will get a Mo payment dec your claim, y procedures i Medicare at: the full cost other insurar	If you select option 3 and a claim is submitted to Medicare, you edicare Summary Notice (MSN) showing Medicare's official sision. If the MSN indicates that Medicare won't pay all or part of you may appeal Medicare's decision by following the appeal in the MSN. If you don't receive an MSN for your claim, you can call a (
Health Agen	below, I understand that I received this notice because this Home acy believes Medicare will not pay for the items/services listed, and be option checked above."

Step 1: The HHA must provide an estimate of the total cost of the items and/or services listed in the first blank in this option box. Since one or multiple items and services could be at issue, the HHA must enter a total cost that reflects each item or service as clearly as possible, including information on the period of time involved when appropriate (i.e., not a one-time service). For example:

• "\$400 in total for 4 weekly nursing visits in 1/06"

• "\$210 in total for 3 physical therapy visits 1/3-17/06, \$50 for medical equipment" (Specific pieces of durable medical equipment [DME] should be identified as space allows.)

NOTE:

- The cost estimate is meant to give the beneficiary an idea of what costs would be if he/she paid out of pocket, not what the beneficiary may actually have to pay given other coverage. The fact that other insurance might pay appears next in the HHABN after the cost estimate; thus, HHAs will inform beneficiaries of cases where other insurance will cover costs.
- The HHA must provide a reasonably good faith estimate of the total cost sufficient to assist the beneficiary in making a decision to accept or decline potential financial responsibility.
- The estimated cost reported on the HHABN may be \$0 if, for example, an HHA chooses not to charge a beneficiary, or if bundled payments with no beneficiary liability are involved.
- Since it may not be possible for HHAs to project all possible costs for future periods into one blank, a proxy like average daily cost can be given. For example, if an average day involves a skilled nursing visit, an average visit charge or private fee charge master amount for this service could be used to give a daily cost, noting when possible the duration over which continuing care could be expected. The use of "posted charges" is also acceptable in making an estimate.
- If an HHA bills for the administration of drugs in cases where it believes that this service will not be covered, although it is usually Medicare covered, the HHA would have to give an HHABN for that specific service if the HHA planned to charge for it, but would not have to include the actual drug in estimated costs if supplied and billed by another entity (i.e., a pharmacy).
- The HHA must annotate the amount the beneficiary may have to pay if he/she later chooses to receive only certain items or services of those listed on the HHABN instead of everything originally listed.
- Abbreviations can be used due to the limited space available for cost estimates.
 Abbreviations generally should still be avoided, but are permitted in this space and overall are more acceptable if spelled out elsewhere on the notice (such as where the care at issue is described). If used, abbreviations would be part of what an HHA must cover verbally to assure the beneficiary comprehends the HHABN.

Step 2: (Check Boxes and the Related Insurance Blank): The two sets of check boxes--the first concerning the beneficiary's desire to get the items or services at issue and numbered 1-3, and the second under Check Box 3 indicating whether Medicare and/or another insurer, i.e., Medicaid for dual eligibles and Medigap insurance for those with such policies, should be billed--are NEVER completed in advance (see 60.6).

However, the HHA may fill in the blank naming the other insurance in advance when it is familiar with the coverage of a beneficiary, such as for an established patient. At a minimum, HHAs must identify all Federal government-funded insurance they are aware the beneficiary may have that could provide coverage.

Step 3: In the space provided in the "PLEASE NOTE:" section of Option Box 1, the HHA must provide the Medicare phone number and the TTY telephone. The phone number is 1-800-MEDICARE (or 1-800-633-4227), and the TTY number is: 1-877-486-2048. These numbers may be pre-printed when the HHA prepares the HHABN.

ii. Instructions for Option Box 2

Option Box 2 is used when an HHA decides to stop providing some or all care for its own financial and/or other reasons, regardless of Medicare policy or coverage. Examples of such reasons include: the lack of availability of staffing, closure of the HHA or safety concerns in a beneficiary home. (See the charts earlier in this section for guidance on when to use this option box for different triggering events.) Generally, this language can be used only when:

- There is no beneficiary liability.
- There is no further delivery of the care described in the body of the HHA (that is, a reduction or termination with no ensuing care of the type described, not a change from covered to noncovered care, such as when Medicare stops paying but care continues).
- There is no related claim (that is, there is no ensuing care described that could be billed later).

Option Box 2 could seem appropriate in similar cases when benefits other than home health are involved. However, notification is not required in these cases, and additionally, the wording of this option box references home care. Note that an HHA may issue HHABNs with Option Box 2 language voluntarily to provide notice that it will not charge nor admit a beneficiary after an assessment is done.

Steps for Completion. If Option Box 2 is used, HHAs should insert the following phrase in the Step 2 blank in the body of the HHABN:

"will no longer provide you"

The HHA would fill out the rest of the body of the HHABN as described above. Unlike for Option Box 1, however, there is no information to complete in Option Box 2 itself, as shown below:

"By signing below, I understand that I received this notice because this Home Health Agency decided to stop providing the items and/or services listed above. The Agency's decision doesn't change my Medicare coverage or other health insurance coverage. I can't appeal to Medicare since this Home Health Agency won't provide me with any more items and/or services; however, I can try to get the items and/or services from another Home Health Agency.

Please note that there are many different ways to find another Home Health Agency, including by contacting your doctor who originally ordered home care. You may then ask the new Home Health Agency to bill Medicare or your other insurance for items and/or services you receive from them."

iii. Instructions for Option Box 3

Option Box 3 is used when the HHA stops providing, or reduces the frequency of, certain items and/or services due to lack of a physician order, but other care continues. That is, this option box is only used with reductions. (See 60.3 regarding definition of triggering events, and clarification of the difference between a reduction and termination of all care; note the charts earlier in this section provide guidance on which option box to use with different triggering events.) Thus, Option Box 3 is appropriate when:

- There is no beneficiary liability.
- There is no further delivery of the care described in the body of the HHA (that is, the reduction entails no ensuing care of the type described, as opposed to a reduction in coverage where particular items/services change from Medicare covered to noncovered, and delivery of care continues thereafter).
- There is no related claim (there is no ensuing care described that could be billed later).

Option Box 3 could seem appropriate in cases when benefits other than home health are involved and affected by similar changes in physician orders. However, notification is not required in these cases, and additionally the wording of this option box references home care.

Steps for Completion. If Option Box 3 is used, HHAs should insert the following phrase in the Step 2 blank in the body of the HHABN:

"will no longer provide you"

The HHA would fill out the rest of the body of the HHABN as described above.

NOTE: An HHA may substitute the phrase "will reduce" or "will stop" for this language-- and delete the following word "WITH" from the notice-- if it believes this phrasing will lead to clearer communications with beneficiaries.

There is no information to complete in Option Box 3 itself, as shown below:

Option Box 3

"By signing below, I understand that I received this notice because my doctor has changed my orders and so my home health plan of care is changing. This home health agency has explained to me that they cannot provide home care without a doctor's order."

3. The Signature and Date Section

Once the beneficiary has reviewed and understands the information contained in the HHABN, the HHA must request that the beneficiary complete all four blanks in the boxed Signature and Date Section at the bottom of the HHABN. The four blanks are:

- Patient's Name: The beneficiary's full name should be inserted in the blank.
- Medicare # (HICN): The beneficiary's Medicare health insurance claim number should be inserted in the blank.
- **Signature:** The beneficiary must personally sign the HHABN.
- **Date:** The beneficiary must personally enter the date that the HHABN was completed.

NOTE: The HHA may complete the first two blanks to assist the beneficiary.

4. Other Considerations During Completion

- **a. Requests for Additional Information.** If while completing the HHABN the beneficiary requests additional information, the HHA must respond timely, accurately, and completely to the information request. See 60.6 for other requirements for effective delivery.
- **b. Refusal to Complete or Sign.** If the beneficiary refuses to choose an option, where applicable, and/or refuses to sign the HHABN, the HHA should annotate its copy of the HHABN, indicating the refusal to sign and individuals present. The HHA must still provide a copy of the annotated HHABN to the beneficiary. The HHA must keep the original version of the annotated HHABN.

Whether item(s) and/or service(s) will be provided or not when the beneficiary has refused to sign (or not expressly agreed to be responsible for payment) must be decided by the HHA. If under these circumstances the HHA decides to provide the care in question, the HHA should have a second person witness the provision of the HHABN and the beneficiary's refusal to sign/select an option by making an annotation on the HHABN indicating that he/she witnessed this event. The witness must then sign and date next to his/her annotation. Where there is only one person on site, the second witness may be contacted by telephone and may sign the HHABN annotation at a later time. The unused patient signature line on the HHABN may be used for such an annotation; writing in the margins of the notice also is permissible. An HHA is not obligated to provide

noncovered care when a beneficiary refuses to accept liability (See 40.3.4.6 in this chapter).

c. Beneficiary Changes His/Her Mind. If a beneficiary chooses a particular option and later changes his/her mind, where possible, the HHA should present the previously completed HHABN to the beneficiary and request that the beneficiary annotate the original HHABN to show and date the beneficiary's current choice. In those situations where the HHA is unable to present the HHABN to the beneficiary in person, the HHA may annotate the beneficiary's current intent on the notice and immediately forward a copy to the beneficiary. In either situation, a copy of the revised HHABN must be provided to the beneficiary within 30 calendar days.

NOTE: For requirements after completion, such as retention, see 60.8 below.

60.5 - Special Issues Associated with the HHABN

(Rev. 1025, Issued: 08-11-06; Effective/Implementation Dates: 09-01-06)

A. Option Selection for Dual Eligibles.

As discussed above, HHAs must use Option Box 1 whenever there is potential beneficiary financial liability. Some States have also established specific HHABN rules involving situations where "dual eligibles" (Medicaid recipients who are also Medicare beneficiaries) would face liability that would be covered by Medicaid. In those cases, such States insist that HHABNs be completed to select the third checkbox in Option Box 1 language (referred to here as "Option 3"), and subsequently that the choice to bill Medicare is also indicated. (Medicaid has the authority to make this assertion under Title XIX of the Act, where Medicaid is recognized as the "payer of last resort", meaning other Federal programs like Medicare (Title XVIII) must pay in accordance with their own policies before Medicaid picks up any remaining charges.)

Medicare HHAs serving dual eligibles need to comply with State policy on HHABNs when it exists. (In the absence of explicit guidance from a State, dual eligibiles may select whatever HHABN choice they want.) However, the State rules apply only when Medicaid will be billed. If Medicaid will not be billed (because the dual eligible makes a choice on the HHABN either not to receive any care at all, or to exercise the right to self-pay), the Medicaid requirement would not apply. (This is consistent with policy that the mandatory billing provisions of §1848(g) of the Act* do not apply when a beneficiary self-pays.)

Normally, an HHA may choose the method of billing it feels is most appropriate in association with a beneficiary's choices on a specific HHABN (though HHAs must always bill Medicare as directed by a beneficiary when he/she expresses a preference). The choices for billing related to HHABNs are: a "demand bill" if detailed review of the HHABN coverage assumption represented on the claim is sought, or a "no-payment bill" in cases where noncoverage is not in doubt and a denial is sought for reasons such as facilitating consideration by a subsequent payer (see Chapters 1 and 10 in this manual for billing information pertinent to HHAs). However, beyond which HHABN option to choose as discussed above, some States have also specified the type of Medicare billing

to be done related to the HHABN, requiring that a demand bill be filed instead of a no-payment claim. Note in such cases, if the HHABN and related demand bill do not appear to be consistent, specifically because the beneficiary has not selected Option 3 and did not specify that Medicare be billed, RHHIs will still process the associated claim, not acting to "return to provider" (RTP) as would be done with other potential administrative errors. (Note that if needed, the intermediary can confirm whether the beneficiary is dual eligible by reviewing the MDS/OASIS items that indicate payer source.)

[*Mandatory claim submission applies when Medicare payment may be sought, and it is a requirement for providers or suppliers in such cases to file claims for services that are or may be covered under Part B (i.e., care outside the home health benefit, see 60.2 E). This includes situations where the provider or supplier believes claims might be denied due to lack of medical necessity. Generally, the only exceptions to mandatory submission are: (1) when a physician or practitioner opts out of Medicare, (2) when a beneficiary does not authorize the physician or supplier to submit the claim (i.e., is receiving a service and accepting personal responsibility for payment), and (3) when a physician or supplier provides care for free. Medicare would not make a payment in any one of these situations. Note that when a State Medicaid program insists Medicare billing be done for dually eligible beneficiaries, the beneficiary still has the right to self-pay and demand no claim be filed. In such cases, neither Medicare nor Medicaid payment would be sought.]

B. Effect of Expedited Determinations

• If a decision is made on a beneficiary request for an expedited determination (see 60.3 C) or reconsideration that contradicts the expectation on coverage made on an HHABN, the HHABN becomes moot for any period of overlap. For example, if an expedited determination finds that 3 days of care listed on an HHABN as noncovered are covered, the HHABN is moot and the Medicare program, not the beneficiary, will pay for that care. In general, decisions made under expedited review are official Medicare determinations that supersede provider projections on coverage made on HHABNs. Specifically, if an HHABN anticipated that a beneficiary would be liable, but a later decision under the expedited process found the provider liable, the provider would be liable and the HHABN moot. HHAs should annotate HHABNs that have become moot in such cases, noting the subsequent expedited determination. Note that the processing of claims related to a decision made under the expedited determination process must conform to that official Medicare decision.

60.6 - Effective Delivery/Effective HHABNs

(Rev. 1025, Issued: 08-11-06; Effective/Implementation Dates: 09-01-06)

As discussed earlier in this chapter, HHABNs are required in specific circumstances (see 60.3 in particular). When an HHABN is required, the delivery of an HHABN must be effective, or notification may not be deemed valid for purposes of assigning liability to a beneficiary. In order for delivery of an HHABN to be considered effective:

■ The HHABN must be delivered to the beneficiary in person whenever possible. However, Medicare's notice policy allows for cases where this may not be possible. For example, notice may instead be given timely by telephone or email and followed up by mail. If e-mail is

used, statutory privacy requirements under the Health Insurance Portability and Accountability Act (HIPAA) are met (i.e., not transmitting any personal identifiers such as social security numbers or HICNs). Instructions on ABN telephone notice are found in this chapter, 40.3.4.2 (these general instructions are also applicable to HHABNs).

- When delivering HHABNs to beneficiaries, HHAs are required to explain the entire notice and its content, and answer all beneficiary questions orally to the best of their ability. HHAs must make every effort to ensure that beneficiaries understand the entire HHABN prior to signing it.
- The HHABN must be received by the beneficiary prior to the beneficiary receiving the item(s) and/or service(s) at issue. This should be far enough in advance to give the beneficiary time to make an informed choice, but not so far in advance as to cause confusion about what care is described by the HHABN.
- Some allowance is made for "immediate" delivery prior to furnishing the care at issue when unforeseen circumstances arise. This should be avoided whenever possible, but is permissible as long as the beneficiary still can make an informed choice.
 - The HHABN must convey the HHA's genuine doubt regarding the likelihood that Medicare may not pay for the listed item(s) and/or service(s), the reason(s) the HHA expects that Medicare may not pay for each listed item or service, the estimated cost for each item and/or service, and the beneficiary's options.
 - The HHABN must be signed by the beneficiary, unless an appropriate reason for the lack of signature is recorded on the HHABN, such as a properly annotated signature refusal.
- o If the beneficiary is physically unable to sign the HHABN, but is fully capable of understanding the notice, so that there is no need for an authorized representative, the beneficiary may allow the HHA to annotate the HHABN on his/her behalf regarding this circumstance. For example, a fully cognizant beneficiary with two broken hands may allow an HHA staff person to sign and date the notice in the presence of and under the direction of the beneficiary, inserting the beneficiary's name along with his/her own name, i.e., "John Smith, Shiny HHA, signing for Jane Doe." Such signatures should be witnessed by a second person whenever possible. Further, the medical record should support the beneficiary's inability to write in the applicable time period.
- In general, an HHABN remains effective for the predicted denial it communicates to the beneficiary as long as no other triggering event occurs (see 60.3 above on

triggering events and exceptions, see 60.5 B and 60.7 D for conditions where HHABNs become moot). HHABNs can at most describe care given over a single year. If a new triggering event does occur, or if care stretches into another year, then another HHABN must be given.

Upon appeal of a related claim, a previously furnished HHABN may serve as acceptable evidence of knowledge that care would not have been covered (i.e., the HHABN cited similar or reasonably comparable item(s) and/or service(s) for which a similar denial was expected). A denial of a claim for such care received not more than 1 year previously may also be acceptable evidence of knowledge a similar denial would be likely. Still, HHAs are advised to provide an HHABN every time it is required, and not rely on a retrospective interpretation of evidence to determine liability.

Regarding notice delivery in general, subcontractors may deliver HHABNs under the direction of a primary HHA. Note however that overall notification responsibility, including effective delivery, always rests with the primary HHA. If however a patient chooses to acquire care from another HHA following care delivered by a previous HHA, the previous HHA is never responsible for providing HHABNs for future triggering events that occur under the care of the "new" HHA. HHAs are always only responsible for providing HHABNs associated with the care that they themselves provide.

Further, if a vendor other than an HHA provides services to a beneficiary receiving home care, it is the vendor that is responsible for providing liability notification to the beneficiary, when required, for the care that vendor furnishes and bills. An example is when a supplier of DME directly supplies equipment to a beneficiary.

60.6.1 - Defective HHABNs

(Rev. 1025, Issued: 08-11-06; Effective/Implementation Dates: 09-01-06)

The following are examples of defective notice that may result in beneficiaries being protected from liability under §1879 of the Act. In such cases, HHAs cannot collect the cost of noncovered item(s) and/or service(s) from beneficiaries.

Failure to Use the Standard Notice. HHAs are strongly encouraged to use the OMB-approved HHABN notice format, consistent with these instructions. HHAs should not alter the standard notice in any way not expressly permitted in these instructions. Failure to use the approved HHABN greatly increases the possibility of an invalid notification.

Unintelligible Notice. Notice will be considered defective if the HHABN is unreadable, illegible, incomprehensible, or it can be demonstrated that the beneficiary did not understand the notice due to particular circumstances that were within the HHA's control, i.e., failure to use plain language.

Unable to Give Consent. Notice may be ruled defective if given when the beneficiary cannot give informed consent, such as during a medical emergency or health crisis, especially if the notice could have been delivered by the HHA at another point in time.

Coercion. Notice may be found defective if the HHA is judged to have forced the beneficiary to complete the HHABN in a certain way, such as by forcing the selection of a given checkbox option in Option Box 1, or if the HHA intentionally misled the beneficiary during completion of the notice.

Routine Notice. Notice may be found defective if the HHA routinely gives the HHABN for all items(s) and/or service(s) the HHA provides, disregarding whether or not the HHABN is required.

Last Minute or Untimely Notice. Last minute notification does not allow the beneficiary time to make an informed decision regarding his/her healthcare options. HHABNs given at the last minute may be found defective. HHABNs are also ineffective if given too far in advance of item(s) and/or service(s) at issue, or after the delivery of such care.

Notice Given More than 1 Year Prior. HHABNs are considered effective for no more than 1 year. HHABNs given for services for a period of over a year will be found defective for the period of time exceeding 1 year.

Generic HHABNs. Generic HHABNs that do not provide sufficient specificity in order for the beneficiary to make an informed decision regarding his/her healthcare are considered defective. For example, HHABNs that do no more than state that Medicare denial of payment is possible, that the HHA never knows whether Medicare will deny payment, or that the HHA never knows the policy of other applicable insurers will be deemed too generic in order to properly notify the beneficiary.

Blanket HHABNs. Blanket HHABNs are given to beneficiaries for all or too broad of a range of item(s) and/or service(s). Therefore, these notices are defective because they do not provide sufficient information for the beneficiary to make an informed decision regarding his/her healthcare options.

Signed Blank HHABNs. An HHA is prohibited from obtaining beneficiary signatures on blank HHABNs, i.e., HHABNs that contain no information regarding item(s) and/or service(s) and the reasons for issuing the notice. A beneficiary's signature must not be obtained until after the HHABN is delivered.

Advance Completion of Information Completed by the Beneficiary. An HHABN may be deemed invalid if an HHA checks off boxes in Option Box 1 before delivering the HHABN to the beneficiary.

Failure to Include Valid Information. An HHABN may be deemed invalid because the HHA fails to include key information in the HHABN. The inclusion of erroneous information will also be treated in the same manner. As examples, the failure to list significant item(s) and/or service(s) or the failure to provide an estimate of the total actual cost of each item or service may result in the HHABN being deemed defective.

NOTE: With regard to the estimated cost, an amount that is different from the final actual cost does not invalidate the HHABN, as long as the amounts

on the notice represent a good faith attempt to estimate costs for all the item(s) and/or service(s) for which the beneficiary may be liable.

Failure to Ensure Comprehension of the HHABN. An HHABN may be deemed defective if the HHA does not make best efforts and take appropriate steps to ensure that the beneficiary understands the information contained in the HHABN. It is not acceptable to hand the beneficiary the notice and have him/her sign it with no oral review of the notice. Failing to select a checkbox in Option Box 1 language, or selecting multiple checkboxes when a choice of one is indicated on the HHABN, will be seen as a lack of comprehension deeming the HHABN defective.

A. Special Exceptions to Defective Notice

Services Which Are Always Denied for Medical Necessity. In any case where a national Medicare coverage determination provides that a particular item or service is neither covered nor reasonable and necessary, an HHABN that gives as the reason for expecting denial that: "Medicare never pays for this item/service under written national policy" may be routinely given to beneficiaries, and no claim need be submitted to Medicare unless the beneficiary requests that a claim be submitted. This exception also applies codified local Medicare coverage policy.

Experimental Items and Services. Any item or service which Medicare considers to be experimental (e.g., "Research Use Only" and "Investigational Use Only" laboratory tests) is denied as not reasonable and necessary under §1862(a)(1) of the Act because Medicare has judged that it has not been proven to be safe and effective. The beneficiary may be given an HHABN that specifies as the reason for expecting denial as: "Medicare does not pay for services which it considers to be experimental/for research use." Alternatively, more specific language with respect to Medicare coverage for clinical trials may be substituted as necessary as the reason for expecting that Medicare will deny the claim.

Frequency Limited Items and Services. Some items or services furnished have established statutory or regulatory frequency limitations on Medicare coverage, or frequency limitations on coverage on the basis of a national coverage decision or on the basis of the contractor's local medical review policy. Since all or virtually all beneficiaries may be at risk of having their claims denied in those circumstances, the HHA may routinely give HHABNs to beneficiaries in such cases. In issuing the HHABN, the HHA must state the frequency limitation as the HHABN's reason for expecting denial (e.g., "Medicare does not usually pay for a flu shot more than once a year").

Repetitive or Extended Notices. A single HHABN covering an extended course of treatment is acceptable provided that the HHABN identifies every item and/or service for which the HHA believes Medicare will not pay. Item(s) and/or service(s) that are provided on a regularly scheduled basis may be considered an extended course of treatment; and a single HHABN may suffice as long as all other applicable notification requirements are fulfilled. If, however, as the extended course of treatment progresses, and additional items or services are to be furnished, which Medicare or other applicable

insurers will not cover, the HHA must separately notify the beneficiary by issuing another HHABN

60.7 - Collection of Funds and Liability Related to the HHABN

(Rev. 1025, Issued: 08-11-06; Effective/Implementation Dates: 09-01-06)

A. Collection of Funds and Beneficiary Liability

A beneficiary's agreement to be responsible for payment on an HHABN means that the beneficiary agrees to pay for expenses out-of-pocket or through any other insurance other than Medicare that the beneficiary may have. The HHA may bill and collect funds from the beneficiary for noncovered item(s) and/or service(s) at the time of delivery of such HHABNs, unless prohibited from collecting in advance of the Medicare payment determination by other applicable Medicare policy, State or local law. Note there is no general Medicare policy affecting timing of such collection by HHAs.

When delivery of an HHABN is effective and Medicare ultimately denies payment of the related claim, the HHA retains the funds collected from the beneficiary. However, if Medicare subsequently pays all or part of the claim for item(s) and/or service(s) previously paid for by the beneficiary to the HHA, the HHA must refund the beneficiary the proper amount. Medicare regulations require prompt payment of refunds to beneficiaries when Medicare provides payment.

When the beneficiary has insurance other than Medicare, and payment is subsequently received from that source, the HHA similarly should refund any previously collected amounts to the beneficiary consistent with the other insurer's payment. Note, however, that Medicare laws or regulations concerning the handling of incorrect collections do not provide for Medicare to ensure that prompt refunds occur when payment is made by another insurer or payer, referred to on the HHABN as "my other insurance." This is true even for the home health benefit and despite the incorporation of the home health COPs in HHABN requirements. Medicare would not have a claim to those monies or be able to act on behalf of the beneficiary in these cases, and Medicare may be unaware of such incorrect collections.

B. Financial Liability for Providers

HHAs may be held financially liable for the cost of item(s) and/or service(s) in situations where the HHA fails to issue an HHABN when required or issues a defective HHABN, since the beneficiary may be afforded liability protection under §1879 (see 60.2 H). When a beneficiary does have liability protection and proper notification has not occurred, HHAs are precluded from collecting funds from the beneficiary, and will be required to make prompt refunds to the beneficiary (if funds were previously collected), or face possible sanctions for failure to do so. HHAs will be held financially liable if unable to demonstrate that they did not know or could not reasonably have been expected to know either that Medicare would not make payment, or that the care in question was noncovered and liability protection applied.

C. Unbundling Prohibition and Shifting of Financial Liability

In issuing HHABNs, HHAs may not use these notices to shift financial liability to a beneficiary when full payment is made through bundled payments (see 60.2 G.); that is, where the beneficiary would otherwise not be financially liable for payment for the service because Medicare made full payment for a bundled group of items and/or services. Using HHABNs to collect from beneficiaries where full payment is made on a bundled basis would constitute double billing. An HHABN may be used, however, for any part of the cost of care that is specifically excluded from the Medicare bundled payment.

D. Effect of Initial Payment Determinations on Liability

An HHABN informs a beneficiary of his/her HHA's expectation with regard to Medicare coverage. If the care described on the HHABN is provided, Medicare makes an actual payment determination on the item(s) and/or service(s) at issue when adjudicating the related claim. Such adjudications may uphold the provider's expectation, in which case the beneficiary will remain liable for payment if agreeing to accept this liability based on a valid HHABN. However, adjudication may not conform to the provider's expectation, in which case the decision made on the claim supersedes the expectation given on the HHABN. That is, Medicare may cover and pay for care despite the HHA's expectation, or deny the claims and find the provider liable. In such cases, if the HHA collected funds from the beneficiary, the HHA must refund promptly the beneficiary for the appropriate amount.

60.8 - Revision, Re-issuance and Retention of HHABN

(Rev. 1025, Issued: 08-11-06; Effective/Implementation Dates: 09-01-06)

A. Requirements for Retention after Completion

The HHA keeps the original version of the completed HHABN, whether annotated or signed, in the beneficiary's record. The primary HHA must retain the HHABN if a subcontractor is used. The beneficiary receives a copy of the completed HHABN.

An HHABN, once signed by the beneficiary, may not be modified or revised. Annotations are only made as permitted under these instructions. When a beneficiary must be notified of new information beyond the scope of the original notice with or without annotations, a new HHABN must be given.

Applicable retention periods are discussed in Chapter 1 of this manual, §110. In general, this is 5 years from discharge when there are no other applicable requirements under State law. Retention is required even if the beneficiary refused to choose an option or sign the notice, and even when no care was ultimately provided to the beneficiary.

B. Beneficiary and Related Party Requests for Copy of the HHABN

HHAs are required to provide a copy of an HHABN not only to a beneficiary but also to the beneficiary's subrogees if a copy is requested during the applicable claim timely filing period. Timely filing periods are described in this manual, Chapter 1, §70. The most common example of a subrogee is a State acting on behalf of a beneficiary with dual Medicare and Medicaid eligibility.

C. Request for Copies by RHHIs/Approved Governmental Agents

HHAs are not required to routinely submit copies of HHABNs to their Medicare RHHIs. However, copies must be supplied upon the request of an RHHI, QIO or other approved CMS administrative agent, or directly to CMS Central or Regional Offices when specified. Such requests may be made in relation to medical review of a claim, statute requirement, court case or Federal oversight agency request (i.e., Office of Inspector General). Medicare or its agents may also request HHAs to report on their HHABNs separate from providing copies (such as counting the number of HHABNs provided in a year by type of checkbox or Option Box language, in order for Medicare to meet applicable reporting requirements under statute).

70 - Form CMS-10055 Skilled Nursing Facility Advance Beneficiary Notice (SNFABN)

(Rev. 1, 10-01-03)

A3-3730.1

Following are the standards for use by Skilled Nursing Facilities (SNFs) in implementing the Skilled Nursing Facility Advance Beneficiary Notice (SNFABN, model Form CMS-10055) notice of noncoverage requirements. This section provides instructions, consistent with the skilled nursing facility prospective payment process (SNF PPS), regarding the notice that SNFs must provide to beneficiaries in advance of furnishing what SNFs, utilization review (UR) entities, quality improvement organizations (QIOs), or Medicare contractors believe to be noncovered extended care services or items or of reducing or terminating ongoing covered extended care services or items. The SNFABN replaces the SNF Notices of Non-Coverage previously used for notification purposes. SNFs must also meet the ABN Standards in §40.3 of the MCPM in completing and delivering SNFABNs.

70.1 - Basic Requirements for SNFABNs

(Rev. 1, 10-01-03)

A SNFABN is a CMS-approved model written notice that the SNF gives to a Medicare beneficiary, or to her or his authorized representative, before extended care services or items are furnished, reduced, or terminated when the SNF, the UR entity, the QIO, or the Medicare contractor believes that Medicare will not pay for, or will not continue to pay for, extended care services that the SNF furnishes and that a physician ordered on the basis of one of the following statutory exclusions:

- Not reasonable and necessary ("medical necessity") for the diagnosis or treatment of illness, injury, or to improve the functioning of a malformed body member \$1862(a)(1); or
- Custodial care ("not a covered level of care") §1862(a)(9).

Except for the exclusions specified above, there is no other statutory authority on which the limitation on liability (LOL, §1879) provision applies to SNF claims denied.

NOTE: The terminology "Medicare will not pay" is used here and in the SNFABN because it is a concept understandable to beneficiaries. A Medicare official determination in favor of the beneficiary will not necessarily result in **additional** Medicare payments being made under the SNF PPS.

70.1.1 - Approved Model Form

(Rev. 1, 10-01-03)

The SNFABN (viz., CMS-approved model Form CMS-10055) is for use with SNF PPS services. This form satisfies the requirements under LOL for advance beneficiary notice and the beneficiary's agreement to pay. The use of any other notices or of modified SNFABNs may be ineffective in protecting users from liability. The SNFABN must be prepared with an original and at least one patient copy, a SNF copy containing the signature of the patient or authorized representative, an attending physician copy, and (when necessary) a Medicare contractor copy. SNFs may produce SNFABNs using self-carboning paper and other methods of producing copies, including photocopying, printing, and electronic generation, but they should conform to the Form CMS-10055 design.

70.1.2 - User-Customizable Section

(Rev. 1, 10-01-03)

Users (SNFs) are permitted to customize the header and the "Items or Services" and "Because" areas on the Form CMS-10055. The contractor will not invalidate a SNFABN solely on the basis that the SNF included in the header and in the two other customizable areas some item(s) of information (e.g., information about the SNFABN's implications for the beneficiary's other insurers) which is/are not explicitly required by these instructions. The SNFABN 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 header and the "Items or Services" and "Because" areas, to suit the user's particular needs. In any case, the SNFABN must be only one page in length and should be modified only in the specified user-customizable sections. The standard sections of the SNFABN (those sections which are not specified as user-customizable) should not be modified in any respect from the replicable PDF (abode acrobat) form. The use of improperly modified SNFABNs may be ineffective in protecting users from liability.

70.1.3 - Where to Obtain the SNFABN Form

(Rev. 1, 10-01-03)

The replicable copy of the Form CMS-10055 in PDF (Adobe Acrobat) format is available online at the CMS Beneficiary Notices Initiative (BNI) Web page at: http://www.cms.hhs.gov/medicare/bni/ under:

• Form CMS-10055 Skilled Nursing Facility Advance Beneficiary Notice (SNFABN).

70.2 - When and to Whom a SNFABN Should Be Given

(Rev. 1, 10-01-03)

70.2.1 - When and to Whom a SNFABN Should Be Given

(Rev. 1, 10-01-03)

Whether a SNFABN should be given in a particular instance depends on the SNF's expectation of Medicare payment or denial for extended care services that it furnishes.

- If the SNF expects Medicare to pay, a SNFABN should **not** be given.
- If the SNF "never knows whether or not Medicare will pay," a SNFABN should **not** be given.
- If the SNF expects Medicare to deny payment, the next question is: "On what basis is denial expected?"

70.2.2 - Situations in Which SNFABN Is Not Given

(Rev. 1, 10-01-03)

SNFs are not to give patients SNFABNs in situations where they are not appropriate.

70.2.2.1 - Categorical Exclusions

(Rev. 1, 10-01-03)

With the exception of the two qualifying categorical exclusions, viz., the "not reasonable or necessary" ("medical necessity") exclusion under §1862(a)(1) and the "custodial care" exclusion under §1862(a)(9), if the extended care service or item is not a Medicare benefit (e.g., personal comfort items excluded under §1862(a)(6)), a SNFABN should not be given. (See §90, "Form CMS-20007 NEMBs.")

70.2.2.2 - Technical Exclusions

(Rev. 1, 10-01-03)

With the exception of such qualifying technical exclusions as are provided under §§1861(i), 1861(s)(2)(D), 1861(w)(1), and 1888(e)(2)(A)(i); viz., an individual being furnished post-hospital extended care services while a resident in a skilled nursing facility, 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., SNF stay not preceded by the required prior three-day hospital stay), a SNFABN should not be given. (See §90, "Form CMS-20007 NEMBs.")

70.2.2.3 - Services Not Under SNF PPS

(Rev. 1, 10-01-03)

SNFABNs are for use with Part A covered extended care services provided in the SNF setting. If Medicare is expected to deny payment for Part B covered medical and other health services which the SNF furnishes, either directly or under arrangements with others, to an inpatient of the SNF, where 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), a SNFABN should not be given. For Part B services, a CMS-R-131 ABN may be used, if appropriate. (See §50.8.3, "Form CMS-R-131 ABNs.")

70.2.2.4 - When Extended Care Items or Services Will Not Be Furnished

(Rev. 1, 10-01-03)

The SNFABN is not to be given in circumstances in which the SNF will not furnish extended care items or services. (This rule is not applicable in the situation where the beneficiary elects to receive extended care items or services but refuses to sign the SNFABN attesting to being personally and fully responsible for payment, in which case, the SNF may then consider not furnishing the specified items or services (see §40.3.4.6).) A SNFABN is evidence of beneficiary knowledge about the likelihood of Medicare denial, for the purpose of determining financial liability for expenses incurred for extended care items or services furnished to a beneficiary and for which Medicare does not pay. Section 70.2.3 specifies that SNFABNs are to be given with respect to extended care items or services furnished to a beneficiary for which denial is expected. For a SNF to give a beneficiary a SNFABN and then refuse to furnish extended care items or services even though the beneficiary elects to receive these items or services by selecting Option 1, is tantamount to the prohibited practice (see §70.4.4.2) of the SNF pre-selecting Option 2 (not to receive items or services) on a SNFABN.

70.2.2.5 - M+C Enrollees and Non-Medicare Patients

(Rev. 1, 10-01-03)

The SNFABN is not to be used for Medicare M+C (Part C) enrollees nor for non-Medicare patients because it is to be used solely for individuals enrolled in the Medicare Fee-For-Service (FFS) program (Parts A and B).

70.2.3 - Situations in Which SNFABN Should Be Given

(Rev. 1, 10-01-03)

If Medicare is expected to deny payment (entirely or in part) on the basis of one of the exclusions listed in §70.1 for extended care items or services that the SNF furnishes to a beneficiary, a SNFABN should be given to the beneficiary.

70.2.3.1 - Triggering Events

(Rev. 1, 10-01-03)

SNFs are required to give a SNFABN to Medicare beneficiaries (including dual-eligibles) when the SNF, the UR entity, the QIO, or the Medicare contractor believes that Medicare will not continue to pay for some or all of the extended care items or services a physician has ordered for the beneficiary. Because of the belief that Medicare will not pay for the extended care items or services ordered by the physician, the SNF is either going to deny, reduce, or terminate the items or services to the beneficiary unless the beneficiary agrees to be personally and fully responsible for payment for such items or services. (Note: A SNFABN is not given when the SNF is unwilling to furnish extended care items or services even if the beneficiary is willing to agree to be personally and fully responsible for payment for such items or services (see §70.2.2.4).) The SNF must give the Medicare beneficiary a SNFABN before reducing or terminating extended care items or services that the beneficiary already is receiving, and that Medicare has been paying for, if the physician's order for such items or services would still continue care, but the SNF, the UR entity, the QIO, or the Medicare contractor expects payment for the extended care items or services will be denied by Medicare. A SNFABN is required when a SNF determines that Medicare is not likely to pay for otherwise covered extended care items or services that a physician has ordered. SNFs must give a SNFABN whenever a triggering event occurs. (A triggering event is defined as one of three changes to services: initiation, reduction, or termination.) The following circumstances constitute the three triggering events for a SNFABN:

A. Initiation of Services

In the situation in which a SNF advises a beneficiary that it will not accept the beneficiary as a Medicare patient because it expects that Medicare will not pay for the extended care items or services that a physician has ordered, the SNF must provide a SNFABN to the beneficiary before it furnishes extended care items or services to the beneficiary.

B. Reduction of Services

In the situation in which a SNF proposes to reduce a beneficiary's extended care items or services because it expects that Medicare will not pay for a subset of extended care items or services, or for any items or services at the current level and/or frequency of care that a physician has ordered, the SNF must provide a SNFABN to the beneficiary before it reduces items or services to the beneficiary.

C. Termination of Services

In the situation in which a SNF proposes to stop furnishing all extended care items or services to a beneficiary, because it expects that Medicare will not continue to pay for the items or services that a physician has ordered, the SNF must provide a SNFABN to the beneficiary before it terminates such extended care items or services.

70.2.3.2 - Dual-Eligibles

(Rev. 1, 10-01-03)

If the patient is a Medicare-Medicaid dual-eligible and a triggering event occurs, the SNF needs to give the patient (or authorized representative) a SNFABN.

70.2.3.3 - Medicare as Sole Payer

(Rev. 1, 10-01-03)

When the SNF predicts that Medicare will not pay for extended care items or services ordered by the physician and the physician continues the prescription for those items or services, this means the SNF will reduce or terminate extended care items or services to the beneficiary if Medicare were the sole payer for the items or services. On this basis, we characterize such situations as "triggering events," as described in §70.2.3.1. When, in describing "triggering events," we say "a SNF proposes to reduce a beneficiary's extended care items or services because it expects that Medicare will not pay" and "a SNF proposes to stop furnishing all extended care items or services to a beneficiary, because it expects that Medicare will not continue to pay," our premise is that Medicare is the sole payer for the items or services, and necessarily so since we are not promulgating instructions for other insurers. It is true that, on a practical basis, physicianprescribed items or services continue without interruption or reduction when a patient changes "payer eligibility" from Medicare to Medicaid. From the Medicare coverage vantage-point, however, there is a reduction or termination when Medicare, which has been paying, stops paying. In other words, there is a triggering event, which underlies the change in "payer eligibility."

70.2.4 - Routine SNFABN Prohibition

(Rev. 1, 10-01-03)

A SNF will not be held to have violated the prohibition on routine SNFABNs solely on the basis of the number of SNFABNs which the user gives to beneficiaries, when those SNFABNs are justified by the SNF having a genuine reason to give a SNFABN. (See §40.3.6, "Routine Notice Prohibition.")

70.2.5 - To Whom a SNFABN Should Be Given

(Rev. 1, 10-01-03)

A SNFABN may be given to a Medicare beneficiary or to the beneficiary's authorized representative (as defined in §40.3.5). Ultimately, if a situation arises in which a beneficiary simply cannot receive a SNFABN and this notice cannot be given to an authorized representative, the beneficiary is protected by not having received a SNFABN. A SNF's inability to give notice to a beneficiary directly or through an authorized representative does not allow the SNF to shift liability to the beneficiary.

NOTE: These SNFABNs do not apply to swing-bed determinations.

70.3 - Delivery of SNFABNs

(Rev. 1, 10-01-03)

70.3.1 - Delivery Must Meet Advance Beneficiary Notice Standards

(Rev. 1, 10-01-03)

A SNF (that is, a qualified notifier as defined in §40.3.2) shall notify a beneficiary by means of timely (as defined in §40.3.3) and effective (as defined in §40.3.4) delivery of a proper notice document (as defined in §40.3.1) to a qualified recipient, viz., to the individual beneficiary or to the beneficiary's authorized representative (as defined in §40.3.5). Delivery of a SNFABN occurs when the beneficiary or authorized representative both has received the notice and can comprehend its contents. All SNFABNs must include an explanation written in lay language of the SNF's, the UR entity's, the QIO's or the Medicare contractor's reason for believing the items or services will be denied payment. SNFABNs must meet the standards for approved model notice language in §40.3, "Advance Beneficiary Notice Standards."

70.3.2 - SNFABN Specific Delivery Issues

(Rev. 1, 10-01-03)

SNFs must provide SNFABNs in every case where a reduction or termination of items or services is to occur, or where items or services are to be denied before being initiated, if there is a physician's order for such care and the SNF, the UR entity, the QIO, or the Medicare contractor expects payment for the extended care items or services to be denied by Medicare. (For situations in which a physician concurs in the reduction, termination, or denial of items or services, see §70.6.6. For situations in which services are statutorily excluded, see §70.2.2). If the SNF, the UR entity, the QIO, or the Medicare contractor expects that Medicare will not pay for the care, the SNF must advise the beneficiary, orally and in writing, before the extended care item or service is initiated or continued that, in the SNF's opinion, the beneficiary will be fully and personally responsible for payment for the specified extended care item or service that it furnishes. The SNF must issue notices each time, and as soon as, the SNF, the UR entity, the QIO, or the Medicare contractor makes the assessment that it believes that Medicare payment will not be made. To be acceptable, a SNFABN (Form CMS-10055) must meet CMS' standards for cultural competency, must clearly identify the particular extended care item or service, must state that the SNF believes Medicare is likely (or certain) to deny payment for the

particular item or service, and must give the SNF's, the UR entity's, the QIO's or the Medicare contractor's reason(s) for its belief that Medicare is likely (or certain) to deny payment for the item or service. The SNF makes an original and two copies of the SNFABN (if the contractor requires a copy, one more copy will be made). The SNF gives the original to the beneficiary (or authorized representative); sends the first copy to the beneficiary's attending physician, and keeps the second copy. The Form CMS-10055 SNFABN is an approved model notice. The online Form CMS-10055 SNFABN should be as closely replicated as possible. Failure to provide a proper SNFABN in situations where a physician has ordered the extended care item or service may result in the SNF being held financially liable under the provisions of Limitation on Liability (LOL), where such provisions apply. (See §40.2.) SNFs may also be sanctioned for violating the conditions of participation (viz., 42 CFR 483.10) regarding resident (beneficiary) rights.

70.3.3 - Timely Delivery

(Rev. 1, 10-01-03)

The contractor will reject SNFABNs that are not given timely. The SNF must notify the beneficiary well enough in advance before terminating or reducing extended care items or services. "Well enough in advance" means the beneficiary has time to make other arrangements. If the SNF, the UR entity, the QIO, or the Medicare contractor denies services, the SNF must notify the beneficiary as required in §70.6.9.2. Last moment delivery of a SNFABN will be considered to be untimely, regardless of the SNF's intentions. Common sense must be applied to this criterion. If a beneficiary alleges she or he did not receive notice timely, the Medicare contractor will investigate the facts. If the SNF has clearly violated the timely delivery rule, the Medicare contractor will hold that the notice was not properly delivered in advance of terminating or reducing extended care items or services and that the beneficiary was not properly notified. The Medicare contractor will ask the SNF to justify any delays in notification.

70.3.4 - Actual Receipt of Notice Required

(Rev. 1, 10-01-03)

If the beneficiary is not capable of receiving the notice, then the beneficiary has not received proper notice and cannot be held financially liable where the LOL provisions apply and the SNF may be held financially liable. It is the SNF's responsibility to ensure that the beneficiary or the authorized representative actually receives a notice that they can comprehend. Failure to provide a comprehensible notice is also a violation of the conditions of participation and may result in enforcement action.

70.3.5 - Understandability and Comprehensibility of Notice

(Rev. 1, 10-01-03)

The beneficiary or authorized representative must be able to understand and comprehend the SNFABN for it to be an effective notice. In general, SNFs should not use abbreviations, diagnosis codes, HCPCS, or similar technical or otherwise unfamiliar language when completing an SNFABN's "Items or Services" and "Because" customizable areas because the beneficiary is likely not to understand them. Of course, abbreviations, codes, etc., accompanying the spelled-out information are not per se confusing and will not invalidate a SNFABN. The SNF is responsible for ensuring that the SNFABN is completed in a manner such that the beneficiary can read and understand it. A SNFABN that the beneficiary cannot understand is defective and will not protect the SNF from financial liability.

70.4 - Form Instructions for the SNFABN (Form CMS-10055)

(Rev. 1, 10-01-03)

70.4.1 - General Rules

(Rev. 1, 10-01-03)

The SNFABN (i.e., model Form CMS-10055) is not a replacement for, but is in addition to, the required UR entity notices. The SNFABN protects the SNF from liability in the event the patient, for some reason, does not receive the UR entity notice.

70.4.1.1 - Delivery of SNFABN When Based on Statutory Exclusion

(Rev. 1, 10-01-03)

The SNF is to prepare and deliver to the patient (Medicare beneficiary) or the patient's authorized representative a SNFABN when it, the UR entity, the QIO, or the Medicare contractor expects Medicare probably will not pay for or will not continue to pay for extended care items or services on the basis of one of the statutory exclusions listed in §70.1.

70.4.1.2 - Guidelines for Replicating the SNFABN Form

(Rev. 1, 10-01-03)

Use of the SNFABN is for model language purposes only and should be replicated as closely as possible. The SNF must ensure that the readability of the SNFABN facilitates beneficiary or authorized representative understanding. No insertions into the blank lines and the two customizable sections of the SNFABN, if typed or printed, should be in italics or be in any font that is difficult to read. If insertions are handwritten, they must be legible. 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. In all cases, both the originals and copies of the SNFABN must be legible and of high-contrast. The form must be clear and obvious to the beneficiary that the SNFABN is issued by the SNF rather than by the Medicare program. The Medicare contractor will reject any SNFABN that does not meet these standards.

70.4.1.3 - Modification of the SNFABN Form

(Rev. 1, 10-01-03)

A SNFABN may not be modified except for the header and the two customizable areas; i.e., the "Items or Services" and "Because" sections of the model Form CMS-10055.

70.4.2 - Header of SNFABN

(Rev. 1, 10-01-03)

70.4.2.1 - Customization of CMS-10055 SNFABN Header

(Rev. 1, 10-01-03)

The header of the SNFABN, located above the title "Skilled Nursing Facility Advance Beneficiary Notice (SNFABN)," is a customizable section of the model Form CMS-10055, which the SNF may customize for its own use, consistent with the requirements of \$70.4.2.2.

70.4.2.2 - Guidelines for Customizing the SNFABN Header

(Rev. 1, 10-01-03)

The SNFABN's header should have the identifying information it requires as a billing entity. The SNF also must include at the top of the SNFABN's header its name, address, and telephone and TTY/TDD telephone numbers or directions for using its other telecommunication system for individuals with impaired speech or hearing. The SNF may elect to include its logo (if any). It is only within these general rules that the SNF can customize the header of the SNFABN.

70.4.3 - Body of SNFABN

(Rev. 1, 10-01-03)

70.4.3.1 - Entering the Required Date(s) on the CMS-10055 SNFABN

(Rev. 1, 10-01-03)

On the "Date of Notice" line of the SNFABN, the SNF must enter the delivery date, i.e., the date on which the SNF gave the notice personally to the patient or to the patient's authorized representative. Where personal delivery is not possible, the SNF is to include both the date it notified the patient or her or his authorized representative by telephone and the date it mailed the SNFABN.

70.4.3.2 - Specifications Required for the "Items or Services" Section of the SNFABN

(Rev. 1, 10-01-03)

In the "Items or Services" section of the SNFABN, the SNF must specify the extended care items or services for which Medicare is expected not to pay (see §70.4.2). The specification must be in sufficient detail so that the patient understands precisely what extended care items or services may not be furnished and include any pertinent dates, e.g., "furnished on or after [date]". It is essential that the effective date(s) be included in the specification of services. The phrase "Items or Services" must also be included in this section. The SNF may customize (see §70.1.2) this section for its own use.

70.4.3.3 - Specifications Required for the "Because" Section of the SNFABN

(Rev. 1, 10-01-03)

In the "Because" section of the model SNFABN form, the SNF must give the specific reason(s) why it, the UR entity, the QIO, or the Medicare contractor expects Medicare to deny payment (see §70.4.2). The reason(s) cited must be in understandable lay language and must be sufficiently specific to allow the patient to understand the basis for the SNF's, the UR entity's, the QIO's, or the Medicare contractor's expectation that Medicare will deny payment. If necessary, the SNF is to gather evidence to the contrary from the physician and/or others in support of the coverage of such services (e.g., "our clinical assessment of your (the patient's) condition indicates that you can benefit from physical therapy services twice weekly, but that daily physical therapy services would not be beneficial"). The word "Because" must be included in this section. The SNF may customize (see §70.1.2) this section for its own use.

70.4.3.4 - Answering Inquiries About the SNFABN Notification

(Rev. 1, 10-01-03)

In the first bullet of the SNFABN that begins, "Ask us to explain ...," the SNF is required to answer inquiries from a patient or the patient's authorized representative who requests further information and/or assistance in understanding and responding to the SNFABN, including the basis for the SNF's, the UR entity's, the QIO's, or the Medicare contractor's assessment that extended care items or services may not be covered. The SNF's refusal to respond to such inquiries may result in the SNFABN being invalidated and, thus, ineffective in protecting the SNF from liability.

70.4.3.5 - Providing Cost Estimation(s) for Items or Services on the SNFABN

(Rev. 1, 10-01-03)

On the first line of the second bullet of the SNFABN that reads, "Estimated Cost: \$," the SNF may provide the patient with an estimated cost of the extended care items or services at issue. The patient may ask about the cost of the items or services and jot down an amount on this line. The SNF should respond to inquiries regarding the

estimated cost to the best of its ability. The lack of an amount on this line, or an amount which is different from the final actual cost, does not invalidate the SNFABN; a SNFABN is not considered to be defective on that basis, unless otherwise specified in instructions to specific categories of users. In the case of a SNFABN that includes multiple extended care items or services, it is permissible for the SNF to give estimated amounts for the individual items or services rather than an aggregate estimate of costs. Amounts may be provided either with the description of extended care items and services (i.e., in the "Items or Services" section) or on the "Estimated Cost" line.

70.4.3.6 - Providing Non-Medicare Insurance Information on the SNFABN

(Rev. 1, 10-01-03)

The second line of the second bullet of the SNFABN that reads, "Your other insurance is:" is provided for a user, that is required by other instructions, to enter the name of the patient's other insurance (e.g., Medicaid, Medigap, employee plan, etc.). Any user, not otherwise required to do so, may enter this information at its own discretion.

70.4.3.7 - Providing Contractor Information on the SNFABN

(Rev. 1, 10-01-03)

In the third bullet of the SNFABN that begins, "If in 90 days you have not gotten ..." the SNF is required to enter (on each of the lines so designated) the name, address, and telephone and TTY/TDD telephone numbers of the contractor to which the associated Medicare claim will be submitted. The information specified on these individual lines permits the patient or the patient's authorized representative to write or telephone the contractor directly should a determination on the associated Medicare claim not be received within 90 days.

70.4.3.8 - Required Guidelines in Preparation for Submitting Medicare Claims

(Rev. 1, 10-01-03)

In the fourth bullet of the SNFABN that begins, "If you receive ...," the SNF is required to submit to Medicare a claim for any and all extended care items or services furnished, except those that may be explicitly specified in other instructions. If, in compliance with other instructions, the SNF does not submit a claim to Medicare, the SNF is to delete or mark out the fourth bullet before delivering the SNFABN to the patient or the patient's authorized representative. In the instance where the patient or authorized representative requests submission of a claim for furnished extended care items or services not explicitly specified in instructions, the SNF is required to notify the patient or authorized representative when that claim has been submitted to the Medicare contractor. The SNF is prohibited from billing the patient or authorized representative for any items or

services at issue until the contractor has determined coverage on the associated Medicare claim

70.4.3.9 - Providing Appropriate Recipient Name on the SNFABN

(Rev. 1, 10-01-03)

On the "Patient's Name:" line of the SNFABN, the SNF is to enter the name of the patient, not substituting the name of the authorized representative.

70.4.3.10 - Providing the Medicare Health Insurance Claim Number on the SNFABN

(Rev. 1, 10-01-03)

On the "Medicare # (HICN):" line of the SNFABN, the SNF is to enter the patient's Medicare Health Insurance Claim Number (HICN). A SNFABN is not invalidated solely for the lack of a Medicare HICN unless the recipient of the SNFABN alleges that someone else of the same name signed the SNFABN and the Medicare contractor cannot resolve the matter with certainty.

70.4.3.11 - Providing Date of Signature on the SNFABN

(Rev. 1, 10-01-03)

On the "Date" line of the SNFABN, the patient, or the patient's authorized representative should enter the date on which she or he signed the SNFABN. If the SNF writes in the date and the beneficiary or authorized representative does not dispute the date, that date is acceptable. A SNFABN is not invalidated simply because the date is typed or printed.

70.4.4 - Option Boxes

(Rev. 1, 10-01-03)

70.4.4.1 - Selecting an Option on the SNFABN

(Rev. 1, 10-01-03)

For Options 1 and 2 on the SNFABN, the patient or authorized representative is to personally select an option by making a mark in the chosen checkbox 1 or 2. SNFABNs with both checkboxes marked are unacceptable and will not protect the SNF from liability. If the patient or authorized representative marks the wrong checkbox accidentally or because either one has changed her or his mind, she or he should mark the correct checkbox and should cross out the erroneously marked checkbox and write her or his initials next to it. A new SNFABN is not required unless the patient or authorized representative changes her or his mind a second time.

70.4.4.2 - Prohibition of Pre-Selection of an Option on the SNFABN

(Rev. 1, 10-01-03)

Any SNFABN on which the SNF pre-selects an option will not be acceptable as evidence of beneficiary notice. Pre-selecting options is prohibited and will invalidate the SNFABN

70.4.4.3 - Effect of Beneficiary's Option Selection

(Rev. 1, 10-01-03)

The patient or the authorized representative must select one option.

- If the patient selects Option 1, the patient may receive the subject extended care items or services, for which a demand bill must be submitted to Medicare for an official determination.
- If the patient selects Option 2 the patient has elected not to receive the subject extended care items or services.

70.4.5 - Proper Denial Paragraphs

(Rev. 1, 10-01-03)

The denial paragraphs (found below under Condition) cover common reason(s) why the extended care items or services are noncovered under Medicare. The SNF may use these denial paragraphs as inserts in the "Because" and "Items or Services" sections of the SNFABN (see §§70.4.3.2 and 70.4.3.3). Where no paragraph exists to explain the reason(s) why the extended care items or services are believed to be noncovered, the SNF is to develop new, or modify current, language to fit the situation. The SNF is to forward the newly prepared language to the Medicare contractor associated with processing its Medicare claims. The associated Medicare contractor will submit the SNF's language to CMS for review and, as appropriate, for inclusion in the MCPM.

NOTE: If applicable, the SNF is to substitute therapy and type of therapist for skilled nursing and skilled nurse. If applicable, the SNF is to substitute URC for "we" (e.g., "we or URC believe that the services you (the patient) received are noncovered."). If applicable, the SNF is to adjust the verb reflections or tense for those paragraphs containing admission denial information.

Condition: Nonskilled care - full denial

Denial Paragraph: Medicare covers medically necessary skilled nursing care needed on a daily basis. You only needed oral medications, assistance with your daily activities and general supportive services. There is no evidence of medical complications or other medical reasons that required the skills of a professional nurse or therapist to safely and effectively carry out your plan of care. Therefore, we believe that your care cannot be covered under Medicare.

Condition: Specific nonskilled service provided - no skilled care (full denial)

Denial Paragraph: Medicare covers medically necessary skilled care needed on a daily basis. You only needed (specify service). This does not require the skills of a licensed nurse to perform the service or to manage your care. Since you needed neither skilled nursing nor skilled rehabilitation on a daily basis, we believe your stay is not covered under Medicare.

Condition: Specify nonskilled service provided - (partial denial)

Denial Paragraph: Medicare covers medically necessary skilled care needed on a daily basis. You only needed (specify service) after (date). Since you no longer required skilled nursing and did not need skilled rehabilitation on a daily basis, we believe your stay beginning (date) is not covered under Medicare.

Condition: Observation and management of care plan - no significant change

Denial Paragraph: Medicare covers medically necessary skilled care needed on a daily basis. You needed skilled nursing care beginning (date) to observe and evaluate your condition. There is no indication of further likelihood of significant changes in your care plan or of acute changes or complication in your condition. Since you no longer need skilled nursing or skilled rehabilitation services on a daily basis, we believe you stay after (date) is not covered under Medicare.

Condition: Observation and management of care plan - condition improved

Denial Paragraph: Medicare covers medically necessary skilled care needed on a daily basis. Because of your condition, you needed a skilled nurse from (date) through (date) to evaluate and manage your care plan. Your condition has improved so the services you need can safely and effectively be given by nonskilled persons. Since you no longer require skilled nursing and did not need skilled rehabilitation on a daily basis, we believe your stay is not covered under Medicare after (date).

Condition: Teaching and training activities - partial denial

Denial Paragraph: Medicare covers medically necessary skilled nursing or rehabilitation services you need including teaching and training activities for a reasonable time where progressive learning is demonstrated. You had learned to perform the tasks ordered by your physician by (date) but the therapist continued services. Since you did not need skilled services after that date, we believe your stay is not covered under Medicare beginning (date).

Condition: Teaching and training activities - no skilled service

Denial Paragraph: Medicare covers medically necessary skilled nursing or rehabilitation services you need including teaching and training activities for a reasonable time where progressive learning is demonstrated. You needed only to be reminded to follow the physician's instructions. This does not require the skills of a professional nurse or therapist. Therefore, we believe that this service is not covered under Medicare.

Condition: Teaching and training activities - little or no progress

Denial Paragraph: Medicare covers medically necessary skilled nursing or rehabilitation services you need including teaching and training activities for a reasonable time where progressive learning is demonstrated. You received teaching and training for a reasonable time but demonstrated you were not able, at this time, to learn or make progress to perform the activities ordered by your physician. Therefore, we believe that skilled services are not covered under Medicare after (date).

Condition: Nursing not needed for foley care

Denial Paragraph: Medicare covers daily skilled nursing care related to the insertion, sterile irrigation and replacement of urethral catheter if the use of the catheter is reasonable and necessary for the active treatment of a disease of the urinary tract or for patients with special medical needs. Skilled nursing is not considered medically necessary when urethral catheters are used only for mere convenience or the control of incontinence. Since your catheter was inserted for convenience or the control or your incontinence, we believe that your care is not covered under Medicare.

Condition: Repetitive exercises - partial denial

Denial Paragraph: Medicare covers medically necessary skilled rehabilitation services. The medical information shows that the only therapy services you needed beginning (date) were repetitive exercises and help with walking. These do not generally require the skills or the supervision of a qualified therapist. There was no evidence of medical complications which would have required that services be performed by a qualified therapist. We believe therapy services are not covered under Medicare after (date).

Condition: Therapy services for overall fitness and well-being. (Skilled therapy is physical therapy, occupational therapy, and/or speech-language pathology.)

Denial Paragraph: Medicare covers medically necessary skilled rehabilitative services when needed on a daily basis. The therapy services you received were for your overall fitness and general well-being. They did not require the skills of a qualified (specify) therapist to perform and/or to supervise the services. Since you did not need skilled nursing or skilled rehabilitation services, we believe your stay is not covered under Medicare

Condition: Therapy to maintain function after a maintenance program has been established

Denial Paragraph: Medicare covers medically necessary skilled rehabilitation services to establish a safe and effective program to maintain your functional abilities. This program was established and beginning (date), the (specify) therapy services you received were to carry out this program. These services do not require the supervision or skills of a (specify) therapist and, therefore, we believe that the services are not/would not be covered under Medicare.

Condition: Specific skilled service is not reasonable and necessary (service not specific or effective)

Denial Paragraph: Medicare covers medically necessary skilled care when needed on a daily basis. The (specify service(s)) you received is/are considered a skilled service by Medicare. However, based on the medical information provided, this/these service(s) is/are not considered a specific and/or effective treatment for your condition. Since the service(s) you received was/were not reasonable or necessary for the treatment of your condition, we believe your stay is not covered under Medicare.

Condition: No material improvement in relation to therapy services required - full denial

Denial Paragraph: Medicare covers medically necessary skilled rehabilitation services when needed on a daily basis. The (specify) therapy services provided was/were not reasonable in relation to the expected improvements in your condition. In this case, since you do not need skilled nursing on a daily basis and the therapy services are not considered reasonable and necessary, we believe your stay is not covered under Medicare.

Condition: No material improvement in relation to therapy services required - partial denial

Denial Paragraph: Medicare covers medically necessary skilled rehabilitation services when needed on a daily basis. While you required skilled (specify) therapy from (date) to (date), the medical information shows that the (specify) therapy services after that time is not reasonable in relation to the expected improvements in your condition. In this case, since you do not need skilled nursing on a daily basis and the therapy services are not considered reasonable and necessary, we believe your stay after (date) is not covered under Medicare.

Condition: Frequency not reasonable and necessary

Denial Paragraph: Medicare covers medically necessary skilled care when needed on a daily basis. Although (specify service) generally requires the skills of a (nurse, physical therapist, speech-language pathologist, occupational therapist), the frequency with which the service is given must be in accordance with accepted standards of medical practice. The service(s) you received is/are not normally needed on a daily basis. The medical information does not show medical complications which require the services to be performed on a daily basis. In this case, the services are not considered reasonable and necessary. Since you did not need skilled nursing or skilled rehabilitation on a daily basis, we believe your stay is not covered under Medicare.

Condition: Skilled rehabilitation services not received daily - no skilled nursing

Denial Paragraph: Medicare covers medically necessary skilled rehabilitation services when needed on a daily basis. Although you required skilled (specify) therapy, you did not receive therapy on each day that it was available in the facility. Therefore, you do not

meet the requirement for daily skilled rehabilitation services. Since you also did not need daily skilled nursing, we believe that your stay is not covered under Medicare.

Condition: Skilled nursing services not daily

Denial Paragraph: Medicare covers medically necessary skilled care needed on a daily basis. Although you required skilled nursing services, you do/did not need them on a daily basis. Because you do/did not need daily skilled nursing or skilled rehabilitation, we believe Medicare will not cover your stay.

70.5 - Signature Requirements for SNFABN

(Rev. 1, 10-01-03)

- On the "Signature of patient ..." line of the SNFABN, the patient, or authorized representative, should sign her or his name.
- The patient may sign a SNFABN. In the case of a beneficiary who is incapable or incompetent, her or his authorized representative, as defined in §40.3.5, may sign a SNFABN.
- If the patient's (or authorized representative's) signature is absent from a SNFABN, in case of a dispute as to the patient's (or authorized representative's) receipt of the SNFABN, the Medicare contractor will give credence to the patient's (or authorized representative's) allegations regarding the SNFABN. However, if the patient (or the authorized representative) refuses to sign the SNFABN but demands extended care items or services, the guidance in §40.3.4.6 should be followed
- The SNF must obtain the signed (containing the signature of the patient or authorized representative) and dated SNFABN with Option 1 or 2 selected as to the action the beneficiary wants to take, from the beneficiary, either in person or, where this is not possible, via return mail from the beneficiary or authorized representative as soon as possible after the SNFABN has been signed and dated. The beneficiary retains the patient's copy of the signed and dated SNFABN and returns the original. The SNF annotates the original of the SNFABN with the date of receipt from the beneficiary. The SNF is to return within 30 calendar days a copy of the SNFABN, including the date of its receipt, to the beneficiary for her or his records. The SNF retains the original SNFABN. These copies will be relevant in the case of any future appeal. Where the SNFABN is signed and dated in the presence of the SNF's staff or employee, the annotation of the date of the SNF's receipt of the signed and dated SNFABN may be made directly on both the original and patient's copy, and a second patient copy of the annotated original is not required.
- If a patient who chose "Option 2 No." later requests that a claim be submitted to Medicare, consistent with Option 1, the SNF should annotate its copy of the

SNFABN with the date of its receipt of the new request and return a copy of the annotated SNFABN within 30 calendar days to the patient for her or his records.

If the patient, or the authorized representative, refuses to sign the SNFABN and/or refuses to choose any option, the SNF should annotate its copy of the SNFABN, indicating the circumstances and persons involved. If this occurs, the SNF must decide whether or not to furnish the items or services to the patient in light of the fact that the patient has not agreed to be fully and personally responsible for payment for extended care items or services that are not covered by Medicare. If, under these circumstances (i.e., the patient refuses to pay but demands the items or services) the SNF decides to provide the extended care items or services, it should have a second person witness the provision of the SNFABN and the patient's refusal to sign. They should both sign an annotation on the SNFABN attesting to having witnessed said provision and refusal. Where there is only one person on site, the second witness may be contacted by telephone to witness the patient's refusal to sign the SNFABN by telephone and may sign the SNFABN annotation at a later time. The unused patient signature line on the SNFABN form may be used for such an annotation; writing in the margins of the form is also permissible. (See §40.3.4.6.A.)

70.6 - Special Rules for SNFABNs

(Rev. 1, 10-01-03)

70.6.1 - Effect of Furnishing SNFABNs and Collection From Beneficiary

(Rev. 1, 10-01-03)

70.6.1.1 - Effective Notice

(Rev. 1, 10-01-03)

When SNFABNs are properly used by a SNF, the SNFABNs will protect the SNF from financial liability under §1879(a)(1) of the Act, which limits beneficiaries' financial liability. A beneficiary who has been given a proper written SNFABN, before an extended care item or service is furnished, reduced, or terminated, giving notice of the likelihood (or certainty) that Medicare will not pay for the specific item or service and the reason therefore and who, after being so informed, has agreed to pay the SNF for the extended care item or service, will be held financially liable. That is, that beneficiary will be found to have known in advance that Medicare will not pay, and the SNF will be free to bill and collect the related charges from the beneficiary.

70.6.1.2 - Defective Notice

(Rev. 1, 10-01-03)

Failure to meet the SNFABN standards and procedures will expose a SNF to the risk of potential financial liability for denied extended care items or services in cases where, in

the absence of a proper SNFABN, the beneficiary would be held not to have known, nor to reasonably have been expected to have known, that her or his claims for the denied items or services he or she received, were likely to be denied by Medicare. Furthermore, any SNF held financially liable for failing to provide a SNFABN, failure to provide a SNFABN in a timely manner, or providing a defective SNFABN to a beneficiary will be precluded from collecting from the beneficiary and third-party payers which includes Medicaid. If a SNF is suspected of furnishing SNFABNs with the intent to induce or coerce referrals for other extended care items or services paid for by Medicare whereby anti-kickback statutes could be implicated, or if a SNF is suspected of issuing SNFABNs for any fraudulent, abusive, or otherwise illegal purposes, the Medicare contractor will refer the matter to the CMS regional office. A SNF that supplies a defective SNFABN (e.g., one which does not meet the standards in §40.3) will not be protected from financial liability. A beneficiary who received a defective SNFABN should be held not financially liable and the SNF that gave the defective SNFABN should be held financially liable.

70.6.1.3 - Collection From Beneficiary

(Rev. 1, 10-01-03)

When a SNFABN is properly executed and given timely to a beneficiary and Medicare denies payment on the related claim, the SNF must wait for the beneficiary to receive a denial Medicare payment determination before it can collect payment on the related claim. Medicare does not limit the amount that the SNF may collect from the beneficiary in such a situation. 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, through Medicaid, or through other Federal or non-Federal payment source.

70.6.1.4 - Unbundling Prohibition

(Rev. 1, 10-01-03)

The SNFABNs may not be used to shift financial liability to a beneficiary in the case of services for which full payment is bundled into other payments; that is, where the beneficiary would otherwise not be financially liable for payment for an extended care item or service because Medicare made a bundled payment. Using a SNFABN to collect from a beneficiary where full payment is made on a bundled basis would constitute double billing. A SNFABN may be used to shift financial liability to a beneficiary in the case of extended care items or services 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.

70.6.2 - Reissuance of the SNFABN

(Rev. 1, 10-01-03)

A SNFABN, model Form CMS-10055, remains effective for the predicted denial it communicates to the beneficiary, without periodic reissuance, for an indefinite period as long as no triggering event occurs. If a triggering event does occur, then another SNFABN must be given immediately. A single SNFABN covering an extended course of treatment is acceptable provided the SNFABN identifies all extended care items and services for which the SNF, the UR entity, the QIO, or the Medicare contractor believes Medicare will not pay. If, as the extended course of treatment progresses, additional extended care items or services are to be furnished for which the SNF, the UR entity, the QIO, or the Medicare contractor believes Medicare will not pay, the SNF must separately notify the patient in writing (i.e., give the beneficiary another SNFABN) that Medicare is not likely to pay for the additional extended care items or services and obtain the beneficiary's signature on the SNFABN. One year is the limit for use of a single SNFABN for an extended course of treatment; if the course of treatment extends beyond one year, a new SNFABN is required for the remainder of the course of treatment. A SNFABN, once signed by the beneficiary, may not be modified or revised. When a beneficiary must be notified of new information, a new SNFABN must be given. The beneficiary may request a demand bill at any point in her or his care.

70.6.3 - Acceptance or Rejection of SNFABN

(Rev. 1, 10-01-03)

These instructions are to assist the Medicare contractor in advising SNFs with respect to their responsibilities in advising beneficiaries with respect to their rights and protections and in dealing with complaints from beneficiaries, or authorized representatives, about the lack of notice or defective notice. The SNF must timely answer inquiries from a beneficiary, or authorized representative, who requests further information and/or assistance in understanding and responding to the notice. The SNF must answer inquiries from a beneficiary, or authorized representative, regarding the basis for the SNF's, the UR entity's, the QIO's, or the Medicare contractor's assessment that extended care items or services may not be covered and, if requested by the beneficiary, or authorized representative, the SNF must give the beneficiary, or authorized representative, access to medical record information or other documents upon which the Medicare contractor based its assessment, to the extent permissible or required under applicable state law. Where state law prohibits such direct disclosure, the SNF must advise a beneficiary, or authorized representative, who has requested access to such information how to obtain that information from the SNF once a demand bill has been submitted. The SNF must respond timely, accurately, and completely to a beneficiary, or authorized representative, who requests information about the extent of the beneficiary's personal financial liability for extended care items or services for which the SNF, the UR entity, the QIO, or the Medicare contractor expects that Medicare may not, or may no longer, pay. If a beneficiary or authorized representative or a physician provides additional information with respect to Medicare coverage of the subject extended care items or services, the SNF must timely submit that additional information to the Medicare contractor. The Medicare contractor will reject a SNFABN in all cases in which the SNF does not meet these requirements.

70.6.4 - Effect of SNFABN on Beneficiary

(Rev. 1, 10-01-03)

Under the statutory provision of LOL, a beneficiary who has received a proper SNFABN and who has agreed to pay for the specified extended care items or services will be fully and personally responsible for payment to the SNF if Medicare denies payment. The Medicare contractor will not hold a beneficiary who does not receive a SNFABN, or who receives a defective SNFABN (i.e., one that does not meet the requirements of these instructions, or one on which an option was pre-selected by the SNF) financially liable under the LOL provisions, unless there is clear and obvious evidence that the beneficiary knew or could reasonably have been expected to know that Medicare would not make payment (in which case, the Medicare contractor will hold the beneficiary financially liable).

70.6.5 - Financial Liability

(Rev. 1, 10-01-03)

A SNF that fails to comply with the SNFABN instructions risks financial liability and/or sanctions. LOL shall apply as required by law, regulations, rulings and program instructions thereunder. Additionally, sanctions under the Conditions of Participation (COPs), when authorized by law and regulations, may be imposed.

70.6.6 - Limitation on Liability

(Rev. 1, 10-01-03)

The Medicare contractor will hold financially liable, under LOL, any SNF that failed to provide notice, or provided a defective notice, to a beneficiary in a particular case, to which LOL (§1879 of the Act) applies, unless the SNF can demonstrate that it did not know, and could not reasonably have been expected to know, that Medicare would not make payment, or there is clear and obvious evidence that the beneficiary knew that Medicare would not make payment. The SNF is to prepare and deliver to the patient (Medicare beneficiary) or her or his authorized representative a SNFABN when the SNF, the UR entity, the QIO, or the Medicare contractor expects that Medicare probably will not pay for, or will not continue to pay for, extended care items or services. If a SNF advises a beneficiary that, in its view, Medicare probably will not pay, but does so in a defective manner such that the beneficiary cannot fully exercise her or his rights and protections (which the Medicare contractor must assume to be the case when a SNFABN was not executed and delivered properly by the SNF), the Medicare contractor will consider that to be prima facie evidence that the SNF knew that Medicare would not make payment and not sufficient evidence to shift financial liability to the beneficiary. If a financially liable SNF collects from a beneficiary, the Medicare contractor shall implement the beneficiary protections under §100.

70.6.7 - Extended Care Items or Services Not Ordered by Physicians

(Rev. 1, 10-01-03)

Medicare never pays for extended care items or services not ordered by a physician. No SNFABN is needed when extended care items or services are reduced or terminated in accordance with a physician's order, where a physician does not order the items or services at issue, or where the physician agrees in writing with the SNF's, the UR entity's, the QIO's, or the Medicare contractor's assessment that the extended care items or services are not necessary. The physician orders must be in writing and be entered into the beneficiary's record. The LOL provisions do not apply in these situations, but certain beneficiary protections under the COP do apply. An ABN (Form CMS-R-131) may be required if a SNF has been acting as a supplier of Part B services or supplies outside a physician's plan of care.

70.6.8 - Regulatory Requirements

(Rev. 1, 10-01-03)

• Under 42 CFR 483.10, "Condition of Participation: Resident rights."

70.6.9 - Standards

(Rev. 1, 10-01-03)

70.6.9.1 - Establishing When Beneficiary Is On Notice of Noncoverage

(Rev. 1, 10-01-03)

If the beneficiary has previously been informed in writing that the extended care items or services were noncovered as a result of a prior stay for the same condition, the beneficiary is liable, but only if it is clear that she or he (or her or his authorized representative) knew that the circumstances were the same. With this exception, the beneficiary is presumed not to have known, nor to have been expected to know, that the extended care items or services are not covered unless, or until, she or he receives notification from an appropriate source (see §70.6.9.2).

70.6.9.2 - Source of Beneficiary Notification

(Rev. 1, 10-01-03)

- Where the SNF serves as the source of beneficiary notification.
 - o The SNF on or before the day of admission furnishes to the beneficiary, or to her or his authorized representative, a SNFABN notifying the beneficiary that the extended care item(s) or service(s) is noncovered.
 - o The SNF, during the inpatient stay, timely furnishes to the beneficiary, or to her or his authorized representative, a SNFABN notifying that the beneficiary no longer required covered extended care item(s) or service(s).

- o The SNF, when advised by the Medicare contractor that the beneficiary's covered extended care items or services have ceased, that very day furnishes to the beneficiary, or to her or his authorized representative, a SNFABN notifying the beneficiary of the Medicare contractor's determination.
- Where the UR entity serves as the source of beneficiary notification.
 - o The UR entity (the group or committee responsible for conducting the SNF's UR) timely furnishes to the beneficiary, or to her or his authorized representative, a SNFABN notifying the beneficiary that the extended care item(s) or service(s) is no longer covered.
- Where the QIO serves as the source of beneficiary notification.
 - o The QIQ, where a beneficiary is in a swing bed, timely furnishes to the beneficiary, or to her or his authorized representative, a SNFABN notifying the beneficiary that the extended care item(s) or service(s) is not covered or the item(s) or service(s) is no longer covered.
- Where a Medicare contactor serves as the source of beneficiary notification.
 - The beneficiary, or authorized representative, receives from the Medicare contractor her or his first notification of noncoverage (e.g., the Medicare contractor's denial notice).

70.6.9.3 - Determining the Notification Date for the Denial Paragraph (Rev. 1, 10-01-03)

SNFs are to insert in the denial paragraph, if applicable, of the SNFABN's "Because" section (see §70.4.5) the appropriate notification date. In instances where the:

- SNF determines prior to, or upon admission, that the services will not be covered, the SNF is to insert the date the determination was made;
- SNF determines that further services will not be covered, the SNF is to insert the first day on which the services are not covered, usually the day following the date of the SNFABN;
- UR entity advises the SNF that the beneficiary's stay was not medically necessary upon admission, the SNF is to insert the date of the first day on which the stay is not medically necessary;
- UR entity advises the SNF that a further stay is not medically necessary, the SNF is to insert the date of the first day on which the beneficiary's stay is not medically necessary; or

Medicare contractor advises the SNF of the noncoverage of extended care item(s)
or service(s), the SNF is to insert the date the covered item(s) and service(s)
ended.

70.6.9.4 - Requesting a Medicare Decision

(Rev. 1, 10-01-03)

A bill for noncovered extended care items or services will only be submitted to Medicare if the beneficiary or her or his authorized representative so requests. Therefore, in order for a beneficiary or authorized representative to appeal the decision of noncoverage on a claim, she or he must request the SNF to submit the bill to Medicare. (See Chapter 29 of the Medicare Claims Processing Manual, "Appeals of Claims Decisions.")

80 - Hospital ABNs (Hospital-Issued Notices of Noncoverage - HINN)

(Rev. 594, Issued: 06-24-05, Effective: 07-01-05, Implementation: 07-01-05)

Instructions for the Hospital ABN have been retracted. Instructions related to HINNs have been relocated as follows:

- Instructions regarding HINNs are found in this instruction, CR 3903, which precedes the placement of full instructions in Chapter 30.
- Instructions regarding hospital billing for cases involving QIO review will be relocated to a new section in Chapter 1 of this manual in the near future. Current procedures should not change in the interim.

Related instructions for QIOs can be found in the Medicare Quality Improvement Organization Manual, Publication 100-10, Chapter 7.

100 - Indemnification Procedures for Claims Falling Within the Limitation on Liability Provision

(Rev. 1, 10-01-03)

A3-3446, B3-7320

Section 1879(b) of the Act provides that when a provider, practitioner, or supplier is held liable for the payment of expenses incurred by a beneficiary for noncovered items or services and such provider, practitioner, or supplier requests and receives payment from the beneficiary or any person(s) who assumed financial responsibility for payment of expenses, the Medicare program indemnifies the beneficiary or other person(s).

Further, any such indemnification payments are considered overpayments to the provider, practitioner, or supplier.

A provider, practitioner, or supplier who is determined liable may not seek payment from a third party payer. (See §30.2.B.)

100.1 - Contractor and Social Security Office (SSO) Responsibility in Indemnification Claims

(Rev. 1, 10-01-03)

A3-3446.1, B3-7320.1

The contractor, SSO, RO, or central office may receive requests or inquiries concerning indemnification. However, a beneficiary or person(s) who made payment on behalf of the beneficiary to a liable provider usually visits his/her nearest SSO or deals directly with the contractor to file a request for indemnification.

Those offices are responsible for assisting beneficiaries or any person(s) in filing claims for indemnification.

100.2 - Conditions for Indemnification (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

A beneficiary or any person(s) who assumed financial responsibility for payment is indemnified for claims filed if all of the following conditions are met:

- The contractor has determined that the beneficiary is without liability under authority of §1879 of the Act for items and services furnished by a provider, practitioner, or supplier;
- The contractor or the QIO has determined that the provider, practitioner, or supplier is liable under §1879 for the items and services furnished to the beneficiary. A provider, practitioner, or supplier is considered to have knowledge that payment will not be made under Medicare for items or services in a particular claim where the following evidence is established regarding the provider, practitioner, or supplier;
 - (1) Evidence that a provider, practitioner, or supplier knew, or could reasonably be expected to have known, of exclusion of items or services
 - o General notice to the medical community regarding exclusion of certain items or services: e.g., colonic irrigation, acupuncture.
 - o General notice to the medical community that services exceeding certain frequencies would be denied or subject to additional review, e.g., vitamin B12 injections, or nursing home visits more frequent than once a month.
 - o Written notice to the particular provider, practitioner, or supplier that a type of service or item would be noncovered in all or certain circumstances.

A distinction must be maintained between coverage rules that specify that a type of service or item would be not reasonable or necessary in all or certain circumstances, and utilization guidelines the contractor established to identify excessive services. Any written policies or other internal edits that are disclosed to a provider, practitioner, or supplier would not be considered as a "notice" of exclusion, since they are used for referring claims for further development rather than as rules to make a contractor coverage decision.

In addition to instances when the Medicare program has given notice, the allegation of a provider, practitioner, or supplier is not accepted without further verification in situations of potential program abuse involving a pattern of unnecessary services by a provider, practitioner, or supplier to a number of beneficiaries. When a provider, practitioner, or supplier frequently renders unnecessary services, i.e., services that significantly exceed the frequency with which the general medical community renders them, it is reasonable to expect the provider, practitioner, or supplier to know that such a pattern deviates from the standard practice.

(2) Evidence that provider, practitioner, or supplier did not have knowledge of exclusion of services.

In contrast to subsection 1, there may be situations where an assumption can be made that neither the beneficiary nor the provider, practitioner, or supplier had knowledge of exclusion, and liability can be limited by the reviewer without a statement by either party. In the following situations, further development would not be necessary:

- a. The service is for a type of treatment that can be rendered only by a physician, but the contractor has not previously denied payment for the treatment, and it is not unreasonable that a particular physician might consider the treatment appropriate. In order to determine whether the services are reasonable and necessary, the contractor requests its physician consultant or CMS to advise whether the services are covered. This is a case for which there are no general coverage guidelines for the services; the contractor has not advised either the physician or the medical community regarding the coverage of the services; and the contractor is uncertain without expert consultation. In such a case, it may be presumed that neither the beneficiary nor the physician could have known that the services would be noncovered.
- b. The item or service is ordinarily covered, but a question is raised as to whether it is reasonable and necessary in treatment of a particular diagnosis. Neither the provider, practitioner, or supplier nor the medical community has been advised that the item or service is not covered for that diagnosis. The case requires a determination by the contractor's medical consultant or is referred to CMS for guidance. As in example (a), the liability of both parties should be limited.

c. The provider, practitioner, or supplier is newly arrived in the contractor service area, and the contractor has not yet communicated to the provider, practitioner, or supplier information in an existing general notice that the item or service is not covered, always or under certain circumstances.

NOTE: If any provider, practitioner, or supplier could reasonably be expected, by virtue of normal medical knowledge, to know that the service was unneeded, the presumption suggested in the above examples would not apply.

- The requester for indemnification has paid the provider, /practitioner or supplier all or some of the charges for items and services for which the beneficiary's liability has been waived under §1879 of the Act; and
- The requester seeks indemnification by filing a written statement prior to the end of the sixth month following:
 - o The month in which payment was made to the provider, practitioner or supplier; or
 - o The month in which the contractor advised the beneficiary that the beneficiary was not liable for the noncovered items or services, whichever is later.

The contractor extends the six month time limit if good cause is shown. The contractor uses the principles for determining good cause outlined in Chapter 29, "Appeals of Claim Decisions."

100.3 - Development and Documentation of Indemnification Requests (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

When the contractor receives a request or inquiry concerning indemnification directly from the beneficiary or the beneficiary's authorized representative, it must obtain the following information and documentation:

- Identifying information sufficient for the contractor to locate the claim(s) for noncovered items or services for which payment has been made to the provider, practitioner, or supplier by the beneficiary or other person and for which the liability of the beneficiary was limited. Ordinarily, the initial MSN or appeal determination suffices.
- A statement on Form SSA-795, "Statement of Claimant or Other Person," (see §100.10, Exhibit 4) to the effect that the requester paid the provider, practitioner, or supplier all or some of the charges for the noncovered items or services for which the beneficiary's liability was limited. The statement must specify the amount the requester has paid the provider, practitioner, or supplier. If the

requester submits this information in a letter, the letter serves as the signed statement.

100.3.1 - Proof of Payment

(Rev. 1, 10-01-03)

The following types of documentation are sufficient to establish that payment was made in the amount alleged:

An itemized bill from the provider, practitioner, or supplier reflecting the items and services for which the provider, practitioner, or supplier has been found liable and has received payment along with the payer's cancelled check, money order receipt, or statement of receipt from the provider, physician, or supplier;

A summary bill from the provider, practitioner, or supplier which pertains to the items and services for which the provider, practitioner, or supplier has been found liable and has collected from the beneficiary or other person along with the payer's cancelled check, money order receipt, or a statement of receipt from the provider, practitioner, or supplier showing the same total amount;

The payer's cancelled check, money order receipt, or the statement of receipt from the provider, practitioner, or supplier if the contractor's records reflect the provider, practitioner, or supplier's charges for the items and services for which the provider, practitioner, or supplier has been found liable and these equal the total of the amount paid; or

If the requester alleges that the provider, practitioner, or supplier did not furnish an itemized bill or a receipted statement and no other proof of payment is available, the contractor obtains a statement on Form SSA-795 to this effect from all parties involved, including the provider, physician, or supplier if possible. The statement should describe the circumstances, such as the manner of payment, and the reasons for not obtaining a receipt or any proof of payment. If there were any witnesses to the payment, the contractor obtains their statements on Form SSA-795. The contractor refers any questions as to the acceptability of proof of payment to the RO.

When the beneficiary or other person on behalf of the beneficiary initially contacts the SSO, that office sends the statements and evidence relevant to the indemnification claim to the appropriate contractor. If future contact with the beneficiary or other person is necessary, the contractor proceeds with a direct contact unless the assistance of the SSO is needed.

100.4 - Beneficiary Requests Indemnification, but Had No Financial Interest in the Claim

(Rev. 1, 10-01-03)

A3-3446.4, B3-7320.4

If a request for indemnification is received from the beneficiary but the beneficiary did not have full financial interest in the claim, then any other person(s) who made full or partial payment to the provider, practitioner, or supplier must be contacted to ascertain if that person wishes to file for indemnification.

If the individual declines to file for the indemnification payment, the SSO or contractor staff should assist in preparing a statement to that effect for the individual's signature. No payment is made in this instance; however, the contractor notifies all involved parties.

If more than one person helped pay the bill; e.g., sons and daughters of the beneficiary got together and each paid a portion of the bill; the contractor must determine the indemnification amount for each payer unless they all agree in writing that payment is to be made to one person. Explain this to the requester for indemnification in such instances.

100.5 - Questionable Indemnification Requests Procedure

(Rev. 1, 10-01-03)

A3-3446.5, B3-7320.5

If the contractor receives a request for indemnification that does not appear to meet the conditions outlined in §100.2, and there is some uncertainty concerning the indemnification claim, it undertakes development to resolve the issues. If the issues cannot be adequately resolved, it obtains the assistance of the RO.

100.6 - Determining the Amount of Indemnification

(Rev. 1, 10-01-03)

A3-3446.6, B3-7320.6

In accordance with §1879(b) of the Act, the contractor indemnifies the beneficiary or other person(s) for actual charges paid to a provider, practitioner, or supplier, rather than the usual allowable charges as determined by the Medicare program, PPS amounts, or established per diem rates that apply to certain provider, practitioner, or suppliers.

Additionally, §4096 of P.L. 100-203 (OBRA of 1987) revises certain limitation on liability requirements for indemnification under §1879(b) of the Act. A beneficiary qualifying for indemnification for denied items and services furnished on or after January 1, 1988 is no longer responsible for paying deductible and coinsurance charges related to the denied claim. Where such indemnification is made, the contractor may not charge the beneficiary's Medicare utilization record for the denied items and services furnished.

100.7 - Notifying the Provider, Practitioner, or Supplier

(Rev. 1, 10-01-03)

A3-3446.7, B3-7320.7

After the contractor has reviewed the claim for indemnification and the indemnification amount has been determined, it notifies the provider or physician/supplier of the proposed indemnification action. (A sample letter for these situations is contained in §100.10, Exhibit 1.) The essential elements of this written notice are:

An explanation of the items and services for which the provider or physician/supplier is liable with reference to the original notice to the provider or physician/supplier;

A statement of the provision of §1879 which allows the program to indemnify the beneficiary and recover an overpayment from the provider, practitioner, or supplier;

An explanation of the amount determined payable to the requester for indemnification;

A statement that the amount the contractor has determined to be payable is paid to the requester and that it constitutes an overpayment to the provider, practitioner, or supplier which is to be recovered from future Medicare payments made to it;

A statement encouraging the provider, practitioner, or supplier to refund any amount(s) already collected; and

A reminder to the provider, practitioner, or supplier of his/her/its Medicare appeal rights.

If the provider, practitioner, or supplier does not respond to this notice within 15 days, the contractor makes payment to the requester in accordance with §100.8. If the provider, practitioner, or supplier disputes the indemnification or the amount to be paid, the contractor resolves any discrepancies before making payment. The payment process takes place even if the provider, practitioner, or supplier might appeal the contractor's initial determination which held the provider, practitioner, or physician liable and that appeal is still pending at the time payment of the indemnification amount is to take place. If the appeal decision reverses the initial determination, then adjustments are to be made at that time in the contractor and provider, practitioner, or supplier records. In all cases, the contractor encourages the provider, practitioner, or supplier to refund any and all amounts collected to this point. If the provider, practitioner, or supplier chooses to refund any money collected, the contractor verifies that such a refund has actually been made to the requester.

100.8 - Making Payment Under Indemnification

(Rev. 1, 10-01-03)

A3-3446.8, B3-7320.8

The contractor pays the indemnification amount if the provider, practitioner, or supplier does not make refund. It takes action to recover this amount as an overpayment from the provider, practitioner, or supplier. Also, it issues a letter of explanation to the requester

for indemnification. (See §100.10, Exhibit 2 and Exhibit 3.) It sends a copy of this notice to the provider, /practitioner or supplier. The fundamental points of the notice include:

Name of the provider, practitioner, or supplier and dates the services in question were rendered; and

the amount of the indemnification check that the requester is to receive.

100.9 - Limitation on Liability Determination Does Not Affect Medicare Exclusion

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

A determination to limit the liability of the beneficiary, as well as a finding that the physician's or supplier's liability may be limited and program payment made, does not change noncovered items or services into covered items or services. This means that the coverage question can still be raised as an issue at a level subsequent to an appeal determination that authorized program payment under §1879. It also means that, for purposes of determining an amount in controversy for an appeal, payment made under §1879 should be disregarded because coverage is still at issue and the amount charged is still in controversy.

100.10 - Exhibits

(Rev. 1, 10-01-03)

A3-3446.9, B3-7320.10

- 1. Letter to Provider (Institutional Services).
- 2. Letter to Beneficiary Who Requests Indemnification (Institutional Services).
- 3. Letter to Someone Other Than Beneficiary Who Requests Indemnification.
- 4. Letter to Practitioner or Supplier (Noninstitutional Services)
- 5. Letter to Beneficiary Who Requests Indemnification (Noninstitutional Services)
- 6. Letter to Someone Other Than Beneficiary Who Requests Indemnification (Noninstitutional Services)
- 7. Form SSA-795, Statement of Claimant or Other Person.

Exhibit 1 - Letter to Provider

(Rev. 1, 10-01-03)

To: Provider

Dear Administrator:

Under §1879 of the Social Security Act, a Medicare beneficiary is relieved of the liability for certain noncovered services if the beneficiary did not know and could not reasonably have been expected to know that the items or services were not covered. Further, the law provides that the provider is liable if it is found that the provider knew or could reasonably have been expected to know that the items or services were not covered by Medicare.

On (date of limitation on liability notice), your facility was notified that the services provided to (beneficiary's name) during the period (______) to (______) were not covered under Medicare and that you were liable for these items and services.

(Requester's name) has submitted evidence that establishes that he paid your facility (amount paid) for the services received by (beneficiary's name). Because your facility has collected payment from (requester's name) after being determined liable for these services, §1879(b) of the Act requires that the Medicare program make direct payment (indemnification) to him for this amount, for which (beneficiary's name) is responsible.

A check in the amount of (amount of check) is being sent to (requester's name). This indemnification payment represents an overpayment to your facility and it will be withheld from future Medicare payments due you unless you advise this office that refund of the incorrect amount(s) has been made to (requester's name).

If you do not agree with the amount determined to have been paid you, please contact this office in writing within 15 days of the date of this letter.

Sincerely yours,

Exhibit 2 - Letter to Beneficiary Who Requests Indemnification

(Rev. 1, 10-01-03)

Dear (Beneficiary's Name):

Your request for refund of improper payment under §1879 of the Social Security Act (the limitation on liability provision) for the noncovered services provided you at (name of provider) from (date) to (date) has been received.

The evidence submitted establishes that, even though you were not responsible for the services you received, you paid (provider's name) (amount paid) for the services. Your refund for these payments to (name of provider) has been calculated to be (indemnification amount). This figure represents full repayment for the charges you paid.

Your Medicare utilization record will not be charged where noncovered services were provided to you and you were determined not liable.

If you have any questions concerning the matters discussed in this letter or the amount of the check enclosed, please call this office. If you prefer to visit your local social security office, please take this letter with you.

Sincerely yours,

Exhibit 3 - Letter to Someone Other Than Beneficiary Who Requests Indemnification

(Rev. 1, 10-01-03)

Dear (Person's Name):

Your request for refund of improper payment under Section 1879 of the Social Security Act (limitation of liability provision) for the noncovered services provided (beneficiary's name) at (name of provider) from (date) to (date) has been received.

It was determined that (beneficiary's name) was not liable for the services. The evidence you submitted establishes that you paid (provider) (amount paid) for the services provided (beneficiary's name). Your refund has been calculated to be (indemnification amount). This figure represents full repayment based on the expenses incurred by (beneficiary's name) in the amount of \$(amount).

If you have any questions concerning the matters discussed in this letter or the amount of the check enclosed, please call this office. If you prefer, you may visit the local social security office. If you do, take this letter with you.

Sincerely yours,

Exhibit 4 - Letter to Practitioner or Supplier (Noninstitutional Services)				
(Rev. 1186, Issued:	02-23-07; Effective:	01-01-06; Implementation:	05-23-07)	
Dear	:			

Under §1879 of the Social Security Act, a Medicare beneficiary is relieved of the liability for certain categories of noncovered items or services submitted as assigned claims if the beneficiary did not know and could not reasonably be expected to know that the items or services would not be covered. Further, the law provides that the practitioner or supplier will be liable for the charges if it is found that he/she knew or could reasonably be expected to know that Medicare would not cover the items or services.

On (date of limitation on liability notification), you were notified that the following items or services provided to (name of beneficiary) were not covered and that you were liable for the charges for these items or services:

Description of Services	Date Provided

(Beneficiary or other person on behalf of beneficiary) has submitted evidence which establishes that he/she paid you \$_____ for the items or services described above. Since it has been determined that you are liable for the items or services, §1879(b) of the Act requires that the Medicare program make payment (indemnification) to him/her for this

amount. The amount of this payment will be treated as an overpayment to you and appropriate collection action will be taken unless you advise this office that refund has been made to (name of requester).

If you do not agree with the amount that (name of requester(s)) has established he/she paid you, please notify this office.

If we do not hear from you regarding the amount of the payment or that you will make refund directly by______ (15 days after date of this notice) payment will be made to (name of requester(s)) and action will be taken to collect the overpayment from you.

If you disagree with this determination, you may request a redetermination. The bases for such a request are: (1) that the services you provided were reasonable and necessary; (2) that you did not know, and could not reasonably have been expected to know, that Medicare would not pay for the services; or (3) that you notified the beneficiary in writing, before the services were furnished, that Medicare likely would not pay for the services. The request for redetermination must be in writing, and it must be filed within 120 days of the date you received the initial determination. If you have already received an adverse redetermination, you may request a reconsideration within 180 days of the date you received the redetermination. Our office will assist you if you need help in requesting a redetermination or a reconsideration. You need not file another request for a redetermination or a reconsideration if you already have taken such action.

Exhibit 5 - Letter to Beneficiary Who Requests Indemnification (Noninstitutional Services)

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

Dear (Beneficiary's name):

Your request for indemnification (i.e., refund of improper payment) under §1879 of the Social Security Act (the limitation on liability provision) for the noncovered services provided you by (physician's/supplier's name) on (date) has been received.

The evidence submitted establishes that you paid (physician/supplier) (amount paid) for the noncovered services. It was determined upon redetermination that you were not liable for these charges. Your refund for these payments to (physician/supplier) has been calculated to be (indemnification amount). This figure represents full repayment for the charges you paid.

If your (physician/supplier) requests an appeal of this claim, it is possible that Medicare might find that your (physician/supplier) also did not know that Medicare would not pay for this service, or that this service should not have been denied. In that case, Medicare would pay your (physician/supplier) for this service. Also, you would be responsible for any deductible and coinsurance amounts. If this happens, you will receive a copy of the notice to your (physician/supplier).

Any future items or services of this type provided to you will be your responsibility because this is your notice that Medicare does not cover these services.

If you have further questions concerning this matter, please call this office. If you prefer to visit your social security office, please take this letter with you.

Exhibit 6 - Letter to Someone Other Than Beneficiary Who Requests Indemnification (Noninstitutional Services)

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

Dear (Person's name):

Your request for indemnification (i.e., refund of improper payment) under §1879 of the Social Security Act (limitation on liability provision) for the noncovered services provided (beneficiary's name) by (name of physician/supplier) on (date) has been received.

It was determined upon redetermination that (beneficiary's name) was not liable for the charges.

The evidence establishes that you paid (physician/supplier) (amount paid) for the services provided (beneficiary's name). Your refund has been calculated to be (indemnification amount). This figure represents full repayment for the expenses incurred by (beneficiary's name).

If his/her (physician/supplier) requests an appeal of this claim, it is possible that Medicare might find that the (physician/supplier) also did not know that Medicare would not pay for this service, or that this service should not have been denied. In that case, Medicare would pay the (physician/supplier) for this service. Also, (beneficiary's name) would be responsible for any deductible and coinsurance amounts. If this happens, (beneficiary's name) will receive a copy of the notice to his/her (physician/supplier).

Any future items or services of this type provided to (beneficiary's name) will be his/her responsibility because this is your notice that Medicare does not cover these services.

If you have further questions concerning the matters discussed in this letter or the amount of the check enclosed, please call this office. If you prefer to visit the social security office, please take this letter with you.

Exhibit 7 - Statement of Claimant or Other Person

(Rev. 1, 10-01-03)

Link to an exhibit of the Form SSA-795, "Statement of Claimant or Other Person," at:

http://www.ssa.gov/online/ssa-795.pdf.

110 - Contractor Instructions for Application of Limitation On Liability

(Rev. 1, 10-01-03)

110.1 - Payment Under Limitation on Liability

(Rev. 1, 10-01-03)

A3-3441

When it is determined during the course of a beneficiary's inpatient stay or during the patient's course of home health visits, or during a patient's course of treatment from a practitioner, physician or other supplier that the care is not covered but both the beneficiary and the provider of services are entitled to limitation on liability, the Medicare program may make payment for the noncovered services up to the date of notice and, if, for inpatient or home health services, the FI determines that additional time is needed to arrange for post-discharge care, also for a "grace period" of 1 day after the date of notice to the provider or to the beneficiary, whichever is earlier. If it is determined that even more time is required in order to arrange post-discharge care, 1 additional "grace period" day may be paid for. (See §§30 and 40 for definition of notice.)

When the provider is given notice as described in §40.1, it is required to advise the beneficiary in writing of the determination on the same date it received the FI's notice. Where the provider fails to give the beneficiary such timely notice, the beneficiary is protected from liability until the beneficiary receives the notice.

For example, if a SNF received the FI's notice of noncoverage on February 15 but failed to advise the beneficiary until February 19, the beneficiary is protected from liability through February 19 - the date on which the beneficiary first received notice. However, the SNF is entitled to program payment only through the date - February 15 - on which it received notice, and for whatever "grace period" is allowed thereafter. In a case in which a SNF received the FI notice on February 15 but failed to give the beneficiary notice until the next day - February 16 - the beneficiary and provider, if the FI determines that additional time is needed to arrange post-discharge care, would be protected from liability under the "grace period" only for the additional day - February 16 - unless it is determined that even more time is required to arrange post-discharge care, in which case 1 additional "grace period" day may be paid for.

NOTE: The "grace period" is applicable only where circumstances have permitted program payment under §1879 of the Act, i.e., limitation on liability was applicable both to the beneficiary and the provider of services. Where the FI concurs with a URC's decision that covered care has ended, any payments made during the "grace period" after the URC's notice are made under the authority of that statutory provision (§1814 of the Act) rather than under §1879.

110.2 - When to Make Limitation on Liability Decisions (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

A - Initial Claims

In implementing the limitation on liability provision, the contractor makes a coverage decision before making a limitation on liability decision. Section <u>1879</u> of the Act provides that limitation on liability can be allowed only in cases:

Where - (1) a determination is made that, by reason of §1862(a)(l) or (9) or by reason of a coverage denial described in subsection (g) of the Act, payment may not be made under Part A or Part B of this title for any expenses incurred for items or services furnished an individual by a provider of services... (Section 1879(a)(1) of the Social Security Act.)

NOTE: Subsection (g) refers to home health service denials under $\S\S1814(a)(2)(C)$ and 1835(a)(2)(A), i.e., the patient is or was not confined to home; or the patient does or did not need skilled nursing care on an intermittent basis; and to hospice denials under $\S1861(dd)(3)(A)$ for services determined to be noncovered because the beneficiary was not "terminally ill".

Only after the contractor makes a decision that care is not reasonable or necessary, is custodial, is not reasonable and necessary for the palliation or management of terminal illness in hospice denials, or does not meet the homebound or intermittent nursing care requirements in home health service denials, or does not meet the "terminally ill" condition for hospice care, should a determination be made regarding limitation on liability. In every such case there will be two parts to the limitation on liability determination.

- 1. Whether and when the beneficiary knew or should have known that the services were noncovered, and
- 2. Whether and when the provider knew or should have known that the services were noncovered.

In any case where the provider gave the beneficiary notice that the services would be noncovered, the contractor will find that the provider knew that the services were noncovered.

B – Redetermination

At the redetermination level, again the contractor first makes a determination on the coverage issue. It considers the question of limitation on liability, if applicable, only if the initial adverse coverage decision is wholly or partially affirmed. (See Chapter 29, "Appeals of Claim Decisions," for discussion of the appeals process.)

110.3 - Preparation of Denial Notices (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

The provider and beneficiary notification procedures discussed in §§30 and 40 for determining liability do not change the instructions for the preparation and issuance of denial notices in Medicare Claims Processing Manual, Chapter 21, "Medicare Summary Notices."

Accordingly, in cases where the services are found to be custodial care or not reasonable and necessary, or in the case of HHA services, are denied for technical reasons under

 $\underline{\$1814(a)(2)(C)}$ or $\underline{\$1835(a)(2)(A)}$, or in the case of hospice services, are denied for technical reasons under \$1861(dd)(3)(A):

An MSN denying the service(s) is sent to the beneficiary in cases where only the beneficiary is entitled to limitation on liability for any part of the noncovered stay. The notice advises the beneficiary of the beneficiary's entitlement to indemnification (see §§100.) in the event the provider seeks payment from the beneficiary for the noncovered services. It uses MSN messages 50.36.2:

It appears that you did not know that we would not pay for this service, so you are not liable. Do not pay your provider for this service. If you have paid your provider for this service, you should submit to this office three things: (1) a copy of this notice, (2) your provider's bill, and (3) a receipt or proof that you have paid the bill. You must file your written request for payment within 6 months of the date of this notice. Future services of this type provided to you will be your responsibility.

All denial notices explain any decision regarding limitation on liability for either the provider, practitioner, or supplier or the beneficiary. (See Chapter 21, "Medicare Summary Notices.")

All denial notices, where either the beneficiary or provider, practitioner, or supplier has been found liable, must state that the provider has a right to a redetermination.

Providers, practitioners, and suppliers do not receive a separate written notification or copy of the MSN. Providers, practitioners, and suppliers must utilize the coding information (e.g., ANSI X12N Reason Codes) conveyed via the financial remittance advice (RA) to ascertain reasons associated with Medicare claims determinations affecting payment and applicable appeal rights and/or appeals information.

110.4 - Bill Processing

(Rev. 1, 10-01-03)

A3-3445

Where payment is made under the limitation on liability provision, because it was determined that both the provider, practitioner, or supplier and the beneficiary did not know and could not have been expected to know that services were not reasonable and necessary, the usual deductible and coinsurance amounts apply.

When payment under limitation on liability is made for noncovered services, the contractor processes the bill in the same manner as any payment bill for covered services. For institutional services, if both the beneficiary and the provider have liability waived, the FI charges the number of days or visits paid for under the limitation on liability provision to the beneficiary's utilization record. For noninstitutional services, it applies deductible and coinsurance, and, where applicable, statutory limits on services.

For situations where the contractor determines that the provider, practitioner, or supplier knew or should have known that the services were not reasonable and necessary, and the beneficiary did not know and could not have been expected to know that the services were not reasonable and necessary, the beneficiary qualifies for indemnification and is not responsible for paying deductible and coinsurance charges related to the denied claim. Additionally, where such indemnification is made, the contractor does not charge the beneficiary's Medicare utilization record days, visits, deductibles, or coinsurance (nor does it apply statutory limits, e.g., the psychiatric services Limit) for the denied items and services furnished.

The contractor follows the no-payment procedures in the relevant bill processing instructions in the following cases:

Either the beneficiary or the provider/practitioner/supplier, or both knew or should have known that services were not covered.

The provider, practitioner, or supplier knew or should have known that the services were not covered even though the beneficiary did not know. In these cases, the notice to the beneficiary will have informed the beneficiary that, even though no Medicare payment is being made, the beneficiary is not liable for the cost of the services and that the beneficiary may be indemnified for any improper payments the beneficiary made to the provider, practitioner, or supplier.

Where no Medicare payment is made because limitation on liability does not apply, or where payment ceases because of notice in a noncovered case, the normal provisions for no-payment situations apply.

For ancillary and outpatient services billed on the Form CMS-1450, the provider follows the instructions in Chapter 4 for hospitals, Chapter 7 for SNFs, and Chapter 10 for HHAs to process bills for these types of claims. Further, where ancillary services may not be paid under Part A because they were rendered in connection with a noncovered inpatient stay, the provider may still bill under Part B for ancillary services that may be covered under §1861(s)(3)-(9) of the Act.

110.5 - Contractor Review of ABNs

(Rev. 1, 10-01-03)

110.5.1 - General Rules

(Rev. 1, 10-01-03)

A. Generally, notifiers (physicians, practitioners, suppliers, providers) are not required to routinely submit copies of ABNs (CMS-R-131) to their Medicare contractor along with their claims (see §50.6.3). This is based on a rebuttable administrative presumption that a certain modifier (GA) or occurrence code (32) on the claims signify that notifiers are using the proper standard form CMS-R-131 and are preparing and delivering ABNs in compliance with the instructions in this Chapter.

- **B.** Contractors may and should request CMS-R-131 ABNs (or any other ABN if the circumstances demand) be submitted to them for review in any circumstance in which the contractor is not confident that the administrative presumption is correct or in which the contractor has good reason to examine the ABNs of either particular notifiers or any class of notifiers. In the case where a contractor requests submission of copies of ABNs, the notifiers must submit such copies (see §50.6.3).
- **C.** All Hospital ABNs (HINNs) will be reviewed by QIOs (see §80.5) and all HHABNs and SNFABNs will be reviewed when the contractor performs complex medical review of the demand bills.

110.5.2 - Situations in Which Contractor Review of ABNs is Indicated (Rev. 1, 10-01-03)

Circumstances involving ABNs (viz., with respect to claims on which there is any payment denial, that include either or both the GA modifier and occurrence code 32, and that do not include a copy of the ABN) in which the contractor should not be confident that the administrative presumption, viz., that notifiers are using the proper form and are properly preparing and delivering ABNs, is correct and should request submission of ABNs include, but are not limited to, the following:

- **A.** Any claim where the contractor has any indication that the notifier may not have given proper notice, either no notice at all or defective notice, whether based on the contractor's experience (with the notifier or class of notifiers, or with the class of items or services), on beneficiary complaint, on any other plausible allegation, or on any other reasonable basis. (Contractors, of course, may not make baseless or capricious requests for routine submission of ABNs.)
- **B.** Any claim for payment for more than one item or service. (In such cases, the contractor must ascertain which item(s) and/or service(s) the ABN specified and, therefore, to which claimed item(s) and/or service(s) the ABN applies with respect to assigning liability to the beneficiary. Liability is shifted to the beneficiary only if the ABN accurately specifies the items or services and if the specified expected reason for denial turns out to be the actual reason for denial.)
- C. Any claim for an item or service for which there is a coverage frequency limit, and which includes one or more other items or services which are not frequency-limited. (Since ABNs may be given routinely for frequency-limited items and services, it is predictable that virtually all claims which include any frequency-limited item or service will include the GA modifier and/or occurrence code 32. When other, non-frequency-limited items or services are included on such a claim, any ABN specifying a frequency-limit as the expected reason for denial would not be applicable to the liability determination with respect to any item or service on such a claim that is not frequency-limited, nor with respect to any different frequency-limited item or service.)
- **D.** Any claim for an item or service for which there is a coverage frequency limit and on which there is a payment denial on any basis other than exceeding the frequency limit.

(Since the notifier can be reasonably expected to have given routine notice on the basis of the frequency limit, and since an ABN specifying a frequency-limit as the expected reason for denial would not be applicable to the liability determination with respect to any item or service on such a claim that is denied on any basis other than that particular frequency limit, such ABNs need to be reviewed for their correct application to any denial.)

E. Any claim about which there is any suspicion of fraud or abuse, whether with respect to the notifier, the category of notifiers, or the class of items or services involved.

110.5.3 - Other Reasons for Contractor Request for Copies of ABNs (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

Other good reasons for contractors to request submission of copies of ABNs include, but are not limited to, the following:

- A Any need that arises from the appeals processes for documentation.
- B Any practical need to identify the particular items and/or services, dates of service, reasons for predicting Medicare denial of payment, or other pertinent facts about the beneficiary notification.
- C Any plausible allegation or dispute as to the form, content, or delivery of a particular ABN or a particular group of ABNs, e.g., all ABNs furnished by a particular notifier, all ABNs for a particular item, etc.
- D For the purposes of a data analysis, utilization study, or other investigation or study.

120 - Contractor Specific Instructions for Application of Limitation on Liability

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

120.1 - Documentation of Notices Regarding Coverage (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

A critical step in the implementation of the limitation on liability provision is the distribution by contractors of notices regarding coverage issues to the medical community, or to specific segments of it, such as laboratories or certain physician specialty groups. An ongoing program of communication by contractors is essential. Timely communication of existing general notices to physicians and suppliers new to a contractor's service area is essential. The existence of written general notices will often determine the extent of program liability. As a minimum, the contractor should have a program for dissemination of the coverage guidelines published in the National Coverage Determinations Manual and the Medicare Benefit Policy Manual, as well as other guidelines contained in this manual for determining medical necessity and others issued from time to time in other CMS issuances.

120.2 - Availability of Coverage Notices to Operating Personnel (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

All review personnel should have ready access to a file of general notices regarding coverage for processing review cases involving the issue of limitation on liability.

In addition to general notices, the contractor must have a mechanism for identifying and locating correspondence with individual physician/suppliers regarding coverage of particular services or items. This mechanism should meet at least the following minimum requirements:

- The contractor must be able to determine if a practitioner or supplier has been sent an explanation, in lieu of, or in addition, to, a routine MSN denial notice, that a type of service or item is not reasonable and necessary. Such explanation may consist of a general notice or may be individual correspondence with the physician/supplier such as is usually found in contractor correspondence units or comparable units. Claims history files can also be checked, but these are generally useful only when the identical item or service in question has been previously denied as not meeting the requirements of §1862(a)(1);
- A copy of such an explanation must be readily available to appeal personnel; and
- Procedures must be established requiring that a check of all files be made to determine if such an explanation was ever sent before the physician/supplier's liability is limited.

Once a physician/supplier receives an explanation of denial for an item or service after an appeal determination, that determination would be considered a notice that should be readily accessible for future use for a similar claim(s).

120.3 - Applicability of Limitation on Liability Provision to Claims for Outpatient Physical Therapy Services Furnished by Clinics (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

A – General

The limitation on liability provision is applicable to claims for items or services furnished by a physician-directed outpatient physical therapy (OPT) clinic that are denied on the basis of §1862(a)(1).

The limitation on liability determination for OPT clinic claims will be made by contractors at the initial determination level, in accordance with §120.4. The procedures discussed in §120.2, second bullet , for determining a physician's/supplier's liability will be followed when processing this category of claims.

120.4 - Limitation on Liability Notices to Beneficiaries From Contractors

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

The contractor adds MSN Limitation of Liability Message 50.36.2 to the MSN sent to the beneficiary (who is presumed not to have knowledge of nonpayment by Medicare) at the time of the initial determination.

To message 50.36.2, it also adds the following language:

Do not apply if your (doctor/supplier) told you in writing, before furnishing the service, that Medicare would not pay.

The contractor adds MSN Limitation of Liability Message 50.36.1 to the MSN sent to the beneficiary (who is held to have had knowledge of nonpayment by Medicare) at the time of the initial determination.

The contractor adds, from the Remittance Advice Remarks Codes, the Justification for Services Remark M25 to the RA sent to the physician/supplier (who is presumed to have knowledge of nonpayment by Medicare) at the time of the initial determination.

The contractor adds, from the Remittance Advice Remarks Codes, the Justification for Services Remark M38 to the RA sent to the physician/supplier who is held to be not liable because the beneficiary is held liable at the time of the initial determination.

In addition to the above, as appropriate, the contractor notifies both the beneficiary and the physician/supplier at the time of the initial determination of their appeal rights (this is contained on the back of the MSN and the RA).

120.5 - Contractor Redeterminations or Reconsiderations in Assignment Cases Conducted at the Request of Either the Beneficiary or the Assignee

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

In every appeal where the limitation on liability provision is applicable, the redetermination consists of two stages. The first stage is a new, independent and critical reexamination of the facts regarding the coverage issue. If the original decision regarding coverage was appropriate, the second stage is the decision whether to limit the liability of the beneficiary and, if so, whether to also limit the liability of the provider, practitioner, or supplier.

Redeterminations in assignment cases are conducted at the request of either the beneficiary or the assignee. Frequently, the redetermination request is received from only one of the parties, either the provider/physician/supplier or the beneficiary, and the only notice to the other party that a redetermination has been requested is a copy of the determination, i.e., after the fact. In a limitation on liability case, the parties may have

adverse interests in the limitation on liability decision, since a provider, practitioner, or supplier may seek to show reason why the beneficiary's liability should not be limited in order to be able to collect his/her fee from the beneficiary. Therefore, when the contractor receives a request for a redetermination, it sends a notice that a request has been filed to the other party to the redetermination indicating that that party may submit additional evidence. This is necessary to satisfy the statutory requirement that both parties be informed of their rights and privileges in the appeal process.

120.5.1 - Guide Paragraphs for Contractors to Use Where §1879 Is Applicable at the Redetermination Level

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

The contractor uses the following paragraphs (in addition to other required appeal decision paragraphs) where the limitation on liability provision applies at the appeal level in the various situations shown below:

Situation I - To the provider, practitioner, or supplier when neither the provider, practitioner, or supplier nor the beneficiary is determined liable (program payment made under §1879 of the Act)

Paragraph(s):

Section 1879 of the Social Security Act permits Medicare payment to be made on behalf of a beneficiary to a physician/supplier who has accepted assignment for certain services for which payment would otherwise not be made under Medicare, if neither the beneficiary nor the physician/supplier knew, or could reasonably have been expected to know, that the services were excluded. The services affected by this provision are those that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. After reviewing (beneficiary's name's) claim for (description of services), we have concluded that these services are excluded under Medicare. However, since we find that neither (beneficiary's name) nor you knew, or could reasonably have been expected to know, that the services were excluded from coverage, the Medicare program will reimburse you under this provision of the law for the reasonable charge for the services, less any deductible and coinsurance. (Beneficiary's name) is responsible for any deductible and coinsurance amounts. Upon receipt of this notice, it will be considered that you now have knowledge of the exclusion of (description of service) for similar conditions, and this limitation of liability will not apply to future claims for the same or substantially similar services.

cc: Beneficiary

Situation II - To provider, practitioner, or supplier when the provider or practitioner or supplier is held liable

Paragraph(s);

Section 1879 of the Social Security Act permits Medicare payment to be made on behalf of a beneficiary to a provider or practitioner or supplier who has accepted assignment for certain services for which payment would otherwise not be made under Medicare. Medicare may make payment under this situation if neither the beneficiary nor the provider, practitioner, or supplier knew, or could reasonably have been expected to know. that the services were excluded. The services affected by this provision are those that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. After reviewing (beneficiary's name's) claim for (description of services), we have determined that (beneficiary's name) did not know and could not have been expected to know, that these services were excluded from coverage. However, we find that (select applicable phraseology from the following): (1) based upon the claim of (date) which was a similar claim in which payment was denied; (2) (our notification to you of (date) that such services are excluded); (3) (or any other basis used to determine the provider, practitioner, or supplier to be liable)), you knew, or could have been expected to know, that these services were excluded. We also find that you did not notify the beneficiary in writing, before the services were furnished, that Medicare likely would not pay for the services. Because of this, you are held liable for the full charges for the services.

We have also reviewed the claim with regard to the issue of whether the services were not reasonable and necessary. We found that the services were not reasonable and necessary.

If you disagree with this determination regarding your liability, on the basis that the services were necessary, or on the basis that you did not know, and could not reasonably have been expected to know, that Medicare would not pay for the services, or on the basis that you notified the beneficiary in writing, before the services were furnished, that Medicare likely would not pay for the services, you may request a reconsideration within 180 days of receipt of this notice, at which time you may present any new evidence that would have a material effect on this determination. Our office, or your social security office, will assist you if you need help in requesting a reconsideration.

cc: Beneficiary

Situation III - To the beneficiary when the beneficiary is held liable

Paragraph(s):

We have reviewed your claim for (description of the services). When we reviewed your claim, we considered two things. First, we considered whether the service you received was reasonable and necessary. Medicare will only pay for reasonable and necessary services. We found that the service was not reasonable and necessary.

Second, we considered whether you knew, or were told, that Medicare would not pay. Medicare would not hold you liable if you did not know and your (doctor/supplier) did not tell you in advance, in writing, that Medicare would not pay. In that case, we would pay you any amount you pay or paid your (doctor/supplier) for the service. Our review

shows that (choose one of the following to complete the sentence: (the (doctor/ supplier) told you in writing, before giving the service, that Medicare would not pay); (this service had been denied on other claims for you); OR (we told you in a letter dated (DATE) that Medicare would not pay for this service)). Since we believe you knew Medicare would not pay for this service, Medicare cannot pay. You are liable for the charges.

If you do not agree with our decision, ask for a reconsideration from a Qualified Independent Contractor (QIC). The QIC will decide whether the service was reasonable and necessary. The QIC will also decide whether you knew, or were told, Medicare would not pay. You must ask for a reconsideration within 180 days of the date you receive this notice. At the reconsideration, you may present any new evidence which would affect our decision. If you need help, your social security office will help you request a reconsideration.

cc: Physician/Supplier

Situation IV - Rider paragraph to be included in the copy of the notice to the beneficiary when the physician/supplier is held liable

If you paid any amounts to (physician's/supplier's name) for this service, Medicare will pay you back the amount you paid. To get this payment, bring or send to this office three things. (1) A copy of this notice. (2) Your (doctor's/supplier's) bill. (3) A receipt or other proof you have paid the bill.

(See §§120.4 for handling requests for indemnification where payment has been made to a liable practitioner or supplier.)

130 - Intermediary Specific Instructions for Application of Limitation on Liability

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

See §120.5.1 for guide language.

130.1 - Applicability of the Limitation on Liability Provision to Claims for Ancillary, Outpatient Provider and Rural Health Clinic Services Payable Under Part B

(Rev. 1, 10-01-03)

A3-3444

The following sections discuss how the limitation on liability provision is applied to claims involving ancillary, outpatient and rural health clinic services billed on Form CMS-1450 (Provider Billing for Medical and Other Health Services), where reimbursement is sought under Part B. The FI determines whether limitation on liability

applies to these categories of claims when the basis for the denial is that the services were not reasonable and necessary (under §1862(a)(l) of the Act).

130.1.1 - Determining Beneficiary Liability in Claims for Ancillary and Outpatient Services

(Rev. 594, Issued: 06-24-05, Effective: 07-01-05, Implementation: 07-01-05)

A presumption will be made that the beneficiary did not know that items or services are not covered unless there is evidence to the contrary. Indication on the claim that the beneficiary received proper advance beneficiary notice before receiving the noncovered ancillary, outpatient, or rural health clinic services is evidence to the contrary which rebuts the presumption in the beneficiary's favor. The definitions of proper "advance beneficiary notice" to the beneficiary are set forth in §40.3. Note that if the reason liability is at issue coincides with the end of coverage for a period of care in specific settings-- inpatient hospital, skilled nursing, home health, hospice or comprehensive outpatient rehabilitation facilities-- notification under the expedited determination process will be required as of July 1, 2005. See CR#3903 for preliminary information on the expedited process, including its interaction with liability notice policy (i.e., ABNs).

130.1.2 - Determining Provider Liability in Claims for Ancillary and Outpatient Services

(Rev. 1, 10-01-03)

A3-3444.2

The procedures in §30.2 apply for determining liability for providers. A provider may have its liability waived in an individual claim if it can establish that it did not know and could not have been expected to know that Medicare would not make payment for the items or services.

130.2 - Prior Hospitalization and Transfer Requirements for SNF Coverage as Related to Limitation on Liability

(Rev. 1, 10-01-03)

A3-3431.1

In order to qualify for post-hospital extended care services, the individual must meet the prior hospitalization and transfer requirements discussed in "Coverage of Extended Care Services Under Hospital Insurance," Chapter 8 of the Medicare Benefit Policy Manual. The following sections discuss the relationship of these requirements to the limitation on liability provision.

A. Three-Day Prior Hospitalization

Before Medicare can pay for post-hospital extended care services, it must determine whether the beneficiary had a prior qualifying hospital stay of at least three consecutive calendar days. When a beneficiary's liability for a hospital stay is waived, the hospital days to which the limitation on liability applies **cannot** be used to satisfy the 3-day prior hospitalization requirement, since the services rendered during the days in question were found noncovered because they were not considered reasonable and necessary or because they constituted custodial care. (See "Coverage of Extended Care (SNF) Services Under Hospital Insurance," Chapter 8, of the Medicare Benefit Policy Manual for determining whether the 3-day prior hospitalization requirement is met.) If a beneficiary's hospital stay was partially covered, the FI considers the covered portion of the stay in determining whether the SNF prior hospitalization requirement is met.

B. Transfer Requirements

1. Transfer Period

The FI applies the limitation on liability provision where it determines that all the SNF care received during the period serving to satisfy the transfer requirements described in "Coverage of Extended Care Services Under Hospital Insurance," Chapter 8 of the Medicare Benefit Policy Manual, either constituted custodial care or was not reasonable and necessary.

Where the FI determines that only the beneficiary's liability can be waived, the limitation on liability applies through the date of the notice to the beneficiary including any inpatient days beyond the transfer period. If the provider is also entitled to limitation on liability and program payment is possible under the limitation on liability provision, such payment is appropriate through the date of the notice and, if the FI determines that additional time is needed to arrange for post-discharge care, for up to 24 hours after the date of notice to the provider or the beneficiary, whichever is earlier. If the FI determines that even more time is needed to arrange post-discharge care, up to 24 additional hours may be paid for. (See §50.)

Where a beneficiary who is entitled to limitation on liability starts to require and receives reasonable and necessary or noncustodial services only **after** the expiration of the SNF transfer period, the beneficiary nevertheless may have his/her liability waived for days where such services were rendered, in addition to those days waived during the noncovered transfer period **but only through the date of notice to the beneficiary**. If the provider is also entitled to limitation on liability, program payment may be made under the limitation on liability provision through the date of notice of noncoverage and, if the FI determines that additional time is needed to arrange for post-discharge care, for a "grace period" of I day thereafter. If the FI determines that even more time is needed to arrange post-discharge care, 1 additional "grace period" day may be paid for. (See §50.) This payment is made because it is inequitable to waive liability for noncovered services rendered during the transfer period but not for a period thereafter (prior to notice) during which the beneficiary needed and received an otherwise covered level of care.

2. Delayed Transfer Due to Medical Appropriateness

The law also provides for an extension of the usual 30-day time limit for transfer where the patient's condition makes it medically appropriate. ("Coverage of Extended Care Services Under Hospital Insurance," in the Medicare Benefit Policy Manual, Chapter 8.) However, if the FI determines that such an extension is not allowable because an interval of more than 30 days for transfer to a SNF was not medically appropriate, it denies the SNF services because the transfer requirement was not met. The limitation on liability provision is not applicable in such a case.

130.3 - Application of Limitation on Liability to SNF and Hospital Claims for Services Furnished in Noncertified or Inappropriately Certified Beds

(Rev. 594, Issued: 06-24-05, Effective: 07-01-05, Implementation: 07-01-05)

A. General

Payment for SNF and hospital claims may not be denied solely on the basis of a beneficiary's placement in a non-certified bed of a participating SNF or hospital. When requested by the beneficiary or his/her authorized representative, a provider must submit a claim to the FI for services rendered in a non-certified bed. When the FI reviews a claim for services rendered in a non-certified bed, it first determines whether the beneficiary consented to the placement. (See subsection C.) If the FI finds that the beneficiary consented, it denies the claim. If it finds that the beneficiary did not consent, it determines whether there are any other reasons for denying the claim. (See subsection D.) If there is another reason for denying the claim, the FI denies it. However, if none of the reasons for denial exist, beneficiary liability must be waived as provided under §1879(e) of the Act and a further determination must be made as to whether the provider, rather than the Medicare program, must accept liability for the services in question. (See "Coverage of Extended Care Services Under Hospital Insurance" in the Medicare Benefit Policy Manual, Chapter 8.)

B. Provider Notice Requirements

When a SNF or hospital places a patient in a noncertified or inappropriately certified portion of its facility because it believes the patient does not require a covered level of care, or for any other reason, it must notify the patient (or authorized representative) in writing that services in a noncertified or inappropriately certified bed are not covered.

The provider uses the appropriate notice specified in §70 of this chapter for SNFs or swing beds, §80 for inpatient hospitals, to advise the beneficiary of its decision to place him/her in a noncertified bed, using language such as:

We are placing you in a part of this facility that is not appropriately certified by Medicare because (you do not require a level of care that will qualify as skilled nursing care/or covered hospital services under Medicare)/(or state any other reasons for the noncertified bed placement). Nonqualifying services furnished a

patient in a noncertified or inappropriately certified bed are not payable by Medicare. However, you may request us to file a claim for Medicare benefits. Based on this claim, Medicare will make a formal determination and advise whether any benefits are payable to you.

(For related general billing requirements, see Chapter 1, §60 of this manual, or other chapters specific to the benefit being billed: Chapter 3 for inpatient hospitals and swing beds, Chapter 6 for swing bed PPS and inpatient SNFs, and Chapter 7 for outpatient SNFs.)

C. Determining Beneficiary Consent

The CMS presumes that the beneficiary did not consent to being placed in a noncertified bed. In order to rebut the presumption of lack of consent, the provider must indicate on the bill the date it provided the beneficiary with an ABN notifying the beneficiary that the accommodations would no longer be covered; and requested the beneficiary's signed acknowledgement (on the ABN) of having received such a statement. Moreover, in any case in which a Medicare beneficiary gives his/her consent to placement in a noncertified bed, the provider must, if requested by the FI (contemplated only at an appeal level of claim processing), submit a copy of the ABN signed by the beneficiary to the FI, for a determination of the ABN's validity. The ABN must be signed by the beneficiary (provided he/she is competent to give such consent) or by the beneficiary's authorized representative. If the beneficiary or his/her authorized representative refuses to sign the form, the provider may annotate the file to indicate it presented the ABN to the beneficiary (or his/her authorized representative), but the beneficiary refused to sign. As long as the provider's ABN notifies the beneficiary of the likely Medicare noncoverage. the beneficiary's refusal to sign the ABN does not render it invalid. (See §40.3.4.6.) If any of the above requirements is not met, the FI automatically determines the ABN is defective.

When the FI receives a claim with an indication that the provider has provided the beneficiary or his/her authorized representative, with an ABN, the FI denies the claim and notifies the beneficiary that §1879 limitation on liability cannot be applied because of the beneficiary's valid consent to be cared for in a noncertified or inappropriately certified bed. If the FI determines that the ABN is not valid, the FI processes the claim in accordance with §130.4.

If the beneficiary appeals the initial denial, the FI obtains the ABN from the provider and determines whether it is valid. If the FI determines that the ABN is invalid, it notifies the provider and the beneficiary that payment **may** be made to the extent that all other requirements are met.

D. Determining Whether Other Requirements for Payment are Met

Denials still are appropriate for any of the following reasons. The FI must undertake the development needed to permit a determination as to whether:

The patient did not receive or require otherwise covered hospital services or a covered level of SNF care;

The benefits are exhausted:

The physician's certification requirement is not met;

There was no qualifying 3-day hospital stay (applicable to SNFs only); or

Transfer from the hospital to the SNF was not made on a timely basis. (However, if transfer to an institution which contains a participating SNF is made on a timely basis, a claim cannot be denied solely on the grounds that the transfer requirement is not met because the bed in which the beneficiary is placed is not a certified SNF bed.)

The FI denies cases falling within these categories under existing procedures. Also, if the beneficiary receives care in a totally nonparticipating institution, denial on the grounds that the beneficiary was not in a participating SNF or hospital is still appropriate.

130.4 - Determining Liability for Services Furnished in a Noncertified SNF or Hospital Bed

(Rev. 594, Issued: 06-24-05, Effective: 07-01-05, Implementation: 07-01-05)

The FI presumes that the provider properly notified the beneficiary of noncoverage, and that the beneficiary assented, if the claim includes the proper indicators of liability notification.

The following development occurs only if the beneficiary appeals the FI's decision that the beneficiary may not have liability waived because the provider gave him/her timely notice that Medicare would not cover the accommodation; and that he/she consented to being placed in a noncertified bed.

A. Beneficiary Liability

If the FI determines that the beneficiary did not consent to placement in the noncertified bed within the participating facility (see §130.3.C), and that no other basis for denial of the claim exists (see §130.3.D), it finds the beneficiary not liable under §1879 of the Act.

B. Provider Liability

If the beneficiary is found not liable under §1879, liability may rest with the provider, or with the program. Liability rests with the Medicare program, unless any of the following conditions exist, in which case the provider is liable for the services.

The provider did not give timely written notice to the beneficiary of the implications of receiving care in a noncertified or inappropriately certified bed as discussed in §130.3.B;

The provider failed to provide the beneficiary with an appropriate ABN and/or did not attempt to obtain a valid consent statement from the beneficiary. (See §130.3.C.); or

The FI determined from medical records in its claims files that it is clear that the beneficiary required and received services equivalent to a covered level of SNF care, or that constituted covered hospital services, and the provider had no reasonable basis for placing the beneficiary in a noncertified bed. Following are examples of situations in which it would be found that the provider did in fact have a reasonable basis to place a beneficiary in a noncertified bed:

EXAMPLES:

- The FI, a QIO, or Utilization Review Committee had advised the provider that the beneficiary did not require a covered level of SNF care or covered hospital services preadmission/admission;
- The beneficiary's attending physician specifically advised the provider (verified by documentation in the medical record) that the beneficiary no longer required a covered level of care or services; note that if covered care had previously existed, effective July 1, 2005, notification under the expedited determination process would be required (see §20 of this chapter);
- A beneficiary not requiring covered services had a change in his/her condition that later required a covered level of care or services and the provider had no certified bed available (of course, the SNF transfer requirement must be met, see the Medicare Benefit Policy Manual, Chapter 8.); or

The FI has other sufficient evidence to determine that the provider acted in good faith but inadvertently placed the beneficiary in a noncertified bed.

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

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

Following are the procedures for implementing §1842(1) of the Act. Under §9332(c) of OBRA 1986 (P.L. 99-509), which added §1842(l) to the Act, new liability protections for Medicare beneficiaries affect nonparticipating physicians.

140.1 - Services Furnished Before October 1, 1987 (Rev. 1, 10-01-03)

Before October 1, 1987, a physician who did not accept Medicare assignment was permitted to collect from a Medicare beneficiary his/her full charge for services which were subsequently denied because they were not reasonable and necessary under §1862(a)(1) of the Act, even though the beneficiary may not have known that Medicare would not pay for the services. This was in contrast to the rules applicable to assigned

claims. Where a physician agrees to accept assignment (either on an individual claims basis or by entering into a Medicare participation agreement), the physician is effectively precluded by the indemnification procedures under the limitation of liability provision from receiving payment for services that are not reasonable and necessary if it is established that the physician knew or should have known that Medicare would not pay for the services and the beneficiary did not. However, under the limitation of liability provision, program payment may be made to the physician if neither the physician nor the patient knew, nor could reasonably have been expected to know, that Medicare would not pay for the items and services.

140.2 - Services Furnished Beginning October 1, 1987

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07) Under §1842(1) of the Act, effective for services furnished on or after October 1, 1987, nonparticipating physicians who

- 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 must refund to beneficiaries any amounts collected for physicians' services which are denied because they are not reasonable and necessary under §1862(a)(1).

This provision is applicable in any case in which the contractor denies payment or reduces the level of payment on the basis of §1862(a)(1). In the latter situation, there is, in effect, a denial of the more extensive service or procedure on the basis that it is not reasonable and necessary under §1862(a)(1), even though Medicare payment is made for the less extensive service or procedure (e.g., an intermediate office visit is allowed as a brief office visit). Where a reduction in the level of payment occurs, the physician must refund to the beneficiary any amounts he/she collects which exceed his/her maximum allowable actual charge (MAAC) for the less extensive procedure. Of course, in the unusual case where the physician's MAAC for the less extensive service equals or exceeds his/her actual charge for the more extensive service, no refund is required.

Section 1842(1) of the Act applies only to physicians' services subject to the Medicare Economic Index (MEI). Certain services, such as those involving injections that can be given by a paramedical person other than a physician (e.g., pneumococcal and hepatitis vaccine injections) which may be denied under §1862(a)(1) are not physicians' services for purposes of the MEI. Therefore, denials of payment on the basis of §1862(a)(1)(B) of the Act for those services are not subject to §1842(1) refund requirements. Additionally, services of physician extenders (e.g., physician's assistants, nurse practitioners, MEDEXes, etc.) are not physicians' services and are not subject to §1842(1) refund requirements. The application of §1842(1) refund requirements on the correct statutory basis, i.e., only on the basis of §1862(a)(1), and only to physicians' services subject to the MEI, is essential. Incorrect application improperly takes away physicians' rights to bill beneficiaries for denied services and incurs unnecessary expenses for review, development, and appeals.

140.3 - Time Limits for Making Refunds

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

A required refund must be made within specified time limits. Physicians who knowingly and willfully fail to make refund within these time limits may be subject to civil money penalties and/or exclusion from the Medicare program. Under §1842(1), a refund of any amounts collected must be made to the beneficiary within the following time limits:

- If the physician does not request an appeal 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 physician receives notice of the initial determination. (See §140.6 for notice requirements.); or
- If the physician requests an appeal 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 physician receives the notice of the appeal determination.

140.4 - Situations Where a Refund Is Not Required (Rev. 1, 10-01-03)

Under §1842(1), a refund is not required of the physician if either of the following conditions is met:

The physician did not know and could not reasonably have been expected to know that Medicare would not pay for the services because they were not reasonable and necessary. To determine whether the physician knew, or could reasonably have been expected to know, use the rules for determining physician liability under §1879. (See §30.2.); or

Before the service was furnished, the physician notified the beneficiary in writing of the likelihood that Medicare would not pay for the specific service and, after being so informed, the beneficiary signed a statement agreeing to pay the physician for the service.

To qualify for waiver of the refund requirements of §1842(1), the advance notice to the beneficiary must be in writing, must clearly identify the particular service, must state that the physician believes Medicare is likely to deny payment for the particular service, and must give the physician's reason(s) for his/her belief that Medicare is likely to deny payment for the service. The Advance Beneficiary Notice (ABN, Form CMS-R-131), given in compliance with §40.3 and §50, satisfies the statutory requirements for the physician's advance notice and the beneficiary's agreement to pay.

140.5 - Appeal Rights

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

Nonparticipating physicians have the same rights to appeal the contractor's redetermination in an unassigned claim for physicians' services if the contractor denies or

reduces payment on the basis of §1862 (a)(1) as they or participating physicians have in assigned claims. These rights of appeal also extend to determinations that a refund is required either because the physician knew or should have known that Medicare would not pay for the 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 service or, if so informed, did not sign a statement agreeing to pay. In addition to the beneficiary's right to appeal the contractor's decision to deny or reduce payment on the basis of §1862 (a)(1), the beneficiary becomes a party to any request for appeal filed by the physician. Since the beneficiary and the physician may have adverse interests in a decision regarding refund, it is essential to notify the beneficiary in any case in which the physician requests an appeal of the denial or reduction in payment or asserts that a refund is not required because one of the conditions in §140.4 is met. (See Chapter 29, "Appeals for detailed appeals instructions.")

140.6 - Processing Initial Denials

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

In any unassigned claim for physician's services furnished on or after October 1, 1987, in which the contractor denies or reduces payment on the basis of §1862(a)(1), the contractor will send separate notices to both the beneficiary and the physician. In some cases, the beneficiary (or physician) may submit a copy of an ABN which satisfies the requirements in §140.4. The contractor should not make an automatic finding that the service is not reasonable and necessary merely because the beneficiary has submitted an ABN. The fact that there is an acceptable ABN must in no way prejudice the contractor's determination as to whether there is or is not sufficient evidence to justify a denial under §1862(a)(1). In the case where there is an acceptable ABN, the contractor will mail a standard denial MSN notice to the beneficiary. In the absence of an acceptable ABN, and depending on whether there is a full denial or a partial reduction in payment, the contractor will include, in addition to one of the "medical necessity" denial notices, one of the following notices in the MSN sent to the beneficiary.

140.6.1 - Initial Beneficiary Notices

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

Notice 1 - Full Denial

If the doctor should have known that Medicare would not pay for the denied services and did not tell you in writing before providing the services, you may be entitled to a refund of any amounts you paid. However, if the doctor requests an appeal of this claim within 30 days, a refund is not required until we complete our appeal. If you paid for this service and do not hear anything about a refund within the next 30 days, contact your doctor's office.

Notice 2 - Reduction in Payment

If the doctor should have known that Medicare would not pay for the more extensive service and did not tell you this in writing before providing the service, you may be entitled to a refund of any amount you paid which is more than the doctor is allowed by law to charge under Medicare for the less extensive service. However, if the doctor requests an appeal of this claim within 30 days, a refund is not required until we complete our appeal. If you paid for the more extensive service and do not hear anything about a refund within the next 30 days, contact your doctor's office.

In addition, add the following paragraph:

You could have avoided paying \$______, the difference between the maximum amount the doctor or supplier is allowed to charge and the amount Medicare approved for the lesser service, if the claim had been assigned.

140.6.2 - Initial Physician Notices

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07) Include in the notice to the physician the following:

- The patient's name and health insurance claim number;
- A description of the service by procedure code, date and place of service, and amount of the charge;
- The same denial notice included on the beneficiary's MSN; and
- Depending on whether the beneficiary submitted a copy of an acceptable ABN with his/her claim, include in the notice to the physician one of the following:

Notice 1 - Advance Beneficiary Notice Received Prior to Initial Determination

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

Or

Notice 2 - Advance Beneficiary Notice Not Submitted

(The service identified above has been denied because/Although payment has been made to the patient for a less extensive service,) the information furnished did not substantiate the need for the (more extensive) service).

If you have collected (any amount from the patient/any amount that exceeds your maximum allowable actual charge (MAAC) for the less extensive service), 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 service; or
- If you notified the beneficiary in writing before providing the service that you believed that Medicare was likely to deny the service, and the beneficiary signed a statement agreeing to pay for the service.

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

If you request an appeal within this 30 day period, you may delay refunding the amount to the beneficiary until you receive the results of the appeal. If the appeal determination is favorable to you, you do not have to make any refund. If, however, the appeal is unfavorable, the law specifies that you must make the refund within 15 days of receiving the unfavorable appeal decision.

The law also permits you to request an appeal of the determination at any time within six months of receiving this notice. An appeal requested after the 30 day period does not permit you to delay making the refund. Regardless of when an appeal is requested, the patient will be notified that you have requested one, and will receive a copy of the determination.

The patient has received a separate notice of this denial decision. The notice advises that he or she may be entitled to a refund of any amounts paid, if you should have known that Medicare would not pay and did not tell him or her. It also instructs the patient to contact your office if he or she does not hear anything about a refund within 30 days.

The requirements for refund are in §1842(1) of the Social Security Act. Section 1842(1) specifies that physicians who knowingly and willfully fail to make appropriate refunds may be subject to civil money penalties and/or exclusion from the Medicare program.

If you have any questions about this notice, please contact (Contractor contact, telephone number).

The contractor will ensure that the telephone number puts the physician 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 the contractor automatically denies under the A/B link procedures. In those cases, the QIO is responsible for notifying the beneficiary and physician of the refund requirements of §1842(1) and making the refund determination where appropriate.

140.7 - Processing Beneficiary Requests for Appeal (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

Where a beneficiary requests an appeal of the initial denial or reduction in payment, the contractor will process the appeal in the normal fashion except that, where the appeal results in a reversal to full or partial payment, the contractor will include the following special paragraph in the appeal notice sent to the beneficiary:

The doctor who furnished this service has been informed of this decision and advised that he/she may collect (his/her full charge for the service/up to the maximum amount he/she is allowed by law to charge under Medicare for the less extensive service for which payment has been made).

If the reversal is for the less extensive service, the contractor will incorporate in the notice the following:

You could have avoided paying \$______, the difference between the maximum amount the doctor is allowed to charge and the amount Medicare approved for the lesser service, if the claim had been assigned.

The contractor will send the physician who furnished the service a separate notice which clearly identifies the service for which full or partial payment is being made (i.e., includes the patient's name, health insurance claim number, a description of the service billed by procedure code, date and place of service, and amount of the charge. Where only partial payment is being made, the contractor will clearly indicate the less extensive service for which payment has been made). The contractor will include the following language:

You were previously advised that Medicare payment could not be made for this service. However, after reviewing this claim, we have determined that payment may be made (for a less extensive service). Therefore, if you have already refunded the amounts you collected from the beneficiary for this service, you may recollect (these amounts/any amounts which do not exceed your maximum allowable actual charge (MAAC) for the less extensive service for which payment has been made).

140.8 - Processing Physician Requests for Appeal (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

Where a physician requests an appeal, the contractor will notify the beneficiary as discussed in §140.5. The appeal process consists of three stages, even though the physician may be contesting only one issue (e.g., the physician may assert that he/she did not know, and could not have reasonably have been expected to know, that Medicare would not pay for the services).

140.8.1 - Appeal of the Denial or Reduction in Payment (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

The first part of the appeal is a new, independent, and critical reexamination of the facts regarding the denial or reduction in payment. If the contractor finds that the initial denial or reduction in payment was appropriate, the contractor will go on to §140.8.2.

140.8.2 - Beneficiary Given ABN and Agreed to Pay (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

A physician who 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 physician claims to have given an ABN to the beneficiary, the contractor will ask the physician to furnish a copy of the signed ABN. The contractor will examine the ABN to determine whether it meets the guidelines in $\S140.4$. In the absence of acceptable evidence of advance notice, the contractor will go on to $\S140.8.3$.

140.8.3 - Physician Knowledge (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

In determining whether the physician knew, or could reasonably have been expected to know, that Medicare would not pay for the services, the contractor will apply the same rules that are applicable in determining physician liability under §1879 of the Act. (See §30.2.)

140.9 - Guide Paragraphs for Inclusion in Appeal Determination (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

The contractor, upon completion of its appeal, will send the physician an appeal notice and send a copy to the beneficiary. If the initial payment determination is reversed to full or partial payment, the contractor will include in the appeal notice the physician notice language required in §140.7. Otherwise, the contractor will include one of the following paragraphs concerning refund.

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

Under §1842(1) of the Social Security Act, a physician who does not accept assignment and collects any amounts from a Medicare beneficiary for services for which Medicare does not pay on the basis of §1862(a)(1) of the Social Security Act, must refund these amounts to the beneficiary. However, a refund is not required if, prior to furnishing the services, the physician notified the beneficiary in writing that Medicare would not pay for the 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 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 - Physician Did Not Know That Medicare Would Not Pay For the Services

Under §1842(1) of the Social Security Act, a physician who does not accept assignment and collects any amounts from a Medicare beneficiary for services for which Medicare does not pay on the basis of §1862(a)(1) of the Social Security Act, must refund these amounts to the beneficiary. However, a refund is not necessary if the physician did not know, and could not reasonably have been expected to know, that Medicare does not pay for the 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 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 services) for similar conditions. The beneficiary has been sent a copy of this notice.

Paragraph 3. Adverse Action on Denial - Refund Required

Under §1842(1) of the Social Security Act, a physician who does not accept assignment and collects any amounts from a Medicare beneficiary for services for which Medicare does not pay on the basis of §1862(a)(1) of the Social Security Act, must refund these amounts to the beneficiary. A refund is not required if (1) the physician did not know, and could not reasonably have been expected to know, that Medicare would not pay for the services; or (2) the physician notified the beneficiary in writing before furnishing the services that Medicare would not pay for the 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 services within 15 days from the date you receive this notice. A refund must be made within 15 days from receipt of this notice for you to be in compliance with the law. If we paid for a less extensive procedure, you need refund only the amount which exceeds your maximum allowable actual charge (MAAC) for the less extensive procedure. The beneficiary has been sent a copy of this notice. Physicians who knowingly and willfully fail to make appropriate refunds may be subject to assessments of double the violative charges, civil money penalties (up to \$2000 per violation), and/or exclusion from the Medicare program for a period of up to 5 years.

140.10 - Physician Fails to Make Refund

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

Under §1842(1) of the Act, a physician who knowingly and willfully fails to make refund within the time limits in §140.3 may be subject to sanctions (i.e., civil money penalties and/or exclusion from the Medicare program). Generally, the failure of a physician to make a refund comes to the contractor's attention as a result of a beneficiary complaint to the contractor, Social Security Administration (SSA), or CMS. If necessary, the contractor will contact the beneficiary to clarify the information in the complaint and to determine the amount the beneficiary paid the physician for the denied services. If the contractor determines that a physician failed to make a refund, it will contact the physician in person or by telephone to discuss the facts of the case. The contractor will attempt to determine why the amounts collected have not been refunded and will explain that the law requires that the physician make refund to the beneficiary and that if he/she fails to do so, the OIG may impose civil money penalties and assessments, and sanctions. The contractor will make a dated report of contact and include the information relayed to the physician and the physician's response. The contractor will recontact the beneficiary in 15 days to determine whether the refund has been made. When the amount in question is \$300 or more or where there are at least three outstanding violations by the physician, the contractor will contact the Sanctions Coordinator in the appropriate field office of the OIG by telephone to discuss whether referral to OIG is appropriate. If the case should be referred, the contractor will make the referral to the regional OIG Sanctions Coordinator in accordance with the procedures following. The contractor should not make a referral until the physician's appeal rights have been exhausted, or until the time limit for an appeal has passed.

140.11 - OIG Referral Procedures

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07) The contractor will include in the sanction recommendation to the OIG/FO (to the extent appropriate) the following:

- Identification of the Subject The subject's name, address and a brief description of the subject's special field of medicine.
- 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 in §1842(1).
- Documentation Copies of written correspondence and written summaries of any meetings or telephone contacts with the beneficiary and the physician regarding the physician's failure to make refund.
- Other Significant Issues Any information that may be of value in the event of a hearing to bar a physician from receiving Medicare payment.

140.12 - Imposition of Sanctions (Rev. 1, 10-01-03)

Section 1842(1)(3) of the Act provides that if a physician knowingly and willfully fails to make a required refund, the Secretary may impose the sanctions provided in §§1842(j)(2) of the Act. These include assessments of double the violative charges, civil money penalties (up to \$2000 per violation), and/or exclusion from the Medicare program for a period of up to five years. However, sole community physicians and physicians who are the sole source of an essential specialty are not excluded from the program. The OIG makes determinations to levy a monetary penalty or program exclusion based upon a failure to make a refund.

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

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

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

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

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

Refund is not required if the supplier is held not to be liable, that is, if it is held that the supplier did not know and could not reasonably have been expected to know that Medicare would not pay on the basis of §1834(a)(17)(B), §1834(j)(1), §1834(a)(15), or §1862(a)(1) of the Act, or if it is held that, before the item or service was furnished, the beneficiary was informed by the supplier that Medicare would not pay and the beneficiary agreed to pay for the item or service. In any case where the supplier is held not to be liable, the beneficiary is liable for payment.

150.1 - Definition of Medical Equipment and Supplies

(Rev. 1, 10-01-03)

The following definitions of medical equipment and supplies control the application of the provisions of this section.

150.1.1 - Unassigned Claims Denied on the Basis of the Prohibition on Unsolicited Telephone Contacts

(Rev. 1, 10-01-03)

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.

150.1.2 - Unassigned Claims Denied on the Basis of Not Being Reasonable and Necessary

(Rev. 1, 10-01-03)

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.

150.1.3 - Unassigned Claims Denied on the Basis of Failure of the Supplier to Meet Supplier Number Requirements

(Rev. 1, 10-01-03)

For unassigned claims denied on the basis of failure of the supplier to meet supplier number requirements under $\S1834(j)(1)$ 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.

150.1.4 - Assigned Claims Denied on the Basis of the Prohibition on Unsolicited Telephone Contacts

(Rev. 1, 10-01-03)

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.

150.1.5 - Assigned Claims Denied on the Basis of Failure of the Supplier to Meet Supplier Number Requirements

(Rev. 1, 10-01-03)

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.

150.1.6 - Assigned Claims Denied on the Basis of Not Being Reasonable and Necessary

(Rev. 1, 10-01-03)

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

150.2 - Items and Services Furnished on an Unassigned Basis on or After January 1, 1995

(Rev. 1, 10-01-03)

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, 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; or

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.

150.3 - Items and Services Furnished On an Assigned Basis On or After January 1, 1995

(Rev. 1, 10-01-03)

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.

150.4 - Time Limits for Making Refunds (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

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 an appeal 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).
- If the supplier requests an appeal 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.

150.5 - Supplier Knowledge Standards for Waiver of Refund Requirement (Rev. 1, 10-01-03)

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.

150.5.1 - Knowledge Standards for §1862(a)(1) Denials (Rev. 1, 10-01-03)

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.

150.5.2 - Knowledge Standards for §1834(a)(15) Denials

150.5.2.1 - Denial of Payment in Advance

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

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

150.5.2.2 - When a Request for an Advance Determination of Coverage Is Mandatory

(Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

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 contractor 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 medically 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.

150.5.2.3 - When a Request for an Advance Determination of Coverage Is Optional

(Rev. 1, 10-01-03)

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.

150.5.2.4 - Presumption for Constructive Notice

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

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

150.5.2.5 - Presumption When Advance Determination was Requested (Rev. 1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

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

150.5.2.6 - Presumption for Listed Overutilized Items (Rev. 1, 10-01-03)

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 nonrebuttable presumption.

150.5.2.7 - Presumption for Listed Suppliers (Rev. 1, 10-01-03)

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 nonrebuttable presumption.

150.5.2.8 - Presumption for Medical Necessity (Rev. 1, 10-01-03)

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 nonrebuttable presumption.

150.5.2.9 - Presumption About Beneficiary Knowledge

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

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

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

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

In determining whether the supplier knew, or could reasonably have been expected to know, that Medicare would not pay because of the prohibition on unsolicited telephone contacts under §1834(a)(17)(B) of the Act, presume that the supplier knew that Medicare would not pay on the basis of constructive notice to the supplier through publication of the prohibition on such contacts through the *contractor*'s professional relations function, as well as publicity through trade organizations' own publications, professional training, conventions, etc. The supplier would have to submit convincing evidence to the contrary, showing ignorance of the prohibition on the supplier's part, to rebut this presumption. A single denial of a claim for any item furnished by a particular supplier on the basis of the prohibition on unsolicited telephone contacts shall be held to be actual notice of the prohibition to that supplier; and that supplier shall be considered, on that basis, to have had knowledge that payment would be denied for all such future claims, even those for different items of medical equipment and supplies. That is, after a single denial under §1834(a)(17)(B) of a claim by a particular supplier, the presumption of that supplier's knowledge becomes nonrebuttable.

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

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

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

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

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

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

150.6 - Advance Beneficiary Notice Standards for Waiver of Refund Requirement

(Rev. 1, 10-01-03)

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 used in accordance with the instructions at §50.

150.7 - Appeal Rights

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

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

150.8 - Processing Initial Denials

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

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

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

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

A. Initial Beneficiary Notice

(MSN 8.54)

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

(MSN 8.54) - In Spanish

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

B. Initial Supplier Notice

Include in the notice to the supplier the following;

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

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

Notice 1. – Signed Advance Beneficiary Notice Obtained

(Remark Code N124)

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

Or

Notice 2. – Signed Advance Beneficiary Notice Not Obtained

(Remark Code N125)

Payment has been (denied for the/made only for a less extensive) service/item because the information furnished does not substantiate the need for the (more extensive) service/item. If you have collected any amount from the patient, you must refund that amount to the patient within 30 days of receiving this notice. The law permits exceptions to this refund requirement in two cases: if you did not know, and could not have reasonably been expected to know, that Medicare would not pay for this service/item; or if you notified the beneficiary in writing before providing it that Medicare likely would deny the service/item, and the beneficiary signed a statement agreeing to pay.

If an exception applies to you, or you believe the *contractor* was wrong in denying payment, you should request an appeal of this determination by the *contractor* within 30 days of receiving this notice. Your request for appeal should include any additional information necessary to support your position. If you request an appeal within 30-days, you may delay refunding to the beneficiary until you receive the results of the appeal. If the appeal determination is favorable to you, you do not have to make any

refund. If the appeal is unfavorable, you must make the refund within 15 days of receiving the unfavorable appeal decision.

You may request an appeal of the determination at any time within 120 days of receiving this notice. An appeal requested after the 30-day period does not permit you to delay making the refund. Regardless of when an appeal is requested, the patient will be notified that you have requested one, and will receive a copy of the determination.

The patient has received a separate notice of this denial decision. The notice advises that he or she may be entitled to a refund of any amounts paid, if you should have known that Medicare would not pay and did not tell him or her. It also instructs the patient to contact your office if he or she does not hear anything about a refund within 30 days.

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

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

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

150.9 - Processing Beneficiary Requests for Appeal (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

Where a beneficiary requests an appeal of the initial denial, process the appeal in the normal fashion except that, where the appeal results in a reversal, include the following special paragraph in the appeal 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.

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.

150.10 - Processing Supplier Requests for Appeal (Rev. 1186, Issued: 02-23-07; Effective: 01-01-06; Implementation: 05-23-07)

Where a supplier requests an appeal, notify the beneficiary as discussed in $\S150.7$. The appeal 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).

150.10.1 - Appeal of the Denial of Payment

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

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

150.10.2 - Beneficiary Given Advance Beneficiary Notice and Agreed to Pav

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

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

150.10.3 - Supplier Knowledge

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

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

150.11 - Guide Paragraphs for Inclusion in Appeal Determination (Rev. 1587, Issued: 09-05-08, Effective: 03-03-08, Implementation: 03-01-09)

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

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

Under §1834(a)(18) and under §1834(j)(4) of the Social Security Act, a supplier which does not accept assignment and collects any amounts from a Medicare beneficiary for medical equipment and supplies for which Medicare does not pay on the basis of §1834(a)(17)(B), §1862(a)(1), §1834(j)(1), or §1834(a)(15) of the Social Security Act, must refund these amounts to the beneficiary. However, a refund is not required if, prior to furnishing the items or services, the supplier notified the beneficiary in writing that Medicare would not pay for the items or services and the beneficiary signed a statement agreeing to pay for them. After reviewing this claim, we have determined that you informed the beneficiary in advance that Medicare does not pay for the above items or services and the beneficiary agreed to pay for them. Therefore, you are not required to make a refund in this case. The beneficiary has been sent a copy of this notice.

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

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

Paragraph 3. Adverse Action on Denial - Refund Required

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

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

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

150.12 - Supplier Fails to Make Refund

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

Under §1834(a)(18)(B) of the Act, a supplier which knowingly and willfully fails to make refund within the time limits in §150.4 may be subject to sanctions under §1128A the Act (i.e., civil money penalties (up to \$10,000 per item or service), assessments (three times the amount of the claim), and exclusion from the Medicare program).

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

Generally, the failure of a supplier to make a refund to a beneficiary comes to the *contractor*'s attention as a result of a beneficiary complaint or a referral from the Social Security Administration (SSA) or the CMS. Document beneficiary complaints and, if necessary, contact the beneficiary to clarify the information in the complaint and determine the amount the beneficiary paid the supplier for the denied items or services. If the *contractor* determines that a supplier failed to make a refund, the *contractor* will contact the supplier in person or by telephone (if that is not feasible, contact the supplier by letter) to discuss the facts of the case. The *contractor* will attempt to determine why the amounts collected have not been refunded. Explain that the law requires that the

supplier make a refund to the beneficiary and that if it fails to do so, the Secretary may impose civil money penalties, assessments, and exclusion from the Medicare program. Make a dated report of contact. Include the information relayed to the supplier and the supplier's response. Re-contact the beneficiary in 15 days to determine whether the refund has been made. Do not make any referral to the CMS regional office until the supplier has been formally notified to refund the money and the supplier's appeal rights have been exhausted, or until the time limit for an appeal has passed.

150.13 - CMS Regional Office (RO) Referral Procedures

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

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

Background of the Subject

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

Origin of the Case

A brief description of how the violations were discovered.

Statement of Facts

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

Documentation

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

- Beneficiary Name and Health Insurance Claim Number;
- Claim Control Number;
- Procedure Code (CPT-4 or HCPCS) of nonrefunded item or service;
- Procedure Code modifier:
- Date of Service;

- Place of Service Code;
- Submitted Charge;
- Units (quantity) of Item or Service; and
- Amount Requested to be Refunded.

Other Significant Issues

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

150.14 - Imposition of Sanctions (Rev. 1, 10-01-03)

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 five 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.

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

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

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

Alternatively, when the contract of sale or rental is cancelled on the basis described above, whether or not the supplier physically repossesses the resaleable or re-rentable item, the supplier may enter into a new sale or rental transaction with the beneficiary with respect to that item as long as the beneficiary has been informed of their liability. If the circumstances which preclude payment for the item have been removed, e.g., the supplier has now obtained a supplier number, the supplier may submit to the *contractor* a new

Part B claim based on the resale or re-rental of the item to the beneficiary. If Part B payment is still precluded, the supplier can establish the beneficiary's liability for payment for the denied resold or re-rented item by giving the beneficiary an ABN notifying the beneficiary of the likelihood that Medicare will not pay for the item and obtaining the beneficiary's signed agreement to pay for the item. The resale or re-rental of the item to the beneficiary does not change the fact that the beneficiary is relieved of liability in connection with the original transaction.

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

200 - Expedited Review Process for Hospital Inpatients in Original Medicare

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Medicare beneficiaries who are hospital inpatients have a statutory right to appeal to a QIO for an expedited review when a hospital, with physician concurrence, determines that inpatient care is no longer necessary. The instructions that follow stem directly from regulations at 42 CFR 405.1205 and 405.1206 and are effective July 1, 2007. These regulations are also referenced at 42 CFR 489.27 and 412.42 (c)(3). The authority for these instructions stems from Sections 1866(a)(1)(M), 1869(c)(3)(C)(iii)(III), and 1154(e) of the Social Security Act. Instructions for managed care will be located in Chapter 13 of the Medicare Managed Care Manual.

Hospitals must notify Medicare beneficiaries who are hospital inpatients about their hospital discharge appeal rights. Hospitals will use a revised version of the Important Message from Medicare (IM) a statutorily required notice, to explain the beneficiary's rights as a hospital patient, including discharge appeal rights. Hospitals must issue the IM within 2 calendar days of admission, must obtain the signature of the beneficiary or his or her representative and provide a copy at that time. Hospitals will also deliver a copy of the signed notice as far in advance of discharge as possible, but not more than 2 calendar days before discharge.

For those beneficiaries who request a QIO review, hospitals must deliver a Detailed Notice of Discharge as soon as possible, but no later than noon of the day after the QIO's notification. Both the IM and the Detailed Notice must be the standardized notices provided by CMS.

200.1 - Scope of the Instructions

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

These instructions implement 42 CFR 405.1205 and 405.1206 which require hospitals to inform Medicare beneficiaries who are hospital inpatients of their right to a QIO review. These instructions delineate the expectations of beneficiaries (or their representative, if applicable), responsibilities of hospitals, and the role of the QIOs when the beneficiary

requests an expedited review by a QIO of the discharge decision. For purposes of this instruction, the term "beneficiary" means either beneficiary or representative, when a representative is acting for a beneficiary.

Hospitals Affected by these Instructions. The term hospital is defined in the regulation as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition includes critical access hospitals. This means all hospitals paid under the Inpatient Acute Prospective Payment System (IPPS), sole community hospitals/regional referrals centers or any other type of hospital receiving special consideration under IPPS (for example, Medicare dependent hospitals, Indian Health Service hospitals); hospitals not under IPPS, including, but not limited to: hospitals paid under State or United States territory waiver programs, hospitals paid under certain demonstration projects cited in regulation (§489.34), rehabilitation hospitals, long-term care hospitals, psychiatric hospitals, critical access hospitals, children's hospitals, and cancer hospitals. Swing beds in hospitals are excluded, because they are considered a lower level of care. Religious nonmedical health care institutions are also excluded.

Hospital Inpatients who are Medicare Beneficiaries. These instructions apply to beneficiaries in original Medicare who are hospital inpatients. Hospital outpatients who are receiving Part B services, such as those in observation stays or in the emergency department, do not receive these notices, unless they subsequently require inpatient care. Medicare beneficiaries in hospital swing beds or custodial care beds do not receive these notices when they are receiving services at a lower level of care.

Definition of Discharge. The term "discharge" is defined as a formal release of a beneficiary from an inpatient hospital. This includes when the beneficiary is physically discharged from the hospital as well as when the beneficiary is discharged "on paper" — meaning that the beneficiary remains in the hospital, but at a lower level of care (for example, the beneficiary is moved to a swing bed or to custodial care).

200.2 - Special Considerations

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Other Insurers. Section 1866(a)(1)(M), delivery of the Important Message from Medicare, applies to each individual who is entitled to benefits under Medicare Part A. Therefore, these requirements apply if a beneficiary is eligible for both Original Medicare and Medicaid (a dual eligible), is eligible for Original Medicare and another insurance program or payer, or has Medicare as a secondary payer. No matter where in the sequence of payers Medicare falls, these requirements still apply.

Inpatient to Inpatient Transfers. Beneficiaries who are being transferred from one inpatient hospital setting to another inpatient hospital setting, do not need to be provided with the follow-up copy of the notice prior to leaving the original hospital, since this is considered to be the same level of care. Beneficiaries always have the right to refuse care and may contact the QIO if they have a quality of care issue. The receiving hospital must

deliver the Important Message from Medicare again according to the procedures in these instructions

Preadmission/Admissions for Services that are Not Reasonable and Necessary.

When a Medicare beneficiary is planning to be hospitalized for services that Medicare usually pays for, but are not considered to be reasonable and necessary in this particular situation, hospitals must deliver a Preadmission/Admission Hospital Issued Notice of Noncoverage (HINN). (See Section 240 of this Chapter.) The Important Message from Medicare would be delivered only if the stay became a covered stay.

Admissions for Services that Medicare Never Covers. When a Medicare beneficiary is admitted for hospital services that are never covered by Medicare, hospitals may deliver the Preadmission/Admission HINN. The IM would be delivered only if the stay became a covered stay.

Change of Status from Inpatient to Outpatient. When a hospital utilization review committee determines that an inpatient admission does not meet the hospital's inpatient criteria, the hospital may change the beneficiary's status from inpatient to outpatient. See CR 3444 (Use of Condition Code 44) and MedLearn Matters article, SE0622, published on March 22, 2006, for notification requirements in this situation.

End of Part A days. For purposes of this instruction, the term discharge does not include exhaustion of Part A days, therefore, when a beneficiary exhausts Part A days, these requirements do not apply.

Hospital Requests QIO Review when the Physician does not Concur. There are separate existing requirements under 405.1208 for notifying a beneficiary when the hospital requests a QIO review. Hospitals should deliver the Notice of a Hospital Requested Review (HRR). (See Section 220 of this chapter.)

200.3 - Notifying Beneficiaries of their Right to an Expedited Review (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Hospitals must notify Medicare beneficiaries who are hospital inpatients about their hospital discharge appeal rights. Hospitals will use a revised version of the Important Message from Medicare (IM) a statutorily-required notice, to explain the beneficiary's rights as a hospital patient, including discharge appeal rights. Hospitals must issue the IM within 2 calendar days of admission, must obtain the signature of the beneficiary or his or her representative and provide a copy at that time. Hospitals will also deliver a copy of the signed notice as far in advance of discharge as possible, but not more than 2 calendar days before discharge.

200.3.1 - Delivery of the Important Message from Medicare (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Hospitals must follow the procedures listed below in delivering the Important Message from Medicare (IM). Valid Notice consists of:

Use of Standardized Notice. Hospitals must use the standardized form (CMS-R-193), see Section 200.6.2. The notices are also available on www.cms.hhs.gov/bni at the Link for Hospital Discharge Appeal Notices. Hospitals may not deviate from the content of the form except where indicated (see Section 200.6 on Completing the Notice). The OMB control number must be displayed on the notice.

Delivery Timeframe. Hospitals must deliver the original copy of the IM at or near admission, but no later than 2 calendar days following the date of the beneficiary's admission to the hospital.

Hospitals may deliver the initial copy of the notice if the beneficiary is seen during a preadmission visit, but not more than 7 calendar days in advance of admission. If a beneficiary receives and signs the initial copy of the IM as part of the preadmission process, the follow-up copy of the notice must be delivered if delivery of the initial copy occurred more than 2 calendar days prior.

In-Person Delivery. The IM must be delivered to the beneficiary in person. However, if the beneficiary is not able to comprehend the notice, it must be delivered to and signed by the beneficiary's representative.

Notice Delivery to Representatives. CMS requires that notification of a beneficiary who is not competent be made to a representative of the beneficiary. A representative is an individual who, under State or other applicable law, may make health care decisions on a beneficiary's behalf (e.g., the beneficiary's legal guardian ,or someone appointed in accordance with a properly executed "durable medical power of attorney").

Otherwise, a person (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 may be a representative for purpose of receiving the notices described in this section. Such representatives should have the beneficiary's best interests at heart and must act in a manner that is protective of the beneficiary and the beneficiary's rights. Therefore, a representative should have no relevant conflict of interest with the beneficiary. A notifier (including the notifier's employees) that has a conflicting interest (such as shifting financial liability to the beneficiary) is not qualified to be a representative. (Note: If the beneficiary wishes to appoint a representative to file an appeal on his/her behalf, a valid Form 1696 or a conforming written instrument must be signed by both the beneficiary and the prospective representative and filed with the appeal request. See Medicare Claims Processing Manual, Publication 100-4, Ch. 29, Section 270 for specific instructions related to the use of Form 1696 and the appointment of representatives).

Notification to the representative may be problematic because that person may not be available in person to acknowledge receipt of the required notification. Hospitals are required to develop procedures to use when the beneficiary is incapable of receiving or incompetent to receive the notice, and the hospital cannot obtain the signature of the beneficiary's representative through direct personal contact.

Regardless of the competency of a beneficiary, if the hospital is unable to personally deliver a notice to a representative, then the hospital should telephone the representative to advise him or her of the beneficiary's rights as a hospital patient, including the right to appeal a discharge decision.

The information provided should include the following at a minimum:

- The name and telephone number of a contact at the hospital;
- The beneficiary's planned discharge date, and the date when the beneficiary's liability begins;
- The beneficiary's rights as a hospital patient, including the right to appeal a discharge decision;
- How to get a copy of a detailed notice describing why the hospital and physician believe the beneficiary is ready to be discharged;
- A description of the steps for filing an appeal;
- When (by what time/date) the appeal must be filed to take advantage of the liability protections;
- The entity required to receive the appeal, including any applicable name, address, telephone number, fax number or other method of communication the entity requires in order to receive the appeal in a timely fashion;
- Direction to the 1-800-MEDICARE number for additional assistance to the representative in further explaining and filing the appeal; and

The date the hospital conveys this information to the representative, whether in writing or by telephone, is the date of receipt of the notice. Confirm the telephone contact by written notice mailed on that same date. Place a dated copy of the notice in the beneficiary's medical file, and document the telephone contact with the beneficiary's representative (as listed above) on either the notice itself, or in a separate entry in the beneficiary's file or attachment to the notice. The documentation should indicate that the staff person told the representative the planned discharge date, the date the beneficiary's financial liability begins, the beneficiary's appeal rights, and how and when to initiate an appeal. The documentation should also include the name of the staff person initiating the contact, the name of the representative contacted by phone, the date and time of the telephone contact, and the telephone number called.

When direct phone contact cannot be made, send the notice to the representative by certified mail, return receipt requested, or other delivery method that requires signed verification of delivery. The date that someone at the representative's address signs (or refuses to sign) the receipt is the date received. Place a copy of the notice in the

beneficiary's medical file, and document the attempted telephone contact to the members' representative. The documentation should include: the name of the staff person initiating the contact, the name of the representative you attempted to contact, the date and time of the attempted call, and the telephone number called.

If both the hospital and the representative agree, hospitals may send the notice by fax or email, however, hospitals must meet the HIPAA privacy and security requirements.

Ensuring Beneficiary Comprehension. Hospitals must make every effort to ensure the beneficiary comprehends the contents of the notice before obtaining the beneficiary's signature. This includes explaining the notice to the beneficiary if necessary and providing an opportunity for the beneficiary to ask questions. The hospital should answer all the beneficiary's questions orally to the best of its ability. The beneficiary should be able to understand that he or she may appeal a discharge decision without financial risk, but may have to pay for any services received after the discharge date if he or she stays in the hospital and does not appeal. Notices should not be delivered during an emergency, but should be delivered once the beneficiary is stable.

These instructions do not preclude the use of assistive devices, witnesses, or interpreters for notice delivery. Thus, if a beneficiary is able to comprehend the notice, but either is physically unable to sign it or needs the assistance of an interpreter to translate it or an assistive device to read or sign it, valid delivery may be achieved by documenting use of such assistance.

Beneficiary Signature and Date. The IM must be signed and dated by the beneficiary to indicate that he or she has received the notice and can comprehend its contents, unless an appropriate reason for the lack of signature is recorded on the IM, such as a properly annotated signature refusal (see below).

Refusal to Sign and Annotation. If a beneficiary refuses to sign the notice, hospitals may annotate the notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice. The annotation may be placed in the unused patient signature line, in the "Additional Information" section on page 2 of the notice or another sheet of paper may be attached to the notice, if necessary. Any insertions on the notice must be easy for the beneficiary to read in order for the notice to be considered valid. See also Section 200.5.6 - Insertions in Blanks.

Notice Delivery and Retention. Hospitals must give the original copy of the signed or annotated notice to the patient. Hospitals must retain a copy of the signed notice and may determine the method of storage that works within their existing processes, for example, storing a copy in the medical record or electronically.

200.3.2 - The Follow-Up Copy of the Signed Important Message from Medicare

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

A "follow-up" copy of the signed IM must be delivered to the beneficiary using the following guidelines:

Delivery Timeframe. The follow-up copy must be delivered as far in advance of discharge as possible, but no more than 2 calendar days before the planned date of discharge. Thus, when discharge seems likely within 1- 2 calendar days, hospitals should make arrangements to deliver the follow-up copy of the notice, so that the beneficiary has a meaningful opportunity to act on it. However, when discharge cannot be predicted in advance, the follow-up copy may be delivered as late as the day of discharge, if necessary. If the follow-up copy of the notice must be delivered on the day of discharge, hospitals must give beneficiaries who need it at least 4 hours to consider their right to request a QIO review. Beneficiaries may choose to leave prior to that time, however, hospitals must not pressure a beneficiary to leave during that time period. If the hospital delivers the follow-up copy, and the beneficiary status subsequently changes, so that the discharge is beyond the 2-day timeframe, hospitals must deliver another copy of the signed notice again within 2 calendar days of the new planned discharge date. Hospitals may not develop procedures for delivery of the follow up copy routinely on the day of discharge.

Alternative to Delivery of the Signed Copy. A hospital may choose to deliver a new copy of the IM (not a copy of the signed IM) during the required timeframes; however, the hospital must obtain the beneficiary's or representative's signature and date on the notice again at that time.

Exception to Delivery of the Follow-Up Copy. If delivery of the original IM is within 2 calendar days of the date of discharge, no follow-up notice is required. For example, if a beneficiary is admitted on Monday, the IM is delivered on Wednesday and the beneficiary is discharged on Friday, no follow-up notice is required.

If a beneficiary receives and signs the initial copy of the IM as part of the preadmission process, the follow-up copy of the notice must be delivered if delivery of the initial copy occurred more than 2 calendar days prior.

Documentation. Hospitals must document timely delivery of the follow-up copy of the IM in the patient records, when applicable. Hospitals are responsible for demonstrating compliance with this requirement. If hospitals have processes in place to document delivery of other information related to discharge that includes a beneficiary signature and date, hospitals may include the follow-up copy of the notice in those documents. If there are no other existing processes in place, hospitals may use the "Additional Information" section of the IM to document delivery of the follow-up copy, for example, by adding a line for the beneficiary's or representative's initials and date.

200.4 - Rules and Responsibilities when a Beneficiary Requests an Expedited Review

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

A beneficiary has a right to request an expedited review by the QIO when a hospital (acting directly or through its utilization review committee), with physician concurrence, determines that inpatient care is no longer necessary.

200.4.1 - The Role of the Beneficiary and Liability (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Submitting a Request: A beneficiary who chooses to exercise the right to an expedited review must submit a request to the QIO that has an agreement with the hospital where the beneficiary is an inpatient. In order to be considered timely, the request must be made no later than midnight of the day of discharge, may be in writing or by telephone, and must be before the beneficiary leaves the hospital. The beneficiary, upon request of the QIO, should be available to discuss the case. The beneficiary may, but is not required to, submit written evidence to be considered by the QIO.

Timely Requests: When the beneficiary makes a timely request for a QIO review – that is, requests a review no later than midnight of the day of discharge – the beneficiary is not financially responsible for inpatient hospital services (except applicable coinsurance and deductibles) furnished before noon of the calendar day after the date the beneficiary receives notification of the expedited determination from the QIO. Liability for further inpatient hospital services depends on the QIO decision:

- **Unfavorable determination**: If the QIO notifies the beneficiary that the QIO did not agree with the beneficiary, liability for continued services begins at noon of the day <u>after</u> the QIO notifies the beneficiary that the QIO agreed with the hospital's discharge determination, or as otherwise determined by the QIO.
- **Favorable determination**: If the QIO notifies the beneficiary that the QIO agreed with the beneficiary, the beneficiary is not financially responsible for continued care (other than applicable coinsurance and deductibles) until the hospital once again determines that the beneficiary no longer requires inpatient care, secures the concurrence of the physician responsible for the beneficiary's care or the QIO, and notifies the beneficiary with a follow-up copy of the IM.

Untimely Requests: When the beneficiary fails to make a timely request for an expedited review, and remains in the hospital, he or she still may request an expedited review at any time, but the beneficiary may be held responsible for charges incurred after the day of discharge, or as otherwise stated by the QIO. If the QIO finds that the patient should have remained an inpatient, the hospital will refund the beneficiary any funds that were collected. When the beneficiary fails to make a timely request for an expedited review and is no longer an inpatient at the hospital, he or she may still request a QIO review within 30 calendar days of the date of discharge, or at any time for good cause.

200.4.2 - The Responsibilities of the Hospital (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Provide the Detailed Notice of Discharge: When a QIO notifies the hospital that a beneficiary has requested an expedited review, the hospital must deliver a Detailed Notice of Discharge (the Detailed Notice) to the beneficiary as soon as possible but not later than noon of the day after the QIO's notification. If a beneficiary requests more detailed information prior to requesting a review, hospitals may deliver the detailed notice in advance of the beneficiary requesting a review.

Use of Standardized Notice. Hospitals must use the standardized form (CMS-10066), see Section 200.6.2. This notice is also available on www.cms.hhs.gov/bni at the Link for Hospital Discharge Appeal Notices. Hospitals may not deviate from the content of the form except where indicated (see Section 200.6.2 on Completing the Notice). The OMB control number must be displayed on the notice.

The Detailed Notice must be the standardized notice provided by CMS and contain the following:

- A detailed explanation why services are either no longer reasonable and necessary or are otherwise no longer covered.
- A description of any applicable Medicare coverage rule, instruction, or other Medicare policy, including information about how the beneficiary may obtain a copy of the Medicare policy. (See instructions for the Detailed Notice of Discharge at Section 200.6.3, Exhibit 2)
- Facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case.
- Any other information required by CMS.

Hospitals must follow requirements in Section 200.5.6 on Insertions in Blanks and Section 200.6. on Completing the Notices.

Provide Information to the QIO. Upon notification by the QIO of the beneficiary's request for an expedited review, the hospital must supply any and all information that the QIO needs to make the expedited determination, including copies of both the IM and the Detailed Notices. The hospital must furnish this information as soon as possible, but no later than noon of the day after the QIO notifies the hospital of the request. At the discretion of the QIO, the hospital may make the information available by telephone or in writing. A written record of any information not transmitted in writing should be sent as soon as possible. If the hospital fails to provide the needed information, the QIO may make a decision based on evidence at hand or defer the decision until it receives the necessary information. If this delay results in extended coverage of an individual's hospital services, the hospital may be held financially liable for those services, as determined by the QIO.

Burden of Proof. The burden of proof lies with the hospital to demonstrate that discharge is the correct decision, either on the basis of medical necessity or based on other Medicare coverage policies.

Provide the Beneficiary with Documentation if Requested. At the request of the beneficiary, the hospital must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO, including written records of any information provided by telephone. The hospital may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The hospital must accommodate the request by no later than the first day after the material is requested.

200.4.3 - The Role of the QIOs

QIO Availability. The QIO should have methods in place to accept requests for reviews outside of normal business hours, such as an answering machine message. QIOs will issue decisions within one calendar day after it receives all pertinent information.

Notify the hospital of the beneficiary's request for an expedited review. When the QIO receives the request from the beneficiary, the QIO must notify the hospital of the request immediately, or immediately in the morning if the request is received after the QIO's business hours.

Receive and Examine records. The QIO will examine medical and other records that pertain to the services in dispute.

Determine if the hospital delivered valid notice. The QIO will determine whether the hospital delivered valid notice, meaning that the notice is the standardized notice published by CMS, meets the notice delivery timeframes, and has been signed and dated by the beneficiary. If the QIO determines that the hospital did not deliver valid notice, the QIO will instruct the hospital to reissue the notice if necessary, proceed with the review, and educate the hospital retrospectively. If the beneficiary or representative makes an untimely request for a review, and the QIO determines that the beneficiary did not receive valid notice, the QIO will determine the date the beneficiary becomes fully liable for the services.

Solicit the views of the beneficiary. The QIO must solicit views of the beneficiary who requested the expedited review.

Solicit the views of the hospital. The QIO must provide an opportunity for the hospital to explain why the hospital and physician believe discharge is appropriate. The QIO may develop guidelines as to the form and extent of this opportunity.

If needed information is not received. If the QIO does not receive the information from the hospital needed to sustain the discharge decision, it may make its determination based on the evidence at hand or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's

hospital services, the hospital may be held financially responsible for these services as determined by the QIO.

QIO Determination. QIOs make their determinations based on criteria in §1154(a) of the Act, which specifies that QIOs will determine whether:

- the services are reasonable and medically necessary,
- the services meet professionally recognized standards of care, and
- the services could be safely be delivered in another setting.

Notification following a timely request. When the beneficiary makes a timely request for an expedited review, the QIO must make its determination and notify the beneficiary, the hospital, and the physician of its determination within one calendar day after it receives all requested pertinent information. When the QIO issues an expedited determination, the QIO must notify the beneficiary, the hospital and the physician of its decision by telephone, followed by a written notice that must include the following information:

- The basis for the determination.
- A detailed rationale for the determination.
- An explanation of the Medicare payment consequences of the determination and the date a beneficiary becomes fully liable for services.
- Information about the beneficiary's right to an reconsideration of the QIO's determination, including how to request the reconsideration and the timeframe for doing so.

Notification following an untimely request. When the beneficiary makes an untimely request for an expedited review, and remains in the hospital, the QIO will make its determination and notify the beneficiary, the hospital, and the physician of its determination within 2 calendar days after it receives all requested pertinent information. When the beneficiary makes an untimely request for an expedited review, and is no longer an inpatient in the hospital, the QIO will make its determination and notify the beneficiary, the hospital, and the physician of its determination within 30 calendar days after it receives all requested pertinent information.

200.4.4 - Effect of a QIO Expedited Determination (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

The QIO determination is binding on the beneficiary, the physician, and hospital except in the following circumstances:

Right to pursue a reconsideration. If the beneficiary is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in 405.1204.

Right to pursue the general claims appeal process. If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, the determination is subject to the general claims appeal process (See Chapter 29 of this manual.).

200.5 - General Notice Requirements

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Since the Important Message from Medicare and the Detailed Notice of Discharge are OMB approved, standardized notices, hospitals must comply with the following General Notice Requirements:

200.5.1 - Number of Copies

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

The Important Message from Medicare: In most cases, a minimum of three copies of the Important Message from Medicare, including the original, will be needed. The beneficiary keeps the original signed notice and will receive a follow-up copy of the signed notice, except when delivery of the original notice falls within two days of discharge. The hospital must retain a copy of the signed IM and may do so electronically.

The Detailed Notice: A minimum of two copies of the Detailed Notice, including the original, will be needed. The beneficiary keeps the original notice. The hospital must retain a copy of the signed document and may do so electronically.

Providing Copies to the QIO: In addition to the above, if a beneficiary requests a review, hospitals are required to provide copies of both notice described in this section to the QIO.

200.5.2 - Reproduction

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Hospitals may reproduce the notices by using self-carbonizing paper, photocopying the IM, or using another appropriate method. All reproductions must conform to applicable instructions.

200.5.3 - Length and Page Size

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

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

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

200.5.4 - Contrast of Paper and Print

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

A visually high-contrast combination of dark ink on a pale background must be used. Do not use reversed print (e.g., white on black), or block-shade (highlight) notice text.

200.5.5 - Modification

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

The notices described in this section may not be modified, except as specifically allowed by these instructions. In no case may either notice be condensed.

200.5.6 - Font

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

The IM and the Detailed Notice must meet the following font requirements in order to facilitate beneficiary understanding:

- Font Type: To the greatest extent practicable, the fonts as they appear in the notices on the CMS Web site should be used. Any changes in the font type should be based solely on software and/or hardware limitations of the notices. Examples of easily readable alternative fonts include: Arial, Arial Narrow, Times New Roman, and Courier.
- Font Effect/Style: Any changes to the font, such as italics, embossing, bold, etc., should not be used since they can make the notices more difficult to read.
- **Font Size:** The font size generally should be 12 point. Titles should be 18 point, but handwritten insertions in blanks of the IM can be as small as 10 point if needed.
- **Insertions in Blanks:** Information inserted by hospitals in the blank spaces on the IM and the Detailed Notice may be typed or legibly hand-written using the guidelines above.

200.5.7 - Customization

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Hospitals are permitted to do some customization of IM or the Detailed Notice such as pre-printing agency-related information to promote efficiency and to ensure clarity for beneficiaries. Guidelines for customization are:

- Maintaining underlines in the blank spaces is not required.
- Information in blanks that is constant can be pre-printed, such as the hospital's name, QIO name and telephone number. Note the TTY phone number also needs to be entered

200.5.8 - Retention of the Notices

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Hospitals are required to retain copies of the signed notices and may do so either in hardcopy or electronically.

200.6 - Completing the Notices

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

When completing the Important Message from Medicare and the Detailed Notice of Discharge, hospitals must utilize the following instructions:

200.6.1 - Translated Notices

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Both the "Important Message from Medicare" and the "Detailed Notice of Discharge" are available at http://www.cms.hhs.gov/BNI/. The notices will be available in English and Spanish, and in PDF and Word formats, under a dedicated link on the left hand margin: "Hospital Discharge Appeal Notices". Hospitals should choose the appropriate version of the Important Message from Medicare and the Detailed Notice of Discharge based on the language the beneficiary best understands. When Spanish-language notices are used, the hospital should make insertions on the notice in Spanish. If this is impossible, additional steps need to be taken to ensure that the beneficiary comprehends the content of the notice.

200.6.2 - Exhibit 1 - Important Message from Medicare (CMS-R-193) and Form Instructions

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Patient Name: DEPARTMENT OF HEALTH & HUMAN SERVICES

Patient ID Number: Centers for Medicare & Medicaid

Services

Physician: OMB Approval No. 0938-0692

AN IMPORTANT MESSAGE FROM MEDICARE

ABOUT YOUR RIGHTS

AS A HOSPITAL INPATIENT, YOU HAVE THE RIGHT TO:

- Receive Medicare covered services. This includes medically necessary
 hospital services and services you may need after you are discharged, if
 ordered by your doctor. You have a right to know about these services, who
 will pay for them, and where you can get them.
- Be involved in any decisions about your hospital stay, and know who will pay for it.

•	Report any concerns you have about the quality of care yo	ou receive to the
	Quality Improvement Organization (QIO) listed here	{Insert Name
	and Telephone Number of the QIO}	

YOUR MEDICARE DISCHARGE RIGHTS

Planning For Your Discharge: During your hospital stay, the hospital staff will be working with you to prepare for your safe discharge and arrange for services you may need after you leave the hospital. When you no longer need inpatient hospital care, your doctor or the hospital staff will inform you of your planned discharge date.

If you think you are being discharged too soon:

- You can talk to the hospital staff, your doctor and your managed care plan (if you belong to one) about your concerns.
- You also have the right to an appeal, that is, a review of your case by a
 Quality Improvement Organization (QIO). The QIO is an outside reviewer
 hired by Medicare to look at your case to decide whether you are ready to
 leave the hospital.
 - If you want to appeal, you must contact the QIO no later than your planned discharge date and before you leave the hospital.
 - If you do this, you will not have to pay for the services you receive during the appeal (except for charges like copays and deductibles).
- If you do not appeal, but decide to stay in the hospital past your planned discharge date, you may have to pay for any services you receive after that date.

To speak with someone at the hospital about this notice, call					
Please sign and date here to show you received th your rights.	is notice and understand				
Signature of Patient or Representative	Date				

• Step by step instructions for calling the QIO and filing an appeal are

CMS-R-193 (approved 05/2007)

on page 2.

STEPS TO APPEAL YOUR DISCHARGE

•	STEP 1: You must contact the QIO no later than your planned discharge da			
	and before you leave the hospital. If you do this, you will not have to pay for			
	the services you receive during the appeal (except for charges like copays			
	and deductibles).			

0	Here is the contact information for the QIO:

{insert name of QIO in bold}
{insert telephone number of QIO}

- You can file a request for an appeal any day of the week. Once you speak to someone or leave a message, your appeal has begun.
- Ask the hospital if you need help contacting the QIO.
- The name of this hospital is <u>{insert the name of the hospital and the provider ID number}</u>.
- STEP 2: You will receive a detailed notice from the hospital or your Medicare
 Advantage or other Medicare managed care plan (if you belong to one) that
 explains the reasons they think you are ready to be discharged.
- STEP 3: The QIO will ask for your opinion. You or your representative need to be available to speak with the QIO, if requested. You or your representative may give the QIO a written statement, but you are not required to do so.
- **STEP 4**: The QIO will review your medical records and other important information about your case.
- **STEP 5**: The QIO will notify you of its decision within <u>1 day after</u> it receives all necessary information.
 - If the QIO finds that you are not ready to be discharged, Medicare will continue to cover your hospital services.
 - If the QIO finds you are ready to be discharged, Medicare will continue to cover your services until noon of the day <u>after</u> the QIO notifies you of its decision.

IF YOU MISS THE DEADLINE TO APPEAL, YOU HAVE OTHER APPEAL RIGHTS:

- You can still ask the QIO or your plan (if you belong to one) for a review of your case:
 - o If you have Original Medicare: Call the QIO listed above.
 - If you belong to a Medicare Advantage Plan or other Medicare managed care plan: Call your plan.
- If you stay in the hospital, the hospital may charge you for any services you
 receive after your planned discharge date.

For more information, call 1-800-MEDICARE (1-800-633-4227), or TTY: 1-877-486-2048.

Additional Information:						

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 0938-0692. The time required to complete this information collection is estimated to average 15 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Notice Instructions

The Important Message from Medicare (OMB #0938-0692) (CMS-R-193)

Completing the Notice

PAGE 1 of the Important Message from Medicare

A. Header

Hospitals must display "DEPARTMENT OF HEALTH & HUMAN SERVICES, Centers for Medicare & Medicaid Services" and the OMB number.

The following blanks must be completed by the hospital. Information inserted by hospitals in the blank spaces on the IM may be typed or legibly hand-written in 12-point font or the equivalent. Hospitals may also use a patient label that includes the following information:

Patient Name: Fill in the patient's full name.

Patient ID number: Fill in an ID number that identifies this patient. This number should not be, nor should it contain, the social security number.

Physician: Fill in the name of the patient's physician.

B. Body of the Notice

Bullet # 3 Report any concerns you have about the quality of care you receive to the Quality Improvement Organization (QIO) listed here ______. Hospitals may preprint or otherwise insert the name and telephone number (including TTY) of the QIO.

To speak with someone at the hospital about this notice call: Fill in a telephone number at the hospital for the patient or representative to call with questions about the notice. Preferably, a contact name should also be included.

Patient or Representative Signature: Have the patient or representative sign the notice to indicate that he or she has received it and understands its contents.

Date: Have the patient or representative place the date he or she signed the notice.

PAGE 2 of the Important Message from Medicare

First sub-bullet - Insert name and telephone number of QIO in BOLD: Insert name and telephone number (including TTY), in bold, of the Quality Improvement Organization that performs reviews for the hospital.

Second sub-bullet – **The name of this hospital is:** Insert/preprint the name of the hospital, including the Medicare provider ID number (not the telephone number).

Additional Information: Hospitals may use this section for additional documentation, including, for example, obtaining beneficiary initials to document delivery of the follow-up copy of the IM, or documentation of refusals.

200.6.3 - Exhibit 2 – The Detailed Notice of Discharge (CMS 10066) and **Form Instructions** (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07) Patient Name: OMB Approval No. 0938-1019 Patient ID Number: Date Issued: Physician: {Insert Hospital or Plan Logo here} DETAILED NOTICE OF DISCHARGE You have asked for a review by the Quality Improvement Organization (QIO), an independent reviewer hired by Medicare to review your case. This notice gives you a detailed explanation about why your hospital and your managed care plan (if you belong to one), in agreement with your doctor, believe that your inpatient hospital services should end on . This is based on Medicare coverage policies listed below and your medical condition. This is not an official Medicare decision. The decision on your appeal will come from your Quality Improvement Organization (QIO). Medicare Coverage Policies: Medicare does not cover inpatient hospital services that are not medically necessary or could be safely furnished in another setting. (Refer to 42 Code of Federal Regulations, 411.15 (g) and (k)). Medicare Managed Care policies, if applicable: (insert specific managed care policies) Other {insert other applicable policies} Specific information about your current medical condition: If you would like a copy of the documents sent to the QIO, or copies of the specific policies or criteria used to make this decision, please call (insert hospital and/or plan telephone number}.

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 0938-1019. The time required to complete this information collection is estimated to average 60 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please

write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

CMS 10066 (approved 5/2007)

Instructions for Completing the Detailed Notice of Discharge (CMS 10066)

This is a standardized notice. Hospitals may not deviate from the content of the form except where indicated. Please note that the OMB control number must be displayed on the notice. Insertions must be typed or legibly hand-written in 12-point font or the equivalent.

Hospitals or plans may modify the following sections to incorporate use of a sticker or label that includes this information:

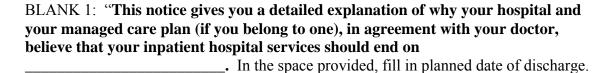
Patient Name: Fill in the patient's full name.

Patient ID number: Fill in the patient's ID number. This should not be, nor should it contain, the patient's social security or HICN number.

Physician: Fill in the name of the patient's physician.

Date Issued: Fill in the date the notice is delivered to the patient by the hospital/plan.

Insert logo here: Hospitals/plans may elect to place their logo in this space. However, the name, address, and telephone number of the hospital/plan must be immediately under the logo, if not incorporated into the logo. If no logo is used, the name and address and telephone number (including TTY) of the hospital/plan must appear above the title of the form.



Bullet # 1: "Medicare Coverage Policies:" Place a check next to the applicable Medicare and/or managed care policies. If necessary, hospitals may also use the selection "Other" to list other applicable policies, guidelines or instructions. Hospitals or plans may also preprint frequently used coverage policies or add more space below this line, if necessary. Policies should be written in full sentences and in plain language. In addition, the hospital or plan may attach additional pages or specific policies or discharge criteria to the notice. Any attachments must be included with the copy sent to the QIO as well.

Bullet # 2: "Specific information about your current medical condition" Fill in detailed and specific information about the patient's current medical condition and the reasons why services are no longer reasonable or necessary for this patient or are no

longer covered according to Medicare or Medicare managed care coverage guidelines. Use full sentences and plain language.

Bullet # 3: "If you would like a copy of the documents sent to the QIO, or copies of the specific policies or criteria used to make this decision, please call

." The hospital/plan should also supply a telephone number for patients to call to get a copy of the relevant documents sent to the QIO. If the hospital/plan has not attached the Medicare policies and/or the Medicare managed care plan policies used to decide the discharge date, the hospital should supply a telephone number for patients to call to obtain copies of this information.

Hospitals or plans may add space below this section to insert a signature line and date, if they so choose.

220 - Hospital Requested Expedited Review

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

When a hospital determines that a beneficiary no longer needs inpatient care, but is unable to obtain the agreement of the physician, the hospital may request a QIO review. Hospitals must notify the beneficiary that the review has been requested. These instructions stem directly from Section 1154(e) of the Act and 42 CFR Part 405.1208.

220.1 - Responsibilities of the Hospital

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

The hospital must comply with the following procedures when requesting a QIO review:

Notify the Beneficiary. Hospitals must notify the beneficiary that the hospital has requested a review using a model language notice called the Hospital Requested Review (HRR) described in this section. See Section 220.4 for General Notice Requirements.

Supply information to the QIO. Hospitals must supply any pertinent information the QIO needs to conduct its review and must make it available by phone or in writing, by close of business on the first full day immediately following the day the hospital submits the request for review.

220.2 - Responsibilities of the QIO

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

The QIO's responsibilities are as follows:

Receive request and examine records. The QIO must notify the hospital that it has received the request for review and must notify the hospital if it has not received pertinent records, examine the pertinent records pertaining to the services, and solicit the views of the beneficiary.

Issue a determination. QIOs make their determinations based on criteria in §1154(a) of the Act, which specifies that QIOs will determine whether:

- the services are reasonable and medically necessary,
- the services meet professionally recognized standards of care, and
- the services could be safely be delivered in another setting.

The QIO will make a determination and notify the beneficiary, the hospital, and the physician of its decision within 2 days of the hospital's request and receipt of any pertinent information submitted by the hospital.

Notification. When the QIO issues the determination, it must notify the beneficiary, the hospital, and the physician of its decision by telephone and subsequently in writing. The written notice of the expedited initial determination must contain the following:

- The basis for the determination;
- A detailed rationale for the determination;
- A statement explaining the Medicare payment consequences of the expedited determination and the date of liability if any; and
- A statement informing the beneficiary of his or her appeal rights and the timeframe for requesting an appeal.

220.3 - Effect of the Hospital Requested Expedited Determination (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

The expedited determination is binding on the beneficiary, physician, and hospital, except in the following circumstances:

When the beneficiary remains in the hospital. When the beneficiary is still an inpatient in the hospital and is dissatisfied with this determination, he or she may request a reconsideration according to the procedures described in Section 300 of this Chapter.

When the beneficiary is no longer an inpatient in the hospital. If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, this determination is subject to the general claims appeal process (See Chapter 29 of this manual).

220.4 - General Notice Requirements

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Providers should use the HRR to notify a beneficiary that it has requested a QIO review. This notice can be found at www.cms.hhs.gov/bni. Since the HRR uses model language, providers have some flexibility in the preparation of this notice. However, it is highly recommended that hospitals use the model language provided in this instruction, or by their QIO, in order to avoid questions of invalid notice. Providers should utilize the General Notice Requirements in Section 200.5 and the Translation requirements in Section 200.6.1 when preparing the notice.

220.5 - Exhibit 3 – Model Language for Notice of Hospital Requested Review

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Hospital Identifier

Model Notice of Hospital Requested Review (HRR)

Name of Patient: Name of Patient ID Number: Do	ame of Physician:ate Issued:
We believe that Medicare will not continue to services are no longer considered medically doctor disagreed with our finding, the hospita organization (QIO) to review your case. The Medicare to look at your case to decide if you of the QIO is(insert the name of the QIO)	necessary in your case. Because your all is asking the quality improvement QIO is an outside reviewer hired by u are ready to leave the hospital. The name
 The QIO will contact you to solicit you need. 	r views about your case and the care you
You do not need to take any action ur	ntil you hear from the QIO.
For more information about this notice, call 1 TTY: 1-877-486-2048.	-800-MEDICARE (1-800-633-4227), or
Please sign your name, the date and time. A agree with this notice, just that you received	
Signature of Patient or Representative	Date Time

240 - Preadmission/Admission Hospital Issued Notice of Noncoverage (HINN)

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Regulations found at 42 CFR Part 476.71 require QIOs to review the medical necessity of hospital discharges **and admissions**, in addition to other requirements specified in that section of the regulation. Therefore, a beneficiary has a right to request an expedited review by the QIO when a hospital (acting directly or through its utilization review committee) has determined at the time of preadmission or admission, that the beneficiary is facing a non-covered hospital stay because the services are not considered to be reasonable and necessary in this case, the services could be safely provided in another setting, or the care is considered custodial in nature.

The utilization review committee or the hospital may issue a preadmission/admission HINN. QIOs may also issue such notices after having been contacted by a hospital regarding care believed to be medically unnecessary, inappropriate, or custodial. The hospital need not obtain the attending physician's concurrence, or the QIO's, prior to issuing the preadmission/admission HINN. This also applies to direct admissions to swing beds (i.e., the beneficiary is admitted to the swing bed when the hospital determines that the beneficiary does not need hospital-level care, but instead needs only skilled nursing (SNF) or custodial nursing (NF) level services).

240.1 - Delivery of the Preadmission/Admission HINN (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

When delivering the Preadmission/Admission HINN, hospitals must follow the notice delivery requirements in Section 200.3.1 regarding:

- In-Person Delivery,
- Notice Delivery to Representatives,
- Ensuring Beneficiary Comprehension.
- Beneficiary Signature and Date.
- Refusal to Sign.
- Notice Delivery and Retention.

240.2 - Notice Delivery Timeframes and Liability (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Preadmission: In preadmission situations, the beneficiary is liable, if admitted, for customary charges for all services furnished during the stay, except for those services for which he or she is eligible to receive payment under Part B.

Admission: If the admission notice is issued at 3 p.m. or earlier on the day of admission, the beneficiary is liable for customary charges for all services furnished after receipt of

the notice, except for those services for which the beneficiary is eligible to receive payment under Part B.

If the admission notice is issued after 3 p.m. on the day of admission, the beneficiary is liable for customary charges for all services furnished on the day following the day of receipt of the notice, except for those services for which the beneficiary is eligible to receive payment under Part B.

240.3 - Timeframes for Submitting a Request for a QIO Review (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Preadmission: In preadmission situations, a beneficiary who chooses to exercise the right to a QIO review should request immediately, but no later than 3 calendar days after receipt of the notice, or if admitted, at any point during the stay, an immediate review of the facts related to the admission.

Admission: In admission situations, a beneficiary who chooses to exercise the right to a QIO review should request immediately, or at any point in the stay, an immediate review of the facts related to the admission.

240.4 - Results of the QIO Review

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

If the QIO disagrees with the hospital's determination and says the stay is reasonable and necessary, the beneficiary will be refunded any amount collected except applicable coinsurance and deductibles, and convenience items or services not covered by Medicare.

If the QIO agrees with the hospital determination and says the stay is not reasonable and necessary, the beneficiary will be responsible for all services on the date specified by the QIO.

240.5 - Effect of the QIO Review

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

The QIO will send the beneficiary a formal determination of the medical necessity and appropriateness of the hospitalization determination is binding on the beneficiary, the physician, and hospital except in the following circumstances:

Right to pursue a reconsideration. If the beneficiary is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in §405.1204 (See Section 300 of this chapter.)

Right to pursue the general claims appeal process. If the beneficiary is no longer an inpatient in the hospital, the determination is subject to the general claims appeal process (See Chapter 29 of this manual.)

240.6 - Exhibit 4 - Model Language for Preadmission/Admission Hospital Issued Notice of Noncoveage

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Hospital Identifier

Preadmission or Admission Hospital-Issued Notice of Noncoverage (HINN)

Model Language

Name of Patient:	Name of Physician:	
Patient ID Number:	Date Issued:	
	likely to pay for your admission for ify service or condition)	_because:
it is not considered	to be medically necessary	
it could be furnished	d safely in another setting	
other		_•
However, this notice is not an of	ficial Medicare decision.	
lf you disagree with our findin	g:	
 You should talk to your do may need. 	octor about this notice and any further health	care you
 You also have the right to an appeal, that is, an immediate review of your case by a Quality Improvement Organization (QIO). The QIO is an outside reviewer hired by Medicare to make a formal decision about whether your admission is covered by Medicare. See page 2 for instructions on how to request a review and contact the QIO. 		
 If you decide to go ahea 	ad with the hospitalization, you will have to	pay for:
	CONTINUED ON PAGE 2	2

For admission notices issued not later than 3:00 P.M. on the date of admission, insert: "customary charges for all services furnished after receipt of this hospital notice, except for those services for which you are eligible under Part B." (If these requirements are not met, insert the liability phrase below.)

For admission notices issued after 3:00 P.M. on the day of admission, insert: "customary charges for all services furnished on the day following the day of receipt of this notice, except for those services for which you are eligible to receive payment under Part B."

If you want an ir	nmediate review of your case:	
	(insert one of the following as appropriate)	
Preadmission:		

 Call the QIO immediately at the number listed below, but no later than 3 calendar days after you receive this notice. If you are admitted, you may call the QIO at any point in the stay.

Admission:

- Call the QIO immediately at the number listed below or you may call the QIO at any point during your stay.
- You may also call the QIO for quality of care issues.

QIO Contact Information:	(insert name of QIO in bold)
	(insert telephone number of QIO)

If you do not want an immediate review:

 You may still request a review within 30 calendar days from the date of receipt of this notice by calling the QIO at the number below.

Results of the QIO Review:

- The QIO will send you a formal decision about whether your hospitalization is appropriate according to Medicare's rules, and will tell you about your reconsideration and appeal rights.
 - o IF THE QIO FINDS YOUR HOSPITAL CARE IS COVERED, you will be refunded any money you may have paid the hospital except for any applicable copays, deductibles, and convenience items or services normally not covered by Medicare.

¹ For preadmission notices, insert: "customary charges for all services furnished during the stay, except for those services for which you are eligible under Part B."

	o IF THE QIO FINDS THAT YOUR you are responsible for payment to (specify date). (see for payment to the control of the cont	or all services beginning	•
For more 2048.	information, call 1-800-MEDICARE (1	-800-633-4227), or TTY:	1-877-486-
•	gn your name, the date and time. You h this notice, just that you received the	•	•
Signature	of Patient or Representative	- — — — Date	Time

260 - Expedited Determination Process for Provider Services Terminations

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

300 - Expedited Reconsiderations

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

A beneficiary who is dissatisfied with a QIO determination can request a reconsideration by an independent review entity (IRE). Such reconsiderations are codified in regulations effective July 1, 2005 (42 CFR 405.1204) but are familiar to inpatient hospital providers as the process previously available under §1155 of the Act. This reconsideration process is the same for hospital and non-hospital providers.

300.1 - The Role of the Beneficiary and Liability

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Submitting a Request: A beneficiary who chooses to exercise the right to an expedited reconsideration must submit a request to the appropriate IRE in writing or by telephone no later than noon of the calendar day following the initial notification (whether by telephone or in writing) of the QIO's determination. The beneficiary, upon request of the QIO, should be available to discuss the case or supply information that the IRE may request. The beneficiary may, but is not required to, submit written evidence to be considered by the IRE.

Untimely Requests: When the beneficiary fails to make a timely request for an expedited reconsideration subsequently may request a reconsideration under the standard claims appeal process (See Chapter 29 of this Manual), but the coverage protection described in Section 300.5 would not extend through this reconsideration, nor would the notification timeframes or the escalation process described in Section 300.2 apply.

300.2 - The Responsibilities of the IRE

(Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Receipt of the Request. On the day the IRE receives the request for an expedited reconsideration, the IRE must immediately notify the QIO that made the expedited determination and the provider of services of the request for the expedited reconsideration.

Examine Records and Other Information. The IRE must offer the beneficiary and the provider an opportunity to provide further information.

Notification. Unless the beneficiary requests an extension (see below), the IRE must notify the QIO, the beneficiary, and the provider of services of its decision no later than 72 hours after receipt of the request for an expedited reconsideration, and any such records needed for the reconsideration. The initial notification may be done by telephone followed by a written notice that includes:

- The rationale for the reconsideration decision,
- An explanation of the Medicare payment consequences of the determination and the beneficiary's date of liability,
- Information about the beneficiary's right to appeal the IRE's reconsideration decision to an ALJ, including how to request an appeal and the time period for doing so.

Escalation. Unless the beneficiary requests an extension, if the IRE does not issue a decision within 72 hours of receipt of the request, the IRE must notify the beneficiary of his or her right to have the case escalated to the ALJ hearing level if the amount remaining in controversy is \$100 or more.

Extensions. A beneficiary who requests an expedited reconsideration may request (either in writing or orally) that an IRE grant such additional time as the beneficiary specifies (not to exceed 14 days) for the reconsideration. If an extension is granted, the deadlines described above under notification, do not apply.

300.3 - The Responsibilities of the QIO (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

When an IRE notifies the QIO that a beneficiary has requested an expedited reconsideration, the QIO must supply all information that the IRE needs to make its expedited reconsideration as soon as possible, but no later than by close of business of the day that the IRE notifies the QIO of the request for the reconsideration.

At the beneficiary's request, the QIO must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the IRE. The QIO may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The QIO must accommodate the request by no later than close of business of the first day after the material is requested.

300.4 - The Responsibilities of the Provider (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

The provider may, but is not required to, submit evidence to be considered by an IRE in making its decision. If a provider fails to comply with an IRE's request for additional information beyond that furnished by the QIO for purposes of the expedited determination, the IRE makes its reconsideration decision based on the information available.

300.5 - Coverage During an Expedited Reconsideration (Rev. 1257, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

When a beneficiary makes a timely request for an expedited determination, the provider may not bill the beneficiary for any disputed services until the IRE makes its determination. Beneficiary liability for continued services is based on the QIO's decision.

Transmittals Issued for this Chapter

Rev#	Issue Date	Subject	Impl Date	CR#
R1587CP	09/05/2008	Revised Form CMS-R-131 Advance Beneficiary Notice of Noncoverage	03/01/2009	6136
R1257CP	05/25/2007	Important Message From Medicare (IM) and Expedited Determination Procedures for Hospital Discharges	07/02/2007	5622
R1186CP	02/23/2007	Changes to Chapter 30 - Updates to Amount in Controversy Requirement and Correction of Appeals Terminology	05/23/2007	5348
R1035CP	08/18/2006	Updating Publication 100-04, Chapter 30 Regarding the CD ROM Initiative for the Annual "Dear Doctor" Mailing	09/18/2006	5214
R1025CP	08/11/2006	Revised Home Health Advance Beneficiary Notice	09/01/2006	5009
R994CP	06/30/2006	Special Issues Associated with the Advance Beneficiary Notice (ABN) for Hospice Providers and Comprehensive Outpatient Rehabilitation Facilities (CORFs)	09/29/2006	5117
R594CP	06/24/2005	Preliminary Instructions: Expedited Determinations/ Reviews for Original Medicare	07/01/2005	3903
<u>R577CP</u>	06/03/2005	Preliminary Instructions: Expedited Determinations/Reviews for Original Medicare	07/01/2005	3903
R001CP	11/01/2003	Initial Publication of Manual	NA	NA

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